

Raising the ante in anti-counterfeit drug legislation

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The definition of a counterfeit drug would at firsthand seem relatively simple: “a medicinal product that is produced and sold to deceptively represent its origin, authenticity or effectiveness”.¹ However, when we actually consider the differences in terminology used among international providers of health care, it would seem that a legal definition of counterfeit as described in a legal text such as Black’s Law Dictionary remains inadequate. The escalation of “Pharma Fraud” has reached globally staggering levels, and is presently estimated to be about US\$200 billion per year. It is therefore important that a universal definition of drug counterfeiting be developed; only then can we even start to police counterfeit drugs.² Consequently, the World Health Organization has attempted to redefine a counterfeit drug and now specifically includes the concepts of correct and incorrect ingredients, insufficient or no active ingredients, and also fake packaging and mislabelling. It may be applied to both branded and generic products, and it is with this definition that most leading health care providers have reached a consensus.³

Hong Kong, as with many other first-world economies, has been distinctly proactive in the governance of counterfeit goods which also includes medicines in an attempt to limit both the economic and ultimate clinical harm of such products. But the additional problem with counterfeit medicinal products is the consequences they may have on general public health. Not only are these products fraudulent, they may cause significant harm, and therefore although legislation is imperative from an economic basis, it is also vitally important from a public health perspective. It is from a health care perspective that anti-counterfeit legislation should and is ultimately driven.

No one will ever really know the global level of medication counterfeiting, but it is estimated conservatively to be between 10 and 15% of all drugs, with some such as diazepam, codeine, and anabolic steroids being primarily of Chinese and Indian origin.^{4,5} Specifically data such as those from Taiwan’s Criminal Investigation Bureau showed that approximately US\$9 million of counterfeit drugs had been seized in Taipei in 2006 and that their primary source was China.⁶ The huge influx of counterfeit drugs from China and India places Hong Kong, Singapore, and other developed economies in the South-East Asia region in a particularly vulnerable

position, as they continue to exert and maintain exacting levels/standards of public health care and consumer protection.

The publication herein by Lai and Chan⁷ is timely in helping to demonstrate estimated levels of drug counterfeiting, continuing escalation of this problem, as well as the ordinances and civil cases enforced in Hong Kong to counter infiltration of these products into the region. What this paper serves to suggest is that the penalty for drug counterfeiting in the Hong Kong Special Administrative Region is perceived to be light and very few cases result in criminal prosecution. Although Hong Kong Ordinances serve to protect the public against drug counterfeiting exist, they are primarily Trade Marks, Patents, Trade Descriptions, and Pharmacy and Poisons Ordinances. As such, they do not address the issue uniquely and are possibly inadequate in dealing with this issue.

Neighbouring countries such as Singapore, Taiwan, and Vietnam have all introduced their respective Health Products and Pharmaceutical Products Acts, with significant penalties levied against perpetrators of counterfeiting medicinal products.⁸ It is hoped that Hong Kong will follow suit and ultimately introduce its own specific anti-counterfeit drug law with subsequent legal enforcement of the respective Ordinance. Similarly, measures such as the serialisation of medicinal products, pharmacovigilance, and the education of lawyers and judges in counterfeit drug issues are all reasonable suggestions by Lai and Chan⁷ and would serve to improve public safety in this environment. Presently, the legal consequences for the counterfeiter appear to be minimal, whereas the adverse consequences for the patient are potentially serious. Thus, ensuring that patients have access to safe and quality assured medicines is surely an important clinical step and the mark of a moral society.

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