

CHAPTER 10 RESOURCES IMPLICATIONS AND ESTABLISHMENT OF A DEDICATED OFFICE ON DRUGS

Overview

10.1 This chapter sets out the additional manpower requirements in implementing all the recommendations of the Review Committee to enhance the regulatory regime on pharmaceutical products in Hong Kong, and outlines the proposed establishment of a dedicated office on drugs to strengthen DH's capacity in drug regulation.

Additional Manpower Requirements

10.2 The Review Committee notes that additional staff will be required to improve existing services including shortening of processing time for drug registration and related applications, monitoring of side effects reports on approved clinical study programmes, enhancement of inspections to drug traders including local manufacturers, importers/exporters, wholesalers and retailers, etc. The Review Committee also notes that many new policy initiatives have staff implications, including licensing of wholesalers and retailers of non-poisons, setting up of a dedicated team for pharmacovigilance and risk communication, inspections of overseas and Mainland drug manufacturers without a PIC/S certificate, liaison with overseas and Mainland State and Provincial drug regulatory authorities, etc.

10.3 Apart from pharmacist grade staff, the Review Committee agrees that professionals from other disciplines including medical officers, scientific officers, engineers, environmental hygienists and veterinary officers should be included in the multi-disciplinary inspection team to enrich the technical basis for regulatory enhancement, while information officers should be available in the pharmacovigilance and risk communication team to assist in the publicity of drug alert and other drug education messages.

10.4 To tie in with the increased professional manpower and the expanded scope of responsibilities, the Review Committee also agrees that the administrative, information technology and technical support should be enhanced correspondingly. The Review Committee understands that DH will go through the established procedures in seeking additional staff resources with detailed justifications for the posts to be created.

Establishment of a Dedicated Office on Drugs

10.5 The Review Committee notes that the drug regulatory functions of DH are principally carried out through its Pharmaceutical Service (PS). Apart from serving as a law enforcement agency over legislations concerning drugs, PS also provides for the procurement, manufacturing and dispensing of drugs at the clinics of DH. PS is now headed by a Chief Pharmacist (CP) at Directorate One (D1) level and supported by 7 Senior Pharmacists (SPs) and 41 Pharmacists. In addition, there are 61 dispensers and some 50 other administrative and information technology supporting staff. The existing organization chart of PS is at *Annex I*. CP reports to the Assistant Director (Special Health Services), who has to look after other services of DH, such as port health, electronic health record management, health care voucher, radiation health and narcotics etc.

10.6 The Review Committee has made reference to overseas practices and observes that the drug regulatory authorities of advanced countries, including the Therapeutic Goods Administration of Australia, Health Canada of Canada, 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 notes that in the Hong Kong context, the Centre for Health Protection (CHP) was set up in 2004 while the Centre for Food Safety (CFS) was set up in 2006 with the objectives of enhancing the prevention and control of communicable diseases and enhancing food safety regulation respectively.

10.7 If the manpower proposals in this chapter are implemented in full, the staff strength of PS will be increased significantly from around 160 to more than 350. In addition, all the other recommendations in this review will also expand the scope of responsibilities of PS. The Review Committee considers that the present organizational setup of PS could no longer enable it to discharge its enhanced role on drug regulation effectively. The Review Committee **recommends** to DH that a dedicated office on drugs be established to strengthen the organizational capacity in drug regulation. This is in line with the practice in advanced countries on drug regulation and local practice in respect of prevention and control of communicable disease and food safety regulation. More importantly, it demonstrates to the general public the Government's strong determination and long-term commitment in ensuring drug safety, protecting public health and restoring public confidence in the use of drugs.

10.8 Having regard to the size and scale of operation when the office commences operation, the Review Committee considers it prudent at the setup stage to have a dedicated head at Directorate 2 Level to oversee the office's operation, make day-to-day management and professional decisions, and formulate strategic plans on drug regulation. The head will report to the Deputy Director of Health and ultimately the Director of Health who will focus on the strategic missions of the office. The statutory authority of the Director of Health vested under the Pharmacy and Poisons Ordinance will remain unchanged, and the Director of Health will still be the Chairman of the Pharmacy and Poisons Board.

10.9 The dedicated office will consist of three functional divisions. The Pharmacovigilance, Risk Communication and Quality Management Division will be responsible for pharmacovigilance matters; monitoring of undesirable medical advertisements; risk analysis, management and communication; international affairs and training; the development and maintenance of a drug information management system and a dedicated website on drug safety; and providing administrative, information technology and technical support to the operation of the office. The Inspection and Licensing Division will be responsible for the licensing and compliance inspection of all drug traders including manufacturers, wholesalers, importers/exporters and retailers; undertaking preparatory works in the journey towards the attainment of PIC/S membership; and the conduct of inspections to overseas and Mainland drug manufacturers without a PIC/S certificate in future. Lastly, the Pharmaceuticals Registration and Business Development Division will be responsible for processing of drug registration and related applications; import and export control of drugs; providing drug procurement, manufacturing and dispensing services to clinics of DH; maintenance of drug information; and organization of training programmes for the pharmaceutical trade and public education programmes on drug safety.

10.10 Having regard to the increased number of pharmacists and senior pharmacists, the addition of professionals of other disciplines comparable to the senior pharmacist level, and the expanded scope of responsibilities, the Review Committee **recommends** that the Inspection and Licensing Division and the Pharmaceuticals Registration and Business Development Division both be headed by a Chief Pharmacist at Directorate 1 level. As for the Pharmacovigilance, Risk Communication and Quality management Division, due to its importance in terms of the public health perspective, the Review Committee **recommends** that it be headed by a Principal Medical Officer at Directorate 1 level. The proposed organization of the office is at *Annex J*.

10.11 In the long run, consideration will be given to expanding the scope of the dedicated office to cover other therapeutic products. The dedicated office could transform into a “Centre for Drug Safety”.