

Is Canada's Supply Chain Ready for a COVID-19 Vaccine?

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Key Points at a Glance

- Distributing a COVID-19 vaccine to 37 million Canadians will be a Herculean task that will be part of the largest public health distribution effort in human history.
- McKesson Canada is most concerned that two of the vaccine manufacturer frontrunners require either frozen (minus 20°C) or ultra-frozen (minus 80°C) storage and transportation conditions—the same two frontrunners with whom the Government of Canada has entered into conditional supply agreements.
- The existing public and private vaccine supply chains in Canada are not equipped to support frozen and/or ultra-frozen COVID-19 vaccines at scale, and even if the vaccine is refrigerated, the sheer scale of doses to be distributed will overwhelm existing infrastructure, particularly if there is a desire to push all these doses in a matter of months, and/or if there is any overlap between COVID-19 vaccine and seasonal flu vaccine distribution.
- The sooner that clarity can be achieved with respect to the unknown variables that drive distribution requirements (e.g., timing, throughput, handling requirements, etc.), the sooner that the public and private vaccine supply chains can start identifying gaps and plan to ramp up infrastructure. A longer lead time will afford greater flexibility and creativity in finding solutions to meet this challenge.
- The just-in-time pharmaceutical distributor-based public flu vaccine distribution model to pharmacies, in place in half of the provinces since 2014, could be a component of a pan-Canadian solution to meet the distribution requirements of a COVID-19 vaccine.
- McKesson Canada has conducted a thought experiment on a potential distribution model for a frozen COVID-19 vaccine, pointing to potential strategies to minimize infrastructure investments.
- To increase infrastructure choices and speed to implementation, there may be a need for temporary exemptions from certain Health Canada regulations to allow the use of alternative (non-GMP) freezer space, refrigerated storage, and transportation to house and distribute large volumes of refrigerated, frozen, and ultra-frozen vaccines.
- We recommend that the COVID-19 Vaccine Task Force bring together the public and private vaccine supply chain stakeholders (perhaps as a sub-working group) to collaborate on ensuring supply chain readiness.

Introduction

The global pandemic of COVID-19 has had an unprecedented impact on Canadians, with almost 10,000 deaths and over 125,000 cases in this country alone. In addition to the immediate strain it has placed on our healthcare system, it has fundamentally changed, at least for now and likely for the long term, how we live, work, and play, along with the public policy environment that governs all of these.

Hopes for a quick recovery are being pinned on the availability of a vaccine to drive immunity to COVID-19, and there are hundreds of potential vaccines at various stages of development. If a vaccine is ultimately found to be successful in conferring immunity, getting that vaccine to 37 million Canadians will be a Herculean task that will be part of the largest public health distribution effort in human history.

As the largest pharmaceutical distributor in Canada, with over one-third of all medicines bound for community and hospital pharmacies passing through our Health Canada-approved distribution centres coast to coast, McKesson Canada is concerned about potential gaps in the readiness of the collective public and private vaccine supply chain.

This white paper will explore the challenges in the public and private vaccine supply chains to distribute anticipated COVID-19 vaccines to 37 million Canadians with respect to:

- The frozen and ultra-frozen handling requirements of vaccine frontrunners.
- The capacity of the existing vaccine supply chain.
- The planning challenges caused by the large number of unknowns.

Canada's Vaccine Supply Chains

The vaccine needs of Canadians are supported by both the public and private vaccine supply chains.

The **public vaccine supply chain** consists of federal/provincial/territorial government supply chains consisting of provincial vaccine depots (and subdepots) and distribution networks that provide public vaccines (from childhood vaccines to seasonal flu vaccines) to immunization points within their jurisdictions, such as pharmacies, physician offices, public health units, and hospitals.

The **private vaccine supply chain** is housed within the country's Pharmaceutical Distributors that are licensed by Health Canada. Pharmaceutical distributors distribute to community pharmacies and hospitals across the country, supporting the distribution of private-market vaccines (e.g., travel vaccines, private flu vaccines, etc.) to community pharmacies. Since 2014, pharmaceutical distributors have supported governments in the distribution of public flu vaccines (and certain other public vaccines) in half of the provinces.

Issue: The Frozen and Ultra-Frozen Handling Requirements of Vaccine Frontrunners

McKesson Canada is tracking over 200 global COVID-19 vaccine candidates, as shown in Figure 1. At the time of writing, there are 25 candidates in Phase I, II, and III trials and it is too early to guess which manufacturer(s) will successfully create a viable vaccine.

