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For information
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LegCo Panel on Health Services

Regulation of Counterfeit Pharmaceutical Products

This paper provides information on the control of counterfeit pharmaceutical products in Hong Kong.

Legislative provisions relating to the control of counterfeit medicines

2. In Hong Kong, the sale and supply of pharmaceutical products[1] are regulated through a system of registration and inspection prescribed in the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). For the protection of public health, all pharmaceutical products are required to be registered with the Pharmacy and Poisons Board (the Board), a statutory body established under the PPO, before they can be sold in Hong Kong. Any person who is guilty of manufacturing or selling unregistered pharmaceutical products shall be liable on conviction to a fine of $100,000 and to imprisonment for two years.

3. In addition, the Trade Descriptions Ordinance (Cap. 362) (TDO) prescribes criminal sanction against activities dealing with all types of counterfeit goods including pharmaceutical products. It is an offence to import, export, sell or manufacture goods to which a false trade description or forged trade mark is applied. The maximum penalty is HK$500,000 and imprisonment for five years on conviction or indictment, and a fine of HK$100,000 and imprisonment for two years on summary conviction.

[1] The terms "pharmaceutical" product and "medicine" carry the same meaning in the context of the PPO.

Monitoring the sale and supply of medicines under the PPO

Dispensaries and medicine companies

4. Registered pharmaceutical products are sold or supplied by dispensaries[2], medicine companies[3] and registered medical practitioners. It is a statutory requirement under the PPO for dispensaries and medicine companies to obtain a licence from the Board prior to commencement of business. The Board will only issue a licence to applicants who have adequate experience, knowledge and a good track record related to the sale of medicines.

5. With the executive support of the Department of Health (DH), the Board monitors dispensaries and medicine companies to ensure their compliance with the law. For dispensaries, their compliance with the Code of Practice, which sets out the standard required of matters including professional independence of the registered pharmacist, publicity for services provided and the working conditions of the premises, is also monitored. Requirements of the PPO applicable to dispensaries include, amongst others -

(a) All medicines must be registered before they can be sold.

(b) Some medicines can only be sold upon a doctor's prescription and under the supervision of a registered pharmacist.

(c) Some other medicines (Part I poisons) can be sold without a doctor's prescription under the supervision of a registered pharmacist.

[2] Dispensaries are premises which are allowed to sell controlled medicines. They are required to employ a full time registered pharmacist who is responsible for personally supervising the dispensing of prescriptions and the sale of medicines classified as Part I poisons. The certificate of registration of the pharmacist and a notice of his duty hours must be displayed in the pharmacy. The premises must have adequate facilities for the dispensing and sale of medicines. The Board has also promulgated a Code of Practice for dispensaries. As at the end of December 2003, there are 417 dispensaries.

[3] Medicine companies can only sell a limited range of medicines which can be used safely without medical supervision or pharmacist's advice. The requirements set out in Footnote 1 above do not apply to medicine companies. As at the end of December 2003, there are 2 731 medicine companies

(d) Prescription medicines must be stored in locked facilities, the key of which must be kept by the registered pharmacist.

(e) Records on the sale of prescription medicines must be kept.

6. Both dispensaries and medicine companies are monitored by pharmacist inspectors of DH who conduct regular and surprise inspections at their premises. The purpose of such inspections is to ensure that the law regulating the possession, sale, storage and record-keeping of the various types of medicines is complied with, and to provide professional advice on the standard of practice as per the Code of Practice of dispensaries. On average, each dispensary and medicine company is inspected twice a year. More frequent visits are conducted at those with a poor record of compliance or are being complained against. A total of 6 485 inspections were conducted in 2003.

7. Apart from inspections, test purchases are also conducted to detect any illegal sale of medicines. In 2003, DH conducted 3 280 test purchases.

8. Prosecution are initiated, upon legal advice, for offences detected during inspections or test purchases. In 2003, there were 60 prosecutions, most of which related to the sale of prescription medicines without a prescription, the sale of controlled medicines without the supervision of a registered pharmacist, or the possession of unregistered pharmaceutical products.

9. For dispensaries, disciplinary actions are also taken by the Board after a disciplinary inquiry. These may result in suspension of the licence for a period of time, or the issue of a warning letter. In 2003, four dispensaries received a warning letter. If the conviction relates to a registered pharmacist, the latter will also be subject to disciplinary action. In 2003, one pharmacist was censored. Likewise, a medicine company convicted of offences may result in cancellation of the licence or the issue of a warning letter. In 2003, six licences were cancelled, and five medicine companies received a warning letter.

<u>Registered Medical Practitioners</u>

10. Registered medical practitioners, who have to comply with the provisions of Medical Registration Ordinance (Cap. 161) and the Professional Code and Conduct promulgated by the Medical Council of Hong Kong, are authorised under the PPO to supply drugs in the course of their professional practice. However, they are required to comply with the relevant provisions of the PPO such as the use of registered medicines and proper record keeping of supplies. Clinic premises of registered medical practitioners are subject to inspections by pharmacist inspectors of DH to ensure compliance with the relevant legal requirements.

Monitoring the sale and supply of counterfeit goods under the TDO

11. This subject of counterfeit drugs has always been of international concern. It was discussed at the 10th WHO International Conference of Drug Regulatory Authorities held in June 2002 in Hong Kong and again in the 11th Conference held last month in Madrid. Two of the major recommendations of the Conferences in relation to combating counterfeit drugs are that countries and territories should establish an effective drug regulation mechanism (e.g. inspection and licensing of traders, registration of individual pharmaceutical products), and that they should made counterfeiting of drugs a crime punishable with severe sanctions.

12. As explained above, both recommendations have been in place in Hong Kong through the provisions of the PPO and also the TDO. The Customs and Excise Department (C&ED) is the enforcement department for control against counterfeit goods under the TDO. The key enforcement efforts are directed at the protection of the rights of consumers and trade mark owners against activities connected with false trade descriptions or forged trade marks. C&ED carries out proactive actions based on self-developed intelligence, in addition to acting on complaints made or information provided by members of the public or trade mark owners on suspected cases of counterfeiting activities. Priority enforcement actions are given to counterfeit pharmaceutical products, as they can be hazardous to health.

13. Rigorous enforcement action has been undertaken against counterfeiting activities in Hong Kong. Where pharmaceutical products are

concerned, there has been no substantive manufacturing activity in the past years, and major cases concerned only low-level retail activities of a relatively limited scale. Enforcement statistics for 2002 and 2003 on counterfeit pharmaceutical products are as follows -

	2002	**2003**
No. of cases	23	43
No. of persons arrested	27	52
Quantity of seizures (nos.)	18,622	218,095
Value of seizures (HK$)	49,000	1,659,000

14. The increase in enforcement statistics in 2003 as compared with 2002 attributed to the enhanced co-operation between Customs and the trade mark owners concerned. As a result of their complaints lodged to Customs, Customs launched a territory-wide operation against counterfeit pharmaceutical products in September 2003. In that operation, Customs effected 31 cases, arrested 38 persons including the supplier, and seized over 212,000 units of various counterfeit pharmaceutical products worth $1.6 million. Other than this specific operation, remaining cases in the year are but isolated violations in small scales.

15. To enhance effective enforcement, C&ED has recently launched a reward scheme in cooperation with the Hong Kong Association of Pharmaceutical Industry in November 2003. Monetary rewards will be given to members of the public who provide information leading to the successful seizure of counterfeit pharmaceutical products and prosecution of the related offenders. C&ED will continue to exercise vigilance in this regard.

16. Members are invited to note the content of this paper.

Health, Welfare and Food Bureau
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