INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

WRITTEN SUBMISSION

COMMENTS ON THE PUBLIC HEALTH AGENCY OF CANADA'S PANDEMIC INSTRUMENT PARTNER AND STAKEHOLDER ENGAGEMENT FORUM

ENSURING A RAPID RESPONSE TO FUTURE PANDEMICS

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INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada (IMC) is the national association representing the voice of Canada's innovative pharmaceutical industry. The association advocates for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians and supports the members' commitment to being a valued partner in the Canadian healthcare system. The association represents 49 companies that invest nearly up to $2.4 billion in R&D annually, fueling Canada's knowledge-based economy, while contributing close to $16 billion to Canada's economy.

The innovative pharmaceutical sector supports 107,000 high-quality, well-paying jobs in Canada. According to Statistics Canada's analysis of the Canadian Research and Development Pharmaceutical Sector, total R&D expenditures by the R&D pharmaceutical sector for 2020, against total sales per the PMPRB's 2020 annual report, placed the industry's R&D-to-Sales ratio between 7.7 and 10.0%.1 2 In 2020, the sector increased its in-house R&D expenditures by 11.9% from the previous year, over half of which ($692 million) funded research activities, and the remaining spent on experimental development ($582 million).

[1] 'The Canadian Research and Development Pharmaceutical Sector, 2020', *Statistics Canada (website)*, January 30, 2023, https://www150.statcan.gc.ca/n1/pub/11-621-m/11-621-m2023001-eng.htm

[2] 'Annual Report 2020', *Patented Medicines Prices Review Board*, March 30, 2022, https://www.canada.ca/content/dam/pmprb-cepmb/documents/reports-and-studies/annual-report/2020/pmprb-ar-2020-en.pdf

ISSUE

While IMC supports certain principles contained in the Zero Draft, such as strengthening healthcare systems, surveillance and trade, and the need for a whole-of-society approach to prepare for, prevent, and respond to, future public health emergencies, the positive elements of the Zero Draft are overshadowed by other proposals that negatively impact the private sector's contributions.

As written, the Zero Draft of the WHO CA+ will undermine the innovative pharmaceutical industry's ability to rapidly develop and scale up countermeasures that will be critical to combating future pandemics.

RECOMMENDATIONS

1) Ensure the world can quickly respond to future pandemics by safeguarding innovation with strong intellectual property protections and opposing the proposed weakening of intellectual property rights.
2) Encourage innovative partnerships by opposing mandatory terms and conditions that limit governments' ability to attract investments and negotiate.
3) Build on strengths of a collaborative, multi-stakeholder response, rather than centralizing authority and creating jurisdictional overreach at the WHO.
4) Facilitate development of countermeasures by addressing pathogen sharing policies outside of the Zero Draft.
5) Reduce uncertainty by opposing limits on indemnity and liability clauses.

RECOMMENDATION 1*:*

> *Ensure the world can quickly respond to future pandemics by safeguarding innovation with strong intellectual property protections and opposing the proposed weakening of intellectual property rights.*

There are a number of global initiatives proposing to erode IP rights in the interest of combating COVID-19 and future pandemics. While there have been many lessons learned from the COVID-19 pandemic that can improve equitable access in the future, weakening IP protections does not address inequitable access to innovative medicines and vaccines. Instead,

the proposals will undermine innovation and industry's ability to partner, invest at risk, and respond quickly to future pandemics, ultimately putting global health security at risk.

As an example, the World Trade Organization's TRIPS Council is considering an extension of the TRIPS waiver to diagnostics and therapeutics. However, there is no evidence to support an extension. In fact, there has been no evidence to suggest IP is a barrier to access, even throughout initial negotiations to waive TRIPS in relation to vaccines. Despite this, an agreement on the waiver was reached at the 12th World Trade Organization Ministerial Conference. To support a vibrant life sciences sector Canada and other nations must engage in evidence-based decision making. At the Global COVID-19 Summit in May 2022, the Prime Minister had underlined that vaccine supply was no longer the key constraint to combating COVID-19 around the world, yet Canada agreed to waive TRIPS for vaccines.

Now faced with the potential extension, a number of WTO Member states, including Canada, have sought clarity from their peers as to whether the TRIPS Agreement actually posed challenges in the production and supply of COVID-19 products. To date, requests for examples have gone unanswered, and in the Government Response to the Fifth Report of the House of Commons Standing Committee on Foreign Affairs and International Development,[3] an evidence-based exchange among WTO Members was encouraged.

Questions regarding the extension have also been raised in other nations. The U.S. International Trade Commission has undertaken an investigation into the value of extending the waiver to diagnostics and therapeutics and is expected to report its findings by October 17, 2023.[4] The investigation was requested by Members of the U.S. House of Representative seeking to understand whether the TRIPS waiver was effective in achieving the original goals set out by World Trade Organization members.

While the Zero Draft acknowledges the importance of IP rights for the development of new medicines, there are repeated references that undermine this notion. For example, language in the Zero Draft calls for further work on the implementation of the flexibilities in the TRIPS Agreement and IP waivers, without any data to support the need for such extreme measures. To this day, no evidence has been advanced demonstrating that IP has been a barrier to COVID-19 vaccine production or access.

In fact, IP enabled unprecedented levels of collaboration: 381 voluntary industry partnerships for COVID-19 vaccines and 150 for COVID-19 therapeutics have been undertaken to date,

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[3] 'GOVERNMENT RESPONSE TO THE FIFTH REPORT OF THE STANDING COMMITTEE ON FOREIGN AFFAIRS AND INTERNATIONAL DEVELOPMENT', *Parliament of Canada* (website), March 6, 2023, https://www.ourcommons.ca/DocumentViewer/en/44-1/FAAE/report-5/response-8512-441-136

[4] 'USITC TO REPORT ON COVID-19 DIAGNOSTICS AND THERAPEUTICS AND FLEXIBILITIES UNDER THE TRIPS AGREEMENT', *United States International Trade Commission* (website), February 1, 2023, https://www.usitc.gov/press_room/news_release/2023/er0201_63483.htm

where 88 per cent and 79 per cent, respectively, involve technology transfer, according to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

Without evidence to suggest that IP is a barrier, the language in the Zero Draft that positions IP as a barrier is unbalanced and takes the focus away from making real progress towards increasing access to pandemic countermeasures. The call to dilute IP protections required under international trade law is also at odds with other principles in the document that highlight evidence-based decision making:

"Emphasizing that policies and interventions on pandemic prevention, preparedness, response and recovery of health systems should be supported by the best available scientific evidence and adapted to take into account resources and capacities at subnational and national levels,"

Canada should oppose the proposed weakening of intellectual property rights.

RECOMMENDATION 2*:*

> *Encourage innovative partnerships by opposing mandatory terms and conditions that limit governments' ability to attract investment and negotiate.*

In addition to the proposed weakening of IP protections, the Zero Draft calls for the imposition of terms and conditions on prices of products for public-private partnerships, including allocation, data sharing and technology transfers, and publication of confidential contract terms.

These partnerships are critical to innovation and the accelerated development of life-saving vaccines and treatments. While various terms and conditions are agreed to by parties in any public-private partnership, imposing stringent requirements that must be adhered to without any opportunity for discussion would be a significant detriment to the establishment of future collaborative initiatives. These requirements could also undermine federal, provincial, territorial, and municipal governments' ability to attract private sector investment and negotiate terms that best suit their needs.

Fewer public-private partnerships, and significant delays in establishing such crucial partnerships, work against our shared objectives to rapidly develop pandemic countermeasures, and to provide Canadian patients with timely access to innovative medicines and treatments.

Canada should oppose imposed terms and conditions in the Zero Draft.

RECOMMENDATION 3*:*

> *Build on strengths of a collaborative, multi-stakeholder response, rather than centralizing authority and creating jurisdictional overreach at the WHO.*

Establishing a WHO Global Pandemic Supply Chain and Logistics Network that gives WHO significant oversight to control global production of pandemic products far exceeds the organization's mandate and duplicates efforts of other organizations with relevant expertise.

For example, there are a number of provisions in the Zero Draft that relate to IP and trade, subject matters that are clearly beyond the mandate of WHO. These complex and technical matters would be more appropriately addressed by the body with existing expertise – the World Trade Organization (WTO). Additionally, the WTO already has several ongoing workstreams to identify and alleviate trade barriers to access where appropriate, and in accordance with international law. This would represent an inappropriate expansion of the WHO's authority and would result in duplication, wasted resources, unnecessary administrative burden, and potentially conflicting approaches.

Overreach is also apparent in provisions of the Zero Draft proposing to authorize the WHO to establish a supply chain and logistics network. Again, operating as a centralized authority to control manufacturing and distribution is beyond the WHO's mandate and expertise. Encroaching on the WTO's mandate would create significant ongoing expenses and undermine the expertise of the private sector.

In response to COVID-19, industry demonstrated its ability to mobilize research and development, scale up manufacturing and utilize voluntary technology transfers with trusted partners. Canada must improve this capacity in the interest of future pandemic preparedness and response by encouraging public and private partnerships, strengthening what worked well, and taking a multi-stakeholder approach to improving equitable access and rollout of vaccines, treatments and tests globally.

