立法會
Legislative Council

LC Paper No. CB(2)1370/16-17
(These minutes have been seen by the Administration)

Ref : CB2/PL/HS

Panel on Health Services

Minutes of meeting
held on Monday, 16 January 2017, at 2:30 pm
in Conference Room 3 of the Legislative Council Complex

Members present	**:**	Prof Hon Joseph LEE Kok-long, SBS, JP (Chairman) Dr Hon Pierre CHAN (Deputy Chairman) Hon James TO Kun-sun Hon Tommy CHEUNG Yu-yan, GBS, JP Hon WONG Ting-kwong, SBS, JP Hon CHAN Kin-por, BBS, JP Hon Paul TSE Wai-chun, JP Hon LEUNG Kwok-hung Hon YIU Si-wing, BBS Hon Charles Peter MOK, JP Hon CHAN Chi-chuen Hon CHAN Han-pan, JP Hon Alice MAK Mei-kuen, BBS, JP Dr Hon KWOK Ka-ki Dr Hon Fernando CHEUNG Chiu-hung Dr Hon Helena WONG Pik-wan Dr Hon Elizabeth QUAT, JP Hon POON Siu-ping, BBS, MH Dr Hon Junius HO Kwan-yiu, JP Hon SHIU Ka-fai Hon SHIU Ka-chun Hon YUNG Hoi-yan Hon HUI Chi-fung Hon Jeremy TAM Man-ho Hon Nathan LAW Kwun-chung

Members attending	:	Hon Starry LEE Wai-king, SBS, JP Dr Hon Priscilla LEUNG Mei-fun, SBS, JP Hon WU Chi-wai, MH
Member absent	:	Hon CHU Hoi-dick
Public Officers attending	:	Item III Dr KO Wing-man, BBS, JP Secretary for Food and Health Mr Chris SUN Yuk-han, JP Head, Healthcare Planning and Development Office Food and Health Bureau Mr Bill LI Chi-pang Deputy Head, Healthcare Planning and Development Office Food and Health Bureau Items IV to VI Professor Sophia CHAN Siu-chee, JP Under Secretary for Food and Health Item IV Ms Ida LEE Bik-sai Deputy Head (Electronic Health Record), Electronic Health Record Office Food and Health Bureau Dr CHEUNG Ngai-tseung Consultant (eHealth), Electronic Health Record Office Food and Health Bureau Dr WONG Wing-nam Special Project Consultant, Electronic Health Record Office Food and Health Bureau

Item V

Miss Linda LEUNG
Principal Assistant Secretary for Food and Health (Health) 2
Food and Health Bureau

Ms Clara CHIN
Director (Finance)
Hospital Authority

Dr CHEUNG Wai-lun
Director (Cluster Services)
Hospital Authority

Ms Ivis CHUNG
Chief Manager (Allied Health)
Hospital Authority

Item VI

Ms Fiona CHAU Suet-mui
Principal Assistant Secretary for Food & Health (Health) 1
Food and Health Bureau

Dr Tina CHAN Siu-mui
Assistant Director of Health (Special Health Services)
Department of Health

Dr WAN Yuen-kong
Principal Medical & Health Officer (5)
Department of Health

Ms Jennifer MAK Kit-shu
Senior Electronics Engineer (Medical Device Control Office) 1
Department of Health

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

Staff in attendance : Ms Janet SHUM
Senior Council Secretary (2) 5

Ms Priscilla LAU
Council Secretary (2) 5

Miss Maggie CHIU
Legislative Assistant (2) 5

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I. Information paper(s) issued since the last meeting
[LC Paper Nos. CB(2)506/16-17(01) and CB(2)623/16-17(01)]

Members noted the following papers issued since the last meeting:

(a) Letter dated 23 December 2016 from Mr CHAN Han-pan requesting the Panel to hold an urgent discussion on the maternal death cases in the Queen Elizabeth Hospital; and

(b) Letter dated 16 January 2017 from Ms Alice MAK requesting the Panel to discuss issues relating to the sexual assault case of the psychiatric wards of the Kowloon Hospital.

II. Items for discussion at the next meeting
[LC Paper Nos. CB(2)555/16-17(01) and (02)]

2. Members agreed to discuss the following items proposed by the Administration at the next regular meeting scheduled for 20 February 2017 at 4:30 pm:

(a) Amendments to the Chinese Medicine Ordinance (Cap. 549); and

(b) Legislative proposal for regulation of private healthcare facilities.

3. Members agreed that the item "Policy on rare diseases and drug for rare diseases" (item 3 on the Panel's list of outstanding items for discussion referred) be scheduled for discussion at the regular meeting in March 2017, instead of February 2017 as originally agreed by members at the meeting of the Panel held on 19 December 2016.

(*Post-meeting note:* The Chairmen has directed after the meeting that the regular meeting in February be rescheduled for 28 February 2017 at 10:30 am to avoid clashing with the duty visit to the Dongjiang

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River Basin of the Panel on Development which was originally scheduled for 19 to 20 February 2017.

At the request of the Administration and with the concurrence of the Chairman, agenda item on (a) above has subsequently been re-worded as "Legislative proposal for conferring power on the Director of Health to issue recall order under the Chinese Medicine Ordinance (Cap. 549)". Separately, arising from the discussion at the special meeting of the Panel held on 17 January 2017, an additional discussion item on "Further discussion on the proposal to amend the health warnings on packets and retail containers of tobacco products" has been added to the agenda for the February regular meeting.)

III. Consultation Report on Voluntary Health Insurance Scheme

[LC Paper Nos. CB(2)554/16-17(01), CB(2)555/16-17(03) and CB(2)600/16-17(01)]

4. Secretary for Food and Health ("SFH") briefed members that, based on the outcome of the public consultation exercise on the Voluntary Health Insurance Scheme ("VHIS") of which the details had been set out in the Consultation Report on VHIS and the Administration's paper (LC Paper No. CB(2)554/16-17(01)), the Government would implement the refined VHIS with 10 Minimum Requirements which had received broad support in the public consultation exercise through a non-legislative means in order to benefit the public with enhanced protection as soon as possible. Given the divergent views received over the proposed establishment of a High Risk Pool ("HRP") under VHIS, the Government would re-examine the HRP proposal, which was necessary for the introduction of the other two Minimum Requirements of guaranteed acceptance with premium loading cap ("guaranteed acceptance") and portable insurance policy, and the need of legislation at a later stage.

5. SFH stressed that VHIS was not intended as a total solution to the challenges faced by the healthcare system, but a supplement financing arrangement complementing public healthcare, and one of the control knobs in redressing the public-private balance. It was aimed at providing an alternative to the middle class who could afford and were willing to pay for private healthcare services, so as to relieve the pressure on the public healthcare system. He assured members that the Government would continue with its commitment to the public healthcare system. Cases in point were the implementation of the 10-year public hospital development plan and the respective increase in the number of publicly-funded degree places in medicines, dentistry and other healthcare disciplines in the 2016-2017 to 2018-2019 triennium pending the completion of the first territory-

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wide strategic review on healthcare manpower planning and professional development. The Government was also implementing other healthcare reform measures, such as enhancing public healthcare services through public-private partnership ("PPP") and further developing the Electronic Health Record Sharing System.

6. Members noted the information note entitled "Voluntary Health Insurance Scheme" prepared by the Legislative Council ("LegCo") Secretariat (LC Paper No. CB(2)555/16-17(03)); and the letter dated 12 January 2017 from Dr Pierre CHAN requesting written reply from the Administration to his enquiries on VHIS (LC Paper No. CB(2)600/16-17(01)). At the request of the Chairman, SFH agreed to provide after the meeting a written reply to Dr Pierre CHAN via the LegCo Secretariat.

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Refined VHIS proposals

7. Mr POON Siu-ping expressed disappointment that while the HRP proposal had been one of the features put forth by the Administration for public consultation for years, the Administration would now re-examine the HRP proposal and adopt a phased approach by launching a VHIS with 10 Minimum Requirements only. Pointing out that HRP was a key enabler of the Minimum Requirement of guaranteed acceptance, which, in his view, was an important feature of VHIS for relieving the pressure on the public healthcare system, he asked about the estimated number of people who would take out insurance policies compliant with VHIS. Mr YIU Si-wing expressed concern about the effectiveness of VHIS in achieving its aim of redressing the balance of the public-private healthcare sectors if only 10 Minimum Requirements were to be implemented at the present stage.

