For discussion on
11 April 2011

Legislative Council Panel on Health Services
Creation of new directorate posts in the Department of Health

PURPOSE

This paper briefs Members on the Administration's proposal to create two new directorate posts for the establishment of the Office on Drugs (DO) and seeks Members' support for the proposal to be put to the Finance Committee (FC) and its Establishment Subcommittee (ESC) for approval.

BACKGROUND

2. At present, the drug regulation functions of the Department of Health (DH) are principally carried out through its Pharmaceutical Service (Pharm Service). Apart from serving as a law enforcement agency over legislations concerning drugs, the Pharm Service is also responsible for the procurement, manufacturing and dispensing of drugs at the clinics of DH. The Pharm Service comprises five Sections, namely the Inspection and Licensing Section, the Pharmaceuticals Registration Section, the Clinic Service and Pharmaceuticals Import/Export Control Section, the Procurement and Manufacturing Section and the Administration Section. Overseen by Assistant Director (Special Health Services) (AD(SHS)), the Pharm Service is now headed by a Chief Pharmacist (C Pharm) and supported by seven Senior Pharmacists and 51 Pharmacists. In addition, there are 33 Dispenser grade staff and other 55 administrative and supporting staff, making up a total of 147 approved posts as at 31.3.2011.

3. In early 2009, a number of incidents concerning pharmaceutical products in Hong Kong aroused wide public concern over drug safety. The Government subsequently set up the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong (Review Committee), chaired by the Permanent Secretary for Food and Health (Health) with members from the pharmaceutical sector, medical profession, academia, patient groups and other stakeholders, to conduct a comprehensive review on the existing regime for the regulation of pharmaceutical products and map out the long term measures to strengthen drug regulation.

4. The Report of the Review Committee was published in December 2009 and presented to this Panel in January 2010 (CB(2)680/09-10(03)). The Review

Committee was of the view that the existing regulatory regime was sound and should continue to be adopted, but the coverage and depth of the regulatory measures should be enhanced. The Review Committee has made a total of 75 recommendations to strengthen drug regulation and enhance the standard and performance of pharmaceutical sector. These recommendations involve enhancing the standard of local drug manufacturers, enhancing the monitoring system on product recall and stepping up regulatory control of drug distribution. Considering that the present setup of Pharm Service inadequate for it to discharge its enhanced role on drug regulation effectively, the Review Committee recommended that DH should establish a dedicated office to strengthen its drug regulation capability. The office would formulate plans on drug regulation and direct the implementation of various measures relating to drug safety, efficacy and quality.

5. The Audit Commission also conducted a review on the control of western medicines in 2009 and the Director of Audit's Report No. 53, published in October 2009, made a number of recommendations similar to those of the Review Committee. The Audit report was discussed by the Public Accounts Committee, which strongly urged that the safety, efficacy and quality of medicines in Hong Kong should be ensured as top priority and that the recommendations of the Review Committee should be expeditiously implemented with the necessary manpower resources sought and the required legislative proposals introduced to improve the regime for the regulation and control of medicines.

ESTABLISHING A DEDICATED OFFICE ON DRUGS

6. In making its recommendation on the dedicated office on drugs, the Review Committee had made reference to overseas practices and observed that the drug regulatory authorities of advanced countries, including the Therapeutic Goods Administration of Australia, Healthcare Products Regulatory Agency of the United Kingdom, and the Health Sciences Authority of Singapore are all independent government departments or agencies. The Review Committee also noted that in the Hong Kong context, the Centre for Health Protection was set up in 2004 while the Centre for Food Safety was set up in 2006 with the objectives of enhancing the prevention and control of communicable diseases and enhancing food safety regulation respectively.

