For discussion on
18 February 2008

Legislative Council Panel on Health Services

Monitoring of Unregistered Drug Used or Contained in Slimming Products

PURPOSE

This paper briefs Members on the drug regulatory regime in Hong Kong, the regulation of slimming products, enforcement actions by the Department of Health (DH) as well as the related publicity and education work.

DRUG REGULATORY REGIME IN HONG KONG

2. To protect public health in Hong Kong, we regulate the manufacture, sale and supply of drugs through the Pharmacy and Poisons Ordinance (PPO) and the Dangerous Drugs Ordinance (DDO).

3. The Pharmacy and Poisons Board (the Board) is a statutory body established under the PPO to take charge of the registration of pharmacists and regulation of their conduct, the registration of pharmaceutical products and the licensing of drug traders. Unless otherwise specified, if a person is to sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product, that product has to be registered with the Board. Offenders are liable on conviction to a maximum fine of $100,000 and imprisonment for two years. The Board will take into account such factors as the safety, efficacy and quality of the pharmaceutical products in vetting applications for registration.

4. As regards licensing control, registered pharmaceutical products are sold or supplied by authorized sellers of poisons (pharmacies), listed sellers of poisons (medicine companies) and registered medical practitioners. Pharmacies and medicine companies

are required to apply for a licence from the Board prior to commencement of business. The Board will only issue licences to applicants who have adequate experience, knowledge and a good track record related to the sale of drugs. Pharmacies must be under the control of a registered pharmacist and must have adequate facilities for the dispensing and sale of drugs. As at 31 December 2007, there are 484 pharmacies and 3 175 medicine companies in Hong Kong.

5. Regarding the sale of drugs, drugs are classified into two categories under the PPO, namely "non-poisons" and "poisons". According to their risks, "poisons" are further classified to be subject to different levels of control as tabulated below:

Listed in the Poisons List of the Poisons List Regulations	**Listed in the First Schedule to the Pharmacy and Poisons Regulations**	**Listed in the Third Schedule to the Pharmacy and Poisons Regulations**	**Level of Control**
Part II	--	--	• May be sold in pharmacies and medicine companies
Part I	--	--	• May only be dispensed and sold in pharmacies by or in the presence of a registered pharmacist
Part I	√	--	• May only be dispensed and sold in pharmacies by or in the presence of a registered pharmacist • Particulars of sales, including the name of the drug, the name and identity card number of the purchaser, etc. must be recorded

Listed in the Poisons List of the Poisons List Regulations	Listed in the First Schedule to the Pharmacy and Poisons Regulations	Listed in the Third Schedule to the Pharmacy and Poisons Regulations	Level of Control
Part I	√	√	• May only be dispensed and sold in pharmacies by or in the presence of a registered pharmacist • Must be sold on prescription by a medical practitioner, dentist or veterinary surgeon

The sale of drugs which are "non-poisons" is not subject to the above restrictions.

6. In addition, those "Third Schedule poisons" which are also psychotropic substances are also subject to regulation under the DDO. Drug traders, hospitals and medical practitioners handling these substances are all required to keep detailed records of the procurement and supply of the substances. Any person who commits any offence involving these substances is liable on conviction to a maximum fine of $5 million and life imprisonment.

REGULATION OF SLIMMING PRODUCTS

7. Slimming products commonly found in the market can be broadly classified into the following three categories:

(i) Bulk-forming agents: Common bulk-forming agents include methylcellulose. Users of such slimming products usually have to take in an adequate amount of water at the same time, which will make users have a sense of satiety in their stomach and hence reduce their appetite;

(ii) Laxatives: Such slimming products can cause users to have diarrhea, which affects the nutrient absorption function of the body; and

(iii) Central nervous system stimulants: Such slimming products suppress users' appetite through stimulating the central nervous system. Common examples include sibutramine and α,α-phentermine.

8. Any person who sells, offers for sale or distributes or possesses for the purposes of sale, distribution or other use any slimming product which contains a pharmaceutical ingredient will be subject to regulation under the PPO, and the drug involved has to be registered with the Board.

ENFORCEMENT ACTIONS BY THE DH

9. Pharmaceutical product importers, exporters, manufacturers, wholesalers, pharmacies, medicine companies, Chinese and western medicine clinics and other suspicious places are monitored by pharmacist inspectors of the 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 under complaint. In 2007, more than 10 250 inspections were conducted by DH at different places.

10. The abovementioned places being inspected include 18 western medicine clinics, four Chinese medicine clinics and six slimming centres. Among them, three Chinese medicine clinics and one slimming centre were found to have in their possession unregistered drugs. On the advice of the Department of Justice, the DH issued a written warning to the person concerned in one of the cases while the other three cases are still under investigation.

11. Apart from inspections, pharmacist inspectors of the DH also conduct test purchases in the market to detect illegal sale of drugs. In 2007, the DH conducted a total of 3 229 test purchases.

12. Prosecutions are initiated by the DH upon legal advice for offences detected during inspections or test purchases. In 2007, a total

of 19 cases of prosecutions were initiated by the DH in connection with the possession of unregistered pharmaceutical products by pharmacies or medicine companies. The defendants in six of these cases were already convicted by the court and fined $1,000 to $16,000.

13. As to slimming products, the DH collected a total of 617 samples 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. The DH followed up on all these 18 cases and conducted investigations. In three of these cases, the defendants were convicted and fined $6,500 to $14,000, and all of them were vendors at auction websites. In another 11 cases, on the advice of the Department of Justice, the DH issued written warnings to the people involved. The remaining four cases are still under investigation. The other 14 cases involved local people purchasing slimming products outside Hong Kong.

PUBLICITY AND EDUCATION

14. To protect public health, the DH has always advised members of the public to achieve and maintain a suitable body weight through balanced diet and adequate exercise, and explained to them that an excessive loss of body weight may cause problems such as malnutrition, osteoporosis and reduction in immunity. The DH communicates these messages to the public through announcements of public interest on television, media interviews, open talks, exhibitions, website, health education hotline as well as audio-visual and printed materials.

15. Whenever the DH finds any slimming products which have not been registered as pharmaceutical products but have been adulterated with western drug ingredients, it will make public announcements about the products, remind the public about their adverse reaction and advise them to stop using them. In addition, the DH will continue to work with the Consumer Council on the publicity front to raise public awareness about slimming products and enable consumers to make informed choices.

16. Besides, the DH also organizes talks for medical practitioners and explains to them the requirements of the PPO and the DDO, such as the requirements on drug storage and record keeping. In particular, medical practitioners are reminded that they should only prescribe and dispense registered drugs.

17. The DH has also issued letters to beauty parlours in Hong Kong, reminding them that they must exercise great care when supplying slimming products or other health products to their customers, and in particular, they should avoid supplying products of unknown sources.

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

Food and Health Bureau
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