8. Ms Alice MAK said that the Hong Kong Federation of Trade Unions was in support of the introduction of VHIS which aimed to enhance the accessibility of private hospital insurance and encourage more people to make use of private healthcare services, so as to allow the public healthcare sector to better focus its resources on serving its target areas including the underprivileged. In her view, a VHIS without the Minimum Requirements of guaranteed acceptance and portable insurance policy could not improve the high-risk individuals' access to private hospital insurance. As such, VHIS would become less attractive and less effective in achieving the above aim. She was also concerned that under the latest proposal of the Administration, it was still legally permissible for insurers to issue and sell non-compliant individual hospital insurance products in the market. Dr Helena WONG asked whether the Administration considered it a failure for having to stall the implementation of HRP in view of the concerns of the insurance industry. Dr Elizabeth QUAT and Mr CHAN Han-pan cast doubt on the attractiveness of a VHIS without the Minimum Requirements

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of guaranteed acceptance and portable insurance policy. Mr WU Chi-wai was concerned about how price transparency of private hospital services could be enhanced under the refined VHIS.

9. Mr CHAN Kin-por, however, held the view that given the relatively small number of high-risk individuals who were able and willing to purchase individual hospital insurance, which was estimated to be less than 30 000 persons, a prudent approach was not to delay the implementation of a VHIS with the 10 Minimum Requirements with strong support from the community. He stressed that the 10 Minimum Requirements, in particular minimum benefit limits, guaranteed renewal of policies without re-underwriting, coverage of prescribed ambulatory procedures, coverage of prescribed advanced diagnostic imaging tests and non-surgical cancer treatments, and adoption of standardized policy terms and conditions, could enhance market competition and consumer protection for the more than one million people currently covered by individual hospital insurance. He added that with the refinements to the Minimum Requirements, insurers, when offering acceptance to subscribers for Standard Plan which met all the Minimum Requirements, would provide a quotation with coverage of pre-existing conditions. They might also provide an extra option to subscribers with case-based exclusions in exchange of a lower premium (i.e. avoidance of premium loading that insurers might charge if pre-existing conditions were covered).

10. In response to Mr POON Siu-ping's enquiry, SFH responded that in the course of formulating the detailed proposals of VHIS, private hospital insurance products with features similar to the Minimum Requirements had started to emerge in the market. The uptake of individual hospital insurance products had also increased. Given the above changes, the projected uptake could not be accurately estimated at this stage. SFH stressed that the 10 Minimum Requirements such as coverage of prescribed ambulatory procedures; coverage of non-surgical cancer treatments; the minimum benefit limits to provide reasonable coverage for general ward in average-priced private hospitals; and the budget certainty requirements including Informed Financial Consent and no-gap (i.e. no out-of-pocket payment was required) or known-gap (i.e. a pre-determined amount of out-of-pocket payment) arrangement for at least one procedure or test could address the existing shortcomings in market practices and hence, enhance quality of insurance protection. It should also be noted that under the pilot programme for enhancing price transparency for private hospitals, private hospitals were encouraged to provide budget estimates for patients receiving 24 common and non-emergency operations or procedures before admission, and publicize the fee schedules of major chargeable items and the historical bill sizes of 12 common operations or procedures for public's reference.

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11. SFH further said that while the Minimum Requirement of guaranteed acceptance and the HRP proposal could enable some of the high-risk individuals to purchase private hospital insurance, it should be noted that the insured could still use public healthcare services if they so wished. SFH stressed that apart from the concern of the insurance industry on the HRP proposal which was mainly on the financial sustainability of HRP, some members of the public had concerns on spending public money on high-risk individuals who could afford private hospital insurance and how far the HRP proposal would affect the uptake of private hospital insurance. That said, the Government had not abandoned the HRP proposal. The HRP proposal would be dealt with at a later stage.

12. Dr KWOK Ka-ki did not agree to the establishment of HRP which required injection of public money. Mr CHAN Kin-por supported the establishment of HRP to enable high-risk individuals to buy individual hospital insurance. He pointed out that under the HRP proposal, all premiums payable and claims and liabilities under the Standard Plan high-risk policies would be accrued to HRP. The insurers concerned would only receive an administration fee payable by HRP. Ms Alice MAK enquired about the timetable for the Government to take forward the Minimum Requirements of guaranteed acceptance and portable insurance policy, as well as the establishment of HRP. SFH advised that relevant figures for funding the operation of HRP would be updated and that views of the relevant stakeholders would be gauged to facilitate follow up by the next term Government on the re-examination of the HRP proposal.

13. Dr Elizabeth QUAT asked how the young and healthy people would be incentivized to take out insurance under VHIS, which, in her view, was essential to ensure the successful implementation of VHIS. SFH advised that while many young people newly joined the workforce might not need to pay tax and hence would not be able to benefit from tax deduction for the VHIS-compliant products, the Minimum Requirement of guaranteed renewal of policies without re-underwriting could provide life-long insurance cover to them. At a young age, they were more likely to be healthy and thus might be able to lock in an underwriting class with a lower premium. They could then maintain in that underwriting class without re-underwriting even when they developed health conditions at a later age.

14. Dr KWOK Ka-ki remarked that many elders and chronic disease patients, who accounted for the largest proportion of patients of public hospital services, would not be able to afford the premium of VHIS-compliant products. SFH advised that it was expected that middle-income individuals were more likely to subscribe to VHIS-compliant products and use the diagnostic, elective and non-emergency therapeutic procedures of the private healthcare sector. If more people were willing to make use of

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private healthcare services through VHIS, resources could be released in the public sector to reduce waiting time.

15. Mr CHAN Han-pan considered that the foremost task of the Government was to step up public education on choosing an appropriate individual hospital insurance product. He expressed concern that the introduction of the 10 Minimum Requirements might result in the insurers charging a higher premium on policyholders of VHIS-compliant products. SFH advised that efforts had been and would continuously be made to educate the public on VHIS. It should be noted that under the refined VHIS, the standardization of wordings of the exclusion clauses as well as policy terms and conditions, combined with better flow of market information, would facilitate easy comparison by consumers and drive market competition. In addition, to strike a balance between consumer protection and freedom of consumers' choice, it would still be legally permissible for insurers to issue and sell non-compliant individual hospital insurance products in the market.

16. Mr WU Chi-wai asked whether the Administration would consider including preventive health assessment as a requirement of VHIS. SFH explained that VHIS was designed to focus primarily on hospital services. That said, it was noted that many insurers had been encouraging the insured to conduct health checks. Separately, the Administration had been taking forward a number of policy initiatives to promote prevention and early identification of disease, such as the Elderly Health Care Voucher Scheme.

Migration arrangements

17. Mr WU Chi-wai asked whether policyholders of existing individual hospital insurance policies could migrate to VHIS-compliant policies of the same insurer without being re-underwritten. Head, Healthcare Planning and Development Office ("H(HPDO)") advised that the proposal of the Administration was that policyholders should be allowed to migrate to their insurers' VHIS-compliant policies at the same underwriting class without re-underwriting if the benefit items of the policies were the same. The proposal would be discussed with relevant stakeholders.

Regulatory agency

18. Ms YUNG Hoi-yan noted that the VHIS Office, which would be established in the Food and Health Bureau ("FHB") to take forward VHIS, might refer to the future Independent Insurance Authority ("IIA"), being the regulator of the insurance industry, those cases amounting to misconduct under the Insurance Companies Ordinance (Cap. 41). According to the Administration, an example of such cases was where an

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insurer marketed a non-VHIS-compliant product as VHIS compliant and misled consumers in purchasing it. She sought elaboration about whether the VHIS Office would consider the definition of cases amounting to "misconduct" and the operation of the referral mechanism.

