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The Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA) represents Canadian pharmaceutical manufacturers operating production facilities in Canada, making medicines for Canadian patients and for export. Our members are the largest manufacturers of medicines by volume in Canada, producing innovative, generic and biosimilar pharmaceuticals, as well as non-prescription medications, without whom Canada's pharmaceutical supply chain would be extremely vulnerable. The members of CPMEA represent 26% of the prescriptions dispensed in Canada.

Impact of Regulations on Domestic Production

There is an increasingly important role for Canadian-based pharmaceutical production especially in the context of global medicine shortages and over-reliance on foreign sources of supply over which Canadians have no control.

CPMEA supports the efforts of Health Canada to mitigate shortages and coordinate supply chains, however, we strongly caution against the draft regulations that will pose an unfair cost burden on local producers, especially for Canadian producers that may have several products in their portfolios that will be subject to the new regulations. Without economic viability, drug shortages will worsen as producers cut production to manage costs. The risk of production cuts is particularly acute because of the threats of 25% tariffs on Canada's exports to the U.S.

Impact of U.S. Tariffs on Canadian Pharmaceutical Production and Drug Shortages

Over almost 40 years, under the WTO Pharmaceutical Agreement, pharmaceuticals have traded tariff-free in most markets in the world. We take for granted our ability to access medicines from anywhere without tariffs on these products.

During the Trump Administration in 2018 when tariffs were imposed on China, there was only one exemption – pharmaceuticals and APIs. On March 4, 2025, the U.S. imposed 25% tariffs on Canada and Mexico (which were subsequently delayed) and an additional 10% on China. This time there is no exemption for medicines. (This means that tariffs on medicines imposed on China is 10% and tariffs on Canadian-made medicines will be 25%. It is unclear whether this was intentional or an oversight.)

President Trump has repeatedly mentioned tariffs on pharmaceuticals as a protectionism policy designed to encourage reshoring, and European countries are bracing for an expansion of the tariff threat on their drug exports to the U.S. Global trade in pharmaceuticals will no doubt be affected by the threat of tariffs, and retaliatory measures will only increase drug costs and reduce access.

Many of Canada's pharmaceutical and contract manufacturers produce for export and most exports from Canada go to the U.S. According to Statistics Canada, Canadian pharmaceutical manufacturers in 2023 produced $12B CAD of drug products for export of which $9B CAD go to the U.S. (Statistics Canada. Canadian International Merchandise Trade, 2023)

Canada is the 5th largest supplier of medicines to the U.S. Canada has had a modest trade surplus with the U.S. in pharmaceuticals, meaning that we export more to the U.S than we import. This is remarkable achievement given the relative size of the Canadian economy, but also understandable based on the size of the U.S. population and volume of demand for affordable generic medicines.

This same statistic, however, also speaks to **the economic vulnerability of the Canadian pharmaceutical manufacturing sector to tariffs**. Of the $9B CAD in pharmaceutical exports to the U.S., we estimate that approximately half are generic medicines. Generic products are particularly endangered by tariffs because the cost can not be passed onto customers due to regulatory constraints in the U.S. such as the CPI penalty, as well as contracting requirements. Other Canadian pharmaceutical exports are produced by contract manufacturers and these products are also very susceptible to tariffs in the highly competitive CDMO sector.

The loss of export sales will severely and directly undermine the economic sustainability of the Canadian pharmaceutical manufacturing sector. The impact of tariffs on Canadian pharmaceutical manufacturers cannot be overstated and will lead to product rationalization and disruption in the supply chain that we can not even begin to evaluate.

CPMEA member companies produce products for both the U.S. and Canadian markets; however, the impact of tariffs and additional regulatory burdens imposed by Health Canada's shortages reform will lead to product discontinuations and further exacerbate drug shortages in Canada.

It is worth noting that Canadian generic pharmaceutical companies, in some cases, supply as much as 50-70% of certain molecules, and innovative companies manufacturing in Canada provide 100% of certain drug products. We predict that tariffs on Canadian medicines will cause stock outs and a cascade of products shortages in the U.S. supply chain. Tariffs on medicines will certainly cause a ripple effect in supply chains.

