



## Covifenz: Medicago's COVID-19 Vaccine

May 2022

### Background

On February 24, 2022, following a thorough review of clinical trial results to ensure safety and efficacy, Health Canada approved the Medicago 'Covifenz' COVID-19 vaccine for use in adults aged 18 to 64.<sup>i</sup> The Covifenz vaccine is a plant-based recombinant adjuvanted vaccine with virus-like particles, the first of its type to be approved for use against COVID-19 in Canada.

The Covifenz vaccine is<sup>ii</sup>:

- Offered as a two-dose primary immunization series
- 71% effective at preventing COVID-19 in clinical trials
- Safe when stored at standard refrigerator temperature (2-8 degrees Celsius)
- Viable at room temperature for up to six hours after being reconstituted

As with other vaccines, due to the length of time required for production and procurement, it may be weeks to months before the Medicago Covifenz vaccine becomes available for use in British Columbia.

### Manufacturer

Medicago, the company that developed the Covifenz vaccine, is a Canadian-based biotechnology company.<sup>iii</sup> Federally funded construction is currently underway to expand their Quebec-based research and development centre into a large-scale manufacturing facility, and upon completion, is projected to be able to produce approximately one billion vaccine doses per year.<sup>iv</sup> It is expected that the centre will be fully operational by early 2024. Federal funding for vaccine development, including funding to Medicago for the development of the Covifenz vaccine, was an integral part of *Canada's Plan to Mobilize Science to Fight COVID-19*. Launched during the first wave of the pandemic, this significant response included \$192 million in new funding through the Strategic Innovation Fund COVID-19 stream.<sup>v</sup> The intention was to rapidly enable domestic researchers and manufacturers to help tackle COVID-19 transmission, morbidity, and mortality. The decision for publicly funding development of the Covifenz vaccine must be considered within this first wave pandemic context.

Medicago announced Health Canada approval for the Covifenz vaccine in February 2022.<sup>vi</sup> However, while the Medicago Covifenz vaccine is authorized for use in Canada, the vaccine was rejected by the World Health Organization (WHO) in March 2022 due to Medicago's ties to the tobacco industry.<sup>vii</sup> Phillip Morris International, a multinational tobacco manufacturing company, owns a one-third equity stake in Medicago. The *WHO Framework Convention on Tobacco Control (FCTC)* treaty directs signatories to not endorse or participate in partnerships with the tobacco industry or organizations working with the industry. The WHO has been clear that it is unlikely that the Medicago Covifenz vaccine will ever receive approval for global use due to such approval violating the FCTC. Canada is a signatory to this treaty. Health Canada has argued that vaccine production does not relate to tobacco control and therefore investment and approval of the Covifenz vaccines does not constitute a violation of Canada's commitment to the FCTC treaty. Global partners including the WHO disagree with this position. As a result, Canada will not be able to contribute doses of Covifenz to COVAX for global distribution, as COVAX requires that vaccines must be listed with the WHO.<sup>viii</sup> As the vaccine is approved by Health Canada, it will still be available domestically, and sale of the vaccine may take place privately to countries with regulatory approval in place.



### **Conflicting Positions: Nursing and Public Health Protection**

Nursing has a long history of professional and patient advocacy in tobacco control and advancing cessation of tobacco use. Indeed, nursing researchers have contributed substantially to the literature on not only the harms of tobacco but also to therapeutic approaches to supporting tobacco reduction and cessation. Nursing has also actively engaged in equity-driven advocacy regarding tobacco use, noting that tobacco use disproportionately impacts equity seeking groups, resulting in preventable health disparities and deaths directly attributable to the use of tobacco products. Nurses acknowledge that they are uniquely positioned in their daily practices to intervene to reduce to harms of tobacco on patients and communities.