Industry has expressed a commitment to improve equitable access of vaccines, treatments, and diagnostics and considered how it can contribute to this objective, as outlined in the Berlin Declaration.[5] A strengthened global supply chain should be established and maintained to

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[5] 'BERLIN DECLARATION: BIOPHARMACEUTICAL INDUSTRY VISION FOR EQUITABLE ACCESS IN PANDEMICS', *International Federation of Pharmaceutical Manufacturers & Associations* (website), July 19, 2022, https://www.ifpma.org/news/berlin-declaration-biopharmaceutical-industry-vision-for-equitable-access-in-pandemics/

reflect the economic realities of global supply and demand over the long term, building on the expertise and capabilities of the private sector. Key enabling measures include eliminating trade barriers, further streamlining regulatory procedures, and expediting cross border supply and movement of skilled workforce.

A multi-stakeholder structure is the only viable solution to managing pandemic crises, while a centralized authority would impede agility, exclude necessary expertise, and would not lead to a better pandemic response.

Canada should oppose expanding the WHO's powers beyond its mandate.

RECOMMENDATION 4:

> *Facilitate development of countermeasures by addressing pathogen sharing policies outside of the Zero Draft.*

In order to effectively safeguard public health, a global approach to surveillance, early warning systems, and data sharing should be implemented to ensure timely, evidence-based decision-making. However, the Zero Draft contains concerning proposals with respect to pathogen sharing which will hinder access to pathogens and delay the rapid development of pandemic countermeasures if implemented. Specifically, the Zero Draft takes a transactional approach, based on concepts of the Nagoya Protocol of the Convention on Biological Diversity (CBD), which links access to pathogens with benefit sharing mechanisms.

A rapid response to global health threats and the development of life-saving medical countermeasures requires that access to pathogens and their associated information be fast, easy, and legally certain, and cannot be built on a transactional principle. The Nagoya Protocol creates bureaucratic hurdles which make this increasingly difficult to achieve. For example, since 2018, vaccine manufacturers have seen delays ranging from three weeks to nine months before being able to access important influenza samples. Delays in accessing samples results in lives lost. In the context of SARS-CoV-2, a delay of just one month in accessing the virus samples could have led to an additional 400,000 lives being lost.

The best way to ensure that critical virus samples are shared in a timely manner is to exclude them from the bilateral obligations CBD, Nagoya Protocol, and national legislation on the grounds of protecting global public health. This should also apply to Digital Sequence Information for pathogens. Moreover, the provision of benefits should be decoupled from the sharing of pathogens and their information to ensure medical countermeasures can be developed as fast as possible by all partners.

Canada should recommend that the WHO CA+ address pathogen sharing policies separately from any measures related to the equitable allocation, distribution, and access to pandemic medicines and vaccines.

RECOMMENDATION 5:

Reduce uncertainty by opposing limits on indemnity and liability clauses.

The Zero Draft includes provisions which would considerably slow down access to pandemic countermeasures. Specifically, language limiting the ability of contracting parties to include indemnity and liability clauses in supply or purchase agreements for pandemic-related products would cause significant uncertainty and would be a departure from standard contracting processes.

A key learning from the COVID-19 pandemic was that in order to develop and deliver novel medical countermeasures, we must support rapid distribution. To do so, it is necessary to promote vaccine confidence and uptake by ensuring individuals around the world understand safety and efficacy profiles. Complementary to improving vaccine confidence, there are ways to address residual risk that will facilitate the work of all actors involved in the pandemic product supply chain and support rapid, widespread vaccine uptake.

To ensure rapid access to pandemic countermeasures, it is crucial for governments to ensure that a legal framework is in place that encourages rapid and accessible compensation for potential pandemic vaccine injuries through a well-designed no-fault compensation system that provides an administrative, non-judicial process for individuals to seek compensation. Implementing no-fault compensation systems during a global health crisis like COVID-19, and at a time when mass vaccination campaigns were foreseeable, created significant challenges. These challenges delayed individuals' access to timely compensation and may have reduced the effectiveness of global vaccination programs.

Governments must either implement a no-fault compensation system, like Canada adopted in 2020, or establish a framework that comes into force when pandemics are declared. Such systems will ensure that parties who experience injuries are appropriately compensated expeditiously without having to prove that any person or entity is at fault for their injury.

Importantly, no-fault compensation systems should be coupled with legislative liability protections for entities throughout the supply chain whose ability to efficiently develop, distribute, and administer vaccines may be hindered by excessive litigation. Doing so will preserve confidence in vaccination efforts, encourage uptake, and ensure that government spending on vaccination programs maximizes efficiency.

Canada should oppose limiting the ability of contracting parties to include indemnity and liability clauses in supply or purchase agreements for pandemic-related products.

CONCLUSION

There have been many lessons learned during the pandemic, and we have a shared responsibility to improve equitable access to medicines and treatments ahead of any future global health crises. However, diluting IP protections, jeopardizing public-private partnerships, and creating greater administrative burden without evidence to support that course of action sends the wrong signal to innovators and ultimately does nothing to address the challenges that are the true barriers to an equitable global pandemic response.