Figure 1: COVID-19 Vaccine Candidates in Human Trials (as of August 21, 2020)

Phase 1	Phase 1/2	Phase 2
<ul style="list-style-type: none">Vaxine Pty Ltd.Imperial College of LondonClover BiopharmaceuticalsGamaleya Research InstituteCureVacPeople's Liberation ArmyMedicagoUniversity of QueenslandZydus Calida	<ul style="list-style-type: none">NovavaxInstitute of Medical Biology, Chinese Academy of Medical SciencesGenexine ConsortiumInovio PharmaceuticalsBharat BiotechJohnson & JohnsonOsaka UniversityArcturus Therapeutics	<ul style="list-style-type: none">CansinoAnhui Zhifei Longcom Biopharmaceutical
		Phase 3
		<ul style="list-style-type: none">Pfizer/BioNTechModernaAstraZeneca/Oxford Univ.Wuhan Institute of Biological ProductsBeijing Institute of Biological ProductsSinovac

Looking at the list of vaccine candidates, there is a large variation in terms of vaccine formats, with numerous candidates being traditional refrigerated vaccines (stable at 2 to 8°C), and a few unique formats, such as orally administered vaccines.

However, McKesson Canada is most concerned that two of the vaccine manufacturer frontrunners require either frozen (minus 20°C) or ultra-frozen (minus 80°C) storage and transportation conditions; these happen to be the two frontrunners with whom the Government of Canada has already entered into conditional supply agreements. Even though these vaccines will eventually need to be thawed to 2-8°C for administration to a patient, the early data suggests that these frozen and ultra-frozen vaccines would only be stable at refrigerated temperatures for a matter of days to weeks.

We believe the overall public and private vaccine supply chains in Canada are not equipped to support frozen and/or ultra-frozen COVID-19 vaccines at scale. Health Canada-compliant supply chain infrastructure to support frozen vaccines is currently limited, as there are only a handful of vaccines and specialty drugs that require such temperatures. This infrastructure is even more constrained, and likely almost non-existent, for handling ultra-frozen vaccines, which requires liquid nitrogen to maintain a -80°C environment. **We estimate that Canada would require 1.7 million cubic square feet of frozen and/or ultra-frozen warehousing space for 75 million doses.**

McKesson Canada has limited frozen and no ultra-frozen infrastructure. Our frozen infrastructure is limited to a single refrigerator-sized freezer (valued at about \$10,000) in one of our distribution centres. Similarly, the transportation of frozen drugs is also limited, with McKesson Canada having access to a very limited number of specialized packouts.

Looking further downstream in the vaccine supply chain, if the stability of frozen and ultra-frozen vaccines at 2-8°C is a matter of days, pharmaceutical-grade freezers (or liquid nitrogen-powered freezers) will be needed at all points of immunization, whether it be pharmacies, physician offices, hospitals, public health units, etc.

Issue: The Capacity of the Existing Vaccine Supply Chain

Even if these frozen and ultra-frozen vaccines end up having a long stability at 2-8°C or the Government of Canada strikes additional agreements that increase the proportion of refrigerated vaccines (e.g., Novavax), **we are concerned that the sheer scale of doses to be distributed will overwhelm the existing public and private vaccine supply chains.** This will be particularly true if there is a desire to push all doses within a matter of months, and/or if there is any overlap between COVID-19 vaccine and seasonal flu vaccine distribution.

With the COVID-19 vaccine regimens likely following an initial dose and a booster dose, 75 million doses will be needed to immunize every Canadian. Indeed, the Government of Canada recently ran a tender to procure 75 million immunization supplies (e.g., syringes, needles, alcohol swabs, etc.) to support such a regimen.

Though the public and private vaccine supply chains have been successfully distributing millions of vaccine doses for years, this is nowhere near the volume that a COVID-19 vaccine will generate. **Seasonal public flu vaccination campaigns distribute approximately 10 to 15 million refrigerated doses across the country each year, immunizing about 30% of the Canadian population; this is a small fraction of the 75 million COVID-19 vaccine doses that will need to be supported.** Even if all COVID-19 vaccines were all refrigerated, there would need to be investments made to scale up Health Canada-compliant refrigerators, cold-chain packouts, and transportation capabilities.

