CANADIAN PHARMACISTS ASSOCIATION
ASSOCIATION DES PHARMACIENS DU CANADA

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Health Products Compliance and Enforcement Unit
Regulatory Operations and Regions Branch
Health Canada

By email to: hc.hpce-cpsal.SC@canada.ca

RE: CONSULTATION ON DRAFT - DRUG AND NATURAL HEALTH PRODUCTS RECALL GUIDE

On behalf of the Canadian Pharmacists Association (CPhA), we would like to thank you for the opportunity to comment on Health Canada's Draft – Drug and natural health products recall guide, which will help responsible parties understand and comply with sections of the Food and Drugs Act and associated regulations that pertain to the recall of drugs and natural health products.

CPhA is the national voice of Canada's 42,000 pharmacists, who are trusted health care providers and medication experts, serving as access points between patients and the medications they require to maintain their health. Across Canada, pharmacists are primarily responsible for managing and monitoring their patients' medication therapy, and they see firsthand the anxiety and frustration patients experience when they are faced with a drug recall. Pharmacists devote considerable time and resources to managing recalls when they occur. This involves, among other tasks, alerting patients and prescribers about the recall, identifying alternative medications, managing returns and patient refunds, counseling patients on substitute medications and monitoring any new therapies to ensure they are working properly for patients.

Canada's drug supply has become increasingly destabilized by drug shortages and recalls. Over the past several months alone there have been EpiPen® and vaccines shortages, as well as the major valsartan recalls. Based on the results of a recent CPhA survey, 74% of pharmacist respondents (total = 1,467) indicated that recalls have increased over the past 3-5 years and 68% (total = 1,424) believe that recalls have increased over the past year alone.

CPhA commends Health Canada for developing guidelines to facilitate compliance by regulated parties to the legislative and regulatory requirements pertaining to recalls. We believe these guidelines will lead to clearer and more consistent notifications, processes and messaging from manufacturers, distributors and other key stakeholders involved in the drug supply chain when recalls occur. Nevertheless, in consideration of pharmacists who are on the frontlines of drug recalls as intermediaries between patients and the drug distribution system, we have identified gaps in the guidelines, and within the regulations themselves, that should be addressed. Our recommendations are aimed at enhancing and clarifying communications to pharmacists and other health care

providers, ensuring consistency with regard to recall procedures and enabling seamless care for patients when they are faced with a recall of a drug they depend on for their health.

Standardized processes for recalls and information related to refunds

The recent valsartan recalls highlight the complexity of recall management when it involves a voluntary recall and/or a recall impacting numerous drug manufacturers. In our recent survey of drug shortages and recalls, pharmacists expressed to us that they were given unclear and, at times, conflicting information regarding recall procedures by different manufacturers of valsartan products. This caused confusion and administrative burden and resulted in inconsistent procedures. Case studies such as these highlight opportunities to improve drug recall processes, and such improvements should have the regulatory oversight from governing bodies such as Health Canada.

CPhA strongly recommends that Health Canada require responsible parties to communicate consistent processes to pharmacists and other parties in the drug distribution system in each case of a drug recall. This could include the development of clear guidelines for pharmacists based on the severity and level (Type I, II or II) of recall and a standardized procedure form to ensure that instructions are easy to interpret and received in a timely manner. Consistent procedures based on the type of recall would allow pharmacists to follow processes more efficiently and consistently, as opposed to relying on each responsible party to issue separate instructions related to their products in an ad hoc manner.

Given trends in drug manufacturing that are consolidating and outsourcing aspects of production and the sourcing of active pharmaceutical ingredients, it is likely that recalls involving multiple drug manufacturers will become the new normal. Until governments and industry can prevent drug recalls from occurring, consistent and unambiguous mitigation processes are necessary for all parties to ensure the proper retrieval and disposal of unsafe medications.

CPhA recommendation: That Health Canada amend regulations with a requirement for consistent procedures and communications from responsible parties to all consignees based on the severity and level of recall.

During the recent valsartan recall, another challenge that arose was patient demand for reimbursement of their remaining supply, as well as insurers requiring that claims be reversed. Information on procedures to process those reimbursements were in some instances inconsistent and unclear. Health Canada should require that manufacturers and other responsible parties provide reimbursement of any stock, either unused pharmacy stock, or returned products. Health Canada should also require consistent and explicit information pertaining to refunds be shared with pharmacists within communications and procedures for drug recalls. When it comes to managing recalls, the priority of pharmacists should be to contact patients and identify safe and appropriate medication substitutes. Pharmacies should not be expected to shoulder the cost of refunds, and staff should have easy access

to the information needed to process these refunds to enable them to focus their time on delivering patient care. This should be requisite information within any recall communication from responsible parties to pharmacists.

CPhA recommendation: That Health Canada oblige responsible parties to provide refunds and clear refund instructions to pharmacists in every case of a recall.

Timeliness of recall notifications

We have heard from pharmacists through our survey of drug shortages and recalls that it is not uncommon for pharmacists to receive drug recall notifications after patients have already heard about recalls through Health Canada or the media. When patients, anxious about a recall affecting a medication they have been prescribed, call or come in to speak to their pharmacist, they expect that their health care provider will have all the information available to address the issue in a timely way.

CPhA understands that Health Canada is responsible for promptly reporting recalls to the public that may lead to adverse health consequences. However, we strongly believe that early notification to pharmacists can assist in managing recalls on the frontlines. Patients depend on their pharmacists, as medication experts, to be well informed about shortages and recalls affecting the Canadian drug supply. It can cause significant anxiety and frustration for patients when their pharmacists are uninformed of drug supply issues.

