

CHAPTER 9 PENALTY REVIEW

Overview

9.1 This chapter sets out the Review Committee's findings on the existing penalty system under the Pharmacy & Poisons Ordinance (Cap. 138) for manufacturers, importers, wholesalers and retailers of pharmaceutical products in Hong Kong and the recommendations on enhancing the existing system for better deterrent.

The Pharmacy and Poisons Ordinance (“the Ordinance”)

9.2 The Pharmacy and Poisons Ordinance, Cap. 138 (the Ordinance) provides the principal framework for the regulation of pharmaceutical products and traders. A penalty system is in place for any infringement of the provisions of the legislation. As a general rule of justice, penalty must be set proportional to the harm and impact that the offence may cause to general public and the society.

Existing Penalty System

The Maximum Penalties under the Ordinance

9.3 Under the Ordinance, the maximum penalties imposed are a fine of \$100,000 and imprisonment of two years. DH has conducted a review of the existing penalty system under the Ordinance in consultation with the Department of Justice (DoJ). DoJ is of the opinion that the current maximum penalty of \$100,000 fine and two years' imprisonment imposed by the Ordinance sufficient for summary convictions of the offences in the Ordinance. However, DH found that, based on past conviction records, 60% of the penalty imposed by the Court in recent years were on the low end of \$5,000 or below.

9.4 According to DoJ, sentencing in any individual case is at the discretion of the Court concerned which is dependant on the circumstance of the case. As such, prosecution should always present to the Court the gravity of the case by including more aggravating factors in the brief facts of the case, such as the nature of the drugs, abuse potential, public interest, etc to reflect the seriousness of the offence concerned. This would provide the Court with more background knowledge in considering the imposition of a penalty proportionate to the seriousness of the offence.

Retailers, Importers and Wholesalers

9.5 DH also found that the Court imposed light penalties on traders of pharmaceutical products in cases regarding illegal possession of Part I Poisons. According to the conviction records of DH, the penalty imposed by the Court in these cases was on the low end of \$5,000 or below.

Manufacturers

9.6 Under the current regulatory regime, it is a licensing requirement for the manufacturer to fully implement the GMP. GMP requires the appointment of an authorized person (AP) responsible for product release to ensure quality. In Hong Kong, the Manufacturers Licensing Committee has the authority to individually assess the suitability of an AP for a particular manufacturer especially taking into consideration the complexity of the products produced by the manufacturer. Penalty system on the manufacturers is in place such as revocation of the licence when there is non-compliance with the GMP.

Practice in other Countries

9.7 In Australia, every manufacturer licensed by the licensing authority, the Therapeutic Goods Administration (TGA), must appoint an AP. Curriculum vitae and other relevant information regarding the AP's education and experience must be provided to TGA for assessment. The TGA has the right to reject the AP nominated by the licensee if they believe that the AP is not sufficiently qualified or experienced. Regulatory action could be taken against the manufacturer if the AP breaches his duties. TGA has the authority to direct manufacturer to remove the AP (such power has not been exercised so far).

9.8 In UK, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK Department of Health acting on behalf of the Licensing Authority, has given authority to three Professional Bodies [the Institute of Biology, Royal Pharmaceutical Society of Great Britain and Royal Society of Chemistry – known collectively as the Joint Professional Bodies (JPB)] to operate an assessment which seeks to determine and certify the eligibility of the applicant for nomination as a Qualified Person (equivalent to AP) on a manufacturer's licence. The JPB is responsible for maintaining a register of AP. The AP is named in the manufacturer's licence and the acceptance of AP on a manufacturer's licence is a matter for the licensing authority (MHRA). MHRA could request the removal of AP from the AP register. Furthermore, it is a

statutory requirement that if an AP fails to discharge its duties, MHRA could notify the licence holder that such person shall not be permitted to act as AP.

9.9 In Canada, the power to appoint and dismiss AP vested in the manufacturer. AP and their qualification are GMP requirements. Non-compliance with the GMP requirements may lead to suspension of licence by the Minister of Health.

9.10 In Singapore, the manufacturer is responsible for assessment of the suitability of AP. The Licensing authority, Health Sciences Authority (HSA) may choose not to approve the nomination or change of AP if there are justifications that the nominee is unfit to carry out the duties as described in the GMP standard. If the competency and or integrity of the AP are concluded as questionable, HSA may consider taking regulatory actions including suspension of the manufacturer's licence.

Findings and Recommendations

9.11 The Review Committees finds that even though the current controls on manufacturers, retailers, importers and wholesalers are in place, there have been criticisms from the public that the penalties imposed by the Ordinance are not commensurate with the seriousness of the offences. The Review Committee makes the following recommendations in this regard –

- (a) The Review Committee notes that the current maximum penalty under the Ordinance is a fine of \$100,000 and imprisonment of two years. Nevertheless, for serious offence leading to the loss of life, the prosecution authority may also charge the manufacturer concerned with manslaughter under another ordinance. Moreover, the victims of drug incidents can make civil claims against the manufacturer concerned.

The Review Committee **recommends** that DH includes more aggravating factors in the facts of the case submitted to the Court, such as the nature of the drugs, abuse potential, public interest, etc. to reflect the seriousness of the offence concerned for the Court to impose an appropriate sentence. DH will track the sentencing of the Court as a first step by gathering the data on sentencing of each case after the implementation of the enhancement strategies to look for any further weaknesses of the current law for review of the maximum penalty at the next stage.

- (b) The Review Committee notes that at present the Manufacturers Licensing Committee does not have the authority to remove an incompetent AP. The Review Committee **recommends** that DH strengthens the current GMP standard by adding different annexes to GMP guidelines. The annexes will include guidelines to strengthen the control on the eligibility of the AP with reference to their qualification and previous experience, to explicitly state the duties and responsibilities of AP, to authorize the Manufacturers Licensing Committee to remove AP when he breaches his duties and to stop the production of the manufacturer when the AP had been removed.
- (c) The Review Committee notes that the analytical costs on exhibits in some prosecution cases were quite substantial and it was unfair for the taxpayers to bear such costs. The Review Committee **recommends** that the Ordinance be amended to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect.