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供各委員傳閱
Pharmacy and Poisons (Amendment) Bill 2014 Committee
Legislative Council, Hong Kong
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3 June 2014

Dr KO Wing-man, BBS, JP
Secretary of Health

Dear Dr Ko,

Views from The Practising Pharmacists Association of Hong Kong regarding the proposed Pharmacy and Poisons Board (Amendment) Bill 2014

On behalf of The Practising Pharmacists Association of Hong Kong (PPAHK), please kindly be informed of the views from our members regarding the current proposed Pharmacy and Poisons Board Amendment Bill 2014.

As one of the largest pharmacy professional associations in Hong Kong established over 44 years ago, it is our duty that we bring to the attention of the government the potential pitfalls of the proposed amendments and the implications the law change will have on the patient and the public at large. It can be expected that pharmacists can support the law amendment if the issues are resolved and concerns are addressed by the government.

Firstly, as one of the members of the Review Committee on Drug Regulatory Review, we would like to express that we were surprised to find that the set of Pharmacy and Poisons Amendment Bill 2014 contains far more amendments than the original recommendations discussed by the Review Committee in 2010. It is even more concerning that the legislative council has been given the impression that all of the Bill amendments had been discussed by the Review Committee members and by all stakeholders of the profession.

It is a fact that the final details of all the recommendations in the proposed Pharmacy and Poisons Amendment Bill 2014 had not been revealed to the public until 21 March 2014 despite the requests from the PPAHK that members need information in full about the law change for due consideration. After the information about the law change had been published, our members have grave concerns that some of the amendments may move the healthcare system backward to become less safe, less effiicient, and less able to fulfill the needs of the public to obtain the necessary levels of healthcare and medicinal products to maintain a high quality of life.

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In the usual practice of law, "justice needs to be seen to be done". We are of the view that the government should be seen to be as just and fair as possible by being responsive to the profession`s concerns on specific principles altered by the pharmacy law change as listed below:

1. The government has not responded favourably to the profession requests to have the opportunity for a legally qualified professional to explain the differences between the current law and the proposed law change. The profession is not able to accept the government refusal to provide a qualified legal person to answer questions of the profession. we belive that pharmacists can not be reasonable be requested to accept the proposed law amendments without having the necessary professional resources to understand the intent and implications of the law changes.

2. It is also a fact that the government had not given feedback on the concerns raised from the profession about the proposed amendments. After the first and second read at the legislative council, the profession met with the Department of Health Drug Office on 10 April 2014 and expressed our concerns face to face. However, we have not heard of any changes being made in response of the issues raised by members of the profession. We believe that the government may not be taking our concerns seriously before progressing with the law amendment process with the legislative council. We fear that if our concerns are not addressed, the profession may not be able to provide our professional services effectively and we will fail to fulfill our responsibility to protect the public safety in the future.

3, Pharmacists working in the community have expressed serious concerns with the proposed amendment to redefine the definition of Authorized Sellers of Poisons. Community pharmacists question about why the original intent of the law is being changed for no apparent and compelling reason. Pharmacy laws should not be changed arbitrarily due to a whim or a new idea of the regulator. Pharmacy laws are changed based actual and real needs of the profession and the society which we serve.

For over 40 years, the ASP has been defined as a Business with the person in charge being the PIC (person in charge) or owners of the business. Currently, it is very clear that the ASP license is issued to a business entity conducting its operations at a specific address and not to an individual person. According to the proposed amendments, the ASP license will be issued to a physical person or a body corporate, or a unincorporated body. The new definition is highly confusing and inappropriately drafted as to whether the ASP is a person or a business body. Furthermore, the appearance of the word Registered Pharmacist in the definition two times is very ambigious and may be expected to lead to problems in law enforcement when trying to identify the status of the registered pharmacist, who may be in the capacity of the owner or may in the position of employee, to take responsiblity for legal liabilities of the ASP business. The government needs to be seen to be more active in responding to the profession:s serious concerns on the balance between responsibility and liability for the ASP owner and for the employee pharmacist.

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4. Pharmacists,doctors, and the public has raised concerns on the inappropriate relaxation of the requirement to be the Authorized Person of local drug manufacturers. Pharmacists believe we have a ethical role and professional duty to protect the public from substandard production of drugs. Since the introduction of the Good Manufacturing Practice in local drug manufacturing in Hong Kong over a decade ago, pharmacists had been entrusted by the government to be the only person able to assume the important role and responsibilty of the Authorized Person. The operations and business volume of local manufacters have increased drarmtically over the past decade to demand more professional pharmacists to ensure for quality of the medicines being produced. It can be anticipated that the higher the volumes of manufacturing may lead to higher incidence of quality issues. We have observed from the tradegy in the year 2009, quality issues with local manufacturers may have already led to the death of 8 hospital patients. To downgrade the exisitng requirements of the Authorized Person, despite the potential and actual risks of substandard quality of drugs being observed in the local manufacturing environment, can not be seen as a logical and reasonable change in law amendment. We realize that the local manufacturing career prospects only account for less then 2 % of all jobs for pharmacists but without any obvious change in the improvement of key personnel to ensure for the quality of the produced medcines, the pharmacy profession can not and will not forsake our professional duty to protect the public by standing firm that pharmacists should be required to be the Authorised Person for local drug manufacturers to provide the highest level of assurance to the public at large as recommended by the World Health Organization guidance. The govenment should also understand that it is premature to change the requirements to rush to relax the current requirement due to the need to reference to the European PIC/S standard when none of the local manufacturers have been able to obtain the PIC/S standards as of today. If the relaxation of the requirements of the Authorized Person is the only aspect that is aligned with PIC/S standards without the entire quality system to be required to be upgraded, we believe the outcome would be detrimental to the public interests. We believe it would be more safe to the public if the laws are only changed upon the successful achievement of the entire quality system upgrade of manufacturers to the European PIC\S standards. Until that time, the law should remain unchanged to require that only pharmacists can be the Authorized Person of local manufactuers as an important and indispensible safe guard to public health and safety.

