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27 May 2014

Prof. the Hon. Lee Kok Long, Joseph
Chairman, Bills Committee
Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Central
Hong Kong

Via Email

Dear Prof Lee,

Ref:- **Pharmacy and Poisons (Amendment) Bill 2014**

On behalf of the Hong Kong Pharmaceutical Manufacturer Association (HKPMA), a body corporate representing a vast majority of the local Pharmaceutical Manufacturers, we write to express our support towards the legislative amendment on the Pharmacy and Poisons Ordinance and related Regulations as proposed by the Hong Kong Special Administrative Region Government (HKSAR). These amendments aim to enhance the existing regulation of pharmaceutical products in Hong Kong, and to ensure the quality and safety of pharmaceutical products in Hong Kong with the ultimate goal of safeguarding the integrity of public health. In addition, there is a need to amend the existing Pharmacy and Poisons Ordinances and Regulations, some of which are not updated and do not fully align with the changed dynamics in the pharmaceutical administration system.

Since the emergence of drug incidents dated back to March 2009, the local pharmaceutical industry has been committed in vigorously upholding the standard of pharmaceutical manufacturing in Hong Kong with an underlying goal of achieving the highly acclaimed PIC/S standard in collaboration with the Department of Health of HKSAR. As one of the key stake-holders in the delivery of healthcare service in Hong Kong, all HKPMA manufacturer members are committed to providing the quality and safe standard of pharmaceutical products and we have no reservation to support the amendment bills in particular of the following :-

1. GMP Upgrade:- the current Hong Kong GMP practice will be upgraded to widely-acclaimed international standard, ie PIC/S. Our manufacturing industry has

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taken initiatives to pursue the PIC/S roadmap and is working hard to achieve this goal.

2. Clause 52 (PPR, Reg. 30A-F):- imposing a register of AP and revising the qualification required for registration as AP are to align with GMP upgrade to international standard ie. PIC/S. For example, the legal basis for the Qualified Person (similar status as AP) is defined in the DIRECTIVE 2001/83/EC. We suggest that a set of qualification requirements, including but not limited to registered pharmacists, of Authorized Persons (APs) and the course structure that would render qualified status to those personnel to be AP should be defined.
3. Clause 50(3) (PPR, Reg. 29(2)):- Manufacturing of pharmaceutical products must be carried out by licensed manufacturer. Manufacturing of pharmaceutical products other than extemporaneous preparations should be conducted by licensed manufacturer that complies with GMP for quality assurance to safeguard public health.
4. Clause 6 (PPO, Section 4B):- To empower the Board to promulgate corresponding Code of Practices (COPs) in order to provide practical guidance and enhance monitoring for the conduct of the activities of registered pharmacists, different licensed traders and traders subject to registration requirement (including manufacturers, wholesalers and retailers). This aims to ensure that all sectors and professionals from different pharmaceutical sectors operate in a responsible, ethical and professional manner for public health benefits.
5. Clause 21(PPO, Section 27):- To replace the text "Poison 毒藥" by "Prescription Drug 處方藥物" or "Drug under Supervised Sales 監督售賣藥物" depending on the sale restriction so as to avoid confusion that the pharmaceutical products might be harmful and unsuitable for use or consumption. This aims to align with international practices and to provide better understanding on the different levels of control of sales/supply of pharmaceutical products.
6. Control of pharmaceutical products:- the proposal to extend the validity of clinical trial certificate for new pharmaceutical products from two years to not more than five years will allow sufficient time to complete and to minimize interruptions to trials especially for those which provide life-saving treatment to patients.

Whilst supporting the amendment bill, we also have the following suggestion:-

1. Clause 30 (PPO, Section 34A):- regarding to Recovery of conviction-related expenses, we suggest to maintain the fixed "fine" with a higher penalty if required as it is not appropriate to empower the Court to order recovery from the defendant of all expenses incidental to the taking, examination and analyses of any sample of pharmaceutical products incurred by the Administration in respect of which the conviction is based

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and that the convicted trade will bear the "civil debt" which is something not required of in other criminal evictions in the HKSAR.

The pharmaceutical industry in Hong Kong has been committed to serving the public of Hong Kong and as such, the industry should be encouraged to operate in a professional, ethical and well-regulated manner to ensure the appropriate use of medicines and to support the provision of high quality healthcare. This commitment should apply to ALL sectors in the pharmaceutical industry. HKPMA therefore strongly support the above-mentioned amendment bills whilst hoping that the proposed suggestions per above be duly considered and adopted thereof.

Thank you for your attention.

Yours sincerely,

For and on behalf of
Hong Kong Pharmaceutical Manufacturers Association

Celine H.K. Cheng
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President