CPhA recommendation: That Health Canada and other responsible parties be mandated to notify pharmacists about recalls 24 hours in advance of public notifications.

Pharmacists' role in managing patient care during drug recalls

Pharmacists are most often the health care provider that plays the largest role in managing drug shortages and recalls. As our survey indicates, these disruptions in the drug supply are causing an increased workload for pharmacists and pharmacy staff. The list of tasks involved in managing drug recalls includes calling parties to inquire about the recall and the availability of alternative medications, alerting prescribers and patients, discussing alternative therapies with prescribers and patients, recovering inventory, managing returns, issuing refunds to patients, performing therapeutic substitution, compounding replacement medications, and consulting patients regarding replacement medications. Pharmacies are not currently compensated for any of these tasks, except for therapeutic substitution in some provinces, and they create opportunity costs when recall management takes time and resources away from regular patient care. We strongly believe that pharmacies should be compensated for the resource intensive administrative and clinical responsibilities associated with drug recalls to ensure that other pharmacy services, which patients depend on, can continue uninterrupted.

CPhA recommendation: That Health Canada compel governments, manufactures and other responsible parties as appropriate to provide mandatory compensation to pharmacies for the administrative and clinical responsibilities surrounding the management of drug recalls in Canada.

Pharmacists also have the responsibility of supplying patients affected by drug recalls with replacement medications. This process can involve multiple health care practitioners and take time to resolve. Pharmacists must often notify the original prescribers of a recalled medication and wait for a new prescription or for their approval to switch their patients to alternative medications. Often, anxious patients must be sent home while pharmacists wait for prescribers to return messages and otherwise approve medication substitution decisions.

Some jurisdictions in Canada have authorized pharmacists to perform therapeutic substitutions, which means the pharmacist can switch a patient's medication from the original drug prescribed to another within the same therapeutic class to meet the individual needs of the patient. In the case of drug shortages and recalls, this authority can save pharmacists considerable time in identifying and providing their patients with an appropriate medication substitute. However, the practical implementation of therapeutic substitution is not without its limitations. For example, during the valsartan recall there were many uncertainties and concerns about the potential contamination of other sartan drugs that had been manufactured in the same facility. Changing a patient's sartan drugs to another class of medication would have been the best option for patients since there was unclear information being provided about the level of risk with other drugs in the same class. Currently, however, only Alberta pharmacists with additional prescribing authorization are able to change a patient's medication to a different therapeutic class.

Many other barriers exist across Canada that limit the potential of therapeutic substitution to help manage drug shortages and recalls and otherwise enhance patient care. Manitoba, Ontario and Quebec[1] have not granted pharmacists this authority, and in the case of drug recalls they must obtain a new prescription from the original prescriber in most instances. Each jurisdiction that does allow the practice of therapeutic substitution also has unique specifications that may differ from other jurisdictions, which can cause uncertainty and confusion among patients expecting the same level of care between provinces. Pharmacists in British Columbia, for instance, can only substitute within certain classes of medications; some provincial drug plans have stringent conditions under which they will pay for a medication substitution, and often the patient must pay for this service out of pocket; and most jurisdictions also only allow pharmacists to perform substitutions on new prescriptions and not on existing prescriptions. In addition, when pharmacists would otherwise have the authority to perform therapeutic substitution, they may not feel confident in doing so when they have not been provided the exact indication for treatment.

Therapeutic substitution is a tool that all pharmacists in Canada should be able to use to ensure their patients' therapy is individualized for their unique needs and to provide seamless therapeutic transitions in the cases of drug shortages and recalls. We believe Health Canada has a role in communicating the benefits of this service and promoting its implementation and reimbursement as a clinical service in all jurisdictions across Canada. We

[1] Quebec pharmacists are authorized to perform therapeutic substitution only in the case of drug shortages.

further believe that the specific policies and protocols surrounding this service should be more consistent across Canada and that barriers to its implementation should be reduced, including standards and regulations specifying that pharmacists may only substitute medications within the same therapeutic class.

Drug recalls and shortages are causing a significant amount of stress, frustration and anxiety among patients and pharmacists alike. It is unlikely that these drug supply issues will be resolved in the near future, therefore it is imperative that governments do everything possible to ensure the health and safety of patients when they must be transitioned to substitute medications. Ensuring that all health care providers within the patients' health care team are empowered to provide the best care possible within the scopes of their practice is a fundamental task, and one that is long overdue, in managing drug recalls and improving access to pharmaceutical care in Canada.

CPhA recommendation: That Health Canada work with jurisdictions across Canada to promote a consistent practice authority for pharmacists in the provision of therapeutic substitutions, along with associated enablers such as indications for treatment and appropriate compensation.

Conclusion

CPhA appreciates the opportunity to comment on Health Canada's Draft – Drug and natural health products recall guide. We are pleased that Health Canada has developed guidelines to help responsible stakeholders understand and comply with the Food and Drugs Act and associated regulations as they pertain to recalls. We believe this is an important step towards better management and communications of recalls. However, as outlined in this submission, there are opportunities for Health Canada to ensure that more consistent, comprehensive and timely messaging and procedures are received by pharmacists, who are key stakeholders in the recall management process and in communicating with patients about drug supply issues. Pharmacists should be compensated for the time and resources they devote to these processes. Their provision of excellence in care during drug supply disruptions also depends on their ability to work to their full scope of practice. Therapeutic substitution is a key service that should be available within this scope of practice and one that pharmacists across Canada should be enabled to perform consistently and without barriers to offer patients the individualized care they need both during and beyond instances of drug supply challenges.

Sincerely,

Glen Doucet
Interim Chief Executive Officer & Vice President, Public & Professional Affairs