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December 9th 2013

Dr Hon LEUNG Ka-lau , JP
Chairman, Panel on Health Services

Dear Dr. Hon. Leung & LegCo Health Panel members,

Legislative Proposals to Enhance the
Regulation of Pharmaceutical Products in Hong Kong

The Pharmaceutical Society of Hong Kong supports the majority of the 75 recommendations proposed by the Review Committee and the required amendments to the Pharmacy & Poisons Ordinance. There are however some comments highlighted in the following that we would like to make regarding the Administration's response to the recommendations.

1. Recommendation 18 & 29: All wholesalers and retailers of non-poisons shall be subject to inspection and licensing control.

We note that the Administration considers it not appropriate to impose licensing control on retailers of non-poisons due to (i) the significant impact to the large number of direct sellers of non-poisons; and (ii) the significant cost to trade arising from the wide range of products involving huge volume. We opined that as long as the non-poisons are pharmaceutical products, both the wholesalers and retailers of these products should obtain a license from DH so that the storage conditions of the products are monitored properly. Moreover, distribution records should be kept such that if a recall is necessary, it could be easily traced. Are there any statistics on the number of direct sellers of non-poisons that would be considered as retailers? We hope that the Administration can set a time table to the trade for the need of license application for retailers of non-poisons.

2. Recommendation 30: Registered pharmacist should be present at authorized seller of poisons ("ASP") whenever an ASP is open for business.

We have reservations regarding the 3/3 attendance of pharmacist whenever a pharmacy is opened. Under the current Government policy, there is no separation of prescribing and dispensing (SPD) in the private sectors. Currently when pharmacists are on duty for 2/3 of the opening hours there are very few prescriptions to dispense. At present, the majority of the prescriptions in the private sectors are dispensed in the doctors' office by staff without formal training in dispensing or drug knowledge. As the dispensing of prescriptions is not verified by a professionally trained and qualified third person such as the pharmacists, there is no way to confirm whether the right drugs have been prescribed and are dispensed according to the patients' needs.

For safe medicine use and the general protection of health of patients, the PSHK recommends the Government to adopt SPD, which is the recognized safe medicine practice adopted by many advanced countries and even our neighbouring asian countries such as Korea, Taiwan, Japan, Philippines and Macao have also adopted for many years the practice of SPD. Not until then PSHK opined that this recommendation of having the pharmacist present for 3/3 of the opening hours would be appropriate. The LegCo Health Panel have discussed about SPD in 1995 and 1999. The PSHK hopes that the Government will set up a Committee to obtain views of the public at large and to review the current system of prescribing and dispensing with the aim to protect public health

Therefore, the PSHK proposes that the 3/3 attendance of pharmacists can only be implemented when there is mandatory SPD in Hong Kong. Until then, Pharmacy should be required to display a notification to state that "Pharmacist is Off Duty" "whenever there is no pharmacist in attendance and no dispensing activities of prescription drugs can take place".

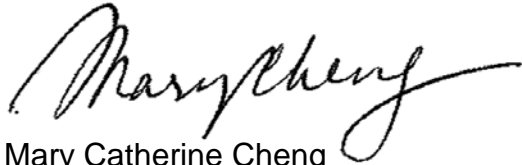
3. Recommendation 31: All Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle.

As most of the ASPs are not owned by the pharmacist, this recommendation would present practical problems because the key and the contents of the locked receptacle are the properties of the ASP. Practically it is difficult to ensure that "only the pharmacist should hold the key to the locked receptacle".

4. Recommendation 33: Give the Pharmacy and Poisons Board the authority to revoke the licence of an ASP at any time after the ASP has been convicted of serious drug offence.

We support the recommendation that the Pharmacy and Poisons Board be given the authority to revoke the licence of an ASP at any time after the ASP has been convicted of any serious offence. It is necessary to ensure that for both convicted offence and breach of Code of Practice for ASP, the cases must go through the Disciplinary Committee of the P&PB.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Mary Cheng', with a long horizontal flourish extending to the right.

Mary Catherine Cheng

President

The Pharmaceutical Society of Hong Kong