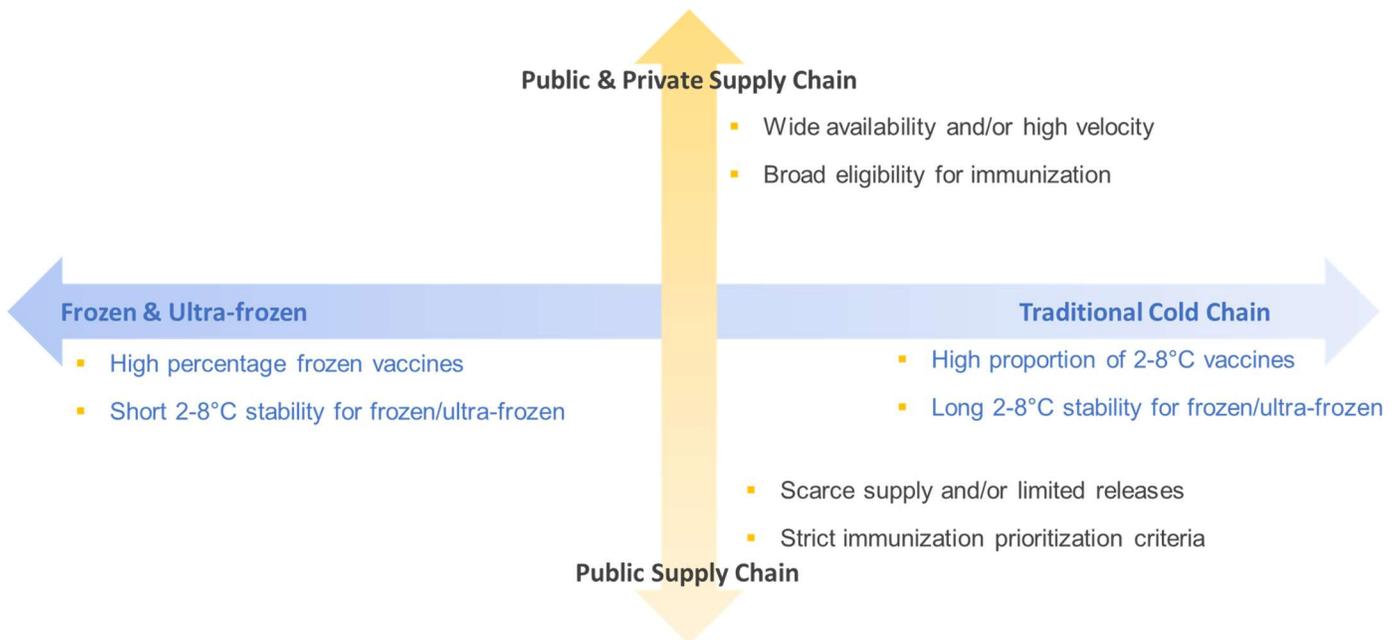
Issue: The Planning Challenges Due to the Large Number of Unknowns

In order to effectively plan for the distribution requirements of a COVID-19 vaccine (whether it be refrigerated, frozen, or ultra-frozen), the stakeholders of the Canadian public and private vaccine supply chains will need to understand:

- How soon will the vaccines arrive in Canada.
- The general availability of such vaccines and how quickly the 75 million doses will arrive in the country (e.g., over a matter of weeks, months, or years, with longer timelines implying scarcity).
- The volume mix between refrigerated, frozen, and ultra-frozen vaccines.
- Public policy direction regarding target populations for immunization (e.g. healthcare workers, elderly, etc.) and their prioritization.
- The immunization channels to be leveraged (e.g., pharmacies, physician offices, public health units, hospitals, etc.).

The potential permutations and combinations of the above factors could lead to a multitude of planning scenarios and infrastructure investment needs. In Figure 2, we have attempted to simplify these factors into what we see as the key drivers that will determine the degree of frozen/ultra-frozen infrastructure required and the extent to which the private vaccine supply chain will need to be leveraged.

Figure 2: How the COVID-19 vaccine supply chain could evolve in Canada



The sooner that clarity can be achieved around these factors, the sooner that the public and private vaccine supply chains can start identifying gaps and planning to ramp up infrastructure. A longer lead time will also afford more flexibility and creativity in finding solutions to meet this challenge.

