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Panel on Health Services

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Regulation of pharmaceutical products in Hong Kong

Purpose

This paper gives an account of the past discussions by the Panel on Health Services (the Panel) on the regulation of pharmaceutical products in Hong Kong.

Background

Drug regulatory regime in Hong Kong

2. In Hong Kong, the sale and supply of pharmaceutical products are regulated through a system of registration and inspection prescribed in the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). "Pharmaceutical product" means any substance, or mixture of substances, used for administration to human beings or animals for -

(a) the diagnosis, treatment, mitigation, alleviation or prevention of disease or its symptoms; or

(b) the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or its symptoms; or

(c) altering, modifying, correcting or restoring any organic function.

3. All pharmaceutical products are required to be registered with the Pharmacy and Poisons Board (the Board), a statutory body established under 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 maximum fine of $100,000 and imprisonment for two years. The Board, chaired by the Director of Health, comprises members from the pharmaceutical, medical and academic sectors.

4. Registered pharmaceutical products may be subject to various kinds of sale control to protect the health of the public. The PPO maintains a Poisons List under the Poisons List Regulations (Cap. 138B) and several Schedules under the Pharmacy and Poisons Regulations (Cap. 138A). Pharmaceutical products will be categorised into different parts of the Poisons List and different Schedules according to their potency, toxicity and potential side-effects. Such categorisation determines the different levels of control when they are sold. For example, some pharmaceutical products can be sold in authorised sellers of poisons (pharmacies) and listed sellers of poisons (medicine companies), while others can only be sold in pharmacies under the supervision of registered pharmacists and in their presence. For certain pharmaceutical products, sale records, including the date of sale, the name and address of the purchaser, the name and quantity of the medicine, as well as the purpose for which it is required, must be kept. The sale of some other pharmaceutical products must be authorised by prescription from a registered medical practitioner, a registered dentist or a registered veterinary surgeon.

5. It is a statutory requirement under PPO for pharmacies 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.

6. The PPO requires manufacturers and wholesalers of pharmaceutical products to keep full records of sale of any drug to any client to enable rapid and, so far as practicable, complete recall of any pharmaceutical product in the event of the product being found to be dangerous or injurious to health. The PPO also specifies that the expiry of dates of drugs have to appear conspicuously on the drug packaging for consumers to see. Any manufacturer or wholesaler found to have failed any of these requirements will be liable on conviction to a maximum fine of $100,000 and imprisonment for two years. Those who are convicted are subject to further sanction by the Board, which may involve suspension of the licence or non-renewal of the licence upon expiry.

Enforcement actions taken by the Department of Health

7. Pharmaceutical product manufacturers, importers, exporters, wholesalers, pharmacies, medicine companies, Chinese and western medicine clinics and other suspicious places are monitored by pharmacist inspectors of the Department of Health (DH) who conduct regular and surprise inspections there. The purpose of such inspections is to ensure that the relevant parties comply with the various requirements on possession, sale, storage and record-keeping of drugs. More frequent visits are conducted at those with a poor record of compliance or are under complaint. Apart from inspections, pharmacist inspectors of DH also conduct test purchases in the market to detect illegal sale of drugs.

8. Prosecution is initiated, upon legal advice, for offences detected during inspections or test purchases. For pharmacies, 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. If the conviction relates to a registered pharmacist, the latter will also be subject disciplinary action. Likewise, a medicine company convicted of offences may have its licence cancelled or may receive a warning letter.

Past discussions

Regulation of counterfeit pharmaceutical products

9. The Panel discussed with the Administration on 8 March 2004 on the regulation of counterfeit pharmaceutical products.

10. Members were advised that monitoring of the sale and supply of counterfeit pharmaceutical products in Hong Kong was made through the provisions of PPO and also the Trade Descriptions Ordinance (Cap. 362) (TDO). The Customs and Excise Department (C&ED) was the enforcement department for control against counterfeit goods under TDO. C&ED carried out proactive actions based on self-developed intelligence, in addition to acting on complaints made or information provided from members of the public or trade mark owners on suspected cases of counterfeiting activities.

11. Noting that the number of counterfeit pharmaceutical products uncovered by C&ED in 2002 and 2003 was 23 and 43 respectively, concern was raised as to whether such low figures were due to cost-saving exercises being implemented in all Government departments.