7. To strengthen the organisational capacity in drug regulation, we propose to expand and reorganise the Pharm Service into a dedicated office on drugs (i.e. the DO) as recommended by the Review Committee. The proposed DO will focus on the areas of pharmacovigilance, risk assessment and communication, market surveillance, public education and health promotion; and foster application of the latest IT technology to enhance the drug database, develop computer systems on import/export control of drugs and revamp the DH website to provide for better public information on drug matters. It will also continue to serve as a law enforcement agency over legislations concerning drugs, and procuring, manufacturing and dispensing of drugs at clinics of DH.

Functions of DO

8. The proposed DO will comprise different divisions focusing on areas in (i) Vigilance and Risk Analysis; (ii) Licensing and Compliance; and (iii) Pharmaceuticals Registration and Business to perform the following major functions –

(a) to promote and maintain a vigilance programme, including the handling of adverse drug reaction (ADR) reports;

(b) to conduct risk analysis as regards ADR and quality defects of drugs and derive risk management plans;

(c) to conduct market surveillance programme and investigate drug incidents;

(d) to implement risk communication plan and organise public education programmes and training programmes for pharmaceutical trade;

(e) to monitor undesirable medical advertisements and enforce the Undesirable Medical Advertisements (UMA) Ordinance;

(f) to enhance regulation of drug manufacturers by upgrading Hong Kong's current Good Manufacturing Practice (GMP) licensing standards to the Pharmaceutical Inspection Co-operation Scheme (PIC/S)[1] standards over a period of four years and equipping and upgrading the current GMP inspection team for the attainment of PIC/S membership;

(g) to conduct inspections of overseas and Mainland drug manufacturers in future;

(h) to enhance regulation of other drug traders including wholesalers, importers/exporters and retailers.

(i) to process drug registrations and related applications (with new bioavailability and bioequivalence (BABE)[2] requirement) and applications for clinical trials; and control import and export of drugs in order to ensure that the drugs in Hong Kong are safe, effective and of good quality;

(j) to provide enhanced drug procurement, manufacturing and dispensing services to the clinics of DH;

[1] The Pharmaceutical Inspection Co-operation Scheme is an international agreement between pharmaceutical inspection authorities of different countries or territories which provide an active and constructive co-operation in the field of GMP. This is to be achieved by developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing inspectorates; and facilitate co-operation and networking of competent authorities and international organisations. There are currently 37 participating authorities including the majority European Union countries, Australia, Singapore, etc.

[2] BABE refers to the therapeutic equivalence of the same pharmaceutical product manufactured by different manufacturers. BABE studies seek to assess whether a generic drug produces the same therapeutic effect as the patent drug.

(k) to maintain a close communication network with overseas authorities and professional bodies, and develop continuous training programmes for professional staff; and

(l) to maintain a drug information management system.

Proposed Staffing Arrangements of DO

9. In view of the much expanded scope of the statutory and regulatory regime of the new drug office in Hong Kong and the importance of co-ordinating and collaborating with a host of stakeholders, we propose to create in DO two permanent directorate posts, including one Assistant Director of Health (AD of Health) (D2) post, designated as AD (Drug Office), to be the Head of DO; and one permanent post of Chief Pharmacist (C Pharm) (D1) post, designated as C Pharm (2).

10. It is necessary to have a dedicated AD of Health at D2 level to assume leadership, provide policy steer, formulate strategies and fully discharge the coordination role of DO. The newly created C Pharm (2) will assist AD (Drug Office) in overseeing pre-market control of pharmaceutical products in Hong Kong, dispensing service and procurement, manufacturing and supply of drugs to clinics in DH, maintenance of drug information databases under the DH as well as implementation of various recommendations of the Review Committee including enhancement of import/export control.

11. In addition, we propose to permanently redeploy the C Pharm under the existing Pharm Service to the dedicated DO, designated as C Pharm (1), to assist AD (Drug Office) in overseeing the enhanced regulation of drug manufacturers, including the upgrading of Hong Kong's current GMP licensing standard to the PIC/S standard over a period of four years, equipping and upgrading the current GMP inspection team for the attainment of PIC/S membership, and conducting inspections of overseas and Mainland drug manufacturers in future; and the enhanced regulation of other drug traders including wholesalers, importers/exporters and retailers. The job descriptions of the proposed permanent posts of AD (Drug Office) and C Pharm(2) are respectively set out at **Annexes A** and **B** while the existing and revised job descriptions of the existing C Pharm are respectively set out at **Annexes C** and **D**.