Nurses are also the cornerstone of public health intervention, serving as the largest group of immunizers in Canada and the leading experts on public health practices including vaccination. Throughout the COVID-19 pandemic, nurses have led population level interventions including mass immunization campaigns, vaccine education, and have worked one-on-one with the vaccine hesitant to achieve the BC's high rate of vaccine uptake. Nurses understand that in addition to following all public health measures, vaccines and booster doses with an approved vaccine are fundamental to protecting against illness and death. As experts in vaccine delivery and as leaders in public health, nurses know that the approval of additional vaccines to fight COVID-19 is beneficial in providing options, opportunities for dialogue and, as a result, increase vaccine uptake to prevent disease and death.

Given the dual history of nursing's leadership and advancement of both addressing harm related to tobacco and public health protection through vaccination, the Medicago Covifenz vaccine presents a unique challenge to nurses and to nursing as a profession. Weighing the benefits of immunization against the harm of tobacco is not simple, nor is it a clear moral line. Nurses have a responsibility to seek out evidence to inform their practices and to ensure that recommendations made to patients, families, and communities are evidence informed and supportive of health and wellbeing. While nursing as a profession may be committed to political advocacy on a multitude of public health interventions, nurses have a responsibility to focus on patient autonomy and support informed decision making in all health and wellness choices. It is therefore important for nurses to understand the issues surrounding a therapeutic intervention such as the Covifenz vaccine so they can both advocate for appropriate use of public funding for the public good as professionals and enable informed consent and patient-centred decision making when offering patients this vaccine as practitioners.

#### **Nurses in Patient Care**

- Provide accurate and evidence-informed information on the full range of Health Canada approved immunizations available to protect against COVID-19.
- Be prepared to answer questions regarding the history and development of the Covifenz vaccine, centring patient autonomy and informed decision making and consent at all times.
- Engage nurse-led nursing teams in dialogue about the difference between patient-led decision making and political advocacy, reinforcing that nursing engages in both and identifying the ways in which nurses can thoughtfully hold the resultant tension in practice.

#### **Nurses in Education and Research**

- Use the Medicago example as a case study in nursing ethics and advocacy to advance dialogue and knowledge on holding ethical tension and advancing conflicting political advocacy agendas from a nursing perspective.
- Grow nursing ethics research to include knowledge regarding ethical decision making in the context of political advocacy for the public good.
- Engage student nurses of all designations in dialogue about the differences between nursing's professional advocacy and the role of the nurse in supporting patient autonomy and decision making.



### Nurses in Policy and Leadership

- Be vocal about nursing's history in both tobacco reform and immunization, centring our disciplinary and professional contributions.
- Provide feedback to elected leaders and public servants regarding the challenges introduced into nursing practice by public funding decisions.
- Ensure nursing's unique perspective and voice are present and active at every table where health decisions are being made; advocate for nursing presence and voice at tables where nurses are currently absent, including in federal funding and pandemic response.

### Conclusion

Nurses are self-regulating, autonomous professionals whose practice includes public health advocacy and political action in the public interest. Our history in tobacco reform is a history of political advocacy because the harms of tobacco are self-evident and the scientific evidence unequivocal. Our history also includes advocacy in support of public health safety, including a significant history of advancing immunization as the most effective public health intervention. Nursing's unique disciplinary and professional contributions to both tobacco reform and immunization introduce complexity when advising patients and communities on the use of the Covifenz vaccine. Nursing as a discipline has held these complexities before, balancing individual patient care with population health advocacy. The Medicago Covifenz vaccine is an opportunity for nurses to recognize and explore the full breadth of nursing practice and to hold political and practice tensions. Nursing knows that health care is complex and that we have what it takes to meet patient care needs while advancing population health.