5. Pharmacists have been contributing to the society for hundreds of years to ensure that the public is able to benefit from the safe medicines. Pharmacy, since ancient times, have been regarded as one of the most important professions along with doctors, dentists, nurses, lawyers, engineers, and many others. It is unjust to regard the pharmacy profession as a group of semi-professsional service providers (eg. tourist agents and insurance intermediaries)
as being refered to by some people that are unfamiliar with the global trends of the pharmacy profession.

The global trends of the pharmacy profession is not being, as some people may have

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mistakenly expressed, that the responsibility to set profession standards and practices are to be transfered to the government. On the contrary, pharmacists all over the world are regarded as professionals that should continue to have the responsibility to establish its standards to serve the patients best interests rather than shifting the responsibilty to government that lacks the professional practice experience to establish standards for the profession. If the government does not have the adequate level of expertise in the practice of pharmacy, the standards which the government may set will be inappropriate in the real world setting and may even cause risks to the patients health and safety due in the long term.

Therefore, we are of the view that Hong Kong should follow the rest of the developed world to continue to let pharmacists set their own professional standards as they are in the best position to ensure that the standards meets patients needs and expectations. The Pharmacy and Poisons Board should not be given a new power to issue Codes of Practice as the original fucntion, structure, and organization of the the Pharmacy and Poisons Board is not to perform the function of setting Codes of Practice in the first place. The pharmacy professional bodies are more than capable to have joined hands to unify a single Code of Practice for the profession and the Pharmacy and Poisons Board may make reference to the guidence document when needed.

6. We are of the view that the length of the expiration date of 2 years for the clinical trial certificate is sufficient at the present moment. When the 2 years expiry period was set originally in the law,it was intended to ensure that clinical trials to be commenced shortly after the clinical trial certificate approval and should be able to last for the period of the entire study usually of a trial study period of 12 - 24 months. The government would need to provide the evidence that clinical trials that need to renew the clinical trial certificate in the past was due to the long length of the study or due to the delay of the investigator to commence the trial after the issue of the clincial trial certificate.

If the trial is commenced immediately after approval, we may anticipate that the variables should not be vastly different within a period of 2 years. However, if the expiry of the Clinical trial certificate is extended to 5 years, the investigator may delay the clinical trial for a number of years and put the patient subjects at great risk of being exposed to varibles that may have changed over the course of half a decade. It is rarely necessary for a clinical trial in Hong Kong to need to continue for as long as 5 years and even when the trial is required to be longer than 2 years, the investigator may apply for a new clinical trial certificate before the expiry date to ensure the trial can be conducted continuously without affecting the study.

We often have experienced that investigators tend to delay the commencement of the study after obtaining the clinical trial certificate and some investigators in Hong Kong fail to apply for a new clinical trial certificate even when important study information is changed after obtaining the clinical trial certificate including the name of the investigator, study objective and design, the nature and quality of drug preparations used on patients in the study. It is worrying to patients and professionals that 5 years is too long a time to have the validity of the clinical trial certificate as the clinical

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trial should be commenced as soon as possible after approval to ensure that varible changes are kept to a minimum for patient safety. Also, the regulator need to be able to ensure that proper review of the details of the study can be done at more frequent intervals. Therefore, we see no apparent need for change of the validity date of the clincial trial certificate as being 2 years at the moment.

However, we do see the need for investigators to be informed to start the clinical trial as soon as possible to avoid the clinical trial to exceed the 2 year validity period.

Finally,the proposed definition of a Pharmaceutical Product is very vague and may cause misunderstandings easily to the public. We suggest that the definition should be discussed further to ensure for more clarity and better understanding between the regulator and the profession. We look forward to more discussion on the options on defining pharmaceutical products in due course.

We hope the views mentioned above is useful for the government to understand more about the expectations of the pharmacy profession on pharmacy law change. We hope that Hong Kong does not deviate from global pharmacy laws and practice in the current regulation change process as it is our responsibility to ensure that professionals and patients can continue to enjoy world class pharmacy law system in Hong Kong.

Thank you for listening to the voice of pharmacists.

Yours truly,
Iris Chang
President

CC: Bill Committee on Pharmacy and Poisons (Amendment) Bill2014, LegCo