19. SFH and H(HPDO) advised that "misconduct" was defined in the Insurance Companies Ordinance to mean, amongst other things, an act or omission relating to the carrying on of a class of insurance business which, in IIA's opinion, was or was likely to be prejudicial to the interests of policy holders or potential policy holders or the public interest. The VHIS Office would issue a set of VHIS practice guidelines to set out the Minimum Requirements and related arrangements. It would also monitor compliance of the practice guidelines. In parallel, IIA would be invited to issue a Guidance Note under the Insurance Companies Ordinance based on the principle of fair treatment of clients and other relevant considerations to provide guidance on various aspects of underwriting individual hospital insurance business, under which insurers would be recommended to comply with the VHIS practice guidelines. If it came to the attention of the VHIS Office that there were extreme cases which warrant consideration of IIA as to whether the action would amount to a misconduct under the Ordinance, the VHIS Office would refer the cases to IIA. An example was an insurer refined a product which had been certified by the VHIS Office as VHIS compliant to become non-VHIS-compliant but continued to market it as a VHIS-compliant product and misled consumers in purchasing it.

Use of the $50 billion earmarked for healthcare reform

20. Mr CHAN Chi-chuen noted that the former Financial Secretary had announced in the 2015-2016 Budget that out of the $50 billion earmarked in the 2008-2009 Budget to support healthcare reform, funds would be injected into HRP under VHIS, and provide tax concession for subscribers to regulated insurance products. He sought information about the use of the $50 billion so far. Mr WONG Ting-kwong and Mr CHAN Han-pan raised a similar question, and asked whether part of the $50 billion could be used for promoting preventive care and primary care, the development of Chinese medicine and the establishment of a Chinese medicine hospital. Dr Helena WONG remarked that the Democratic Party was of the view that the Administration should consider using the $50 billion to promote PPP and enhance primary care and preventive care, instead of spending public money on those who could afford private health insurance. Dr KWOK Ka-ki considered that public money should not be used to encourage the uptake of individual hospital insurance if there was no regulation of the levels of premium and expense loading of the insurers. In his view, more resources should be allocated to promote preventive care, such as introducing health assessment and disease screening programmes

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for different age groups in order to reduce hospital admissions. Mr CHAN Kin-por remarked that during the period of January to September 2016, the expense loading of health insurance market only stood at around 21%, in which commissions payable and management expenses accounted for 8.8% and 12.5% respectively, and an underwriting loss of $40 million was reported.

21. SFH advised that in the face of an ageing population, an objective of the healthcare reform was to address the public-private imbalance in provision of hospital services through various measures, which included, among others, PPP. In this regard, $10 billion had been allocated for setting up the Hospital Authority PPP Fund. To help alleviate the current pressure on the public healthcare sector, a loan of $4,033 million had been provided to the CUHK Medical Centre Limited, a wholly-owned subsidiary of the Chinese University of Hong Kong, for the purpose of developing a non-profit making private teaching hospital. Separately, a provision of $200 billion had been earmarked for the implementation of a 10-year public hospital development plan to ensure the development of an appropriately balanced healthcare system with capacity and capability for delivering holistic services to members of the public. The Government would also finance the construction of a Chinese medicine hospital, with details of the arrangement to be available in due course. A number of initiatives had also been introduced by the current term Government to enhance health promotion and primary care services. Cases in point were the Pilot Study of Newborn Screening for Inborn Errors of Metabolism, the Colorectal Cancer Screening Pilot Programme and enhancements to various free vaccination programmes or subsidy schemes.

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22. At the request of Dr Helena WONG, SFH undertook to provide after the meeting information on a breakdown of the use of the $50 billion earmarked for healthcare reform; and a breakdown of the expenditure involved on programmes aimed at helping to relieve the pressure on the public healthcare system, such as PPP and promotion of preventive care and primary care in order to reduce hospital admissions.

Way forward

23. Mr POON Siu-ping sought information about the staff establishment of the VHIS Office and the concrete timetable for implementing VHIS in 2018. Mr CHAN Chi-chuen sought elaboration about the types of products eligible for tax deduction under VHIS and the timetable for introducing tax deduction for VHIS-compliant products.

24. SFH said that the Executive Council advised and the Chief Executive ordered at the meeting of the Executive Council on 13 December 2016 that

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VHIS should be implemented through a non-legislative framework. It was expected that the VHIS practice guidelines and details of the tax deduction arrangement would be finalized for implementation in 2018. Subject to the progress of the above work, tax deduction would be introduced in the 2018-2019 Budget such that those products which were certified by the VHIS Office to be VHIS-compliant products would be eligible for tax deduction. H(HPDO) added that at present, the Healthcare Planning and Development Office under FHB was tasked to, among others, develop the proposals for implementing VHIS. This Office would hammer out the VHIS practice guidelines to prepare for the implementation of VHIS before the establishment of the VHIS Office. The staff establishment of the latter might be limited at the initial stage.

25. Mr WU Chi-wai was concerned about whether there would be an adequate supply of healthcare manpower for meeting the service needs arising from the implementation of VHIS in 2018. SFH advised that the report of the strategic review of healthcare manpower planning and professional development would be published in 2017. However, given that it took time to train healthcare professionals, it was expected that the problem of doctor shortage would only be improved starting from 2020.

IV. Development of the stage two Electronic Health Record Programme

[LC Paper Nos. CB(2)386/16-17(08) and (09)]

26. Under Secretary for Food and Health ("USFH") briefed members on the Administration's proposal for the stage two development of the Electronic Health Record Sharing System ("eHRSS"), details of which were set out in the Administration's paper (LC Paper No. CB(2)386/16-17(08)).

27. Members noted the background brief entitled "Development of the Electronic Health Record Programme" prepared by the LegCo Secretariat (LC Paper No. CB(2)386/16-17(09)).

28. The Chairman reminded members that in accordance with Rule 83A of the Rules of Procedures, they should disclose the nature of any direct or indirect pecuniary interests relating to this funding proposal before they spoke on the subject.

Scope of data sharing

29. Dr KWOK Ka-ki said that he was in principle in support of electronic health record ("eHR") sharing. Noting that the project scope for the stage two eHRSS development would cover data sharing of Chinese

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medicine information, he sought information about the proportion of registered Chinese medicine practitioners ("CMPs") and practising CMPs who kept the health data of their patients in electronic form. He also expressed concern about how the coverage of Chinese medicine information in the stage two eHRSS could facilitate interface between primary care services and hospital services. Dr Helena WONG expressed support for the development of the stage two eHRSS, in particular its target to cover data sharing of Chinese medicine information which would be of great benefit to patients given the increasing prevalence of integrated Chinese-Western medicine treatment. To her understanding, many relatively younger CMPs were accustomed to using computers in their practice. Mr Charles MOK expressed a similar view.

30. Special Project Consultant, eHR Office ("SPC, eHRO") advised that there were currently more than 7 000 registered CMPs and 2 600 listed CMPs. At present, all the clinical records of the Chinese Medicine Centres for Training and Research of the Hospital Authority ("HA") had been computerized. According to an earlier survey conducted by HA, around 60% of CMPs in the private sector were deploying information technology ("IT") systems to support their practice, albeit mainly for billing and patient administration purposes. It was expected that with the standardization of Chinese medical terms and herbal medicine terminology and the technical readiness for data sharing in the future, computerization of health records in the Chinese medicine sector could be enhanced. The Administration would adopt an optimal approach for sharing of Chinese medicine information on eHRSS. SPC, eHRO further said that with the increasing use of integrated Chinese-Western medicine to provide medical treatment for patients, the sharing between CMPs and medical practitioners of the health data of the patients concerned, such as the operations performed and adverse drug reactions and allergies, could facilitate the provision of holistic patient care.

31. Expressing support to the development of the stage two eHRSS, Mr POON Siu-ping enquired about the timetable for completing the task of standardization of Chinese medical terms and herbal medicine terminology. Deputy Head (eHR), eHR Office ("DH(eHR)") advised that the task had already been commenced under the stage one eHR Programme and would be continued under the stage two eHR Programme, which would straddle five years from 2017-2018 to 2021-2022. The above task apart, a Chinese medicine information system on-ramp (i.e. a clinical management software with sharing capability for use by private Chinese medicine clinics) would be developed under the stage two eHR Programme.

32. Pointing out that radiological images, the use of which was often transient in nature, could at present be shared among healthcare providers ("HCPs") under the Radiology Image Sharing Pilot project,

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Dr KWOK Ka-ki queried the cost-effectiveness of developing the technical capability of eHRSS for sharing of radiological images in improving healthcare delivery. SPC, eHRO advised that radiological investigation reports (without images) had already been included in the sharable scope of the stage one eHRSS. It was expected that enabling the sharing of visualized radiological investigation results under the stage two eHRSS would better support collaborative effort among HCPs and facilitate continuity of care for patients in different settings. A case in point was the cancer patients of HA who took part in the Pilot Project on Enhancing Radiological Investigation Services through Collaboration with the Private Sector.

