CHAPTER 2 EXISTING REGULATORY REGIME

Overview

2.1 This chapter states the objectives of the review, gives an overview on the existing regime for the regulation and control of pharmaceutical products in Hong Kong, and sets out the underlying principles of existing regulatory regime.

Objectives of the Review

2.2 The Review Committee intends to achieve the following objectives in this review -

(a) to protect public health and ensure patient safety as the top priority;

(b) to ensure that all pharmaceutical products supplied in Hong Kong fulfill a set of stringent safety and quality criteria in order to protect public health;

(c) to restore and maintain public confidence on the consumption and use of drugs;

(d) to sustain and upgrade the standard of Hong Kong drug manufacturing industry to international level; and

(e) to foster the development of Hong Kong pharmaceutical trade and industry and promote the trademark of Hong Kong.

2.3 While striving to improve the effectiveness of the existing regulatory regime, the Review Committee is mindful of the challenges to the trade and the professionals. Moreover, the proposed regulatory regime should be fair, accountable, consistent and transparent.

Existing Regulatory Regime

2.4 The existing drug regulatory regime adopts a risk management, dual target and multi-pronged approach backed by the law. The regime targets at both the pharmaceutical products and the pharmaceutical trade. Multi-pronged approach embraces legal requirements and administrative measures which

provide the framework of the control system; education for players in the pharmaceutical sector to equip them with the necessary professional knowledge; promotion and publicity to educate the public on safe use of drugs; and a penalty system to deter the pharmaceutical sector from malpractices.

2.5 The regulatory regime is risk and evidence based, starting at the source and following through each point in the production line and the supply chain until the drug reaches its target patients. A penalty system is in place with penalty for non-compliance of drug regulations proportional to the harm and impact that each mal-practice or defective drug products may cause to the patients and general public.

Legal Framework

2.6 Regulation of the pharmaceutical trade in Hong Kong is essentially provided for by the Pharmacy and Poisons Ordinance (Chapter 138) ("the Ordinance") and its regulations. Section 3 of the Ordinance provides for the establishment of a Pharmacy and Poisons Board for the enforcement of the Ordinance. Section 4A of the Ordinance further allows the Pharmacy and Poisons Board to establish executive committees to license various medicine dealers, to register pharmaceutical products and to approve clinical trials of drugs. The Review Committee notes that the Ordinance is subject to regular review taking into consideration changes in the operating environment and needs of the trade.

Pharmaceutical Trade

2.7 There are four levels of players in the drug supply chain, viz. manufacturers, importers/exporters, wholesalers and retailers (including the pharmacists overseeing the operations of the retailers). At present, there are 25 manufacturers, around 240 importers/exporters, 860 wholesalers and 3,800 retailers in Hong Kong. They are all subject to licensing control under the Ordinance.

Classification of Pharmaceutical Products

2.8 The Ordinance provides for a Poisons List which is divided into two parts: Part I and Part II respectively. Drugs included in Part I of the Poisons List are termed "Part I Poisons" while drugs included in Part II of the Poisons List are termed "Part II Poisons". "Part I Poisons" in general are drugs with more serious side effects which warrant enhanced supervision in handling, while "Part II Poisons" have less serious side effects. Drugs which are not

included in the Poisons List are commonly referred to as "non-poisons" by the traders.

2.9 Some Part I Poisons are further classified into the First Schedule and the Third Schedule with additional restrictions on their sale at retailers (the Second Schedule refers to drugs exempted as "poisons").

2.10 Currently, there are about 19,500 pharmaceutical products registered in Hong Kong, including 12,300 poisons and 7,200 non-poisons. Among the 12,300 poisons, 10,800 are Part I Poisons and 1,500 are Part II Poisons. Of the Part I Poisons, 400 are First Schedule Poisons and 10,400 are Third Schedule Poisons.

Two-tier Monitoring and Control of Pharmaceutical Products

2.11 It is stipulated under the Pharmacy and Poisons Regulations that all drugs in Hong Kong must be registered with the Pharmacy and Poisons Board before sale. In line with international practice, only products which are safe, efficacious and of good quality will be registered. To ensure proper control of the safety, efficacy and quality of drugs, Hong Kong has a two-tier monitoring and control system that is very similar to those in many other overseas drug authorities, comprising pre-market and post-market control.

Underlying Principles of Existing Regulatory Regime

2.12 Since there are over 19,000 pharmaceutical products registered in Hong Kong, it is impossible for the Government to conduct regular tests on each of the drug items, given that each item is also produced at different time. As with the practice in other overseas drug authorities, the primary responsibility falls on the pharmaceutical trade, in particular the drug manufacturers, to ensure that the pharmaceutical products they produce or supply to the patients are safe, efficacious and of good quality. Specifically, local manufacturers are required to comply with the Good Manufacturing Practices (GMP) which is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled according to appropriate quality standards. GMP emphasizes on self-inspection and quality audits. The Government's role is more on monitoring of the pharmaceutical trade in compliance with the licensing requirements, and education of the public on drug safety.

2.13 The Review Committee notes that government oversight plus self-regulation by the trade is an internationally accepted mode of regulatory regime

in advanced countries, and has proven to be sound and effective. It also underlines the importance of enhancing corporate governance of players in the drug supply chain. The Review Committee agrees that the basic principles of the existing regulatory regime in Hong Kong are in order and should be maintained. However, improvements should be made to expand its coverage and depth of the implementation details.