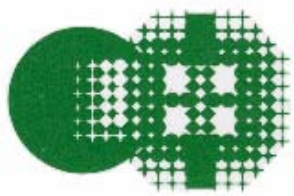
# DIRECT INVESTIGATION REPORT

# CONTROL OF HEALTHCARE PROFESSIONS NOT SUBJECT TO STATUTORY REGULATION

**October 2013**



**Office of The Ombudsman**

**Hong Kong**

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## Control of Healthcare Professions Not Subject to Statutory Regulation

### Background

In Hong Kong, statutory regulation of healthcare professions can be traced back to the 1950's with the enactment of the Medical Registration Ordinance and the Dentists Registration Ordinance. Nurses, midwives, pharmacists and dental hygienists were put under statutory regulation in the 1960's. The Supplementary Medical Professions Ordinance (Cap 359) was enacted in 1980 to regulate five more disciplines which included medical laboratory technologists, occupational therapists, physiotherapists, radiographers and optometrists. The practice of chiropractors and Chinese medicine practitioners were regulated in 1993 and 1999 respectively in view of their popularity. Since then, no more healthcare professions have been put under statutory regulation.

2. However, from time to time, media reports suggested that the health of the public might be at risk as a result of emergence of new types of treatments that have healthcare implications and substandard service provided by practitioners providing such treatments. Recent incidents concerning improper treatments by beauty salon practitioners pointed to the need for tighter monitoring and review of the regulatory regime for healthcare professions. Hence, The Ombudsman initiated this direct investigation on 21 January 2013 to examine whether the current control mechanism is sufficient and identify areas for improvement.

### Regulatory system in Hong Kong

3. DH all along adopts a risk-based approach to consider whether a particular healthcare profession should be subject to statutory regulation. The major consideration is the nature and scope of work of the professionals and the risks associated with their practices. Other considerations include patient interface, size of profession, employment distribution in public and private sectors and presence of alternative control (ie society-based registration system). In general, healthcare personnel who perform invasive or critical procedures are accorded with higher priority for statutory regulation.

***Statutory Regulation***

4. In Hong Kong, currently around 87,000 healthcare professionals from 13 disciplines are subject to statutory regulation. The regulatory bodies formed under respective pieces of legislation are given the power to prescribe the registration requirements, establish disciplinary mechanism to handle and investigate complaints and take disciplinary actions against their members.

***Society-based Registration***

5. Under society-based registration, professional bodies concerned administer an enrollment system and promulgate a list of qualified members to enable members of the public to make informed choices when seeking certain healthcare services. To provide quality services to the public, some professional bodies may also adopt a professional code of practice, encourage their members to pursue continuing professional development, develop quality assurance scheme and devise a disciplinary mechanism to ensure that only qualified personnel could stay on their lists. According to DH's manpower survey conducted in 2009, over 7,300 practitioners were engaged in 15 healthcare sectors not subject to statutory regulation. All these 15 healthcare disciplines have established associations/societies and have maintained membership registers.

**DH's monitoring and review system**

***DH's position***

6. DH considers that excessive regulation may pose unnecessary barriers to market entry, discourage competition and cause resource implications to society. Statutory regulation of healthcare professions should, therefore, be called for only when there is evidence showing that the practice of a healthcare profession has demonstrated an unacceptable level of risk to the public.

7. DH also considers that, while there are healthcare personnel not specifically regulated, there is legislation in place to guard the public against general medical malpractices. Moreover, under common law, all healthcare practitioners have a duty of care towards their patients, and they are required to exercise due care and skill reasonably expected of them as competent practitioners practising in the field. Any aggrieved patients may seek legal remedy/redress through civil litigation.

***DH's monitoring***

8. DH has developed certain guidelines, codes of practice, surveillance and reporting systems, market assessment, risk monitoring and risk communication vehicles. DH adopts these administrative tools to ensure safety of medical devices and Western medicines. It also collaborates closely with other bodies, such as law enforcement agencies, consumer advocates and regulatory bodies, to handle complaints about healthcare services, including even those not within its own portfolio.

***Administration's review***

9. The Administration set up a high-level steering committee, chaired by the Secretary for Food and Health in January 2012, to conduct a strategic review on healthcare manpower planning and professional development. It will cover and focus on the regulatory structure for the healthcare professions, including the functions and composition of the existing regulatory bodies for healthcare professionals. For other healthcare professions not statutorily regulated at the moment, the review will also look into matters relating to their future development, including whether or not they should be subject to regulatory control of some form.

10. In addition, The Secretary for Food and Health has been meeting representatives of various healthcare professions to discuss issues of mutual interest every one or two years.

**Our Observations**

11. We believe that statutory control will allow DH to closely monitor qualified healthcare personnel and prevent unqualified personnel from practising, whereby professional conduct of the practitioners can be upheld and their professional standard enhanced. In other words, the quality of treatment and service standard can be guaranteed.