33. Dr Helena WONG noted that under the stage two eHR programme, the Administration would initiate further data standardization exercises on existing and new data categories, which included, among others, personal life-style habits, to facilitate data sharing. She sought information about the types of personal life-style habits that would fall into the scope of data sharing. USFH advised that it was the existing practice of healthcare professionals to enquire about patients' personal life-style habits when providing healthcare. After all, various habits such as smoking, physical inactivity and excessive alcohol intake might increase the risk of many chronic diseases. That said, it would be up to the patients to disclose such habits when required.

Data access and correction requests

34. Holding the view that registered patients should be given the right to have online access to their health data kept in eHRSS, Dr Helena WONG sought elaboration of the functions of the Patient Portal to be developed under the stage two eHRSS.

35. DH(eHR) advised that according to the Personal Data (Privacy) Ordinance (Cap. 486), registered patients could at present approach the eHR Registration Office to make a data access request for a copy of their personal data kept in eHRSS. During the scrutiny of the eHRSS Bill, the Administration had undertaken to conduct a study in the first year of the stage two eHR Programme on the setting up of a Patient Portal. The study would review relevant overseas experience as well as merits and risks, propose possible functionalities and examine feasibilities. A balance would need to be struck between convenience of access and additional security risks due to access through a more open Patient Portal. In the meantime, it was envisaged that the Patient Portal would enable patients' access to some key health data kept in eHRSS and facilitate patients' management of their eHRSS registration and related matters, such as managing the giving of sharing consent to individual HCPs. Noting that the component-project of

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Patient Portal would only be completed closer to the end of the stage two eHR Programme, Dr Helena WONG urged the Administration to expedite the completion of the project.

36. Mr LEUNG Kwok-hung considered that a mechanism should be put in place to allow registered patients to amend their health records kept in eHRSS. DH(eHR) advised that according to the Personal Data (Privacy) Ordinance, a data correction request would be handled by the prescribed HCP from which the health data originated. The HCP concerned, being the data user, might correct the data, or refuse to do so if it was not satisfied that the data to which the request related was inaccurate. Pointing out that it might take a long time for HA, which was the HCP of the public sector serving the largest number of patients, to handle the data correction requests, Mr LEUNG Kwok-hung called on the Administration to ensure that such requests would be handled by the prescribed HCPs without delay.

Engagement of the stakeholders

37. Mr Charles MOK remarked that according to the Government's road-map proposed in 2009, the development of eHRSS was a two-stage eHR Programme. The major targets and component-projects of the stage two eHR Programme as set out in the Administration's paper were undertakings made by the Administration during the public consultation exercise conducted in 2011-2012 or commitments made in response to the requests of the Bills Committee on eHRSS Bill and the community. Pointing out that an engagement exercise was conducted under the stage one eHR programme to invite views from the IT sector and the healthcare sector, he asked whether the Administration would engage the relevant stakeholders, such as patient groups and the Chinese medicine sector, in the development of the new functions of the stage two eHRSS.

38. DH(eHR) assured members that efforts had been and would continuously be made to maintain close communication with the relevant stakeholders. It should also be noted that the Steering Committee on eHR Sharing and its working groups, which were tasked to take forward the development of eHRSS, comprised representatives from the relevant professions and patient groups. Mr Charles MOK was of the view that the Administration should, apart from seeking advice of the Steering Committee and its working groups, conduct an open public engagement exercise in the course of developing the stage two eHRSS.

39. Mr LEUNG Kwok-hung sought clarification from the Administration as to whether the outsourcing of certain work assignments by HA, which served as the technical agency for the eHR programme, to the private IT sector would give rise to the risk of leakage of health data of the registered

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patients kept in eHRSS. Consultant (eHealth), eHR Office advised that the outsourced work would be confined to technical assignments and would not involve the health records kept in eHRSS.

Participation in eHRSS

40. Dr Elizabeth QUAT said that to her understanding, the response of members of the public to the stage one eHRSS was positive. She therefore welcomed the implementation of the stage two eHRSS with broadened scope of data sharing, a sharing restriction feature to enhance patients' choice over the scope of data sharing, and a portal to enable patients' access to their health data. She asked about the measures to be put in place by the Administration to enhance the participation of HCPs and members of the public in eHRSS, and encourage the prescribed private HCPs to provide to, not just to obtain from, eHRSS the sharable health data of their patients.

41. DH(eHR) advised that participation in eHRSS was voluntary. A series of publicity and promotional activities for patients and HCPs had been launched to encourage their participation in eHRSS. These included, among others, setting up eHR registration desks at various service locations of HA, Department of Health ("DH"), private hospitals and other private healthcare organizations; on-site patient registration campaigns at HA and DH healthcare outlets, elderly homes and through home visits to elders; and production of Announcement in Public Interests and other promotional materials. It was expected that the development of the stage two eHRSS would attract more participation from patients and HCPs. At present, about 1 100 private HCPs had registered in eHRSS and more than 3 000 accounts had been opened for private doctors working in these HCPs. As regards the uploading of the sharable data of the registered patients by the prescribed private HCPs, DH(eHR) explained that this would depend on, among others, the capability of the local electronic medical record systems of the prescribed HCPs.

Financial implications

42. Mr POON Siu-ping was concerned about whether the estimate of some $422 million of non-recurrent expenditure would be adequate for implementing the stage two eHR Programme. DH(eHR) advised that the development of the stage two eHRSS would immediately commence upon approval of the funding proposal by the Finance Committee. The estimate was considered adequate for developing the stage two eHRSS with new functional features.

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Conclusion

43. In closing, the Chairman concluded that members present raised no objection to the submission of the proposal to the Finance Committee for consideration.

V. Review of the fees and charges for public hospital services

[LC Paper Nos. CB(2)555/16-17(04) to (05) and CB(2)609/16-17(01)]

44. Members noted the following papers on the subject under discussion:

(a) the Administration's paper entitled "Review of the fees and charges for public hospital services" (LC Paper No. CB(2)555/16-17(04));

(b) the background brief entitled "Fees and charges for public hospital services" prepared by the LegCo Secretariat (LC Paper No. CB(2)555/16-17(05)); and

(c) letter dated 13 January 2017 from Dr Pierre CHAN enclosing a joint submission from Society for Community Organization and Elderly Right League and four submissions from Health in Action, Rehabilitation Alliance Hong Kong, Alliance for Protection of Low-income Families and Patients' Alliance on Healthcare Reform (LC Paper No. CB(2)609/16-17(01)).

[At this juncture, the Chairman suggested and members agreed that the meeting be extended for 30 minutes beyond its appointed time.]

Guiding principles for public hospital fees and charges setting

45. Mr POON Siu-ping asked about the weighting of the six guiding principles for public hospital fees and charges setting (i.e. cost sharing, affordability, appropriateness, resource prioritization, facilitating access by vulnerable groups, and public acceptance) as detailed in paragraph 5 of the Administration's paper. He agreed that fees and charges was a means to encourage appropriate use of public hospital services. Dr Pierre CHAN sought elaboration on the mechanism for HA to review the fees and charges for public hospital services.

46. USFH advised that according to the Hospital Authority Ordinance (Cap. 113), HA should recommend to SFH appropriate policies on fees for the use of hospital services by the public, having regard to the principle that

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no person should be prevented, through lack of means, from obtaining adequate medical treatment. It should be noted that the fees and charges for public hospital services to local residents, or referred to as eligible persons ("EP") in the context of fee-charging by HA, had not been adjusted since 2003. Director (Cluster Services), HA ("D(CS), HA") supplemented that HA would review its level of fees and charges for public hospital services on a biennial basis and submit its recommendations to SFH for consideration. The guiding principles of cost sharing, appropriateness and facilitating access by vulnerable groups were based on the overarching principle that the public healthcare system would serve as a safety net for the provision of highly subsidized public healthcare services to all local residents. The current revision had taken into account, among others, the increased cost and the fee gap between the existing Accident and Emergency ("A&E") charge and the median charge of private doctors.