12. We also propose the three directorate officers be supported by an ultimate number of 207 non-directorate civil service posts, comprising the existing staff of Pharm Service and 36 new non-directorate civil service posts for creation in 2011-12 and a further 25 posts for creation in 2012-13. They include Pharmacists, Scientific Officers (Medical), Executive Officers and supporting clerical and secretarial staff. These posts cut across different disciplines in order to provide the necessary support and enhancements for the regulation of Pharmaceutical Products. The proposed civil service staffing of dedicated drug office is set out at **Annex E**. DH will create the additional non-directorate civil service posts in accordance with the established mechanism.

Filling of the proposed AD (Drug Office) post

13. Having regard to the specialised functions of this office, its Head will need to possess an in-depth knowledge in pharmacy and the necessary qualifications and experience in drug safety and regulatory work. We therefore propose the AD (Drug Office) post be filled by a Pharmacist grade officer with relevant regulatory experience in pharmacy. This AD post will be a designated post to be taken up by an officer from the Pharmacist grade. As the regulatory framework of drugs involves drug manufacturers, wholesalers, importers/exporters and retailers, the AD should also be well experienced in and familiar with the operations of these stakeholders and be able to gain their respect and rapport. Besides, he/she should be able to keep abreast of new developments in various areas of manufacturing, new drug developments and the regulatory decisions made by international drug authorities. In addition, the post holder should have relevant training in pharmacovigilance and public health so that he/she could take an active part in the worldwide pharmacovigilance network.

14. The proposed organisation chart of DO is at **Annex F.** The organisation chart of DH after the establishment of the proposed DO is at **Annex G.**

ALTERNATIVES CONSIDERED

15. At present, AD (SHS) is responsible for overseeing the regulation of pharmaceutical products and planning for the set-up of DO. He also oversees the control on port health and radiation health, medical device, licensing of human reproductive technology centres, information technology development and management in DH and planning and development of the electronic Health Record Management System.

16. As the scope of services provided by Pharm Service will be significantly expanded, the Head of DO should possess an in-depth knowledge in pharmacy and the necessary qualifications and experience in drug safety and regulatory work. Besides, it is beyond the capacity of AD (SHS) to oversee its functions as part of his wide portfolio. The job description of AD (SHS) will be revised accordingly as set out at **Annex H**.

17. We have also critically examined the possible redeployment of the other existing directorate officers under the Director of Health to take on the work of the proposed directorate post. We conclude that it is not operationally feasible as the Head of DO requires expertise in pharmacy and regulatory experiences in the relevant areas.

FINANCIAL IMPLICATIONS

18. The creation of the two proposed directorate posts will incur an additional notional annual salary cost at mid-point of $2,768,400. The additional full annual

average staff cost, including salaries and staff on-cost, is $3,560,000.

ADVICE SOUGHT

19. Members are invited to comment on the establishment of DO and the proposed staffing arrangements. We plan to seek the necessary approval from ESC on 8 June 2011 and FC on 24 June 2011 for the creation of the two proposed directorate posts and permanent redeployment of the existing C Pharm post.