This is not the time to impose additional and costly regulatory measures that will harm local producers and lead to a greater number of shortages. Such actions will only make Canada more reliant on imports and less self-sufficient and will benefit importers over Canadian companies.

Instead of regulatory measures that will hurt local companies, we urge Health Canada to consider actions to support local producers the best way to alleviate shortages. A strong domestic pharmaceutical manufacturing sector will ensure drug supply sovereignty.

Health Canada should step up to support the procurement of Canadian-made medicines for supply reserves, to help replace the loss of export sales, and to improve regulatory access to the Canadian market for domestic companies as a fundamental part of policy initiatives to prevent shortages.

Policies to Support Domestic Production to Alleviate Shortages

In the current uncertain commercial environment, marked by a trade war with the United States and lessons learned from the COVID-19 pandemic that revealed the fragility of drug supply chains, it is crucial to consider this situation as a matter of national security. Drug shortages increasingly threaten the Canadian healthcare system and the reliability of the supply of essential medicines. Therefore, we recommend classifying medicines as national security products. If Canadians cannot rely on domestic production to meet their needs, we are facing an imminent public health and national security crisis.

To ensure our national security and reduce vulnerability to drug shortages, Canada needs a strong domestic manufacturing presence. We urge Health Canada consider policies to support local production to prevent shortages and ensure access for Canadians. The Government of Canada should consider a broad range of strategies to support domestic manufacturers of pharmaceuticals and encourage additional investment, including in the areas of reimbursement, economic development, government procurement, international trade, and national defence.

Other governments are taking a ‘whole of government’ approach to manage drug shortages. Agencies typically engaged in regulatory oversight are also working to promote broader solutions including economic incentives.

For example, to mitigate drug shortages, the European Medicines Agency (EMA) recommends economic strategies such as investment incentives to boost production in the EU as well as procurement contracts with local producers.

The EU Commission created the Critical Drugs Alliance with industry to boost European manufacturing as a remedy to persistent storages. A **Critical Drugs Act** is expected in 2025 to translate their recommendations into law. In an increasingly risky geopolitical landscape, the Commission has noted that the "weaponization of drug supplies" by non-allied countries is possible if domestic production is unavailable.

The Biden Administration fostered the BIO5 Supply Chain Coalition with 4 other allied nations (not Canada) to diversity the supply chain through shared government procurement. HHS has acknowledged the importance of domestic manufacturing, and to reward domestic manufacturing capabilities for essential medicines, including domestic sourcing in Federal procurement.

Economic Sustainability Must be Addressed as the Root Cause of Shortages

The most important root cause of drug shortages is the impact of the low generic prices and the knock-on effect of discontinuations and supply disruption. It is well documented and accepted by other governments in developed marketplaces that the decline in generic prices has led directly to portfolio rationalization, supplier consolidation and drug shortages. This reality is referenced in the RIAS, yet there are no recommendations to address this fundamental problem.

The pCPA-negotiated reimbursement prices for generic medicines have declined in Canada over the last decade and are inversely correlated with the increase in drug shortages. At the same time, unit costs to produce and distribute medicines have increased, due to global inflation, wage demands and rising transportation costs. Producers have pared the number of product offerings and/or reduced their capacity. Consolidation has led to fewer suppliers as the global generic industry retrenches and cuts costs. Under the pan Canadian Tiered Pricing Framework (TPF), in almost all cases, producers are prohibited from raising prices. It is set of conditions that have directly contributed to shortages.

Although Health Canada does not regulate reimbursement prices, the agency should be mindful of the implications of regulatory requirements that will drive costs for Canadian manufacturers even higher and can be expected to lead to additional discontinuations and shortages.

Health Canada's Role at pCPA

The consultation is silent on the need to coordinate actions with the pCPA. In the interest of public health, it is Health Canada's mandate to ensure a well functioning drug supply system. This obligation should include engagement with provinces to ensure that price constraints do not jeopardize access for Canadians.

