**For discussion on**
**19 May 2008**

**Legislative Council Panel on Health Services**

**Undeclared Blood Sugar Lowering Drug in Products for Male Sexual Dysfunction**

## PURPOSE

This paper briefs Members on the recent incidents where products for male sexual dysfunction (commonly known as "virility products") containing undeclared blood sugar lowering drug have caused unwellness in some public members. The follow-up actions and preventive measures taken by the Department of Health (DH) are also reported.

## BACKGROUND

2. Between 1 February and 30 April of this year, DH received a total of 51 reports on cases of suspected health damage due to the consumption of virility products. Forty-nine patients were involved and they were all admitted to hospitals for treatment. Their urine specimen were found to contain western drug ingredients glibenclamide (for lowering blood sugar level) and sildenafil (for treating male sexual dysfunction), but they did not have diabetes problems and had no record of taking any diabetes mellitus drugs.

3. The cases involve patients between 39 and 86 years of age. The symptoms went onset in Hong Kong in 40 cases, and in the Mainland in the remaining 11 cases where patients were transferred back to Hong Kong for treatment. So far, the incidents have resulted in two deaths and two patients are still in hospital. All patients developed symptoms related to low blood sugar level, including shock, coma, intoxication, immobility and perspiration. In 19 cases, patients claimed to have taken virility products. Among them, eight claimed to have obtained such

products in places including Sheung Shui, Yuen Long, Tsuen Wan and Wan Chai; 10 said the products were from the Mainland; and the remaining one could not provide relevant information.

## PRODUCTS FOUND CONTAINING UNDECLARED WESTERN DRUGS

4. The virility products involved included red/yellow capsules sold in package carrying the word "Maxman" (男根增長素), brown diamond-shaped tablets referred to as "Jiubianwang" (九鞭王) by the patients, and some unlabelled red/yellow capsules. Other products which the patients claimed to have consumed but could not provide samples for verification included "Nangeng" (男根), "Zengzhangsu" (增長素), "Fake Viagra" (假偉哥), "Sanbian" pills (三鞭丸) and the unbranded "Sanbian Wine" (三鞭酒) and "Deer Pilose Antler Wine" (鹿茸酒), etc.

5. Among the several samples of virility products provided by the patients, the "Maxman" capsules, "Jiubianwang" tablets and the unlabelled red/yellow capsules were detected to contain glibenclamide. The sample with the highest dose of glibenclamide was found to contain a level that was 15 times higher than the normal dose. For an adult man, taking such a high dose of glibenclamide may result in too low a blood sugar level with serious health risks and even death.

6. Among the samples obtained, we found another western drug ingredient sildenafil. Sildenafil is mainly used for the treatment of male sexual dysfunction, and its side effects include low blood pressure, headache, vomiting and transient vision disturbances. Taking sildenafil and nitroglycerin (a drug for coronary heart disease) at the same time may also threaten one's life.

## SIMILAR CASES IN NEIGHBOURING REGIONS

7. After verification with the authorities concerned, we understand that recently there were similar cases in Singapore and Japan,

which involved such virility products as "Power 1 Walnut" (動力一號核桃素片), "Maxman", "Weigewang Sanbianli" (威哥王三鞭粒) and "Lishen Capsule" (力神膠囊). All such products were purported to be manufactured in the Mainland.

**REGULATION OF VIRILITY PRODUCTS**

8. The virility products involved come in different packages, forms and sales channels. Under the existing law of Hong Kong, the manufacture, sale and supply of western drugs and Chinese medicine are governed by the Pharmacy and Poisons Ordinance (PPO) and the Chinese Medicine Ordinance respectively. As glibenclamide and sildenafil are both western drugs, they are subject to the regulation of the PPO.

9. 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.

10. 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. Pharmacies must be under the control of a registered pharmacist and must have adequate facilities for the dispensing and sale of drugs. As at 30 April 2008, there are 480 pharmacies and 3 254 medicine companies in Hong Kong.