12. While it is accepted that not all healthcare professions need to be regulated by Government and probably even less by statutory control, it is imperative that DH should be vigilant on any risks that practices of unregulated healthcare personnel may bring to the public. However, from information provided by DH, no effective mechanism is currently in place to monitor the service standards of unregulated healthcare personnel and review the need for statutory regulation as media have reported alleged malpractices of unregulated healthcare personnel from time to time. In the course of our investigation, we observed the following deficiencies:

***Monitoring Mechanism***

*Lack of complaint information*

13. DH only keeps complaint figures against unregulated healthcare personnel it employs. These figures do not cover personnel in six of the 15 disciplines and those working in private sector. Worse still, DH keeps no complaint statistics about other healthcare disciplines not falling into its healthcare framework. Thus, the information collected is incomplete and insufficient.

*Lack of information exchange*

14. Although DH had established a long term working relationship with the Consumer Council, yet a mechanism to analyse the information of safety related complaints only started in October 2012, a few months after our inquiry on this subject and an incident of improper treatment in a beauty salon resulting in death and injuries. Furthermore, DH took no initiative to obtain complaint statistics or the details of malpractice of their members from the societies of unregulated healthcare personnel.

*No monitoring on societies and service standard of their members*

15. DH emphasises that voluntary society-based registration can be an effective alternative to statutory control. However, we do not find DH to have provided any assistance to relevant societies or made genuine efforts to understand how they are organised and how their regulatory schemes operate. We find that some of the societies do not have a homepage for public access or provide its members' list to patients for reference. Also, DH seems to show no interest whether they have any code of practice/conduct and appears to be unaware of their operation and development.

***Review mechanism***

*No review mechanism*

16. DH did not conduct any consultation or review to assess the need for putting any healthcare personnel under statutory control since the enactment of Cap 359 in 1980. There is no specific plan or timetable to do so. Nor is there any mechanism to trigger such review.

*Lack of communication with societies*

17. DH did not establish a formal communication channel with the societies of unregulated healthcare professionals to help promote their development in accordance with the self-regulatory system. In the past, open forums with the representatives of healthcare sectors were held to discuss healthcare-related issues only at irregular intervals. Meeting with representatives of unregulated healthcare personnel for the discussion of statutory regulation was for the first time arranged in June 2012. There was no such meeting between 1980 and 2011.

***Role of DH***

18. DH has the duty to assure the qualification of the healthcare personnel in order to maintain a high quality of healthcare service. DH discharged such duty in the past by putting 13 healthcare professions under its regulatory framework. However, our investigation reveals that DH did not have any monitoring mechanism on the operation of unregulated healthcare personnel. Nor did DH have any review mechanism on the need to put them under statutory regulation.

**Recommendations**

19. The Ombudsman has made seven recommendations to DH, as follows:

(1) To collect relevant complaint statistics for conducting regular risk-based analyses (**para. 13**);

(2) To enhance communication with the law enforcement agencies, related organisations and societies for gathering relevant complaint information for risk-based analyses (**para. 14**) ;

(3) To consider providing guidance to societies of healthcare personnel not statutorily regulated on monitoring the qualification and service standard of their members (**para. 15**);

(4) To follow up cases related to malpractice of unregulated healthcare personnel in order to assure that the service provided meets the standard as required (**para. 15**);

(5) To examine the complaint statistics periodically for analysing whether more stringent regulation should be introduced to a particular group of healthcare personnel (**para. 16**);

(6) To discuss with its policy bureau in the Administration to map out a long-term review strategy for the scope and ways to strengthen regulatory control of unregulated healthcare personnel and also the need for putting them under statutory control (**para. 16**); and

(7) To enhance communication with societies of unregulated healthcare personnel for exchanging opinions regularly (**para. 17**).

20. DH has indicated its welcome of the above recommendations and undertook to take appropriate follow-up actions.

**Office of the Ombudsman**
**October 2013**

# 1

# *INTRODUCTION*

## BACKGROUND

**1.1** The need to consider regulating healthcare professions is obvious: the public should be protected as far as practicable from potential health hazards arising from substandard services rendered by unqualified personnel.

**1.2** In Hong Kong, statutory regulation of healthcare professions can be traced back to the 1950's with the enactment of the Medical Registration Ordinance and the Dentists Registration Ordinance for regulating the practices of medical practitioners and dentists respectively.

**1.3** Professions supplementary to medicine are those professions other than doctors and dentists who are concerned with the care of patients in the operation of health services. These paramedical workers can be classified into three main streams:-

(a) scientific and technical diagnostics and therapeutic services (e.g. medical laboratory technologists, radiographers, pharmacists, optometrists, dietitians, dental hygienists and prosthetists);

(b) remedial and rehabilitatory services (e.g. physiotherapists, occupational therapists, chiropodists and speech therapists); and

(c) nursing and midwifery services (e.g. nurses and midwives).

**1.4** Nurses, midwives, pharmacists and dental hygienists were put under statutory regulation in the 1960's.

**1.5** A series of paramedical training courses were offered by tertiary educational institutes from 1978. In order to safeguard the public interest further, the Supplementary Medical Professions Ordinance (Cap 359) was enacted in 1980 to regulate five more disciplines which included medical laboratory technologists, occupational therapists, physiotherapists, radiographers and optometrists. Government's stated policy at that time was that it would give consideration to include other paramedical professions for regulation should the need arise at a later stage.