Food and Health Bureau
Department of Health
April 2011

Annex A

Proposed Job Description for the Post of Assistant Director (Drug Office)

Rank **:** Assistant Director (AD) of Health (D2)

Responsible to **:** Deputy Director of Health (D3)

Major duties and responsibilities –

1. To plan and oversee development and implementation of a comprehensive strategy for effective and efficient management of the regulatory regime on pharmaceutical products in Hong Kong;
2. To steer and supervise the operation of the dedicated office on drugs to ensure that the regulatory control of pharmaceutical products, drug manufacturers and dealers, in Hong Kong are carried out effectively;
3. To keep abreast of international development on pharmaceutical matters, exchange information and maintain communication with stakeholders of drug trade;
4. To oversee the implementation of the 75 recommendations made by the Review Committee;
5. To spearhead in the areas of pharmacovigilance, risk assessment and communication, market surveillance; and
6. To provide professional support to the Pharmacy and Poisons Board and the Director of Health on regulation of pharmaceutical products.

Annex B

Proposed Job Description for the Post of
Chief Pharmacist 2

Rank **:** Chief Pharmacist (D1)

Responsible to **:** AD (Drug Office) (D2)

Major duties and responsibilities –

1. To assist the Head of dedicated drug office on pharmaceutical registration and clinical trial matters;
2. To assist the Head on the dispensing service and procurement, manufacturing and supply of drugs of clinics under the DH;
3. To assist the Head to oversee the pre-market control of pharmaceutical products in Hong Kong;
4. To oversee the implementation of computerisation projects and maintenance of drug information databases for the drug office;
5. To manage staff of Pharmacist and Dispenser grades; and
6. To provide professional support to the Pharmacy and Poisons Board and the Director of Health on regulation of pharmaceutical products.

Annex C

Job description for the Existing Chief Pharmacist

Rank **:** Chief Pharmacist (D1)

Responsible to **:** AD (Special Health Services) (D2)

Major duties and responsibilities –

1. To oversee the enforcement of the legislations on drugs and assist in the formulation of policies on law enforcement activities;
2. To advise on the aspects concerning drugs and other pharmaceutical matters;
3. To oversee the drug procurement and administration of the Pharmaceutical Service;
4. To oversee undesirable medical advertisements and the Adverse Drug Reactions reporting system;
5. To manage staff of Pharmacist and Dispenser grades; and
6. To provide professional support to the Pharmacy and Poisons Board and Director of Health on regulation of pharmaceutical products.

Annex D

Proposed revised job description for the Post of Chief Pharmacist 1

Rank **:** Chief Pharmacist (D1)

Responsible to **:** AD(Drug Office) (D2)

Major duties and responsibilities –

1. To assist the Head of dedicated drug office on licensing controls and inspections to drug manufacturers, wholesalers, retailers, importers and exporters in Hong Kong;
2. To assist the Head to oversee the enhanced regulation of drug manufacturers, including the upgrade of Hong Kong's current Good Manufacturing Practice (GMP) licensing standards to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) standards over a period of four years;
3. To assist the Head to oversee the upgrading of the current GMP inspection team for the attainment of PIC/S membership;
4. To oversee the conduction of inspections to overseas and Mainland drug manufacturers in future and the enhanced regulation of other drug traders including wholesalers and retailers;
5. To assist the Head to oversee the operation of the Vigilance, Risk Analysis and Undesirable Medical Advertisements teams;
6. To manage staff of Pharmacist and Dispenser grades; and
7. To provide professional support to the Pharmacy and Poisons Board and Director of Health on regulation of pharmaceutical products.

Annex E

Proposed Civil Service Staffing for the Dedicated Office on Drugs

Major scope of responsibilities / Rank	**Approved Establishment of Pharm Service**	**Posts to be created in 2011-12**	**Posts to be created in 2012-13**
Professional and technical support			
Assistant Director of Health	0	1	0
Chief Pharmacist	1	1	0
Senior Pharmacist	7	2	2
Pharmacist	51	14	23
Scientific Officer (Medical)	1	5	0
Chief Dispenser	3	0	0
Senior Dispenser	7	0	0
Dispenser	23	0	0
Administration support			
Chief Executive Officer	0	1	0
Senior Executive Officer	1	0	0
Executive Officer II	1	2	0
Clerical Officer	3	2	0
Assistant Clerical Officer	13	5	0
Confidential Assistant	1	0	0
Clerical Assistant	11	4	0
Personal Secretary I	0	1	0
Personal Secretary II	1	0	0
Supplies Supervisor II	3	0	0
Supplies Assistant	3	0	0
Office Assistant	2	0	0
Artisan	6	0	0
Workman I	1	0	0
Workman II	8	0	0
Sub-total	**147**	**38**	**25**