Proposed adjustment to the charge for public A&E services

Management of patients of semi-urgent and non-urgent conditions

47. Dr Helena WONG noted that at present, the consultation hours of those public general outpatient clinics ("GOPCs") which provided evening services only lasted until 10:00 pm. In addition, only 13 public GOPCs opened on Sundays and public holidays, with many districts such as Sham Shui Po, Kowloon City, Tseung Kwan O, Kwai Tsing and Islands in lack of public primary care services on Sundays and public holidays. Against the above, the Democratic Party objected to the proposed drastic increase of the charge for A&E services for EP from $100 to $220 per attendance, as this would create difficulty for the low-income group in seeking consultation at the A&E departments of HA at times when no public general outpatient ("GOP") services were available.

48. Dr Elizabeth QUAT said that the Democratic Alliance for the Betterment and Progress of Hong Kong considered that the proposal alone could not help easing the A&E workload. HA should first step up public education on appropriate use of A&E services, strengthen its evening GOP services and provide round-the-clock GOP services at selected districts. Mr CHAN Han-pan held the view that the fact that there were inadequate evening, Sundays and public holidays' public GOP services was the underlying factor leading to heavy demand for A&E services. Pointing out that attendances for A&E services at certain acute public hospitals, such as Prince of Wales Hospital, Queen Elizabeth Hospital and Tuen Mun Hospital, were particularly high, Dr KWOK Ka-ki considered that HA should make an undertaking to provide evening, Sunday and public holiday GOP services at the districts concerned if the proposed revision of A&E charge was to be implemented. HA could also consider engaging the

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private healthcare sector to provide primary care services at a low charge for A&E patients triaged as semi-urgent and non-urgent cases (i.e. Triage categories 4 and 5) in the regions concerned.

49. D(CS), HA advised that at present, patients of semi-urgent and non-urgent A&E cases constituted around 65% of overall A&E attendance. In the last four years, HA could not meet its performance pledge that 90% of patients triaged as urgent (i.e. Triage category 3) would be treated within 30 minutes. The proposed revision of A&E charge for EP was aimed at encouraging appropriate use of the much overloaded A&E services. It was hoped that patients of semi-urgent and non-urgent cases could seek other appropriate services, so that priority could be given to urgent cases (i.e. Triage categories 1, 2 and 3). USFH and D(CS), HA added that HA would increase the service quota for GOPCs, particularly those of the New Territories East ("NTE") and New Territories West ("NTW") Clusters, by more than 40 000 attendances in 2017-2018 including evening, Sunday and public holiday GOP services. It also planned to strengthen the primary care services in 2018-2019 when the current healthcare manpower constraint could be partly eased. As regards the provision of round-the-clock public GOP services, HA would explore how to ensure efficient use of resources for the benefit of the largest number of patients. Separately, clinically stable diabetes mellitus patients and patients having hypertension with or without hyperlipidemia who were currently being taken care of by HA's GOPCs could choose to receive subsidized medical consultations, covering both chronic and acute care, from private doctors at their clinics under the GOPC Public-Private Partnership Programme.

50. Dr Fernando CHEUNG remarked that the increase in the service quota for GOPCs in 2017-2018, which only accounted for about 0.7% of the more than 6 million general outpatient attendances, was far from adequate to meet the service demand. Mr CHAN Han-pan asked HA whether it had a concrete target to increase the service capacity of GOPCs in each of the next five years. D(CS), HA advised that HA would consider the service quota for GOPCs through its annual service planning and budget allocation process. At the request of Dr Elizabeth QUAT, D(CS), HA agreed to provide in writing the timetable for the provision of public GOP services in the evening and/or during public holidays in each hospital cluster.

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51. Mr SHIU Ka-chun stressed that patients could not assess by themselves as to whether they were in urgent medical conditions. In his view, the heavy workload of A&E departments of HA was not caused by the service demand of patients of semi-urgent and non-urgent conditions, as the attendance of semi-urgent and non-urgent A&E cases of all clusters had, on average, recorded a decrease in the past five years. For semi-urgent cases, a drop ranging from around 4% to 20% was recorded in the Hong

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Kong East, Kowloon Central and NTE Clusters. For non-urgent cases, a drop of around 50% was recorded in the Hong Kong West, Kowloon Central, NTE and NTW Clusters. The average waiting time for semi-urgent and non-urgent A&E cases had, however, increased by around 30 minutes in the past five years. This was mainly due to misallocation of resources amongst clusters and mismatch of resources in meeting the service need for primary care services. Holding the view that an increase of 12.5% in the attendance of public GOPCs in the past five years might partly explain the decrease in the attendance of semi-urgent and non-urgent A&E cases during the same period and having regard to the fact that about 20% of patients of non-urgent and semi-urgent A&E cases currently sought services during the hours when public GOPCs were not in service, he considered that HA should strengthen its GOP services, including extending the service hours of public GOPCs, but not increase the A&E charge for EP.

52. Dr Fernando CHEUNG expressed similar views. He added that it was difficult for the elderly episodic disease patients to make use of HA's telephone appointment system to book a consultation time slot at a GOPC on the same day. At present, these patients might choose to go to the A&E departments of public hospitals. He was concerned that the proposed increase in the A&E charge might deter these patients from seeking timely and affordable medical consultation. Mr CHAN Han-pan was of similar view. He urged HA to be prudent in considering whether the proposed revision should be applied to elderly patients seeking A&E services. Dr KWOK Ka-ki suggested that elderly patients aged 65 or above should be granted half fee concession for using A&E services if the A&E charge for EP were to be adjusted as proposed.

53. D(CS), HA advised that the overall attendance of semi-urgent and non-urgent A&E cases stood steady at around 1.4 million in the past few years. At present, the average waiting time for these cases was two to three hours. It was expected that with the revision of A&E charge for EP and the measures to be put in place by HA to strengthen its GOP services, the pressure on HA's A&E departments could be relieved. Separately, elderly patients could make use of vouchers under the Elderly Health Care Voucher ("EHV") Scheme to receive primary care services in the private sector if they so wished. While more efforts could be made to improve the GOP services of HA which were primarily targeted at the elders, the low-income individuals and patients with chronic diseases, public hospitals' A&E departments should remain target at patients with severe and acute symptoms.

54. Dr Pierre CHAN referred members to the submissions from various organizations, which objected to the proposed increase in the A&E charge for EP, as attached to his letter dated 13 January 2017. These organizations

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called on the Administration and HA to strengthen the public GOP services, in particular the evening, Sunday and public holiday services; provide round-the-clock public GOP services; simplify the medical fee waiver mechanism for public healthcare expenses; strengthen community care services; and lower the eligibility age for EHV Scheme from 70 to 65 and increase the annual voucher amount to $3,000.

Effectiveness of and alternatives to the proposal

55. Dr Elizabeth QUAT expressed concern that some private clinics might increase their consultation fees in view of the anticipated increase in service demand following the increase in the A&E charge of HA. This might not only defeat the purpose of the revision which was to encourage patients of semi-urgent and non-urgent A&E cases to seek private healthcare services through narrowing the fee gap between the A&E departments of HA and private doctors, but also result in the unwillingness of the less privileged to seek medical consultation. Expressing a similar concern, Mr POON Siu-ping asked whether the Administration had conducted any assessment on whether the proposed fee revision would induce an increase in the consultation fees of private clinics and hence, defeat the original purpose of the revision. Dr Pierre CHAN remarked that the effectiveness of the introduction of a new charge of $100 for A&E services in 2003 in reducing the number of semi-urgent and non-urgent cases only lasted for one year. Mr YIU Si-wing suggested that HA could consider charging a lower fee for the A&E services provided during daytime to guard against the possibility that the proposal would induce those private clinics currently charged a fee lower than $220 to increase their charges, or increasing the A&E charge for EP in phases up to the level of $220. Dr Fernando CHEUNG held the view that if a revision of the A&E charge was to be implemented, only the daytime A&E charge for the semi-urgent and non-urgent cases should be increased as the objective of the fee revision was to encourage these patients to use private primary care services.