**1.6** The practice of chiropractors and Chinese medicine practitioners were regulated in 1993 and 1999 respectively in view of their popularity. Since then, no more healthcare professions have been put under statutory regulation.

**1.7** However, from time to time, media reports suggested that the health of the public might be at risk as a result of emergence of new types of treatments that have healthcare implication and substandard service provided by practitioners providing such treatments. Recent incidents concerning improper treatments by beauty salon practitioners pointed to the need for tighter monitoring and review of the regulatory regime. Although the incidents were considered to relate more to the control of the medical profession, they did heighten the importance of regulatory control of healthcare professions generally.

## SCOPE

**1.8** On 21 January 2013, The Ombudsman initiated, pursuant to section 7(1)(a)(ii) of The Ombudsman Ordinance, Cap. 397, a direct investigation into the Department of Health ("DH")'s control of healthcare professions not subject to statutory regulation with a view to examining whether the current control mechanism is sufficient and identifying areas for improvement.

## METHODOLOGY

**1.9** In the course of this investigation, we studied relevant papers, statistics and notes of meeting of DH. We held meetings with management staff of the Food and Health Bureau and DH. We also asked the Consumer Council ("CC") for statistical data in relation to improper healthcare treatment it received in the past ten years for our reference.

## REPORT

**1.10** We sent a draft investigation report to DH for comment on 29 July 2013. This final report, incorporating the comments of DH, was issued on 18 October 2013.

# 2

# *REGULATORY SYSTEM*

**2.1** DH all along adopts a risk-based approach to consider whether a particular healthcare profession should be subject to statutory regulation. The major consideration is the nature and scope of work of the professionals and the risks associated with their practices. Other considerations include patient interface, size of profession, employment distribution in public and private sectors and presence of alternative control (ie society-based registration system). In general, healthcare personnel who perform invasive or critical procedures are accorded with higher priority for statutory regulation.

## SITUATION IN HONG KONG

### Statutory Regulation

**2.2** In Hong Kong, currently around 87,000 healthcare professionals from 13 disciplines are subject to statutory regulation. A breakdown of their numbers is set out in **Annex A**.

**2.3** Various pieces of legislation confer upon the professions a high degree of autonomy and status and allow them to set up their own regulatory bodies. These regulatory bodies are given the power to:-

- prescribe their own entry and registration requirements, licensing examinations, education and accreditation standards as well as code of

practice/ethics for their members to follow;

- establish a disciplinary mechanism to handle and investigate complaints lodged by the public; and

- take disciplinary actions against their respective members.

**2.4** As the regulatory frameworks are statute-based, changes to them (such as attempts to reduce entry barriers, prescribe continuing education requirements, or enhance the credibility of the disciplinary mechanism) require legislative amendments after a proper consultative process. The role of DH is to provide secretarial support to these regulatory bodies established under the relevant legislations (e.g. the Nursing Council was set up in accordance with the Nurses Registration Ordinance).

**2.5** In considering whether a particular healthcare profession should be subject to statutory regulation, the Administration will assess the risk associated with the practice and consider whether the level of risk warrants control of the practice through enactment of legislation. As such, the major consideration is the nature and scope of the work of the professions and the risks associated with malpractice.

**2.6** The level of risk arising from malpractice differs from one healthcare profession to another. In general, healthcare personnel who perform invasive or critical procedures are more prone to pose imminent threat to the well-being of service recipients, and their practices should therefore be accorded with higher priority for statutory regulation. Other considerations include:-

(a) Patient interface: The mode of service delivered by healthcare personnel varies. Some have frequent contacts with patients and provide direct clinical treatment while others are limited to providing support to their frontline colleagues. Practice of the former carries a higher level of risk, and therefore has a relatively stronger base for being subjected to statutory regulation. For example, dental surgery assistants normally work in a managed environment under the supervision of dentists, and dispensers prescribe medicine to patients direct but under the supervision of pharmacists;

(b) Size of profession: It is an indicator of the community's demand for and acceptance of such services and the extent of impact to which the

professions may have on the well-being of the population at large;

(c) Employment distribution in public and private sectors: As quality assurance measures such as the issue of practice guidelines, the existence of clinical governance systems, the provision of on-the-job training and continuing professional education are more readily available in the public sector, professions whose members are employed mainly in the public sector tend to pose less threat to public health than those professions predominated by private sector practitioners; and

(d) Presence of alternative control: Apart from statutory regulation, some healthcare professions have developed self-regulatory mechanisms through voluntary, society-based registration.

**Society-based Registration**

**2.7** Under society-based registration, professional bodies concerned administer an enrollment system and promulgate a list of qualified members to enable members of the public to make informed choices when seeking certain healthcare services. To provide quality services to the public, some professional bodies also adopt a professional code of practice, encourage their members to pursue continuing professional development, develop quality assurance scheme and devise a disciplinary mechanism to ensure that only qualified personnel could stay on their lists.

