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Paper for the House Committee meeting
on 12 November 2004

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

Purpose

This paper reports on the deliberations of the Subcommittee on the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2004 and the Poisons List (Amendment) (No. 3) Regulation 2004.

Background

2. The Secretary for Health, Welfare and Food (SHWF) gave notice in September 2004 to move a motion at the Council meeting on 20 October 2004 to seek the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2004 and the Poisons List (Amendment) (No. 3) Regulation 2004 (the Amendment Regulations), both made by the Pharmacy and Poisons Board (PPB) pursuant to section 29 of the Pharmacy and Poisons Ordinance (PPO) (Cap. 138).

3. As the information provided by the Administration did not include details of the consultation with the relevant professional bodies and trade associations on the two Amendment Regulations, Members agreed at the House Committee meeting on 15 October 2004 that a subcommittee should be set up to enable Members to obtain further information from the Administration. In response to the House Committee's request, SHWF withdrew his notice for moving the proposed motion.

The Amendment Regulations

4. The Pharmacy and Poisons (Amendment) (No. 3) Regulation 2004 and the Poisons List (Amendment) (No. 3) Regulation 2004 seek to add four new substances, i.e. Articaine and its salts, Atazanavir and its salts, Efalizumab and Pemirolast and its salts, to part A of the First and Third Schedules to the

Pharmacy and Poisons Regulations (PPR) and part A of Part I of the Poisons List. Their addition means that pharmaceutical products containing any of these four substances must be sold in pharmacies by or under the supervision of a registered pharmacist and in his presence, with the support of prescriptions given by a registered medical practitioner, a registered dentist or a registered veterinary surgeon.

The Subcommittee

5. At the House Committee meeting on 15 October 2004, Members agreed to form a subcommittee to study the two Amendment Regulations. The membership list of the Subcommittee is in **the Appendix**.

6. Under the chairmanship of Hon Audrey EU, the Subcommittee held one meeting with the Administration.

Deliberations of the Subcommittee

Registration and classification of pharmaceutical products

7. The Administration has provided the Subcommittee with an information paper outlining the deliberation process in relation to the registration and classification of pharmaceutical products in Hong Kong.

The PPB

8. In Hong Kong, the sale and supply of pharmaceutical products are regulated through a system of registration and classification provided by the PPO. The PPO establishes the PPB as the statutory authority responsible for the registration and classification of pharmaceutical products.

9. Members note that the three criteria for drug registration, as laid down in the 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 under section 4A of the PPO to study and approve applications for registration of pharmaceutical products.

10. The PPB also determines 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 categorised into different parts of the Poisons List and different Schedules according to their potency, toxicity and potential side-effects. Such categorisation determines the different levels of control when they are sold.

11. The Poisons Committee, established by virtue of section 31 of the PPO, advises the PPB on the category in which a pharmaceutical product should fall.

In the case of new pharmaceutical products, the Poisons Committee will take into account the recommendations put forward by the Registration Committee. Legislative amendment to the PPR is required for the classification of new pharmaceutical products as well as re-classification of existing ones.

The process of registration and classification of pharmaceutical products

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

13. Applicants for drug registration are required to submit pre-clinical and clinical studies in support of the safety and efficacy of the pharmaceutical products concerned. Review of these documents requires professional knowledge and expertise in pharmacy. Therefore members appointed to the Registration Committee and the Poisons Committee are all professionally qualified experts who possess in-depth knowledge in the evaluation of new drugs and/or experience in their usage and analysis.

Whether and when consultation are conducted

14. Noting that no consultation has been conducted regarding the new drugs in question, Dr Hon KWOK Ka-ki has asked the Administration to explain under what circumstances consultation will be conducted.

15. The Administration has pointed out that applicants for drug registration are required, in regard to the quality aspect of the drug, to provide relevant information on the master formula, the manufacturer, the manufacturing process as well as quality control methods in ensuring the quality of the drug. Some of the documents and information provided are considered commercially sensitive. To avoid conflict of interests, consultation with the trade on individual applications will not be conducted. All members of the PPB, Registration Committee and the Poisons Committee are professionally qualified experts, including two full-time teaching pharmacologists nominated by the University of Hong Kong and the Chinese University of Hong Kong respectively. Other specialists will also be consulted as necessary.

Pharmaceutical products already approved by other drug regulatory authorities

16. Hon Vincent FANG has asked the Administration whether registration of pharmaceutical products which have already been approved by the drug regulatory authorities in developed economies such as the Food and Drug Administration (FDA) of the United States are subject to the same vigorous registration screening as other drugs without such approval.

17. The Administration has explained that based on the recommendation of the World Health Organisation, the decisions of the FDA and the European

Medicines Agency of the European Union (EMEA) are used as reference. For pharmaceutical products with FDA and/or EMEA approval, the registration process could therefore be expedited. The performance pledge for the registration of new drugs is five months.

Review of the PPO

18. Both Dr Hon KWOK Ka-ki and Hon Albert CHENG are of the view that the PPO, in particular the composition of the PPB, should be reviewed. Dr KWOK considers that the regulation of pharmacists and over the counter sales of drugs should also be examined in the review.

19. The Administration has informed members that a comprehensive review of the PPO is in progress. Apart from refining the provisions to make them clearer, the review will also examine the composition of the PPB and its committees to see whether public participation could be included to represent consumer interest. As the PPO also deals with the registration of pharmacists and traders of pharmaceutical products, the PPB considers that individuals who are non-professionals may have a useful role to play in that regard. In reporting the progress of the legislative review, the Administration is mindful of the competing priorities of other legislative exercises in the pipeline.

Members' comments on the Amendment Regulations

20. Members have no comments on the two Amendment Regulations and agree that the Administration should give fresh notice of 12 clear days for moving the motion at a future Council meeting.

Recommendation

21. The Subcommittee recommends support of the Amendment Regulations.

Advice Sought

22. Members are invited to note the recommendation of the Subcommittee in paragraph 21 above.

Council Business Division 2
Legislative Council Secretariat
10 November 2004

Appendix

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

Membership List

Chairman	Hon Audrey EU Yuet-mee, SC, JP
Members	Hon Vincent FANG Kang, JP
	Hon LI Kwok-ying, MH
	Dr Hon Joseph LEE Kok-long
	Dr Hon KWOK Ka-ki
	Hon Albert Jinghan CHENG
	(Total : 6 Members)
Clerk	Ms Doris CHAN
Legal adviser	Miss Monna LAI
Date	2 November 2004