12. C&ED responded that resources being put in to combat counterfeit goods, including counterfeit pharmaceutical products, had not been reduced as a result of the efficiency saving exercise being carried out in C&ED. Rigorous enforcement had been undertaken against counterfeiting activities in Hong Kong. Where counterfeit pharmaceutical products were concerned, there had been no substantive manufacturing activity in the past years, and past cases concerned only low-level activities of a relatively limited scale. Despite such, priority enforcement actions were given to counterfeit pharmaceutical products as they could be hazardous to health. C&ED further advised that the increase in enforcement statistics in 2003 as compared to 2002 was mainly due to a territory-wide operation launched in September 2003. In that operation, C&ED effected 31 cases, arrested 38 persons including the supplier, and seized over 212 000 units of various counterfeit pharmaceutical products. Other than this specific operation, remaining cases in the year were but isolated violations in small scale.

13. Members noted that apart from inspections, test purchases were conducted by DH to detect any illegal sale of medicines. Noting that only 3 280 test purchases were conducted in 2003, concern was raised as to whether this was due to the fact there were only 28 pharmacist inspectors in DH.

14. A member suggested disclosing the names of the pharmacies and medicine companies found to be selling counterfeit pharmaceutical products. C&ED advised that it could only disclose such after the owners concerned were convicted of dealing with counterfeit drugs. C&ED was in the process of working out the implementation details for such disclosure.

15. Another member was of the view that another effective way to combat counterfeit pharmaceutical products was to step up efforts on educating the public on how to identify counterfeit pharmaceutical products and to buy pharmaceutical products from registered pharmacies and medicine companies. DH advised that it had been educating the public on how to identify genuine pharmaceutical products through various channels, such as DH's website. A hotline had also been set up to receive complaints or information from members of the public on suspected cases of counterfeit pharmaceutical products.

Monitoring of unregistered drug in slimming products

16. The Panel held discussion with the Administration on 18 February 2008 on monitoring of unregistered drug used or contained in slimming products.

17. In response to members' concern that inspections had only been made by DH to six slimming centres in 2007, DH advised that inspections to slimming centres were generally taken upon information provided by members of the public or other sources, such as detection of unreasonably large quantity of dangerous drugs purchased by a doctor or clinic. To better protect public health, DH had stepped up its enforcement work to slimming centres by more proactively conducting surprise inspections.

18. Members noted that DH collected a total of 617 samples of slimming products to examine if they contained pharmaceutical products between 2005 and 2007, and 32 of them were found to have been adulterated with western drug ingredients. Among these 32 samples, 18 were sold via retail shops and local auction websites in Hong Kong. A question was raised about the actions that had been taken by DH to stamp out the sale of slimming products containing unregistered drugs on the Internet.

19. The Administration advised that DH staff regularly monitored frequently-visited websites selling slimming products. Test purchases were conducted to detect whether these products contained illegal pharmaceutical product; and if so, prosecution would be initiated. Arrangements would be made

to get in touch with the internet service providers where practicable. Internet service products of local auction websites in Hong Kong had all long been very cooperative in removing the product from the auction list upon request by DH. The Administration further advised that it was presently looking at ways to better meet the challenges posed by the proliferation of sale of illegal products.

20. Some members were of the view that slimming centres should be regulated through a licensing scheme to better protect public health. The Administration did not see the need for such at this stage, as the public was guarded against the consumption of slimming products which contained unregistered drugs through PPO, the Dangerous Drugs Ordinance (Cap. 134) and TDO. Further protection would be provided upon the coming into force of the Undesirable Medical Advertisements (Amendment) Ordinance 2005.

Control of virility products

21. Arising from the incidents where products for male sexual dysfunction (virility products) containing undeclared blood sugar lowering drug had caused unwellness in some public members, the Panel held discussion with the Administration on 19 May 2008 to discuss the follow-up actions and preventive measures taken by DH.

22. As some patients claimed that the virility products were from the Mainland, DH was urged to work closely with the Mainland authorities to stem the manufacture, sale and supply of such products to bring them under control.