**2.8** Healthcare professionals who voluntarily sign up under a voluntary register are committed to protecting the public by meeting the standards set by the organisation holding the voluntary register, and agree to behave in compliance with their codes of practice. In case of breach, the organisation can strike them off their register and inform the public about this. This means that employers, patients and the public at large can check whether a person engaged in a profession is on the register and meets relevant standards. Although the fact that a person is not listed on a voluntary register will not by itself debar him from practising in that profession, it may however lead or contribute to other consequences, e.g. employers being reluctant to employ him and patients not choosing his service. These may be reasons for keeping the professionals' desire to remain on the voluntary register.

**Practice and employment distribution of unregulated healthcare practitioners**

**2.9** According to DH's manpower survey conducted in 2009, over 7,300 practitioners were engaged in 15 healthcare sectors not subject to statutory regulation. A breakdown of these 15 disciplines and their numbers are listed in **Annex B**.

**2.10** All these 15 healthcare disciplines have established associations/societies and have maintained membership registers. Details of these associations/societies are listed in **Annex C**.

**2.11** DH currently engages nine types of practitioners of these 15 disciplines. For employment purpose, the majority of them are holders of a bachelor degree or diploma of the relevant discipline from a local or overseas recognised university/institution.

# 3

# *MONITORING AND REVIEW MECHANISMS*

**3.1** This chapter examines the strategy and mechanisms adopted by DH to monitor and review the need to regulate healthcare professions.

**DH'S POSITION**

**3.2** There is no universally agreed definition for healthcare profession. It ranges from a professional or an expert in a particular specialty, to a general-skilled person providing support to a healthcare profession. The growing diversity of medicine, medical treatment and health services further complicates this matter. It is, therefore, difficult to decide on whom to regulate.

**3.3** DH considers that excessive regulation may pose unnecessary barriers to market entry, discourage competition and cause resource implications to society. Statutory regulation of healthcare professions should, therefore, be called for only when there is evidence showing that the practice of a healthcare profession has demonstrated an unacceptable level of risk to the public.

**3.4** Healthcare personnel mainly serve in hospitals and institutions run by the Hospital Authority or DH. They are practising under comprehensive quality assurance measures (such as detailed work procedures and guidelines, clinical governance systems and on-the-job training). This provides a greater safeguard against malpractice.

**3.5** According to the manpower survey conducted in 2009, most of 15 unregulated healthcare personnel were moderate in size and engaged in the public sector only. For those who were engaged in the private sector, their professional groups developed society-based registration system for self regulation. Furthermore, many of them were not involved in performing critical or invasive procedures or had limited direct patient interface.

**3.6** DH also considers that, while there are healthcare personnel not specifically regulated, there is legislation in place to guard the public against general medical malpractices (covering prescription and use of drugs and the making of health claims). Moreover, under common law, all healthcare practitioners have a duty of care towards their patients, and they are required to exercise due care and skill reasonably expected of them as competent practitioners practising in the field. Any aggrieved patients may seek legal remedy/redress through civil litigation.

**DH'S MONITORING**

**3.7** DH has developed certain guidelines, codes of practice, surveillance and reporting systems, market assessment, risk monitoring and risk communication vehicles. These administrative tools are used by the following DH offices, targeting at different aspects of healthcare:-

(a) The Medical Device Control Office has set up a risk-based voluntary Medical Device Administrative Control System since 2004 to raise public awareness of the importance of medical device safety and pave the way for implementing long-term statutory control. The system comprises:-

- pre-market control, through listing of medical devices and traders;

- post-market control, through an adverse incident reporting system; and

- a surveillance system on medical device safety alerts;

(b) The Drug Office is responsible for market surveillance to ensure safety of Western medicines, e.g. to detect illegal possession or sale

of pharmaceutical products. It also conducts risk assessment in response to safety alerts, adverse drug reaction reports and complaints about drugs, and oversees the enforcement of the Undesirable Medical Advertisements Ordinance; and

(c) The Client Relations Unit handles complaints about matters concerning healthcare, including complaints against personnel currently not subject to statutory regulation. Between 2002 and 2012, it received 119 complaints about the performance of the personnel engaged in those 15 disciplines listed in **Annex B**. Eight cases were substantiated, of which two related to dispensers and six related to dental therapists. The subject matter giving rise to complaints was attitude, rather than competence.

**3.8** In addition to its own complaint channel, DH also collaborates closely with law enforcement departments such as the Police and the Customs and Excise Department; consumer advocates such as the Consumer Council; and regulatory bodies of healthcare professions. Through multi-partite collaboration, DH aims to handle complaints that go beyond its own portfolio in a more comprehensive manner, and provide better facilitation for investigating cases of malpractice.