As the sponsor of the NIHB program, Health Canada is a full participant in the pCPA negotiations and is a meaningful voice at that table and is accountable if price decisions made in the pan-Canadian context undermine Health Canada's responsibility to manage supply security.

Under the TPF, the price of a generic product can not be increased, except in the rarest of circumstances and with a very long timeframe. The ability to move up from one low price tier to a higher price tier is equally daunting. Without the ability to raise prices and recoup costs, producers are forced to discontinue products, even those in short supply.

We recommend that multisource drugs on the CVD List be considered as an exception to the pan Canadian Tiered Pricing Framework and be allowed to adjust price to avoid shortages. The very nature of products on the CVD List will mean they are necessary for patient care and at risk of causing a public health crisis if unavailable. As a member of the pCPA consortium, Health Canada can make this recommendation to the other participants.

Safety Stock Medicines List

Health Canada has proposed to establish a list of drugs that are critical and may be vulnerable to shortages, the Critical and Vulnerable Drug (CVD) List and communicate this list by reference. A subset of this list, the Safety Stock list, will be determined in the future. These lists will be updated from time to time with notice to manufacturers.

Other jurisdictions have developed lists of critical drugs **at the beginning** of their process to mitigate and prevent shortages, not at the end. The information provided in the Health Canada consultation on which drugs might be included in the Safety Stock List is inadequate to fully evaluate the impact of the regulatory proposals. Our comments are provided without a full understanding of the number and types of drugs covered by the list.

Safety Stock Requirement

Health Canada proposes requiring manufacturers to ensure that 3 months of safety stock is maintained in Canada for drugs that are critical and vulnerable to shortage, based on historical demand.

Mandatory safety stocks are not a solution to drug shortages and will have unintended consequences and will paradoxically lead to further shortages. Holding 3 months of additional stock that cannot be sold is extremely expensive, economically unsustainable, and is effectively a massive tax on drug producers. Safety stock requirements as proposed will increase costs and will force companies to reassess products in their portfolios. If products become economically unviable, withdrawal decisions will accelerate.

Requiring Canadian drug manufacturers to increase production to 125% and warehouse large volumes of uncommitted inventory is **unfairly punitive to Canadian producers** given the higher costs of manufacturing in Canada compared to lower cost regions such as India and China. Such a requirement will further erode the viability of domestic production and increase Canada's dependency on imported products.

The costs of stockpiling will fall disproportionately on multisource producers who supply most drug products; almost 80% of all medicines dispensed in Canada are generic. By the nature of their business, originator companies market fewer products and sell at higher prices with greater margins and can absorb additional costs. If multisource medicines are not financially viable and suppliers leave the market, more expensive brand products will be the only therapeutic option available.

The additional costs and reporting complexity are **especially burdensome for low price and/or low volume medicines** and will further hasten portfolio rationalisation, market consolidation and future shortages. It is not hard to imagine a health care system where the least expensive, therapeutically equivalent medicines are no longer available.

It is not clear that **holding additional stock will prevent a shortage**. For example, if a supplier has low market share, e.g. 20% of the market, the mandated safety stock will not be enough product to fill the gap if a supplier with large market share is out of stock. Instead, the increased cost of holding 3 months extra stock will more likely lead to a decision to discontinue the product because it is too costly.

This is not a hypothetical example; market shares for generic medicines can be very skewed - meaning that one or two producers often have the lion's share of a molecule, and smaller players have very low market share. Rarely does a product have evenly distributed shares.

Safety stocks are inherently wasteful and will create considerable redundancy in supply, and consequently, unnecessary destruction of medicines, especially for medicines with a short shelf-life. Destruction of stock will also present additional environmental management costs; again, unfairly born by generic suppliers of low margin products.

Canadian Strategic Reserve - Alternative to Safety Stock Requirements

Health Canada seems committed to the concept of safety stocks to mitigate shortages. A feasible alternative to requiring companies to hold adequate safety stocks is to establish a ***Canadian strategic reserve*** based on the CVD, paid for by the government, and held centrally by Health Canada or locally by producers. Health Canada would procure these stocks held in the reserve, either in the form of finished product or as API ready for production.

