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Prof Hon Joseph Lee Kok-long
Chairman
Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

By Email: bc_54_13@legco.gov.hk

9th May 2014

Dear Prof Hon Joseph Lee & Members of the Bills Committee,

Pharmacy and Poisons (Amendment) Bill 2014

1. Code of conduct or code of practice of pharmacists should not be issued by the Pharmacy and Poisons Board for incorporation into the Amendment Bill

On behalf of the Pharmaceutical Society of Hong Kong, we wish to reinstate that the power of the Pharmacy & Poisons Board (PPB) should focus on registration of drugs and licensing of pharmaceutical manufacturers, wholesalers and retailers.

A Pharmacy Council which shall be an independent body must be established, in a similar manner to the Medical Council or the Nursing Council, to regulate and oversee the development of the Profession's practice standards and development direction including such professional conduct and matters of issuing and revising from time to time the codes of conduct or codes of practice for its pharmacist members and to look into disciplinary action of pharmacists, registration requirement of pharmacists and continuing professional development requirements of pharmacists. The Pharmacy and Poisons Board should not be continued to deal with the disciplinary actions.

We do not agree that the PPB be given the power to issue code of conduct or code of practice of Pharmacists which there is clearly a conflict of interest when the Pharmacy & Poisons Board have the power of holding disciplinary actions . This should be issued by the pharmacy profession as guidance for its members and the PPB but should not be incorporated into the Amendment Bill.

Hence, Clause 6 of the Amendment Bill, section 4(B) which stipulates that the Board may issue codes of conduct and codes of practice that it considers suitable for providing practical guidance in respect of this Ordinance should add "except for the code of conduct or the code of practice for pharmacist".

2. To consult the views of stakeholders for any revision in the codes of practice for Licenced Manufacturers and Authorized Persons, Licensed Wholesale Dealers, Authorized Sellers of Poisons and Listed Sellers of Poisons

Under Clause 6 of the Amendment Bill, section 4(B) is added which stipulates that the PPB may issue the codes of conduct and the codes of practice that it considers suitable for providing practical guidance in respect of this Ordinance.

Section 4B (4) further states that The Board is proposed to be given the power that the Board may from time to time revise the whole or any part of a code of conduct or code of practice.

It is a big concern to us that the PPB be given such new, wide and unlimited powers without having changes in the structure and working processes of the PPB. Currently, the Director of Health is the Chairman of the PPB and the officers in the Drug Office under the Department of Health are responsible for law enforcement. There is already a lack of an independent body to monitor the law enforcement action of the PPB. If the PPB is further given the wide and unlimited power to issue or revise the codes of conduct and codes of practice, there is a conflict of interest and a total lack of independence when the law enforcement body is the same body as the maker of the relevant professional codes.

To reflect the concerns of the pharmacy industry and the pharmacy profession, we request that the PPB to state how the consultation process with the concerned stakeholders in the existing structure of the PPB be carried out before any amendment in the Bill to empower the PPB to perform the issue or the revision in any codes of conduct and codes of practice.

It is necessary to state clearly and specifically in the law that a thorough consultation process with the concerned stakeholders must be fully and openly undertaken before issuance or revision of any codes of conduct or codes of practice to avoid the mis-use of the wide power given under the new law. Moreover, an independent body must be set up which has the power to monitor the law enforcement action of the PPB.

3. Definition of Authorized Sellers of Poisons (ASP)

Under section 11 of the Pharmacy and Poisons Ordinance (Cap138), the **existing definition** of “authorized sellers of poisons” is "A business comprising the retail sale of poisons carried on by a registered pharmacist or by a body corporate or an unincorporated body of persons shall be an authorized seller of poisons if the actual sale of poisons is conducted on premises duly registered under this Ordinance by a registered pharmacist or in his presence and under his supervision"

Under Clause 2 of the Amendment Bill, the definition of "authorized seller of poisons" is redefined as "registered pharmacist, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons under section 11”.

Under Clause 12 of the Amendment Bill, Section 11 of the Ordinance is amended to " Subject to Section 16, a **registered pharmacist**, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons if the actual sale of poisons is conducted on premises registered in respect of the seller under this Ordinance by a **registered pharmacist** or in his presence and under his supervision”.

In the new revision, the wordings in the definition are unclear. The registered pharmacist cannot be included and defined as an “authorized seller of poison” since “authorized seller of poison” should be a business operation and not the registered pharmacist himself. We are of the opinion that the definition of ASP can be revised to say “a body corporate or unincorporated body of persons that carry on the retail sale of poisons if the actual sale of poisons is conducted on premises duly registered under this ordinance by a registered pharmacist or in his presence and under his supervision”. Or else, the definition of ASP should remain status quo.

4. **Definition of Pharmaceutical Product and medicine**

It is of concern that the proposed new definition of Pharmaceutical Product is unclear.

The **existing** definition of pharmaceutical product is:
"pharmaceutical product" (藥劑製品) and "medicine" (藥物) mean any substance or mixture of substances manufactured, sold, supplied or offered for sale or supply for use in-
(a) the diagnosis, treatment, mitigation, alleviation or prevention of disease or any symptom thereof;
(b) the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or any symptom thereof;
(c) altering, modifying, correcting or restoring any organic function,
in human beings or in animals; (Replaced 50 of 1977 s. 2)

Under Clause 4 of the Amendment Bill, Section 2(1) of the Ordinance, definition of pharmaceutical product and medicine -means any substance or combination of substances,
(a) presented as having properties for treating or preventing disease in human beings or animals; or

(b) **that may be used in**, or administered to, human beings or animals, either with a view to-
(i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
(ii) making a medical diagnosis;

"**That may be used in**" is subject to different interpretation by the end users or the suppliers. The existing definition of pharmaceutical product is considered by the profession and the trade industry as adequate and the new definition is too wide and cannot have a clear meaning. Accordingly, the definition should not be changed as proposed.

5. ASP should be allowed to repackage drugs under the supervision of a registered pharmacist

Clause 50(3) of the Amendment Bill repeals regulation 29(2) of the Pharmacy and Poisons Regulations so that an authorized seller of poisons (ASP) is no longer exempt from the requirement for a licence to manufacture.

Under Clause 2, the new definition of manufacturer means (a) the preparation of pharmaceutical products, from purchase or acquisition of materials, through processing and packaging, to their completion as finished products for sale or distribution; or
(b) the repackaging of pharmaceutical products as finished products for sale or distribution, but does not include individual dispensing on a prescription or otherwise of any pharmaceutical product, and manufacture has a corresponding meaning;

Currently, the registered pharmacist of the ASP is allowed to repack and dispense smaller packs of OTC drugs or part 1 poisons from bulk bottles to help patients for minor ailments. It is extremely important that the ASP should be allowed to continue the existing practice of repackaging of drugs under the supervision of a registered pharmacist.

Hence, we opined that there is no need to repeal regulation 29(2) of the Pharmacy and Poisons Regulations which states that:
Paragraph (1) and regulations 33 and 35 shall not apply to an authorized seller of poisons, who in the course of his ordinary retail business, manufactures any pharmaceutical product at any premises register by him under the Ordinance in quantities which in the opinion of the Board, are consistent with the scope of his business.

Yours sincerely,

Mary Cheng
President
The Pharmaceutical Society of Hong Kong