CHAPTER 1 INTRODUCTION

Overview

1.1 This chapter sets out the background of the review; the terms of reference and membership of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong; and its work in the last nine months.

Background

1.2 In March 2009, a number of incidents concerning pharmaceutical products broke out in Hong Kong, causing public concerns and calling into question the adequacy and performance of the existing regime for the regulation and control of pharmaceutical products. A chronology of these drug incidents since March 2009 is at *Annex G*.

1.3 Immediate after these drug incidents, the Department of Health (DH) conducted an additional round of inspections to all the 25 drug manufacturers in Hong Kong for risk and microbiology safety assessment. Written advices were also issued to all manufacturers, importers/exporters, wholesalers, retailers and professional associations in the drug industry to remind them of the essential licensing requirements on drug safety.

1.4 The Government considered that in order to ensure patient safety, protect public health and restore public confidence, a comprehensive review on the existing regime for the regulation and control of pharmaceutical products was necessary to identify gaps and areas for improvement.

1.5 Against this background, the Secretary for Food and Health announced on 19 March 2009 the setting up of a Review Committee on Regulation of Pharmaceutical Products in Hong Kong (Review Committee), to be chaired by the Permanent Secretary for Health with members from the pharmaceutical sector, medical profession, academia, patient groups and consumer representative. The Review Committee was tasked to complete the review in six to nine months' time.

Membership and Terms of Reference of the Review Committee

1.6 The membership and terms of reference of the Review Committee, as adopted at its first meeting held on 3 April 2009, are at *Annex A*.

Work of the Review Committee

1.7 To facilitate in-depth examination of the wide range of drug issues, Members of the Review Committee formed two subcommittees on drug manufacturing, and drug distribution and procurement respectively. The membership of the two subcommittees is at *Annex B*. Besides, to support the work of the Review Committee, a Task Force was set up under DH to make proposals, through the engagement of overseas consultancy studies, on the updating of the Good Manufacturing Practices (GMP) scheme and on the enhancement of pharmacovigilance in Hong Kong. Furthermore, DH also formed an Expert Group to give advice on microbiological hazards on drug manufacturing, based on the trial run testing results in a local drug manufacturer, to the Task Force. The memberships and terms of reference of the Task Force and Expert Group are at *Annex C*. Recommendations from the Task Force were first deliberated at subcommittee level before they were put forward to the Review Committee for deliberation and endorsement.

1.8 During the review period from April to December 2009, the Review Committee held a total of five meetings to consider the work reports of its subcommittees and the findings and recommendations in the review report. In addition, the Subcommittee on Drug Manufacturing and the Subcommittee on Drug Distribution and Procurement both met on three occasions to conduct detailed examination on a wide range of drug issues.

1.9 In order to have a deeper understanding on the actual operation of local drug manufacturers, Members of the Review Committee visited the premises of two local drug manufacturers in Yuen Long in May 2009.

1.10 The Review Committee has examined all aspects of the current drug regulatory regime and the supply chain of pharmaceutical products, from manufacturing, distribution, import and re-export, procurement, supply of drugs and delivery to the public and private sectors, to control of pharmaceutical products, pharmacovigilance, penalty for non-compliance as well as risk communication, education and training. The Review Committee has also considered the additional resources requirements to implement all its recommendations.

1.11 In the course of the review, the Review Committee has sought and duly taken into account the views of its Members. The majority views of Members are taken before arriving at the final recommendations. Detailed recommendations of the Review Committee are set out in the ensuing chapters.