Stocks of API is a preferred alternative for the strategic reserve. Holding API allows for greater flexibility to produce different dosages and formulations and provides longer dating as compared to finished goods.

Priority in the strategic reserve should be given to companies with Canadian manufacturing, for making and holding enough paid safety stock in reserve to satisfy market demands as determined by Health Canada.

A truly Canadian strategic reserve would support sustainability of the Canadian pharmaceutical sector, would be an incentive to boost manufacturing in Canada, and would ensure security of supply for the future.

Supply Management Plans

Health Canada proposes to require manufacturers to establish, document and maintain plans to reduce and prevent shortages for drugs that are critical and vulnerable to shortage.

Pharmaceutical manufacturers already manage their stocks carefully to ensure that all supply obligations can be met based on sales forecasts. Regulated mandatory supply management plans are not necessary. It is an essential business practice to ensure supply is managed effectively and reliably. Producers already have systems that enable them to take the necessary steps to prevent and mitigate shortages, if possible. Repackaging this information into a Shortage Prevention and Management Plan (SPMP) that must be continuously updated is not expected to provide additional value beyond what these industry processes are already providing; it only creates redundancy.

The obligations for providing supply management plans will disproportionately affect providers of multisource medicines. Generic companies typically have large portfolios; so regulatory requirements to produce supply management plans for each critical medicine will be a costly and significant administrative burden requiring additional regulatory affairs headcount to manage the process.

It is also very important to point out that increased administrative costs for Canadian producers as an additional regulatory requirement **makes manufacturing in Canada less**

competitive, **and disproportionately harmful to domestic producers – compared to producers based in lower cost jurisdictions**. The net result will be competitive benefits to pharmaceutical products made in foreign countries to the detriment of Canadian-made medicines.
Additionally, the proposal for demand surge reporting by importers only adds administrative burden after shortage reports have already been filed and will not be a meaningful advanced signal of potential shortages. Any regulation that will prompt the need to report an insignificant drug shortage could lead to panic buying, thus provoking a real/greater shortage.

It is also unlikely that obligatory documented plans to reduce and prevent shortages will have any meaningful impact. The causes of shortages are multi-faceted, often based on unforeseen events, not in the control of manufacturers. As the RIAS points out, even weather events can cause shortages.

Exceptional Importation Framework

Canadian manufacturers are ready to step up and harness their supply chains and networks to be able to import these products from foreign suppliers. However, CPMEA recommends Health Canada adopt actions to increase certainty for manufacturers utilizing the pathway. As it stands, manufacturers take on all the risk in committing to purchase volumes of imported product to prevent a drug shortage, with no protection from government. Producers need guaranteed volumes and a supported withdrawal strategy once the supply of the Canadian-approved product restabilizes.

Exceptional sale of foreign authorized, domestically manufactured drug

Health Canada recommends allowing the exceptional sale of a foreign-authorized, domestically manufactured drug to address a shortage. With appropriate regulatory oversight, allowing the sale of foreign approved products in Canada to meet supply shortages is a common-sense solution to fill a gap with locally made, high quality pharmaceuticals manufactured in Canadian facilities that are compliant and regularly audited by like-minded regulators such as the FDA.

However, exceptional sale of foreign products is not a panacea to reduce drug shortages; it is only a temporary solution in a crisis. Long term strategies to build a strong domestic pharmaceutical manufacturing sector is the best way to alleviate the need for exceptional approval of foreign products.

Canada's pharmaceutical manufacturers want to work with Health Canada to make Canada the very best place in the world to manufacture medicines. Even as we face the daunting prospect of tariffs on medicines across the globe, and an upending of the tariff-free trade we have enjoyed for so long, with the right kind of government support, we can supply Canadians with the high-quality, Canadian-made medicines they have come to

trust. Otherwise, these proposed regulations will undermine these efforts and make Canadians even more reliant on imports at this time of uneasy geopolitical tension.

Sincerely,

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