**REVIEWS TO BE CONDUCTED BY ADMINISTRATION**

**3.9** In the face of major challenges such as a rapidly aging population leading to increasing healthcare needs, increasing occurrence of lifestyle-related diseases and rising medical costs due to advances in medical technology, the Administration has taken steps towards reforming the healthcare system for long-term sustainability, while improving service and quality. Based on the outcome of a public consultation on healthcare reform, the Food and Health Bureau set up a high-level steering committee, chaired by the Secretary for Food and Health in January 2012, to conduct a strategic review on healthcare manpower planning and professional development. The committee will formulate recommendations on how to cope with anticipated demand for healthcare manpower, strengthen professional training, and facilitate professional development having regard to the findings of the review, with a view to ensuring the healthy and sustainable development of the healthcare system. The review will also recommend measures on professional development to upkeep the professional qualities of the various healthcare professions. It will cover and focus on the regulatory structure for the healthcare professions,

including the functions and composition of the existing regulatory bodies for healthcare professionals. For other healthcare professions not statutorily regulated at the moment, the review will also look into matters relating to their future development, including whether or not they should be subject to regulatory control of some form.

**3.10** To assist the steering committee in making informed recommendations on the means and measures to ensure an adequate supply of healthcare professionals and strengthen professional development of the professions concerned, two local universities have been commissioned to provide professional input and technical support to the review. Specifically, one of the universities will conduct a comparative review of the regulatory frameworks in local and overseas contexts governing registration, licensing, qualifications and professional conduct of the healthcare professions concerned, as well as mechanisms for setting and upholding professional standards and maintaining continuing competence.

**3.11** The review will allow the Administration to look further into its existing regulatory measures in the healthcare sector and, making reference to international practices, identify areas of enhancement.

**3.12** In addition, the Administration is regularly on the watch with respect to developments in the healthcare landscape. The Secretary for Food and Health has been meeting representatives of various healthcare professions to discuss issues of mutual interest every one or two years. All interested professional associations are welcome to take part.

# 4

# *OUR OBSERVATIONS*

**4.1** We believe that statutory control will allow DH to closely monitor qualified healthcare personnel and prevent unqualified personnel from practising. In the same vein, professional conduct of the practitioners can be upheld and their professional standard enhanced. In other words, the quality of treatment and service standard can be guaranteed.

**4.2** During the Legislative Council motion debate on 12 January 2011 regarding "Legislating for regulating allied health staff to protect public health", a Member quoted some cases raised by the trades illustrating potential hazards faced by members of the public if current control system was not tightened. Three of the cases are listed below:-

(a) A child with problems of slurring speech and difficulties in swallowing saliva and food consulted an unqualified speech therapist for treatment. There were several occasions when the child was almost choked to death because he was taught to speak and use his vocal cord in an improper way;

(b) A patient suffering from mood disorder consulted an unqualified clinical psychologist. After the counselling, her condition did not improve. Worse still she became more depressed and even had suicidal thoughts; and

(c) Unqualified dietician prescribed inappropriate medication to a person on diet, causing adverse effect to her renal function.

**4.3** These examples demonstrate the wide range of risks associated with unregulated healthcare treatment. While it is accepted that not all healthcare professions need to be regulated by Government and probably even less by statutory control, it is imperative that DH should be vigilant on any risks that practices of unregulated healthcare personnel may bring to the public. However, from information provided by DH, no effective mechanism is currently in place to monitor the service standards of unregulated healthcare personnel and review the need for statutory regulation. We observe the following deficiencies:

Monitoring Mechanism

(a) lack of information about complaints against unregulated healthcare personnel working in the private sector;

(b) lack of information exchange with relevant organisations for the collection of complaint information about unregulated healthcare personnel;

(c) no monitoring of society-based registration systems and service standards of unregulated healthcare personnel;

Review Mechanism

(d) lack of review mechanism on the need to put unregulated healthcare personnel under control; and

(e) lack of communication with societies of unregulated healthcare personnel.

## (a) LACK OF COMPLAINT INFORMATION

### Findings

**4.4** DH only keeps complaint figures against unregulated healthcare personnel it employs. These figures only cover nine of the 15 disciplines listed in **Annex B** (**para. 2.11**). The complaint figures, such as those mentioned in **para. 3.7(c)** above, do not cover personnel in the remaining six disciplines and those

working in private sector.

**4.5** Worse still, DH keeps no complaint statistics about other healthcare disciplines not listed in **Annex B** (e.g. Naturopathy and Complementary and Alternative Medicine) as it does not consider that them as falling into the healthcare framework. Thus, the information collected is incomplete and insufficient.

**Our comments**

**4.6** On the one hand, DH emphasises that it adopts a risk-based approach in assessing whether statutory regulation should be introduced for a particular healthcare discipline. On the other hand, DH does not have a systematic way to collect and collate relevant complaint statistics for conducting risk-based analysis and identifying which healthcare sector posing potential health hazard to the public. For example, there is a lack of monitoring and follow-up inquiry in respect of media reports. We, therefore, consider that DH should:

(a) review the need to collect all relevant information about complaints against all unregulated healthcare personnel, whether practising in the public or private sector; and

(b) establish a database for keeping such complaint statistics for the purpose of conducting risk-based analysis regularly.

