



Consultation: Notice of intent to amend the regulations to address health product shortages in Canada

The Canadian Pharmacists Association (CPhA) would like to thank Health Canada and the federal government for the opportunity to participate in this consultation on regulations to address health product shortages in Canada. We appreciate the ongoing dialogue with pharmacy stakeholders, to ensure that the perspectives and experiences of pharmacists and their patients are taken into account as we develop and implement solutions to prevent and mitigate the impact of shortages. As the national voice of pharmacists, representing over 42,000 pharmacists and more than 11,000 pharmacies across the country, CPhA has played a significant role, working with Health Canada, to navigate dozens of high-profile shortages.

Our responses to this consultation are informed by our vast experience in this area, as well as our engagement with front line pharmacists and the patients that they serve. While we are largely supportive of the actions identified in the notice of intent, we believe that more emphasis needs to be placed on supporting pharmacists manage drug shortages when they occur. As the last point of contact between the supply chain and patients, they are the ones who are communicating difficult and potentially life-threatening information to their patients. These interactions can cause friction and negatively impact the pharmacist-patient relationship. As such, we encourage the federal government to look for funding mechanisms to support pharmacists and the associations that help governments navigate these shortages.

1. Identifying and addressing shortage risks

Action 1: Publish a list of drugs that are critical and vulnerable to shortages

CPhA supports this action and has previously recommended that such a list be developed. This will provide Canada with a more targeted way to anticipate potential shortages and assist in developing appropriate contingency plans for specific drug classes.

- The methodology and consultation process to identify the drugs for this list should be transparent and well-defined.
- Pharmacists should be included in any process to develop such a list.
- Ensuring effective collaboration with diverse stakeholders is essential. It is good to see that people of Canada will be invited to this consultation along with others.
- The list should be continuously reviewed and updated as needed to respond to the real time needs of Canadians.

Action 2: Require shortage management plans and safety stocks for drugs that are critical and vulnerable to shortages

While CPhA believes that drug shortage management plans and safety stocks could protect Canadians from shortages in certain situations, we are also mindful that the requirement in maintain safety stocks could have consequential effects including:



- Establishing and maintaining shortage management plans and safety stocks can be costly. Manufacturers and wholesalers will likely need to invest in additional storage facilities and inventory management, etc to manage these processes.
- These increased costs will likely be passed on to pharmacies and consumers, potentially leading to higher drug prices.
- Mandating safety stocks might lead to overproduction, resulting in excess inventory that could ultimately go to waste if not used before expiration. The environmental impact of increased production and waste disposal needs to be considered.
- Ensuring that safety stocks are appropriately rotated and do not expire can add complexity to inventory management for pharmacists and wholesalers.
- Smaller pharmaceutical companies may find it more difficult to comply with these regulations due to limited resources and infrastructure which could potentially lead to further market consolidation. This in turn can further exacerbate shortages.

2. Enhancing and sharing supply chain information

We agree with and support efforts to ensure clear and transparent communication as well as improved systems for data analytics, reporting and information sharing.

By enhancing and sharing supply chain information, pharmacy and other stakeholders will be better prepared to handle drug and medical device shortages. This will give pharmacists and their teams more time to plan and source alternative treatments or medications when supporting patients on the frontline at the pharmacy counter.

Action 3. Enhance regulatory responses and reporting requirements

CPhA is generally supportive of this action. We look forward to further details about the proposed refinements to ensure these ultimately meet the needs of end users, who are often time community pharmacies.

Action 4: Improve reporting systems

Although pharmacies are not required to report shortages, we support any action to make the platforms easier to use.

When developing an online system or platform for shortage reporting, we recommend getting input from community pharmacies. This will ensure systems and processes are created with knowledge and understanding of pharmacy operations – this will also help identify and mitigate potential challenges with adoption of new reporting requirements.

Action 5: Strengthen data analytics and shortage management capacity

We strongly support enhancing data analytics which we believe is critical to the prevention and mitigation of shortages. For example, a key data point that is necessary to assess the impact of a shortage is a manufacturer's market share. This information is not readily available and makes it difficult for affected stakeholders to plan and respond to shortages.



Action 6: Improve information sharing

Information sharing has consistently been a challenge. Pharmacies rely on key information to make practice decisions about how to order, manage inventories to extend supply, or even restrict supply. Because information is often considered confidential in nature, pharmacy associations are expected to translate information and communicate recommendations without being able to disclose specific data being shared with stakeholders.

Any improvements to this approach would be welcome by pharmacy.

Action 7: Enhance transparency and clear communication

CPhA appreciates the significant communication efforts by Health Canada officials during a shortage. Health Canada officials are always available to discuss specific shortages and help work through communication strategies that will support health providers and patients.

As the leading source of drug and therapeutic information in Canada, CPhA has played a significant role in developing alternative drug tables for clinicians to use during shortages. Furthermore, CPhA has created several webpages for pharmacists, other clinicians and patients to provide up to date information about a specific shortage. Health Canada often links to our pages.

Giving the increased frequency of shortages, the federal government should help build capacity within organizations that play a leading role in communicating directly to health providers and patients. We have previously sought financial support to do so and would welcome a further discussion about funding opportunities to support the creation of resources and communication aids during shortages.

3. Improving access to health products

Action 8: Modernize regulatory frameworks

Modernizing Canada's regulatory frameworks with a view of increasing access is commendable as our collective set of regulations can impeded our ability to prevent and mitigate shortages.

For example, our regulatory and pricing frameworks can disincentivize companies from bringing their products to the Canadian market, which in the long term can impact our ability to respond to shortages. Canada is most vulnerable to shortages when we have a limited number of products for a specific drug class. If the primary manufacturer experiences a disruption/shortage, it is unlikely that another company will be able to make up the difference.

While the consultation highlights Canada's investments in a national pharmacare plan as an example of an initiative aimed at developing Canada's market for health products, a single, limited formulary could negatively impact Canada's overall supply of medications. If the drugs listed for diabetes and contraception are the only ones that are funded (or primarily funded), companies who manufacture other products may not be left with a sufficient market to continue to operate in Canada.



Likewise, regulations can hinder drug shortage mitigation strategies. A key example is the ability for pharmacists to adjust patients' treatments or substitute for other alternatives. The Controlled Drugs and Substances Act currently restricts pharmacists from substituting controlled drugs in the event of a shortage, which can result in delayed access to medications.

We strongly encourage the federal government to include a requirement for any regulatory or pricing framework (e.g. PMPRB) to include a drug shortage assessment, to identify potential risks associated with any given measure. This will ensure that regulatory frameworks are not developed in a vacuum without consideration of the impacts of drug shortages.

We also recognize that while removing barriers to market entry can have benefits, it can also introduce potential risks. For example, the entry of substandard products into the market has the potential to compromise patient safety. For newer products, Health Canada should consider a phased approach or conditional approval processes to allow products to enter the market initially with restricted indications and further expansion as more data becomes available.

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