The Foundation for a Solution: Pharmaceutical Distributor-based Public Flu Vaccine Distribution Model

There are obvious parallels between the requirements in support of a COVID-19 vaccine mass immunization and those of the annual public flu vaccine. Provincial governments will need to get vaccines to as many immunization points as quickly, efficiently, and safely as possible, leveraging immunization settings that are most accessible to Canadians.

Since 2014, Canada’s pharmaceutical distributors have worked in partnership with some provincial governments to support the distribution of public flu vaccines to the fastest growing immunization channel, community pharmacy, which has now become the number-one or number-two flu immunization destination in every province. This could be a component of a pan-Canadian solution to meet the distribution needs of a COVID-19 vaccine.

The distributor-to-pharmacy model offers just-in-time management and allows pharmacies to order public flu vaccines with their daily pharmaceutical order from their regular pharmaceutical distributor and receive them with their next scheduled delivery (usually the next business day). In contrast, prior to the development of this model, pharmacists may have received infrequent deliveries of vaccines from provincial vaccine depots or would have to drive to their local public health unit with a cooler to pick up vaccines.

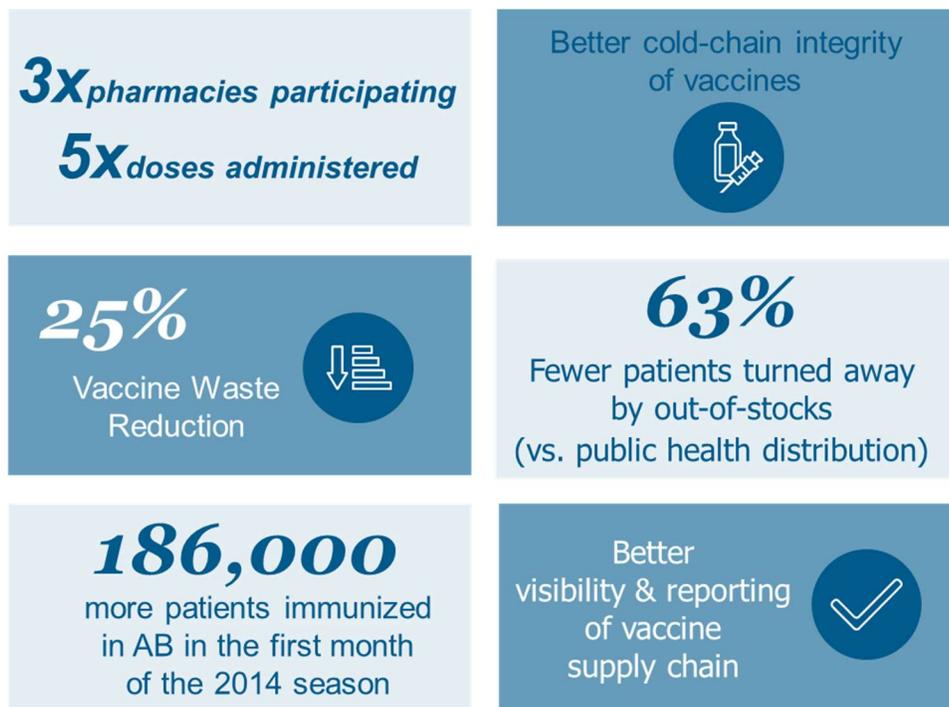
The benefits of such a model to governments and Canadians are numerous and result in higher immunization rates. These benefits include:

- The ability for governments to maintain control over distribution through vaccine allocations to distributors and partnerships with distributors to manage pharmacy-level allocations.
- More equitable distribution of vaccines, as pharmacies only order what they need for the next few days and can react more quickly to peaks and valleys in demand.

- With predictable supply, regular deliveries, and short turnaround times, there is less incentive for the hoarding of vaccine and, in turn, less leftover vaccines (i.e., waste) at the end of the season, while also ensuring high availability of vaccines for walk-in patients.
- Ease of replenishment also encourages more pharmacies to support public flu immunization campaigns.
- Cold-chain integrity of the vaccines is protected by Health Canada-approved packouts.
- More flexibility for governments as the bulk of vaccines are kept at the pharmaceutical distributor level in Good Manufacturing Practices (GMP) conditions, allowing them to be quickly redeployed to other immunization channels to deal with outbreaks.
- Leveraging the existing pharmacy network ensures there would be no need for governments to invest in expanded infrastructure and staffing to supply hundreds or thousands of new immunization points.
- Full transparency as to where vaccines are in the system via a combination of distributor-provided shipment reports and pharmacy immunization billings.