**(b) LACK OF INFORMATION EXCHANGE**

**Findings**

**4.7** DH remarked that it had established a long term working relationship with CC. Yet, a mechanism to analyse the information of safety related complaints (**para. 3.8**) only started in October 2012, a few months after our inquiry into this subject and an incident of improper treatment in a beauty salon resulting in death and injuries.

**4.8** Furthermore, DH did not request CC to provide complaint statistics related to healthcare disciplines listed in **Annex B** up till November 2012.

**4.9** DH also took no initiative to obtain complaint statistics or the details of malpractice of their members from the societies of unregulated healthcare personnel.

**Our comments**

**4.10** DH seemed to have no idea about malpractice, if any, of unregulated healthcare personnel practising in private sector as it started the information exchange programme with CC only in late 2012. Therefore, we doubt whether DH could apprise itself of the trend and nature of complaints against the unregulated healthcare personnel, and the emergence of any new healthcare services. By the same token, we also query how DH could conduct risk-based analysis without obtaining relevant complaint statistics or malpractice details.

**4.11** Even though information exchange between DH and CC has started, we still urge DH to fine tune the data collection system with a view to building up a comprehensive complaint database, as CC's complaint statistical data focus mainly on consumer protection rather than health safety.

**4.12** Apart from CC, law enforcement departments and societies of unregulated healthcare personnel would also be a source of obtaining complaint information. As such, DH should consider approaching them on a regular basis for obtaining such information.

## (C) NO MONITORING ON SOCIETIES AND SERVICE STANDARD OF THEIR MEMBERS

**Findings**

**4.13** DH emphasises that voluntary society-based registration can be an effective alternative to statutory control (**paras. 2.7 and 2.8**). However, we do not find DH to have provided any assistance to relevant societies or made genuine efforts to understand how they are organised and how their regulatory schemes operate. We find that some of the societies do not have a homepage for public access (e.g. Hong Kong Society of Dental Technicians) or provide its members' list to patients for reference (e.g. Hong Kong Podiatrists Association and Hong Kong Orthoptist Association). Also, DH seems to show no interest whether they have any code of practice/conduct and appears to be unaware of their operation and development.

**4.14** According to the registration requirements of the societies/associations listed in **Annex C**, their members can be classified as full, associate, honorary and student members and the academic requirements vary from class to class. Most of the societies require their full members to be a holder of degree or diploma in relevant discipline of a recognised university/institution. However, in some of these societies/associations, a person who is interested in the field may also apply to become an associate member. In the circumstances, members of the public may feel confused as they are unfamiliar with their registration system. We have browsed the websites of the societies concerned and found that some did not publicise their members' list or have not updated the list for a long period of time.

**4.15** It appears that DH does not play any proactive role in the setting of membership requirements of these societies. Furthermore, as mentioned above, DH has no comprehensive complaint statistics about unregulated healthcare personnel.

**Our comments**

**4.16** This reveals DH's passive role in promoting society-based registration (**paras. 2.7 and 2.8**). In the circumstances, we cannot see how DH could monitor their service standards and prevent malpractices.

**4.17** From time to time, media have reported alleged malpractices of unregulated healthcare personnel. It appears that DH has no follow-up mechanism on such reports. We consider that DH should:-

(a) at least provide guidelines to unregulated healthcare personnel assisting them to form self-regulatory societies with clear codes of practice/conduct, including the requirement to publicise their members' lists so that members of the public may know whether or not a service provider is a member of the society concerned and meets the service standards as required by the society. In case of deregistration of a member arising from malpractice, DH should encourage the society concerned to report to it for follow-up and checking if any offence has been committed;

(b) play a more proactive role in promoting the self-regulatory system. It may share its experience in establishing regulatory framework with relevant societies to assist their setting up of a registration system with

higher credibility and reliability; and

(c) communicate with relevant societies for collecting updated complaint information and taking follow-up actions if public health is likely to be affected.

## (D) NO REVIEW MECHANISM

### Findings

**4.18** The policy paper of 1980 for the enactment of Cap 359 stated clearly that the Administration would reconsider the need to include other paramedical professions (several professions were mentioned) for regulation should the need arise. However, DH did not conduct any consultation or review to assess the need for putting any healthcare personnel under statutory control since then. There is no specific plan or timetable to do so. Nor is there any mechanism to trigger such review.

**4.19** DH also did not have any formal meeting with the unregulated healthcare sector, not until June 2012. Before then, DH just held open forum with interested healthcare disciplines (regulated or unregulated) every one or two years for discussing general healthcare issues (**para. 3.12**).

**4.20** In January 2012, the Administration commenced a strategic review on healthcare manpower planning and professional development (**para. 3.9**). However, that review is not focused on this issue.

### Our comments

**4.21** Without a proper framework for review, it is difficult for DH to determine whether additional legislation should be introduced to regulate any healthcare personnel that might have brought increasing health hazards to the patients. We consider that DH should establish a standing mechanism to regularly assess the state of individual professions against the risk factors mentioned in **Chapter 2**. If necessary, DH should raise the issue with its policy bureau in the Administration to map out an overall and long-term strategy.

