Abstract

Macao is a miniature economic city with a terrestrial area of 27.3km^2 and a population of 448.000. Current pharmaceutical laws and regulations of Macao have been inherited from its colonial Portuguese past for over 400 years. As a consequence of limited financial and professional human resources, Macao currently encounters a great obstacle regarding implementation of a comprehensive drug regulatory system similar to such a kind adopted by most other advanced countries. Certain loopholes within the drug administration in Macao were identified due to imperfections in drug legislation. After handover of the Macao government to China in 1999, the situation became even more complicated and consecutively aggravated long existing problems in drug regulation. Presently, Macao's government is in a transition period of healthcare reformation including amendments of relevant laws applicable to pharmaceuticals, changes that are gradually being performed in order to establish a more mature drug regulatory system.

Since imported drugs have covered 98% of the drug supply in Macao, strengthening of import drug regulatory control is one of the most important measures to be taken in order to guarantee safe use of drugs by the public. Having considered technical limitations on one hand as well as assuring consistent drug supply for the local market on the other hand, Macao's government not only had difficulties in implementing a sophisticated drug registration system, as it has been in effect in advanced countries, but also seemed not to be capable of performing comprehensive evaluation on safety and efficacy of imported drugs. Quality,. safety, and efficacy are three major components of the pharmaceutical entity. Among them, quality is the prerequisite of the other two. To Macao, where imported drugs dominate the majority of the local market, strengthening of the drug quality assurance system becomes extremely important and absolutely necessary.

For many years, World Health Organization (WHO) has developed a series of guidelines in assisting governments, especially those in developing countries with limited resources, to promote an effective functioning of national regulatory and control mechanisms. By studying relevant guidelines, Macao's government has to find a way to

establish its own drug regulatory and legislative model that best suits to its current situation and future development.

Major aspects of the first chapter of this thesis cover background, objective, and methodology of the study. Moreover, interpretation and limitations of the relevant terminology is also included. It has been stated that study of current drug regulatory and quality assurance systems is essential and should be commenced without any delay. Additionally, WHO guidelines are an invaluable source for development of these systems.

The second chapter mainly discusses current drug legislation and regulatory authority in Macao by retrospective review of the available literature. The result indicates that Macao's government has preliminarily developed a particular framework for its own drug regulation over a decade of experiments. However, present pharmaceutical laws need to be re-evaluated, modified, and enhanced because of their current limitations and some additional historical factors.

The third chapter discusses and analyzes three aspects involved in Macao's drug regulation: pre-marketing drug quality assurance, drug quality assurance of post-marketing supply, and quality assurance of drug manufacturing in Macao. Analysis shows that Macao's drug quality assurance and monitoring systems have their own distinctive characteristics and have achieved a certain level of satisfaction.

By comparison, the fourth chapter of the thesis compares the current situation of Macao's drug regulation with "WHO Guidelines for Developing National Drug Policy, Guiding Principles for Small National Drug Regulatory Authorities, and Regulation of Pharmaceuticals in Developing Countries Legal Issues and Approaches." The results indicate that Macao has actually established a particular drug quality assurance system governed by relevant laws, basically complying with WHO guidelines. However, there is still lack of some essential elements to "immaculate" those relevant pharmaceutical laws. At the same time, there is an ongoing need to introduce new policies strengthening relevant drug regulatory activities.

The fifth chapter mainly deals with existing problems encountered in the current drug quality assurance system by aspects on pharmaceutical laws, drug registration, quality analysis, professional pharmaceutical management, and measures on combating counterfeit

drugs. By using SWOT analysis, we have finally come up with six suggestions to consolidate several current issues for future development of Macao's drug regulation, i.e. enhancement of pharmaceutical laws, introduction of a drug registration system, participating on "WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce," establishment of drug quality control laboratories, setting up standards for drug analysis, and improving the quality of practice by the pharmaceutical profession. All these factors will act as essential components to provide necessary directions for future drug policy reformation.

Key words: Macao, Drug Regulation, Pharmaceutical Laws, Drug, Quality Assurance