For discussion
on 2 November 2004

Subcommittee on
the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2004 and
the Poisons List (Amendment) (No. 3) Regulation 2004

Registration and Classification of Pharmaceutical Products

Purpose

This paper describes the deliberation process in relation to the registration and classification of pharmaceutical products in Hong Kong.

The Pharmacy and Poisons Board (PPB)

2. In Hong Kong, the sale and supply of pharmaceutical products are regulated through a system of registration and classification provided by the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). The Ordinance establishes the PPB as the statutory authority responsible for registration and classification of pharmaceutical products. The three criteria for drug registration, as laid down in the Pharmacy and Poisons Regulations (Cap. 138A) (PPR), are safety, efficacy and quality. Pharmaceutical products can be imported or manufactured for sale in Hong Kong once they are registered . The Registration Committee is set up under the PPB by virtue of section 4A of the PPO to study and approve applications for registration of pharmaceutical products .

3. Another function of the PPB is to determine how each pharmaceutical product should be classified for the purpose of public health protection. The PPO maintains a Poisons List and several Schedules under the PPR. Pharmaceutical products will be categorized into different parts of the Poisons List and different Schedules according to their potency, toxicity and potential side-effects. Such categorization determines the different levels of control when they are sold. For example, some pharmaceutical products 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 authorized by prescription from a registered medical practitioner, a registered dentist or a registered veterinary surgeon.

4. The Poisons Committee, established by virtue of section 31 of the PPO, advises the Board on the category into which a particular pharmaceutical product should fall. In the case of new pharmaceutical products, the Poisons Committee will take into account recommendations put forward by the Registration Committee. Legislative amendment to the Pharmacy and Poisons Regulations is required for the classification of new pharmaceutical products as well as re-classification of existing ones.

5. The composition of the PPB, the Registration Committee and the Poisons Committee are detailed in ***Annex***.

Registration and Classification of Pharmaceutical Products – The Process

6. The applications for registration of new drugs are discussed at the meetings of the Registration Committee. The recommended classification of each of the new drug is considered by the Poisons Committee before final endorsement by the PPB.

7. Applicants for drug registration are required to submit pre-clinical and clinical studies in support of the safety and efficacy of the pharmaceutical product concerned. As regards its quality aspect, relevant information on the master formula, the manufacturer, the manufacturing process as well as quality control methods in ensuring the quality of the drug should also be provided. . Review of these documents requires professional knowledge and expertise in pharmacy. Members of the Registration Committee and the Poisons Committee appointed are all professionally qualified experts who possess in-depth knowledge in the evaluation of new drugs and / or experience in their usage or analysis. It is noted that some of the submitted documents and information is considered commercially sensitive.

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

Health, Welfare and Food Bureau
30 October 2004

Annex

Composition of the Pharmacy and Poisons Board (PPB)
(as provided for in Section 3 of PPO)

- The Director of Health (ex-official Chairman)
- The Government Chemist
- The Chief Pharmacist of DH
- A medical officer in DH
- A full-time teaching pharmacologist nominated by the University of Hong Kong
- A full-time teaching pharmacologist nominated by the Chinese University of Hong Kong
- Three pharmacists nominated by the Pharmaceutical Society of Hong Kong
- A medical practitioner nominated by the Hong Kong Medical Association
- A legal adviser

Current Composition of the Registration Committee[1]

- The Chief Pharmacist of DH (Chairman)
- The Government Chemist
- A pharmacologist from the Chinese University of Hong Kong
- A registered pharmacist
- A medical practitioner
- A veterinary surgeon

Composition of the Poisons Committee[2]

(as provided for in Section 31 of PPO)

- The registered medical practitioner nominated by the Hong Kong Medical Association as member of the PPB
- Two of the three registered pharmacists nominated by the Pharmaceutical Society of Hong Kong as member of the PPB
- Three other members of the Board[3].

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[1] Section 4A(2) of the PPO requires that the Chairman of Registration Committee established under the PPB must be a member of the Board, while members of this committee may or may not be members of the PPB.

[2] Section 31(1) requires that all members of the Poisons Committee should be members of the PPB

[3] Currently, the three other Board members also serving this Committee are the pharmacologist nominated by the University of Hong Kong (Chairman), the Government Chemist and the Chief Pharmacist.