## (E) LACK OF COMMUNICATION WITH SOCIETIES

### Findings

**4.22** DH encourages unregulated healthcare personnel to regulate themselves through society-based registration. However, DH did not establish a formal communication channel with them in order to promote their development in accordance with the self-regulatory system. In the past, open forums with the representatives of healthcare sectors were held to discuss healthcare-related issues only at irregular intervals (**para. 3.12**). Meeting with the representatives of unregulated healthcare personnel for the discussion of statutory regulation was for the first time arranged in June 2012. It shows that DH did not maintain an efficient communication with relevant societies.

### Our comments

**4.23** DH informed us that the Secretary for Food and Health meets with representatives of various healthcare professions periodically and that issues of mutual interests are also discussed as and when warranted at various Government statutory and advisory committees. However, we note that, between 1980 and 2011, DH conducted no formal meetings with representatives of unregulated healthcare personnel for discussing the issue of statutory regulation. We consider that DH should set up an effective communication channel with relevant societies and hold regular meetings with unregulated healthcare personnel to keep abreast of their current development.

# 5

# *RECOMMENDATIONS*

**5.1** DH has the duty to assure the qualification of the healthcare personnel in order to maintain a high quality of healthcare service. DH discharged such duty in the past by putting 13 healthcare professions under its regulatory framework. However, our investigation reveals that DH did not have any monitoring mechanism on the operation of unregulated healthcare personnel. Nor did DH have any review mechanism on the need to put them under statutory regulation.

**5.2** We note that the Administration has set up a steering committee in January 2012 for reviewing the healthcare manpower planning and professional development (**para. 3.9**). Although it is of an ad-hoc nature, we hope that its findings can pave the way for a sustainable system to control unregulated healthcare personnel thereby protecting the patients' health and welfare from malpractice by unqualified healthcare personnel.

**5.3** In this connection, The Ombudsman makes the following recommendations to the Director of Health:

**Monitoring mechanism**

(1) To collect relevant complaint statistics for conducting regular risk-based analyses (**paras. 4.6(a) and (b)** );

(2) To enhance communication with the law enforcement agencies, related organisations and societies for gathering relevant complaint information

for risk-based analyses (**paras. 4.11 and 4.12**);

(3) To consider providing guidance to societies of healthcare personnel not statutorily regulated on monitoring the qualification and service standard of their members so that they are in line with the spirit of society-based registration (**para. 4.17(a) and (b)**);

(4) To follow up cases related to malpractice of unregulated healthcare personnel referred by the professional societies concerned or reported by the media in order to assure that the service provided meets the standard as required by relevant societies. (**para. 4.17(c)**);

**Review mechanism**

(5) To examine the complaint statistics periodically for analysing whether more stringent regulation should be introduced to a particular group of healthcare personnel with increasing health hazard (**para. 4.21**);

(6) To discuss with its policy bureau in the Administration to map out a long-term review strategy for the scope and ways to strengthen regulatory control of unregulated healthcare personnel and also the need for putting them under statutory control (**para. 4.21**); and

(7) To enhance communication with societies of unregulated healthcare personnel for exchanging opinions regularly (**para. 4.23**).

**FINAL REMARKS**

**5.4** DH has indicated its welcome of the above recommendations and undertook to take appropriate follow-up actions. We thank DH for its support to this investigation.

**Office of The Ombudsman**
**Ref.: OMB/DI/278**
**October 2013**

**Annex A**
**(para. 2.2)**

# Number of Registered Healthcare Professionals
# (as at 31 December 2012)

| Type of Registered Healthcare Personnel | | No. |
|---|---|---|
| 1. | **Doctors** | **13,456** |
| | *Full Registration* *(13,006)* | |
| | *Provisional Registration* *(275)* | |
| | *Limited Registration* *(175)* | |
| 2. | **Dentists** | **2,258** |
| 3. | **Dental Hygienists** | **344** |
| 4. | **Pharmacists** | **2,127** |
| 5. | **Nurses** | **43,698** |
| | *Registered Nurses* *(32,831)* | |
| | *Enrolled Nurses* *(10,867)* | |
| 6. | **Midwives** | **4,504** |
| 7. | **Medical Laboratory Technologists** | **3,088** |
| 8. | **Occupational Therapists** | **1,517** |
| 9. | **Optometrists** | **2,072** |
| 10. | **Physiotherapists** | **2,428** |
| 11. | **Radiographers** | **1,891** |
| 12. | **Chiropractors** | **172** |
| 13. | **Chinese Medicine Practitioners** | **9,372** |
| | *Registered Chinese Medicine Practitioners* *(6,565)* | |
| | *Registered Chinese Medicine Practitioners with Limited Registration* *(74)* | |
| | *Listed Chinese Medicine Practitioners* *(2,733)* | |
| **Total:** | | **86,927** |

