香港製藥商會
Hong Kong Pharmaceutical Manufacturers Association
1/F., GMP Centre, 12 Dai Fu St., Tai Po Industrial Estate, Tai Po, New Territories, Hong Kong
香港新界大埔工業村大富街十二號 GMP 中心一樓
Tel:- (852) 2407 3271 Fax: (852) 2407 5707

8 December 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:- **Support of 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 Manufacturers for Pharmaceutical Products, we would like 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). The amendment bill not only aims to improve the existing regulations of controlling pharmaceutical products in Hong Kong ensuring the quality and safety of pharmaceutical products in Hong Kong with the ultimate goal of safeguarding the integrity of public health, but also there is a need to amend the existing Pharmacy and Poisons Ordinances and Regulations, some of which have not been updated since the 1970's and do not fully align with the changed dynamics in the pharmaceutical administration system both in Asia and around the world.

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 strongly support the amendment bills in particular of the following :-

1. Including the requirement of Written Order of Drugs into the Codes of Practice:- the written order requirement aims to reduce errors throughout the supply chain to ensure that the correct drugs are delivered to their recipients. We can see the following benefits on imposing of written orders of drugs:-
   - Eliminating errors due to miscommunication of verbally orders;
   - Allowing cross-checking by both parties concerned in placing and receiving orders to ensure the accuracy of the orders;
   - Allowing traceability in the case of any complaints or errors;
   - Improving work efficiency as orders are placed and delivered right

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on first time.

- Completing the supply chain by including the first step of drug ordering to align the requirement of current logistic system.

As with any other newly implemented systems and/or policies, it is inevitable to cause some kinds of inconveniences and may possibly cause some delay in the initial stage as all stakeholders are adopting to the new requirement and system. We believe that well-prepared set up and appropriate training along with clear implementing time schedule will help to assist the smooth implementation of the requirement. Comparing to phone order, placing orders by way of written order will only improve the efficiency in the supply chain by reducing error in delivery and it will not cause any undue delay in the whole logistics and supply chain including the delivery of drugs once all sectors are used to the requirement. The ultimate benefit to further reducing risks in the supply chain outweighs the initial inconveniences.

2. GMP Upgrade:- the current Hong Kong GMP practice will be upgraded to widely-acclaimed international standard, ie PIC/S. Our manufacturing industry has taken initiatives to pursue the PIC/S roadmap and is working hard towards this goal.

3. 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.

4. 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.

5. 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

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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.

6. 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.

7. 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.

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 and shall be most grateful if the proposed suggestions per above would be duly considered and adopted thereof.

Thank you for your attention.

Yours sincerely,

Celine H.K. Cheng
BPharm, MRPharmS, PhD, MBA
President