56. USFH advised that HA was conducting various public engagement activities to engage community stakeholders, including, among others, LegCo Members, District Councils and patient groups, on the revision proposals of hospital fees and charges. The current-term Government would decide on the way forward having regard to the views received by HA during the public engagement exercise. D(CS), HA supplemented that HA was open minded about all the suggestions. It would submit a report summarizing the views and feedback received to SFH for reference. However, it should be noted that many semi-urgent and non-urgent cases currently sought A&E services at public hospitals during daytime and in the evening (i.e. before 10:00 pm). As regards the effectiveness of the

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introduction of a new charge for A&E services in 2003, there recorded a sustainable decrease of semi-urgent and non-urgent cases from 1.8 million to 1.4 million. He agreed to provide after the meeting detailed information on the effectiveness of the measure in continuously reducing the number of A&E attendances, in particular the number of semi-urgent and non-urgent cases. Separately, the main factors to be taken into account by private doctors in deciding their charges should be the operation cost and inflation rate.

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57. D(CS), HA further advised that recipients of Comprehensive Social Security Assistance ("CSSA") were currently waived from payment of their public healthcare expenses. For non-CSSA recipients who could not afford medical expense at the public sector, they could apply for a medical fee waiver. Each application would be assessed against the prevailing financial eligibility criteria and where appropriate, non-financial factors (such as the patient's medical expenses and whether a patient had any special expenses that made it difficult to pay for the medical fees) on a case-by-case basis. The medical fee waiver granted could be one-off or valid for a period of time, say, one year. At present, the amount of hospital or clinic fees and charges waived for each financial year was about $0.5 billion. Mr YIU Si-wing urged HA to set up help desks at public hospitals' A&E departments to actively provide information on the medical fee waiving mechanism to the less privileged. D(CS), HA took note of the suggestion. At the request of the Chairman and Mr POON Siu-ping, D(CS), HA undertook to provide in writing information on the number of cases granted with medical fee waivers in the past three years, with a breakdown by whether or not the patients were CSSA recipients and the hospital services they received. Dr Pierre CHAN remarked that the number of patients to be affected by the proposed fee revision could be estimated by deducting the number of waiver cases receiving A&E services from the number of A&E attendances.

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Income to be generated from the proposed fee revision

58. In response to Dr Fernando CHEUNG's enquiry, Director (Finance), HA advised that the annual medical fee income and the overall operating expenditure of HA currently stood at around $2 billion and $58 billion respectively. It was estimated that the medical fee income of HA would be increased by $0.9 billion (i.e. less than 2%) if the fees and charges for services of HA were to be adjusted as proposed.

59. Mr CHAN Han-pan asked whether HA would use the additional medical fee income so generated to strengthen its GOPC services. D(CS), HA advised that the additional medical fee income would be counted towards the total income of HA for the provision of public healthcare services,

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including primary care services which were primarily targeted at the elderly, low income families, and patients with chronic illnesses.

Motions

60. The Chairman informed the meeting that Dr KWOK Ka-ki and Dr Helena WONG had respectively proposed to move a motion under this agenda item, the wording of which had been tabled at the meeting. The Chairman ruled that the two motions were related to the agenda item under discussion, and invited members to consider whether the motions should be proceeded with at this meeting. Members agreed.

The first motion

61. Dr KWOK Ka-ki moved the following motion which was seconded by Dr Pierre CHAN:

"就紓緩急症室輪候情況，本委員會要求：

除調高急症室收費外，於"普通科門診公私營協作計劃"增設基層名額，為低收入人士提供可負擔的醫療服務，以紓緩急症室輪候情況。"

(Translation)

"For the purpose of relieving the waiting time problem of Accident and Emergency ("A&E") service, this Panel requests that:

apart from increasing the fees for A&E service, quota for the public of the grass-root level should be added under the General Outpatient Clinic Public-Private Partnership Programme so as to provide the low-income group with affordable healthcare services and relieve the waiting time problem of A&E service."

62. The Chairman put the motion to vote. The results were: five members voted for and two members voted against the motion, and three members abstained from voting. The Chairman declared that the motion was carried.

The second motion

63. Dr Helena WONG moved the following motion which was seconded by Mr CHAN Chi-chuen:

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"本委員會認為醫管局在未改善門診服務，包括夜診及假日公立診所服務之前，不宜大幅增加急症室服務收費。"

(Translation)

"This Panel considers it inappropriate for the Hospital Authority to substantially increase the fees for Accident and Emergency service before improvement is made to its outpatient services, which includes the provision of public outpatient services in the evenings and on Sundays and public holidays."

64. The Chairman put the motion to vote. The results were: nine members voted for and no members voted against the motion, and one member abstained from voting. The Chairman declared that the motion was carried.

Conclusion

65. Dr Fernando CHEUNG suggested the Panel to invite deputations to give views on the proposed increase in fees and charges for public hospital services. The Chairman remarked that a stakeholder engagement exercise was being conducted by HA. At the suggestion of the Chairman, members agreed that the Administration should revert to the Panel on the proposed way forward having regard to, among others, the views expressed by members at the meeting and the views to be received by HA during the engagement exercise on its revision proposal. Dr Fernando CHEUNG suggested that the Panel should consider at that meeting whether there was a need to hold a further meeting to receive views from deputations on the Administration's proposal.

VI. Proposed regulatory framework for medical devices

[LC Paper Nos. CB(2)545/16-17(01), CB(2)555/16-17(06), CB(2)600/16-17(02) and CB(2)620/16-17(01)]

66. Members noted the following papers on the subject under discussion:

(a) the Administration's paper entitled "Proposed regulatory framework for medical devices" (LC Paper No. CB(2)545/16-17(01));

(b) the updated background brief entitled "Proposed regulatory framework of medical devices" prepared by the LegCo Secretariat (LC Paper No. CB(2)555/16-17(06));

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(c) a submission from Federation of Beauty Industry (H.K.) (LC Paper No. CB(2)600/16-17(02)); and

(d) letter dated 16 January 2017 from Dr Pierre CHAN enclosing a submission from Hong Kong College of Dermatologists (LC Paper No. CB(2)620/16-17(01)).

Classification of the risk levels of medical devices

67. Dr Junius HO noted that the proposed regulatory regime for medical devices would adopt a risk-based approach whereby the level of control would be proportionate to the degree of risk classified for medical devices. He sought explanation as to the reason why the risk levels for medical devices respectively set out under the proposed use control of selected medical devices (i.e. Annex V to the Administration's paper) and the classification of medical devices (i.e. Annex VI to the Administration's paper), which were both denoted with a Roman numeral ranging from I to IV, appeared to be in reverse order.

68. Assistant Director of Health (Special Health Services) ("ADoH(SHS)") explained that the classification of the risk levels of general medical devices, with Class I being the class with the lowest risk and Class IV with the highest risk, as set out in Annex VI to the Administration's paper was based on the classification rules of the Global Harmonization Task Force (now known as International Medical Device Regulators Forum). As regards the clinical risk levels and the associated use control categories of selected medical devices for cosmetic purposes as set out in Annex V to the Administration's paper, the external consultant which was commissioned by DH to conduct a study on the use control of 20 types of selected medical devices for cosmetic purposes ("the study") had used Roman numeral I to denote an extreme clinical risk level and hence required the users of which to be a registered healthcare professional (i.e. use control category I), and Roman numeral IV to denote a low clinical risk level and hence required no user restriction (i.e. use control category IV). The Chairman requested the Administration to explain, in writing and in the form of a consolidated table, the classification of general medical devices under the proposed regulatory framework, as well as the use control categories of selected medical devices for cosmetic purposes recommended by the external consultant. USFH agreed.

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Registration of medical devices

69. Mr Jeremy TAM noted that under the pre-market control of the proposed regulatory framework, medium to high-risk medical devices (i.e. Class II to IV general medical devices and Class B to D in vitro diagnostic

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medical devices) were required to be registered with DH before they could be supplied to the market. Expressing concern that the new compliance cost might create burden on beauty sector, he asked whether DH would recognize the standards of those medical devices having obtained relevant approvals from overseas regulators. ADoH(SHS) advised that supporting documents in this regard could facilitate the processing of the registration concerned. It should also be noted that for medical devices manufactured in places outside Hong Kong, it was the device traders concerned which would be responsible for the registration of these devices.