*(Source: The Department of Health)*

**Annex B**
**(para. 2.9)**

## Estimated size and distribution of the 15 healthcare personnel currently not subject to statutory regulation[(1)] (as at 31 March 2009)[(2)]

| Type of Healthcare Personnel | Public Sector[(3)] | Private Sector | Total |
|---|---|---|---|
| 1. Audiologists | 28 (45.2%) | 34 (54.8) | **62** |
| 2. Audiology Technicians | 15 (30.0%) | 35 (70.0%) | **50** |
| 3. Chiropodists/Podiatrists | 23 (57.5%) | 17(42.5%) | **40** |
| 4. Clinical Psychologists * | 264 (65.5%) | 139 (34.5%) | **403** |
| 5. Dental Surgery Assistants * | 412 (14.5%) | 2,435 (85.5%) | **2,847** |
| 6. Dental Technicians/Technologists * | 80 (25.2%) | 238 (74 .8%) | **318** |
| 7. Dental Therapists * | 296 (100.0%) | N.A. | **296** |
| 8. Dietitians * | 105 (33.7%) | 207 (66.3%) | **312** |
| 9. Dispensers * | 1,028 (52.4%) | 933 (47.6%) | **1,961** |
| 10. Educational Psychologists | 115 (75.2%) | 38 (24.8%) | **153** |
| 11. Mould Laboratory Technicians | 24 (70.6%) | 10 (29.4%) | **34** |
| 12. Orthoptists * | 16 (53.3%) | 14 (46.7%) | **30** |
| 13. Prosthetists/Orthotists | 96(74.4%) | 33 (25.6%) | **129** |
| 14. Scientific Officers (Medical) * | 128 (74.4%) | 44 ( 25.6%) | **172** |
| 15. Speech Therapists * | 334 (66.0%) | 172 (34.0%) | **506** |
| **Total** | **2,964(40.5%)** | **4,349(59.5%)** | **7,313** |

*(Source: The Department of Health)*

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(1) *The number of healthcare personnel (full-time/part-time employment) employed by their working institutions which responded to the survey.*

(2) *DH conducts Health Manpower Survey on the 15 healthcare personnel currently not subject to statutory regulation every four to five years. The previous surveys were conducted in 2005 and 2009 and the next is scheduled for 2014.*

(3) *Public sector includes the Government, Hospital Authority, academic institutions, and subvented organisations.*

* *Professions with personnel currently engaged by DH.*

**Annex C**
**(para. 2.10)**

# Associations/Societies of non-statutorily regulated healthcare personnel in Hong Kong

| Healthcare personnel | Associations/Societies |
|---|---|
| 1. Audiologist | Hong Kong Society of Audiology Limited (http://www.audiology.org.hk) |
| 2. Audiology Technician | Hong Kong Association of Audiologists |
| 3. Chiropodist/Podiatrist | Hong Kong Podiatrists Association (http://www.hkpoda.org) |
| | International Podiatrists Association of Hong Kong (http://www.ipahk.com) |
| 4. Clinical Psychologist | Division of Clinical Psychology, The Hong Kong Psychological Society (http://www.hkps.org.hk) |
| | Hong Kong Clinical Psychologists Association (http://www.hkcpa.org.hk) |
| 5. Dental Surgery Assistant | Hong Kong Association of Dental Surgery Assistants (http://www.fmshk.com.hk/hkadsa/index.htm) |
| | Government Dental Surgery Assistants Association |
| 6. Dental technologist / Dental technician | Hong Kong Society of Dental Technicians (http://www.hkstd.org) |
| 7. Dental Therapist | Hong Kong Department of Health Dental Therapists Association |
| 8. Dietitian | Hong Kong Dietitians Association Limited (http://www.hkda.com.hk) |
| | Hong Kong Nutrition Association Limited (http://www.hkna.org.hk/en/default/asp?page=home) |
| | Hong Kong Practicing Dietitians Union (http://www.hkda.com.hkJdocs/HKPDU/index.html) |
| 9. Dispenser | Hong Kong Government Pharmaceutical Dispenser Association http://hkgdisp.tripod.com/index.html |
| 10. Educational Psychologist | Division of Educational Psychology, The Hong Kong Psychological Society (http://www.hkps.org.hk) |
| 11. Mould Laboratory Technician | Hong Kong Radiotherapy Mould Laboratory Technicians and Technologists |
| 12. Orthoptist | Hong Kong Orthoptist Association (http://www.fmshk.com.hk/hkoa) |
| 13. Prosthetist / Orthotist | Hong Kong Society of Certified Prosthetist-Orthotists (http ://www.hkscpo.org) |
| | Hong Kong Prosthetists and Orthotists Association |
| | International Society for Prosthetics and Orthotics, Hong Kong National Society |
| 14. Scientific Officer (Medical ) | Hong Kong Society of Clinical Chemistry (http://www.medicine.org.hk/hkscc) |
| 15. Speech Therapist | The Hong Kong Association of Speech Therapists (http://www.speechtherapy.org.hk) |

*(Source: The Department of Health)*