CB(2)1038/99-00(08)

For discussion
On 14 February 2000

Legislative Council Panel on Health Service

Process of registration of new pharmaceutical products

Purpose

This paper informs Members of the registration process of new pharmaceutical products in Hong Kong. New pharmaceutical products refer to those which are newly introduced into Hong Kong.

Background

2. In Hong Kong, the sale and supply of pharmaceutical products are regulated through a system of registration and classification prescribed in the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance"). Under the Ordinance, a Pharmacy and Poisons Board ("the Board") has been established to be responsible for such functions.

Registration of pharmaceutical products

3. Pharmaceutical products for local consumption are required to be registered with the Board before they can be imported into or manufactured in Hong Kong. The criteria for approval of registration, as stipulated in the Pharmacy and Poisons Regulations, relate to the safety, efficacy and quality of the pharmaceutical products. The Registration Committee, established under the Board, is responsible for studying and approving applications for registration of pharmaceutical products. The manufacturers or the importers of new pharmaceutical products are required to submit sufficient evidence to substantiate that their products fulfil the above criteria. On average, the Registration Committee studies and approves the registration of about 40 new pharmaceutical products each year.

Control of sale of pharmaceutical products

4 Registered pharmaceutical products may be subject to various kinds of sale control to protect the health of the public. The Ordinance maintains a Poisons List and several Schedules, which are subsidiary legislation. Pharmaceutical products listed in different parts of the Poisons List and in the different Schedules are subject to different levels of sale control. For example, some pharmaceutical products are classified as "prescription only medicines".

They can only be sold in pharmacies under the supervision of a pharmacist and with the support of a prescription from a doctor, a dentist or a veterinary surgeon. The Poisons Committee, established under the Board, advises the Board on how each pharmaceutical product should be classified.

5. In the case of new pharmaceutical products, the Poisons Committee will also consider any recommendations from the Registration Committee. If sale control is to be imposed on a new pharmaceutical product, legislative amendments to the Pharmacy and Poisons Regulations and the Poisons List Regulations are necessary. The Board is empowered to make the legislative amendments subject to the approval of the Legislative Council.

Approval of registration and the legislative process

6. The Board considers that new pharmaceutical products subject to sale control should only be approved for registration after the completion of the relevant legislative amendments to effect such control.

7. The legislative process for regulating pharmaceutical products is coordinated by the Health and Welfare Bureau. After the preparation by the Department of Justice and the endorsement by the Board of the legislative instruments, the Secretary for Health and Welfare moves a resolution before the Legislative Council for the approval of the legislative amendments. The approved amendments are then published in the Gazette and may become effective immediately or on a later date. Depending on the complexity of the amendment exercise, the legislative process usually takes about 3 months.

****

Department of Health
February 2000