Proposed use control of specific medical devices

Scope of selected medical devices

70. Dr Helena WONG said that the Democratic Party supported the introduction of a statutory regulatory regime for the pre-market control, post-market control and use control of medical devices. On the use control of specific medical devices, she noted that the use control assessment framework and use control categories proposed in the study would form the basis on selection of medical devices to be subject to use control. Declaring that she was a staff of the Hong Kong Polytechnic University, she relayed the concern of the physiotherapy academia and profession that some types of medical devices which, in their views, were of high risk of serious injury or harm would be classified into use control category IV whereby no user restriction would be imposed. A case in point was the extracorporeal shock wave therapy ("ESWT") devices which could be used to break up kidney stones. She sought clarification from the Administration as to whether the use control would be confined to medical devices for cosmetic but not medical purposes. Referring to the discrepancies in the wording of paragraph 9 of the Administration's paper and paragraph 9 of the Executive Summary of the study as set out in Annex II to the Administration's paper, Ms YUNG Hoi-yan sought clarification on the criteria adopted by the external consultant for selecting the 20 types of medical devices for inclusion in the use control assessment framework.

71. Mr CHAN Chi-chuen said that he supported the broad direction of regulation of medical devices. However, he was concerned that some medical devices of high risk, such as high voltage pulsed current and ESWT devices, were classified under use control category IV with no user restriction. In addition, it was not clear as to whether a medical device which was proposed to be subject to use control in the Administration's paper would fall outside the regulation if it was used at home, as the use control assessment of the study only covered those non-home-use medical devices. Against the above, he did not support the proposed regulatory framework for medical devices. Dr Fernando CHEUNG expressed similar

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view that he supported the broad direction of subjecting medical devices under regulation. However, he opposed to the proposed regulatory framework. He was particularly concerned that use control would only be imposed on selected medical devices for cosmetic purposes but not all medical devices, and there would be no restriction on users of the high-risk ESWT devices. Mr Jeremy TAM was of a similar view.

72. USFH explained that since the practice of registered healthcare professionals would be subject to the respective professional code of conduct, the proposed regulatory framework would focus on the use control on specific medical devices for cosmetic purposes which were often used by persons other than registered healthcare professionals, and the use of these devices might pose a high risk of serious injury or harm to the public if the users had not undergone proper training and acquired appropriate qualifications. To determine the appropriate use control category for a non-home-use medical device which was either active or invasive and used for cosmetic proposes, the external consultant had devised a three-pronged assessment approach whereby separate assessments respectively on clinical risk, regulatory, as well as knowledge and skills were conducted. USFH added that for the two other main areas of the proposed regulatory regime for medical devices (i.e. pre-market control and post-market control), the requirements concerned would apply to all medical devices regardless of whether they were used for medical or cosmetic purposes. ADoH(SHS) and Principal Medical & Health Officer (5), DH supplemented that the ESWT devices referred to in Annex V to the Administration's paper was those ESWT devices used for cosmetic purposes (such as body contouring) but not medical purposes (such as breaking up kidney stones).

73. Mr Jeremy TAM suggested that the Administration should specify clearly, where applicable, the level of electrical current of those medical devices which would be subject to use control, including, among others, the ESWT devices. Dr Fernando CHEUNG said that it was not logical that while the use of the ESWT devices by registered healthcare professionals such as physiotherapists would be subject to the relevant professions' code of conduct, their use by beauty practitioners would be without regulation. Dr Helena WONG considered that the use control should cover all types of medical devices which were used for different purposes, including, among others, home use, medical and beauty purposes.

74. Mr SHIU Ka-chun was concerned that the physiotherapy academia and profession had not been properly consulted on the proposed use control of selected medical devices. USFH advised that the external consultant had approached various stakeholders, including representatives of the Hong Kong Physiotherapy Association and the Department of Physiotherapy of the Hong Kong Sanatorium & Hospital, in the course of the study.

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Mr CHAN Chi-chuen remarked that the physiotherapy profession might not be well aware that the proposed regulatory regime would cover all types of medical devices, as the scope of the study was on use control of the 20 types of selected medical devices for cosmetic purposes.

75. Referring to an incident in June 2015 whereby a woman died when receiving meridian treatment provided by a non-healthcare personnel using an electrical device, Mr SHIU Ka-chun asked whether the proposed regulatory regime could avoid the recurrence of similar incidents. USFH advised that under the existing legislation, practising medicine without licence would constitute the offence of illegal practice of medicine.

[At this juncture, the Chairman suggested and members agreed that the two motions respectively proposed by Dr Elizabeth QUAT and Mr SHIU Ka-fai, which were directly related to the agenda item under discussion and the wording of which had been tabled at the meeting, be dealt with towards the end of the discussion of this agenda item.]

76. Mr SHIU Ka-fai noted with concern that according to the regulatory assessment conducted by the external consultant, regulatory requirements might exist for the use of certain medical devices for cosmetic purposes if the use of prescriptive local anaesthetic (drug or cream) was required. He pointed out that anaesthetic cream was commonly used by beauticians in eyebrow tattooing. USFH advised that body tattooing was not regarded as a medical procedure.

77. Dr Pierre CHAN said that he was supportive of the proposed regulatory framework for medical devices in order to safeguard public health. Referring to the views of Hong Kong College of Dermatologists as detailed in its submission which was attached to his letter dated 16 January 2017, he called on the Administration to be vigilant in controlling the use of plasma devices for skin resurfacing. Making reference to the proposed regulatory regime for strengthening the regulation of private healthcare facilities whereby registered private healthcare facilities would be required to devise mechanism regarding infection control on diagnosis, treatments, operations and other medical procedures, etc. performed in the facilities, he was of the view that beauty service providers which provided services involving the use of the specific medical devices for cosmetic purposes should also be required to put in place infection prevention and control measures to ensure proper handling of the devices concerned.

Qualification requirement of users for the selected medical devices

78. Dr Elizabeth QUAT declared that her family members were involved in beauty business but she had no pecuniary interest in the business. She

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said that the Democratic Alliance for the Betterment and Progress of Hong Kong agreed the broad direction that high-risk medical devices should be subject to regulation. However, the current proposal put forth by the Administration would stifle the development of the beauty trade and affect the livelihood of the some 70 000 beauty practitioners. Pointing out that those medical devices classified under use control category II (with the exception of the colon hydrotherapy and robotic hair restoration devices) were commonly used by the beauty trade in Hong Kong, she considered it impracticable to require the thousands beauty companies in Hong Kong to employ registered healthcare professionals to supervise the use of these devices. She expressed her intention to move a motion to oppose to the proposed regulatory framework for medical devices.

79. While supporting the broad direction of the need to regulate medical devices, Ms Starry LEE was of the view that beauty practitioners would be competent to use the various devices for cosmetic purposes after receiving appropriate training and accreditation. Dr Helena WONG expressed a similar view, added that it was impracticable to require even the small and medium-sized beauty parlors to employ registered medical practitioners to station on site to supervise the use of the selected medical devices, in particular when the public healthcare sector was currently facing a medical manpower shortage problem.

[At this juncture, the Chairman suggested and members agreed that the meeting be further extended for 30 minutes.]

80. Dr Priscilla LEUNG was of the view that the adverse incident in October 2012 involving invasive procedures conducted in a beauty parlour was caused by professional misconduct on the part of the registered medical practitioners concerned but not frontline beauty practitioners. She expressed concern that the proposed use control of selected medical devices for cosmetic purposes would bring a negative impact on the long-term development of the beauty industry. From her experience as a consumer of beauty services, there was no need to limit the use of radiofrequency devices to registered healthcare professionals as proposed in the study if the devices were used for cosmetic but not medical purposes, as this would make the relevant beauty services become unaffordable to many members of the public. In her view, use control of the devices of the beauty industry should be through training and promulgation of an industry code.

81. Mr SHIU Ka-fai pointed out that Hong Kong had referenced to the practices of Australia and the United Kingdom ("UK") in developing its Qualifications Framework (which covered the beauty industry) and beauty care training programmes offered by the Vocational Training Council. Against the above, he considered that the Administration should not follow

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the practices of the United States of America ("US") to restrict the use of selected medical devices for cosmetic purposes to registered medical practitioners. It should be noted that the devices being recommended to be subject to use control category II were commonly used by the beauty trade. According to the findings set out in the report on consumer protection of medical beauty services published by the Consumer Council in December 2016, users were overall highly satisfied with the medical beauty services they purchased. The main reason for satisfaction was that the results of the services met their expectations. The proposed use control of specific medical devices for cosmetic purposes had failed to strike a proper balance between safeguarding public health and sustaining the development of the beauty industry, but would instead affect the livelihood of the frontline beauty practitioners and stifle the development of the beauty industry. In his view, devices used for medical purposes and devices used for cosmetic purposes should be regulated separately. He expressed his intention to move a motion to oppose to the proposed regulatory framework.