11. 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<br>• Particulars of sales, including the name of the drug, the name and identity card number of the purchaser, etc. must be recorded |
| Part I | √ | √ | • May only be dispensed and sold in pharmacies by or in the presence of a registered pharmacist<br>• 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.

12. Both glibenclamide and sildenafil are classified as "Part I, First and Third Schedules" poisons under the PPO. Any person who sells, offers for sale or distributes or possesses for the purposes of sale, distribution or other use products which contain these two pharmaceutical ingredients are subject to regulation under the PPO, and the drugs involved have to be registered with the Board.

**FOLLOW-UP ACTIONS OF DH**

13. In view of the incidents, DH has joined hands with the Hong Kong Police Force in taking enforcement actions. Based on the information provided by the patients, a medicine company in Sheung Shui was found in possession of the product "Maxman" which was detected to contain the undeclared drug ingredients glibenclamide and sildenafil. An investigation is under way to find if the medicine company has committed the two offences under the PPO, namely the unlawful possession of unregistered pharmaceutical products and the unlawful possession of Part I poisons.

14. As some patients claimed that the products concerned were from the Mainland, DH has informed the State and Guangdong authorities on health and drug administration about these incidents. DH has also met with the authorities to exchange information and views on such issues as drug registration, safety information notification, and law enforcement actions. The Mainland authorities have confirmed that all the known products involved (including the products causing the incidents in Singapore and Japan) have not been registered as drugs in the Mainland. The Mainland authorities would launch investigation into the products concerned. We will maintain close communication and cooperation with the Mainland authorities in a bid to find out the source of the products so as to bring them under control. As the exchanges between Guangdong and Hong Kong have become more frequent, we consider it necessary to strengthen mutual cooperation on drug regulation. We have therefore established point-to-point working contact with the Guangdong Food and Drug Administration, and will deliberate about how we can further our cooperation.

15. The operation of pharmaceutical product importers, exporters, manufacturers, wholesalers, pharmacies, medicine companies, Chinese and western medicine clinics and other suspicious places is monitored by the pharmacist inspectors of DH through regular and surprise inspections. 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. In 2007, DH conducted 10 243 inspections at different places, whereas in the first four months of 2008, 3 769 inspections have been conducted. Apart from inspections, the pharmacist inspectors of DH also conduct test purchases in the market to detect illegal sale of drugs. In 2007, DH conducted 3 229 test purchases, whereas in the first four months of 2008, 1 665 test purchases were conducted. Besides, DH collects samples of proprietary Chinese medicines and health food in the market to test for adulteration with western medicines.

16. In light of the recent incidents, DH has stepped up its inspections of the relevant products and has taken the following actions:

(i) stepping up inspections of drug stores and collecting samples for tests, especially those stores in such districts as Sheung Shui, Yuen Long, Tsuen Wan, Sha Tin and Wan Chai, where illegal sale of the products had taken place;

(ii) stepping up inspections of drug stores in the vicinity of hot spots for sex service and collecting samples for tests;

(iii) stepping up inspections of hawker stalls; and

(iv) collecting product samples for tests from sex shops in Hong Kong.

**PROMOTION OF HEALTHY LIVING AND HEALTH EDUCATION**

17. To prevent the public from inadvertently consuming the products, DH has made various announcements through the press, television and radio programmes. In addition, DH has written to

wholesalers and retailers of Chinese and western medicines in Hong Kong to remind them not to supply virility products from unknown sources.

18. In view of some patients' claim that the products concerned were bought in the Mainland, DH distributes leaflets at various control points to provide information on the proper use of drugs during travel and remind tourists to be particularly alert to virility products.

19. In addition, DH is working with the Information Services Department to produce an Announcement of Public Interest with a view to disseminating the relevant health messages to the community at large.

**Food and Health Bureau**
**Department of Health**
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