The distributor-based model is currently in place in Alberta, Saskatchewan, Ontario, New Brunswick and Prince Edward Island, and the province of Quebec will be launching this model in the fall of 2020. Over the years, the benefits of the model have been documented by the industry association for pharmaceutical distributors, the Canadian Association for Pharmacy Distribution Management (CAPDM):

Figure 3: Learnings from Wholesale Public Flu Vaccine Distribution in AB, SK, ON, and PE (Canadian Association for Pharmacy Distribution Management)



For COVID-19 vaccines, a number of the needs will be the same. Cold-chain (or even frozen-chain) integrity will be paramount. There may be limited quantities of vaccines available, requiring a distribution model that is equitable, just-in-time, and minimizes waste. Pharmacy, already a top destination for public flu shots, can provide over 10,000 convenient locations to immunize patients. Provincial governments would need full transparency as to where vaccines are residing in the system, as well as the ability to control how vaccines are allocated throughout their jurisdiction.

Thus, the pharmaceutical distributor-based public flu vaccine distribution model could play a key role in a pan-Canadian solution for COVID-19 vaccine distribution. However, as stated before, investments will be needed to ready this infrastructure for the scale and frozen/ultra-frozen handling requirements.

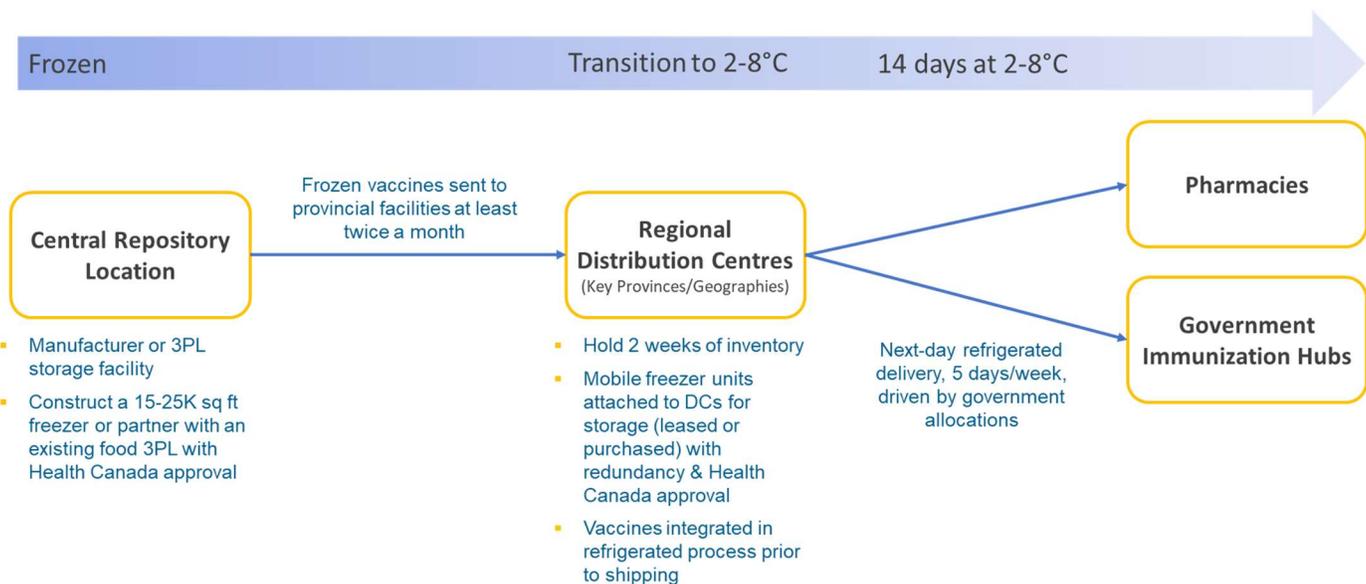
How a Pharmaceutical Distributor-based Vaccine Distribution Model Could Work

As pointed out earlier, there are a lot of unknowns that could drive distribution and infrastructure requirements in a dozen different directions.

