

## **Bills Committee on Trade Marks Bill**

### **Parallel Importation and the Control of Unregistered Pharmaceutical Products**

#### **Introduction**

This note sets out the Government's response to the submission of 14 January 2000 from the Hong Kong Association of the Pharmaceutical Industry ("HKAPI").

#### **Safety of Pharmaceutical Products distributed in Hong Kong**

2. Contrary to the allegation made by the HKAPI, it should be noted that parallel-imported pharmaceutical products are not the same as unregistered drugs. The Pharmacy and Poisons Ordinance (Cap.138) stipulates that no person shall sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product unless it is registered with the Pharmacy and Poisons Board. Contravention of this requirement is an offence liable to a maximum fine of \$100,000 and to imprisonment of 2 years. This registration system ensures that all pharmaceutical products, whether imported or locally manufactured, comply with the necessary safety, efficacy and quality requirements. Parallel imported pharmaceutical products are subject to the same regulation and must be registered.

3. If a pharmaceutical product is imported into Hong Kong by more than one importer, each of them is required to apply for registration separately and will be assigned different registration numbers. The same stringent safety requirements are applicable to all pharmaceutical products distributed in Hong Kong, regardless of whether or not they are parallel imports. The Department of Health investigates complaints on breaches of these requirements and conducts regular and surprise inspections of pharmaceutical wholesalers and retailers to ensure compliance with the law.

## **Control of Unregistered Pharmaceutical Products**

4. Under the existing law, pharmaceutical products imported into Hong Kong for the purpose of re-export are exempted from the need for registration. The HKAPI is concerned that these unregistered drugs are illegally distributed within Hong Kong. The association suggested that more safeguards would be required to curb these offences, in addition to vigorous enforcement action by the Department of Health.

5. The Pharmacy and Poisons Board has consulted the pharmaceutical industry as well as the Legislative Council Panel on Health Services on new measures to combat illegal diversion of unregistered drugs. The Board will continue to monitor the implementation and effectiveness of the proposed measures.

## **Conclusion**

6. The sale and supply of unregistered drugs is an illegal activity prohibited under the Pharmacy and Poisons Ordinance. Only products that are in compliance with the required standards on safety, efficacy and quality will be approved for registration and distribution in Hong Kong. There is no question on a relaxation of these safety controls as a consequence to the liberalisation of parallel imports of trade mark goods.

Trade and Industry Bureau  
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