Total = 147 + 38 + 25 = 210

Annex F

Proposed Organization Chart of Office on Drugs for 2011-2012

AD(Drug Office)
~
(AD of H, D2)

1 PS I

1 C Pharm

1 PS II

1 C Pharm ~

Vigilance and Risk Analysis Division

Vigilance and Risk Analysis Unit

1 S Pharm

1 S Pharm

Vigilance Team
7 Pharm
1 SO(M)

Risk Analysis Team
6 Pharm

Undesirable Medical Advertisements Team
3 Pharm
8 DISP

Administration Team
1 EO II
1 CO
2 ACO
1 CON ASS
1 CA

Licensing and Compliance Division

Licensing and Compliance Unit

1 S Pharm

1 S Pharm

Importer/Exporter Regulatory Team
2 Pharm

Wholesalers Regulatory Team
6 Pharm

Retailers Regulatory Team
8 Pharm

Administration Team
1 EO II
1 CO
6 ACO
3 CA

PIC/S Unit

1 S Pharm

1 S Pharm

Manufacturing Quality Assurance Team
12 Pharm

PIC/S Membership Team
2 Pharm
3 SO(M)

Pharmaceuticals Registration and Business Division

Pharmaceuticals Registration and Import/Export Control Unit

1 S Pharm

1 S Pharm

Drug Information Management System Team
2 Pharm

Pharmaceuticals Registration Team
8 Pharm
2 SO(M)

Import and Export Control Team
2 Pharm

Clinical Trials Team
3 Pharm

Administration Team
2 CO
8 ACO
8 CA
1 OA

Clinic Service and Business Unit

1 S Pharm

Clinic Service Team
1 Pharm
1 C DISP
1 S DISP
5 DISP #
1 SS II
1 SA
1 CA
1 ACO

Procurement & Manufacturing Team
3 Pharm
2 C DISP
6 S DISP
10 DISP
6 Artisan
2 SS II
2 SA
1 CA
1 WM I
8 WM II

Administration Division

Administration Unit

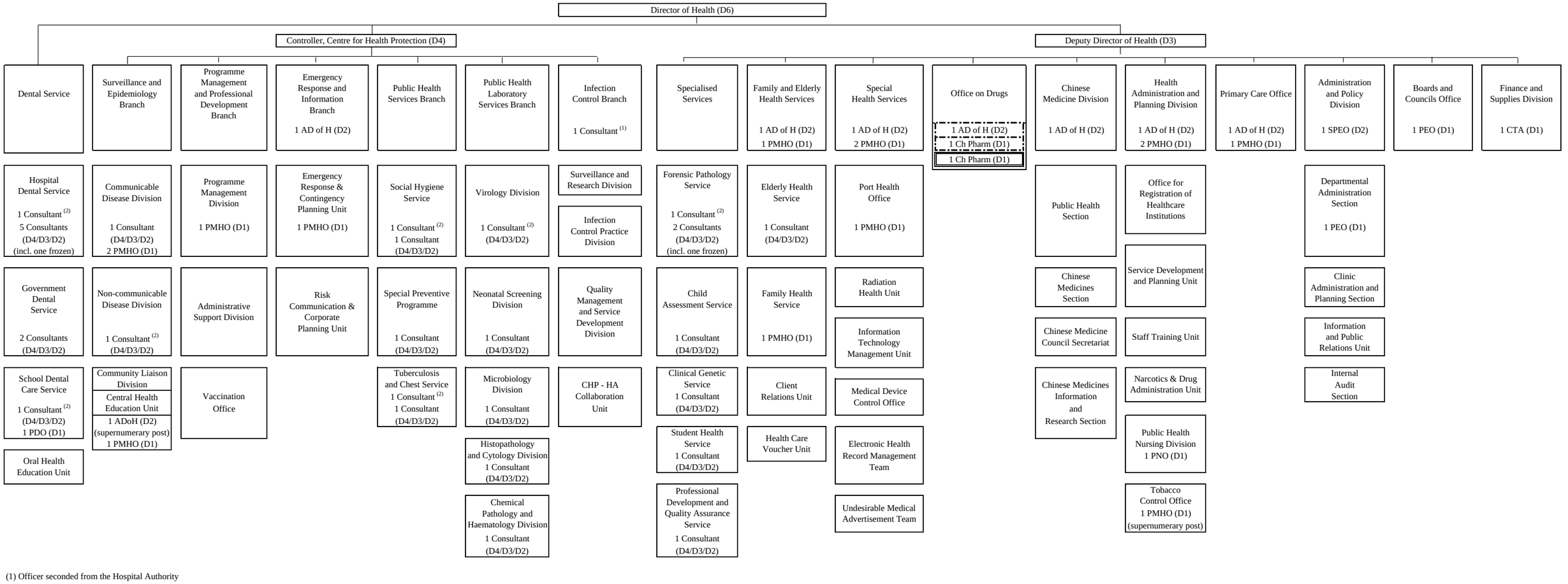
1 CEO
1 SEO
1 EO II
1 CO
1 ACO
1 CA
1 OA

