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2 December 2013

**Practising Pharmacists' Views on the Recommendations on the Regulation of
Pharmaceutical Products in Hong Kong**

On behalf of The Practising Pharmacists Association of Hong Kong, please kindly find our views in regards to the recommendations by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong:

The Practising Pharmacists Association of Hong Kong (PPAHK) was established in 1972 and is currently one of the largest professional bodies representing practising pharmacists in Hong Kong. The PPAHK embraces the values of professionalism, service, and teamwork. Our mission is to " Make Hong Kong a Better Place " and proudly place patient's interests are our first priority. When being invited to provide our views on the recommendations of the Review Committee, we have placed the patient's best interests and the needs of the Hong Kong society ahead of all other considerations.

Patients and the general public depend on the retail community pharmacist to provide convenient, efficient, high quality and cost-effective services to meet their daily healthcare and medication needs and pharmacists in the practice depend on an efficient and effective healthcare system with regulations that are reasonable and just to protect the interests of the public and the pharmacist. As most of the pharmacists practising in the community pharmacy sector is represented by our association, we would be in the best position to provide a more practical and down-to-earth view as to the practicality and feasibility of the recommendations and the implications to the professionals actually practising in the retail community sector.

We would like to request that the members of the legislative council consider our opinions, particularly about changes in pharmacy regulations affecting retail pharmacy practice, to have more relevance than the views of other pharmacy professional bodies that have no members or relatively less members currently practising in the retail community sector as those representatives may not have the most up-to-date information about the current practice situation.



After formal consultation with our members, we would like to bring to the attention of the members of the legislative council about the concerns of practising pharmacists in regards to the following proposed recommendations by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong:

1. Recommendation of “ Registered Pharmacist should be present at authorized seller of poisons (ASP) whenever an ASP is open for business.”

Current Law Intended to Provide Public Safety and Convenience

At the present time, the law requires the pharmacist to be present no less than two-thirds of the opening hours of the pharmacy. **We are of the view that no change is needed for the current regulations.** The original intent of this legal requirement is to allow sufficient time for the pharmacist to be available during the main hours of the day to provide patient care and dispensing services and also to enable for the pharmacy to remain open for the convenience of the general public to obtain the necessary shopping services even after the dispensing service is closed when the pharmacist leaves for the day in the evening time when business volume is low for dispensing or patient care services.

It is most common and a general way of life for the public to visit the neighborhood pharmacy during the evening time to make purchases of needed personal care items, replenish baby milk formula, to seek for chinese medicine, to buy vitamins and health supplements, and to rush to obtain over-the-counter medicines for the common minor ailments that do not require the dispensing services of the pharmacist during late hours in the evening. The law must not be changed in a way to compromise the general way of life and the levels of public health, safety, and convenience that had been enjoyed by citizens and travelers in Hong Kong for the past century.

Hong Kong Currently Adopts a Global Standard Business Model for Modern Retail Pharmacies

To allow for the dispensing department of the pharmacy to close before the rest of the store is the standard business model for modern pharmacies around the world as it is not viable for pharmacies nowadays to exist just to provide dispensing services only and be open for



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business just during the main hours of the day. More and more pharmacies in the world are using the modernized form of operation of allowing the pharmacy to remain open for shopping services even after the dispensing department is closed. The laws of Hong Kong must continue to take into consideration the global market trends of retail pharmacy practice and the practical needs of the Hong Kong public to have other shopping services available at the pharmacy after the dispensing department is closed for the day.

Public Safety is Not a Concern When Dispensing Department is Closed Earlier

It is important to note that public safety has never been a cause for concern for any pharmacy operating around the world even when the law allows for the dispensing department to close earlier than other parts of the store. As the current law requires that the dispensing service hours are clearly indicated outside of the dispensing department, the public is clear when the pharmacist is available or not available for dispensing services. Furthermore, there has been no consumer outcry about lack of public safety at pharmacies world-wide that have dispensing departments closing before the other shopping areas of the store. On the other hand, many consumers find it convenient to have more places to be open late in the evening time to shop for baby care products, personal care items, over-the-counter medicines, and minor wound care for their families.

Pharmacist Presence During All Opening Hours of the Pharmacy Should Not Be Mandatory

It is also a known fact that many pharmacies in Hong Kong do not have large volumes of prescriptions to fill, especially in the evening hours, in the existing market situation with no separation of prescribing and dispensing. If some individual pharmacies have high volumes of prescriptions to fill in the late evening hours, those operations may have the option to hire an additional pharmacist to serve patients in the evening hours but this should not be a mandatory requirement for all pharmacies.

Change in Law Requirement Will Ultimately Result in Public Inconvenience and Higher Costs to Consumers

To change the current law to require the pharmacist to be present during all opening hours of the pharmacy will ultimately work to the detriment of the public. If in the case that the



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pharmacy business is required to mandatory hire an additional pharmacist to work in the evening hours until the pharmacy closes, it is anticipated that many pharmacy operations may decide to shorten their operation hours and discontinue their shop services thus resulting in causing great inconvenience to the public to have fewer places to shop for their daily use items or to take care of their minor ailments.