As a thought experiment, we have calculated a possible distribution model for a frozen vaccine, assuming:

- Monthly volume of 5-7 M doses to be distributed (i.e., 75 M doses over 12-18 months)
- Frozen vaccines stable for 14 days at 2-8°C

Figure 4: A Potential Readiness Scenario for Frozen COVID-19 Vaccine Distribution



Depending on the characteristics of the vaccine and immunization strategy, the investment in frozen infrastructure could be reduced in the above if, for example:

- Frozen and ultra-frozen vaccines are limited to small, targeted populations that would allow the concentration of frozen infrastructure investments to only where they are needed
- Frozen and ultra-frozen vaccines have longer stability at 2-8°C for 60-90 days, thereby negating the need for frozen handling capabilities at the regional level
- There is a lower anticipated throughput of vaccines (i.e., the number of doses distributed per month), this would lower total system square footage of refrigerated, frozen, and/or ultra-frozen infrastructure investments required in the 'last mile'
- Higher availability of vaccines would allow mass immunization at pharmacies, making pharmaceutical distributors an efficient channel to leverage

Furthermore, our thought experiment highlights the potential need to leverage frozen infrastructure in other industries (such as the food industry) that would not be Health Canada-compliant. **Thus, to increase infrastructure choices and speed to implementation, temporary exemptions from certain Health Canada regulations may be**

needed to allow the use of alternative (non-GMP) freezer space, refrigerated storage, and transportation to house and distribute large volumes of refrigerated, frozen, and ultra-frozen vaccines.

McKesson Corporation's Role in Operation Warp Speed

In support of the U.S. government's Operation Warp Speed initiative, McKesson Canada's parent company, McKesson Corp., has been selected as the centralized distributor of future COVID-19 vaccines and ancillary supplies needed to administer vaccinations on behalf of the Centres for Disease Control (CDC).

Vaccines and related supplies will be delivered to point-of-care sites across the country at the U.S. government's direction, with allocations being driven by the CDC's VTrckS vaccine tracking system. At the request of the CDC, McKesson Corp. will be kitting the vaccines and ancillary supplies (e.g., syringes, needles, and other immunization supplies) together to ensure immunization points have everything they need in one bundle.

Under this agreement, the U.S. government will be investing \$178M USD for McKesson Corp. to build four centralized distribution centres. Construction is expected to start in September, with federal and state licensing to be accelerated to ensure operational readiness before the end of the calendar year.

This agreement builds on McKesson Corp.'s long-standing role in public health distribution in the U.S., which includes:

- Distributing 150 M doses of all vaccines annually via its long-standing partnership with the CDC Vaccines for Children program since 2016.
- Being the largest seasonal flu vaccine distributor in the U.S.
- Distributing H1N1 vaccines on behalf of the CDC in 2009.

Conclusion

McKesson Canada believes that the immense task of distributing 75 million doses of COVID-19 vaccines will be an unprecedented challenge that will require the close collaboration of both the public and private vaccine supply chains.

We recommend that the COVID-19 Vaccine Task Force bring together the public and private vaccine supply chain stakeholders (perhaps as a sub-working group) to:

- Bring clarity to key unknowns that will drive the distribution requirements.
- Conduct a readiness assessment of both the public and private vaccine supply chains to support the distribution of 75 million COVID-19 vaccines, whether they be refrigerated, frozen, or ultra-frozen.
- Identify gaps, solutions to address those gaps, and the investments required.
- Develop a pan-Canadian strategy to ensure supply chain readiness for COVID-19 vaccines.

As the leading distributor of pharmaceuticals and vaccines in the country, McKesson Canada is ready and able to make our supply chain and logistics expertise available for such a collaboration, and we look forward to the opportunity to help bring an end to COVID-19.

About McKesson Canada

Founded more than 100 years ago, McKesson Canada is dedicated to delivering vital medicines, supplies and information technologies that enable the health care industry to provide patients better, safer care.

Our solutions empower pharmacies, manufacturers, hospitals and other health care institutions by enabling them to get closer to the millions of patients they serve every single day, while contributing to the quality and safety of care in Canada.

Since the start of COVID-19, McKesson Canada's thousands of employees across the country have been focused on ensuring the continued availability of vital medications and personal protective equipment despite volatile demand and supply, as well as ensuring patients have access to the services they need close to home. Today, we are preparing for a second wave in collaboration with our government partners, suppliers, and pharmacy customers (hospital and community).

For more information, please visit www.mckesson.ca.