~ Posts to be created

Post to be redeployed from the previous Pharmaceutical Service

Include 1 post subject to further review

Proposed Organisation Chart of the Department of Health



(1) Officer seconded from the Hospital Authority

(2) Also assuming the role as Consultant in-charge of the Service / Branch taking care of the overall administration and management matters.

Legend

AD of H	Assistant Director of Health
AOSGC	Administrative Officer Staff Grade C
PMHO	Principal Medical & Health Officer
PDO	Principal Dental Officer
PNO	Principal Nursing Officer
SPEO	Senior Principal Executive Officer
PEO	Principal Executive Officer
CTA	Chief Treasury Accountant
Ch Pharm	Chief Pharmacist
	Posts to be created
	Post to be redeployed

Annex H

Revised Job Description for the Post of
Assistant Director (Special Health Services)

Rank **:** Assistant Director of Health (D2)

Responsible to **:** Deputy Director of Health (D3)

Major duties and responsibilities –

1. To oversee the Port Health Office to enforce the provisions of Prevention and Control of Disease Ordinance and the International Regulations at HK International Airport, sea port and various land boundary control points to prevent infectious diseases from being introduced into or carried away from the territory;
2. To oversee the Radiation Health Unit (RHU) on regulation of import, export, possession and use of radioactive substances and irradiating apparatus and provision of advice and services to protect the health of workers and members of the public from deleterious effects arising from the use of ionising radiations in Hong Kong;
3. To steer the Medical Device Control office (MDCO) on consultations with the trade and stakeholders, commissioning of a business impact assessment study, and preparation for legislation on medical devices;
4. To steer the formulation of strategic framework on the development and implementation of the eHR projects in consultation with stakeholders, evaluates different implementation options and liaises with EU, OGCIO, FHB and HA on matters related to these projects;
5. To oversee the setup of the DH eHR Management Team (eHRMT) and provides directives on resources and tendering for these projects, development of territory-wide electronic health data standards and implementation of the territory-wide e-HR programme;
6. To oversee the implementation of the licensing system laid down by law for regulating human reproductive technology procedures, embryo research and related activities in support of the Council on Human Reproductive Technology;
7. To formulate information technology (IT) plan, IT development and management in DH;
8. To keep abreast of international development on radiation and port health, reproductive technology matters; exchange information and maintain communication with the trade and stakeholders; and
9. To provide professional advice to the Director of Health and Council on Human Reproductive Technology.