Another scenario that may also occur would be the pharmacy operation may hire an additional pharmacist to work the evening hours just for sake of compliance to the regulations but at the increased expense of the consumer because the volumes of prescriptions may not actually be able to support the cost of hiring the additional pharmacist. Therefore, we are of the view that unless the government intends to immediately change the Hong Kong healthcare system to become similar to other countries with separation of prescribing and dispensing which may generate more prescription volumes for retail community pharmacies, then it may not be a practical option, as of now, to require pharmacies to have the pharmacist present at all opening hours of the pharmacy.

2. Recommendation of “ All part 1 poisons be stored in locked receptacle in the premises of the ASP and that the pharmacist should hold the only key to the locked receptacle.”

Current Law Does Not Provide Sufficient Legal Rights to Employee Pharmacists

After seeking legal opinion, we are of the view that the employee pharmacist lacks the legal rights of tenancy of the ASP premises and the legal rights of ownership of the locked receptacles and of the property locked inside the locked receptacles and therefore, the law can not have a requirement to have an employee pharmacist to perform the due diligence necessary to take all reasonable steps to ensure that the pharmacist should hold the only key to the locked receptacles in the premises of the ASP. In the practical setting, the owner of the ASP , rather than the employee pharmacist, is the only individual who can ensure that he or she should have the only key to the locked receptacles as it is the owner that have the right of ownership in the premises where he also has the right of tenancy. The legislative council needs to consider every legal aspect of the recommendation so as to be fair and just for practising pharmacists.

Unless the government intends to make immediate changes to the law to be similar to other



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countries in the world where the pharmacist is also the owner of the ASP, the pharmacist, who is an employee, can not be reasonably be expected to take all steps necessary to ensure that he or she holds the only key to the locked receptacle in the premises of the ASP.

Therefore, we recommend the law should be changed that the owner of the ASP should have the only key to the locked receptacles of the ASP premises as he or she is the only person who can ensure that he or she has the only key to the ASP premises and locked receptacles which he has the rights of ownership.

Then, the owner can open the locked receptacles for the employee pharmacist when the dispensing department is open for service and the owner can lock the receptacles when the dispensing department close for the day.

3. Recommendation to “ Add a provision in the PPO for the issuance and revision of the COP for ASPs in order to give a legal status to the COP to enhance monitoring on the operations of ASPs; and to introduce a COP for "listed sellers of poisons" (LSP) which should enjoy the same legal status as the COP for ASPs.”

We would like to bring to the attention of the legislative council members that by definition, the Code of Practice for ASP and LSP is a set of agreed professional practice standards developed by the profession for the professionals in the practice and the Code of Practice is not developed by law-makers or the regulator for the purpose of monitoring the ASP and LSP. One must not confuse the purpose and role of the Code of Practice with the purpose of the law.

In general, professional Code of Practices of healthcare professional practising across the world do not need to be given a legal status for the purpose of facilitating the regulator to enhance the monitoring of the ASP or LSP because the regulator can make use of the current pharmacy law and regulations, which should already have the fundamental legal requirements, for the regulator to effectively monitor the ASP or LSP. If in the event the law is outdated or insufficient for the regulator to monitor the ASP or LSP effectively, then the due and proper process for law amendment should be employed to ensure that the legal basis with which the regulator needs to monitor the ASP or LSP should be put in place through a formal, open, transparent, and fair process through the legislative council rather than having the regulator having to depend on using the Code Of Practice document, rather



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than the law, as a means to facilitate the regulator to monitor the ASP or LSP effectively.

4. *Recommendation that drugs should be ordered in writing.*

In the current law, medicines may be ordered by the following two ways:

(1) *CAP 138A Reg 5 (3)*

" Subject to paragraph (4), so much of section 22(3)(b) as requires an entry in the poisons book to be signed by the purchaser of a poison shall not, as respects the sale of a poison to a person for the purpose of his trade, business or profession, apply if the following requirements are satisfied

- (a) the seller shall obtain before the completion of the sale an order in writing signed by the purchaser stating his name and address, trade, business or profession, the name and quantity of the article to be purchased, and the purpose for which it is required;
- (b) the seller shall be reasonably satisfied that the signature is that of the person purporting to have signed the order, and that that person carries on the trade, business or profession stated in the order, being one in which the poison to be purchased is used; and
- (c) if the article sold is sent by post, it shall be sent by registered post."