82. Ms YUNG Hoi-yan noted that there was no uniform and full-fledged regulatory approach on the use of medical devices for cosmetic purposes among the five major economies being studied by the external consultant (i.e. Australia, the Mainland China, Singapore, UK and US). Some of these economies that had some use-related regulations in place imposed little or no user qualification requirements. She sought explanation as to the reason why the Administration considered it necessary to introduce a use control on medical devices for cosmetic purposes. In her view, the Administration should consider introducing separate legislation to regulate the devices for medical purposes and those for cosmetic purposes.

83. USFH advised that following the adverse incident in October 2012, a Working Group on Differentiation between Medical Procedures and Beauty Services was set up under the Steering Committee on Review of Regulation of Private Healthcare Facilities ("the Working Group"). The Working Group had identified in late 2013 that certain types of procedures should be performed only by registered medical practitioners or registered dentists due to their inherent risks. As for the other devices commonly used in beauty procedures, given their heterogeneity, the Working Group considered that the control of their use should be deliberated under the regulatory framework for medical devices. It should be noted that a voluntary Medical Device Administrative Control System had already been established by DH since 2004 to pave the way for implementing the long-term statutory control. The Administration had earlier assessed the likely regulatory impact on the industry, and conducted a study to further assess the business impact of the proposed regulatory regime for medical devices. The results of these assessments had been reported to the Panel in 2010 and 2014 respectively.

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84. USFH further advised that the external consultant had taken into account the market situation of Hong Kong, local stakeholders' views, as well as the practices and regulations on the use of the selected medical devices in Australia, the Mainland China, Singapore, UK and US, in developing the recommendations on the use control of 20 selected medical devices. The assessment result was that 10 types of medical devices should be subject to use control category III whereby user had to be either a registered healthcare professional or a person supervised by a registered healthcare professional on site, or had completed device-specific training through training programme recognized by the Government; and eight types of medical devices should be subject to use control category IV whereby there should be no user restriction. The remaining seven types of medical devices had been assessed as use control category II whereby user had to be a registered healthcare professional or a person supervised by a registered healthcare professional on site. Based on the recommendations of the study, the proposal of the Administration was that users of specific medical devices for cosmetic purposes had to be supervised on site by a registered medical practitioner for management of any complications that might arise. For some other specific medical devices used for cosmetic purposes, the users of which could either be supervised on site by a registered medical practitioner, or be a personnel who had successfully completed the relevant training programme as recognized by the Government. In response to Dr Junius HO, USFH advised that DH was in discussion with the relevant education and training providers in this regard. Dr Elizabeth QUAT remarked that many beauty practitioners had attained qualifications in respect of the use of various devices under the Qualifications Framework.

85. The Chairman noted with concern that while the recommendation of the study was that users of certain medical devices for cosmetic purposes should be a registered healthcare professional or a person supervised by a registered healthcare professional, the Administration's proposal was that registered medical practitioners should assume the supervision role. Dr Pierre CHAN pointed out that among the some 1 000 beauty service complaint cases the Consumer Council received in the last two years, few cases involved registered medical practitioners. He remarked that the medical profession in general had no intention to be involved in the use of all medical devices for cosmetic purposes, except for those that would pose a high risk of serious injury or harm to the public if used inappropriately. It should also be noted that some of these medical devices could be used by other healthcare professions such as physiotherapists. Mr SHIU Ka-fai and Dr Elizabeth QUAT were concerned about whether the device-specific use control could catch up with the technology advancement in such devices.

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86. Ms Starry LEE remarked that the stakeholder engagement exercise carried out by the external consultant might not be comprehensive enough. She urged the Administration to communicate with the relevant stakeholders, including the beauty industry and the healthcare professions, before taking forward the proposed use control of selected medical devices for cosmetic purposes. USFH responded that the Administration would consider the way forward for the regulation of medical devices having taken into account the views and concerns raised by members and different sectors.

87. At the suggestion of Dr Helena WONG, Dr Elizabeth QUAT, Ms Alice MAK, Mr SHIU Ka-fai and Mr CHAN Chi-chuen, members agreed that the Panel should hold a special meeting to receive views from deputations on the proposed regulatory framework for medical devices.

[At this juncture, the Chairman suggested and members agreed that the meeting be further extended for 15 minutes.]

Regulation and development of the beauty industry

88. Dr KWOK Ka-ki expressed concern that the Administration did not introduce a licensing system to deter unscrupulous acts of owners of beauty companies. Dr Helena WONG pointed out that members had called for the development of a regulatory and training regime for the beauty industry in the Fifth LegCo. Dr Elizabeth QUAT expressed disappointment that the Administration had turned a deaf ear to the repeated call from members to formulate a regulatory regime for the beauty industry, including a licensing system for beauticians, to foster the long-term development of the industry. Ms YUNG Hoi-yan considered that the Administration should actively promote the development of the beauty industry in Hong Kong.

89. Mr SHIU Ka-fai said that the Administration should help developing the beauty industry by providing a well-structured training ladder for the beauty practitioners. He suggested to set up a subcommittee under the Panel to study issues relating to the regulation of devices and development of the beauty industry. The Chairman invited Mr SHIU Ka-fai to provide in writing the proposed terms of reference, time frame and work plan of the proposed subcommittee for consideration at a future Panel meeting.

(*Post-meeting note:* Subsequent to the meeting, Mr SHIU Ka-fai has revised his proposal and suggested to set up a joint subcommittee under the Panel on Health Services and the Panel on Commerce and Industry ("CI Panel") on issues relating to the regulation of devices and development of the beauty industry. The proposal concerned was set out in LC Paper Nos. CB(1)540/16-17(01) and CB(2)793/16-17(01) for consideration of the CI Panel and the Panel at their February

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regular meetings which were held on 21 February and 28 February 2017 respectively.)

Motions

90. Dr Elizabeth QUAT proposed to move the following motion:

"鑒於政府提交的資料文件未能清晰說明選定醫療儀器使用管制建議的訂立標準及理據，以及政府提出的醫療儀器使用管制分類建議，未有考慮對美容業界所造成的影響，及未能在確保儀器使用安全及美容業界發展之間取得平衡，本事務委員會反對政府就規管醫療儀器提出的建議架構。"

(Translation)

"Given that the information paper provided by the Government has failed to give a clear account of the setting of standards and rationale for the proposed use control of selected medical devices; and that the proposed classification for use control of medical devices has failed to take into account the impact on the beauty trade, as well as strike a balance between ensuring the safe use of devices and development of the beauty trade, this Panel is opposed to the regulatory framework for medical devices proposed by the Government."

91. Mr SHIU Ka-fai proposed to move the following motion:

"鑒於政府現時提出的《規管醫療儀器的建議架構》嚴重傾斜及疏漏，將醫療用途的儀器和美容用途的儀器混為一談，將會扼殺美容業界，本委員會要求政府當局擱置現時的立法計劃，並且重新研究相關事宜，包括醫療用途的儀器和美容用途的儀器分開研究、提升美容專業等事宜。"

(Translation)

"Given that the 'Proposed regulatory framework for medical devices' currently put forward by the Government is not only seriously lopsided with inadequacies, but also has mixed up devices used for cosmetic purposes with those used for medical purposes, which will as a result stifle the development of the beauty trade, this Panel requests the Administration to shelve its current legislative plan, and study afresh the relevant issues, including conducting separate studies on devices used for cosmetic purposes and those used for medical purposes, and upgrading the beauty profession, etc."

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92. As the meeting was near the extended closing time and in view of the earlier decision of the Panel to hold a special meeting to receive views from deputations on the subject, Dr Elizabeth QUAT and Mr SHIU Ka-fai respectively decided not to move their motions at this meeting. However, they requested to put on record their objection to the proposed regulatory framework for medical devices for the reasons as set out in their motions. They would respectively consider whether to propose any new motions at the special meeting under the agenda item to which it related.

(*Post-meeting note:* The special meeting for receiving views from deputations on the proposed regulatory framework for medical devices has been scheduled for 13 February 2017 from 8:45 am to 2:45 pm.)

VII. Any other business

93. There being no other business, the meeting ended at 7:45 pm.

Council Business Division 2
Legislative Council Secretariat
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