### Key Messages

- The COVID-19 Medicago 'Covifenz' vaccine was approved for use in Canada on February 24, 2022.
- Covifenz is authorized for use as a two-dose primary series of COVID-19 vaccines for adults aged 18 to 64.
- Federal funding released during wave one of the COVID-19 pandemic has enabled the expansion of Medicago's Quebec-based research and development centre into a manufacturing facility which once completed, is expected to produce as many as one billion doses of the Covifenz vaccine per year.
- The WHO rejected the Medicago Covifenz vaccine for global pandemic response due to Medicago's stakeholders including Philip Morris International, a multinational tobacco manufacturer.
- Canada is a signatory to the WHO Framework Convention on Tobacco Control (FCTC) treaty, which directs signatories to not support or participate in partnership with the tobacco industry.
- Health Canada has argued that vaccine development is not tobacco control and that funding and approval of the Covifenz vaccine does not violate the FCTC treaty. The WHO has not accepted this argument.
- Nursing includes a strong history of tobacco control advocacy and interventions to support patients in smoking cessation. Nursing has also contributed significant knowledge and practice guidance on the equity related issues of tobacco use, where equity seeking groups experience disproportionate harm related to tobacco use.
- Nursing also including a history of public health advocacy and immunization leadership, including leading and implementing COVID-19 mass immunization campaigns. Nursing knows that immunization is the single most effective public health intervention in human history.



- The Medicago Covifenz vaccine introduces into nursing and nursing practice ethical, moral, and practice complexity and is an opportunity for nurses to consider how we simultaneously support patient-led decision making and population health advocacy.
- There are actions related to the Medicago Covifenz vaccine that nurses in very domain of practice can take, from patient care to education and research to policy and leadership.
- Supported by a unique knowledge base and a trusting relationship with Canadians, nursing has what it takes to work in both public and patient good in ethical, moral, and practice complexity.

### Further Reading/Resources

- [NNPBC: Guide to COVID-19 Vaccines](#)
- [Health Canada: Medicago Covifenz COVID-19 Vaccine](#)
- [COVID-19 Vaccine Tracker: Medicago Covifenz](#)

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<sup>i</sup> Health Canada. 'Health Canada authorizes Medicago COVID-19 vaccine for adults 18 to 64 years of age.' Feb 24, 2022. <https://www.canada.ca/en/health-canada/news/2022/02/health-canada-authorizes-medicago-covid-19-vaccine-for-adults-18-to-64-years-of-age.html>.

<sup>ii</sup> Health Canada. 'Medicago Covifenz COVID-19 vaccine.' Mar 31, 2022. <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/medicago.html>.

<sup>iii</sup> Arthur, Rachel. *BioPharma Reporter*. 'Plant-based COVID-19 vaccine approved in Canada.' Feb 28, 2022. <https://www.biopharma-reporter.com/Article/2022/02/28/Plant-based-COVID-19-vaccine-approved-in-Canada>.

<sup>iv</sup> Palmer, Eric. FiercePharma. 'Medicago building \$200M plant to manufacture vaccines from plants.' May 20, 2015. <https://www.fiercepharma.com/supply-chain/medicago-building-200m-plant-to-manufacture-vaccines-from-plants>.

<sup>v</sup> Government of Canada. *Prime Minister of Canada*. 'Canada's plan to mobilize science to fight COVID-19.' Mar 23, 2020. <https://pm.gc.ca/en/news/news-releases/2020/03/23/canadas-plan-mobilize-science-fight-covid-19>.

<sup>vi</sup> Medicago. *Medicago: News releases*. 'Medicago and GSK announce the approval by Health Canada of COVIFENZ®, an Adjuvanted Plant-Based COVID-19 Vaccine.' Feb 24, 2022. <https://medicago.com/en/press-release/covifenz/>.

<sup>vii</sup> Khan, Ahmar. *Global News*. 'WHO rejects Medicago's COVID-19 vaccine due to ties to tobacco giant.' Mar 25, 2022. <https://globalnews.ca/news/8709277/who-rejects-medicago-covid-vaccine-tobacco-industry/>.

<sup>viii</sup> Dyer, Owen. *BMJ*. 'Covid-19: WHO set to reject Canadian plant based vaccine because of links with tobacco industry.' Mar 28, 2022. <https://doi.org/10.1136/bmj.o811>.