(2) *CAP 138A Reg 5 (4)*

" Where a person represents that he urgently requires a poison for the purpose of his trade, business or profession, the seller may, if he is reasonably satisfied that the person so requires the poison and is, by reason of some emergency, unable before delivery either to furnish to the seller an order in writing duly signed or to attend and sign the entry in the book, deliver the poison to the purchaser on an undertaking by the purchaser to furnish such an order within 48 hours next following"

We are of the view that there is no need to change the current regulations. The current law, as stated above, already requires the the seller of the drug products to obtain before the completion of the sale an order in writing signed by the purchaser (i.e. ASP) and it also allows for purchasers (i.e. ASPs) to place urgent verbal orders when and if required for patients in need of life-saving medications provided that the purchaser furnishes the written order within 48 hours. The original intent of the law is to provide for a legal process to have written records of a complete set of drug movement records which facilitates the tracing of source of drugs minimizing errors in the delivery and receipt of drugs but also



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providing a mechanism for sellers to receive verbal orders so as to ensure that urgent orders of drug items can be provided to patients as quickly as possible while the order in writing is subsequently furnished by the purchaser (i.e. ASP) to the seller by 48 hours. The practice of ordering drug items through verbal means for urgent situations is consistent with the law and practice in other developed countries in the world including USA, UK, Australia, and Singapore.

We would be most concerned for the well-being of patients if the recommended law change does not allow sellers to receive orders verbally from purchasers (i.e. ASP) for placing urgent orders for medicines as it will pose a great risk to patient health and safety if life-sustaining medications can not be delivered efficiently in urgent situations..

Please kindly find the summary of the concerns of practising pharmacists in the attached Appendix One for your ease of reference.

Thank you for your kind attention and please do not hesitate to contact us at 8101 5771 for further information if needed.

Iris Chang

President

The Practising Pharmacists Association of Hong Kong

Appendix One:

Summary Table of Pharmacists Concerns on Recommendations of the Review



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Committee

Recommendation	Reasons for Concern	Our Recommendation
1. <i>“ Registered Pharmacist should be present at authorized seller of poisons (ASP) whenever an ASP is open for business.”</i>	<ul style="list-style-type: none"> - Inconvenience to the public will be caused if retail pharmacies are not able to be open for personal needs shopping services after dispensing department is closed - Hong Kong will deviate from global market practices in modern community pharmacy practice - Increased costs to consumer if retail pharmacies need to hire an additional pharmacist just for sake of legal compliance but has insufficient business volume to cover additional pharmacist costs 	No Need for Change to current regulations
2. <i>All part 1 poisons be stored in locked receptacle in the premises of the ASP and that the pharmacist should hold the only key to the locked receptacle.</i>	<ul style="list-style-type: none"> - legal rights of employee pharmacists is insufficient to perform due diligence to ensure the employee pharmacist should have the only key to the locked receptacles of the ASP premises - the owner of the ASP premises and the property of the locked receptacle is the only person who has the right of tenancy to the ASP premises and the right of ownership to the locked receptacle and all products inside the locked receptacle to perform the due diligence that he or she should have the only key to the locked receptacles. 	<p>Law should be changed that the owner of the ASP should have the only key to the locked receptacles of the ASP premises as he or she is the only person who can ensure that he or she has the only key to the ASP premises and locked receptacles which he has the rights of ownership.</p> <p>Then, the owner can open the locked receptacles for the employee pharmacist when the dispensing department is open for</p>



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		<p>service and the owner can lock the receptacles when the dispensing department close for the day.</p>
<p><i>Add a provision to the Pharmacy and Poisons Ordinance that the Code of Practice (COP) for ASPs in order to give a legal status to the COP to enhance monitoring on the operations of ASPs; and to introduce a COP for "listed sellers of poisons" (LSP) which should enjoy the same legal status as the COP for ASPs.</i></p>	<ul style="list-style-type: none"> - <i>The true purpose and intent of the Code of Practice for ASP and LSP is for professionals to develop a set of standards of practice for their own profession.</i> - <i>It is not the intent of the Code of Practice for ASP and LSPs to be used for the purpose of regulators to enhance the monitoring on the operations of ASPs and LSPs because the law should be sufficient to serve the purpose to enable regulators to effectively monitor ASPs and LSPs.</i> - <i>Giving the Code of Practice legal status may result in situations where the differences in the Code of Practice and the law may lead to confusion of legal requirements.</i> - <i>It is more appropriate for regulators to propose the necessary law change through due process in an open, fair, transparent, and formal manner, through the legislative council rather</i> 	<p>There is no need to give legal status to the Code of Practice for ASP and LSPs as the law should be sufficient for regulators to monitor the operations of ASPs and LSPs.</p>



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	<p>than depending on amendments to the Code of Practice as a means to introduce new changes in legal requirements.</p>	
<p><i>Drugs should be ordered in writing</i></p>	<ul style="list-style-type: none"> - It is unclear why new amendment to the law is needed when the existing law already have the provision to require drugs to be ordered in writing - Public health and safety is at risk if amendment to the law does not provide for the same provisions provided by the existing law to allow for urgent orders to be placed verbally to provide life-sustaining drugs to serve medical needs of patients. - It works to the detriment of the public if the Hong Kong healthcare system becomes so inflexible to require written legal documentation for ordering drugs without allowing for any way to provide written documentation after the sale and ultimately fails to serve the true needs of the population to have the life-sustaining drug products provided to patients in need. 	<p>There is no need for change in law as it already has a provision to require drug to be ordered in writing unless in urgent situations when the order in writing can be provided in the next 48 hours.</p>