23. DH advised that it had been working closely with the State and Guangdong Food and Drug Administration to exchange information on the incidents and views on such issues as drug registration, safety information notification and law enforcement actions. Apart from this, leaflets were handed out at various control points to remind travellers about the dangers of using unregistered virility products. DH had also planned to broadcast the message and put up posters at various control points to remind tourists to be particularly alert to virility products. DH would liaise with the Information Services Department to expedite the production of the Announcement of Public Interest. In line with latest international trend, DH would adopt a social-marketing, rather than the traditional didactic approach on the promotion of public health messages, with a view to enhancing the effectiveness of the promotion programmes. Overseas experts had been invited to Hong Kong to exchange views with DH in this regard.

24. Members urged the Administration to increase the penalty level under PPO to enhance deterrent effect, having regard to the fact that human lives were at stake. The Administration would give consideration to the penalty issue.

Regulation and control of pharmaceutical products

25. In the light of the recent incidents concerning pharmaceutical products Kong, such as fungal contaminated Allopurinol, the Panel held a special meeting on 31 March 2009 with the Administration to discuss ways to strengthen regulation and control of pharmaceutical products in Hong Kong

26. Members noted that the Secretary for Food and Health announced on 19 March 2009 the setting up of a Review Committee to conduct a comprehensive review on all the relevant issues including safety and quality assurance of drugs, standard and practices of the pharmaceutical industry, and whether there was a need for legislative amendments. To support the work of the Review Committee, the Director of Health had set up a Task Force to comprehensively review the existing control of the drug supply chain, including manufacturers, importers, wholesalers and retailers, as well as the control of drugs. An Expert Group on Microbiological Hazards on Drug Manufacturing would also make proposals to the Task Force. HA would also implement seven initiatives, such as requiring manufacturers to introduce microbiology testing as a prerequisite to the procurement for high risk drug items and for the provision of batch release reports on delivery of drug products, to strengthen its procurement of drugs.

27. Members considered that the main reason for the recent drug incidents was the inadequate manpower of DH to perform inspection and surveillance on the drug supply chain. The Administration advised that as an immediate measure, DH would recruit 10 additional pharmacists to strengthen inspection to manufacturers, wholesalers and retailers of drugs and the sampling of drugs for analysis. More pharmacists might be recruited upon completion of work by the Review Committee in six to nine months' time.

28. Hon Andrew CHENG opined that another reason was because the General Manufacturing Practices (GMP) used in Hong Kong was less stringent than the GMP used in countries such as Singapore, Australia and US. The Administration clarified that the fact that GMP in countries such as US, EU and Australia was recognised to be of a standard higher than GMP in Hong Kong should not be taken to mean that GMP in Hong Kong was substandard, as GMP used in Hong Kong followed exactly the GMP guidelines promulgated by WHO. The reason why the GMP in US, EU and Australia was recognised to be of a higher standard was because manufacturers in these countries also produced new/patent drugs which required more detailed and rigorous quality requirements, whereas local manufacturers only produced off-patent generic drugs. Nevertheless, to enhance safety and quality assurance of drugs, plan was in hand to make certain GMP aspects governing high risk manufacturing process in Hong Kong more comprehensive. For instance, one of the major works of the Review Committee would involve expanding the scope of GMP to include microbiological testing for high risk drug items.

29. On the suggestion of raising the penalty to ensure GMP compliance, the Administration advised that a demerit point system capable of proportionate penalty ranging from for example written warnings, announcement of serious noncompliance cases, suspension or termination of licences would be considered by the Review Committee.

30. As to the question of whether the Administration would consider requiring local pharmaceutical manufacturers to engage external auditors to ensure they conformed to GMP standards, the Administration agreed to consider. The Administration further advised that it would implement enhancement measures where practicable prior to completion of work by the Review Committee.

Recent development

31. The Review Committee announced on 23 October 2009 a number of recommendations covering the entire supply chain of pharmaceutical products and procurement and supply of drugs in the public and private sector, to enhance the regulatory regime of pharmaceutical products in Hong Kong. The Review Committee aims to complete its final report on the detailed recommendations at the end of 2009.

Relevant papers

32. Members are invited to access the Legislative Council website (http://www.legco.gov.hk) for details of the relevant papers and minutes of the meetings.

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