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1. Opening remarks

2023-01-25

9:14 AM

Remarks for

President Harpreet S. Kochhar Public Health Agency of Canada

Office of the Auditor General Performance Audit on COVID-19 Vaccines

February 6, 2023 Ottawa, ON

Speech length: words 704 (currently 5 mins)

Good morning,

Thank you for the opportunity to appear before this committee to talk about the Public Health Agency of Canada's role in access to COVID-19 vaccines. Joining me today is Stephen Bent, Vice President of the Vaccine Rollout Task Force, and Luc Gagnon, Chief Digital Transformation Officer for Health Canada and the Public Health Agency of Canada.

I would like to start by acknowledging the findings and recommendations from the OAG Audit on COVID-19 Vaccines. You will recall that the period of time covered by the audit – January 1, 2020 to May 31, 2022 – was a time of unprecedented mobilization to procure, allocate, distribute, and track the administration of COVID-19 vaccines. Since May 31, 2022, another 13 million doses of vaccine have been administered in Canada.

Additionally, 13.5 million more doses were donated and 11.4 million doses (mRNA and non-mRNA) had their shelf life extended.

Early in the pandemic, the government needed to make decisions on COVID-19 vaccine procurement. This was at a time when global demand was high and there was uncertainty about which, if any, vaccine candidates would be approved for use.

To help the government make the necessary evidence-based decisions in this uncertain environment, the COVID-19 Vaccine Task Force was established in April 2020.

Guided by the advice of this Task Force, Canada adopted a diversified vaccine strategy and built its vaccine portfolio with seven suppliers through Advance Purchase Agreements.

Our strategy was successful and Canada was among the first in the world to secure early supply and administer COVID-19 vaccine doses in December 2020.

The Public Health Agency of Canada is proud of its role in the success of the largest vaccination campaign in our country's history – a campaign that was central to Canada's COVID-19 response and recovery. We are also pleased that the OAG Audit on COVID-19 Vaccines noted that the Public Health Agency of Canada allocated and distributed COVID-19 vaccines to provinces and territories equitably and in a timely manner.

Addressing Recommendations

The Government of Canada will continue to ensure a sufficient supply of COVID-19 vaccines for anticipated demands and population protection. This includes recommended booster doses and new bivalent formulations for people in Canada.

At the same time, we are taking steps to manage our COVID-19 vaccine surplus. This includes making surplus doses available for donation to other countries to help address global vaccine inequity, however this has become increasingly difficult due to global oversupply and diminishing demand.

The Agency is also working closely with Public Services and Procurement Canada and vaccine manufacturers to adjust contractual commitments and delivery schedules, where possible.

Furthermore, we continue to work with provinces, territories, and Indigenous and federal partners on demand planning and forecasting to determine supply requirements for COVID-19 vaccination programs.

Concerning the safety of COVID-19 vaccines, PHAC is committed to continued transparency. This includes improving information sharing among partners, including Health Canada, the World Health Organization, and vaccine companies.

We understand that information sharing is an important part of our public health and regulatory systems. Canada's vaccine safety surveillance systems continue to effectively monitor, detect, share and act on any vaccine safety signals.

The Agency will continue to lead consultations with provincial and territorial partners on current proposals that address information-sharing issues identified by the audit, including a proposal to provide Health Canada with access to the Canadian Adverse Events Following Immunization Surveillance System.

The Public Health Agency of Canada will continue to share data in aggregate form from this System with the World Health Organization on a regular schedule, and on an as-needed basis with vaccine manufacturers.

The Agency is actively working to fully implement VaccineConnect, an IT system to manage nationwide vaccination programs. As of November 2022, the system has a newer module for tracking orders and inventory at the central level to support supply chain management. The Agency will also continue to work closely with provinces and territories to identify data quality gaps and will continue engaging with jurisdictional partners to identify service gaps and needs.

Conclusion

The Public Health Agency of Canada will review lessons learned and collaborate with other implicated departments and stakeholders to optimize COVID-19 vaccine supply management and reduce COVID-19 vaccine surpluses.

Thank you. I would now be happy to respond to any questions you may have.

2a. Key Messages

2022-12-08

4:42 PM

- PHAC acknowledges the comprehensive report by the Officer of the Auditor General of the COVID-19 vaccine response.

- The Agency has agreed to all recommendations put forward in the report.

- Canada's vaccine supply management is complex and is continually impacted by an uncertain disease trajectory, evolving public health advice based on the latest science, changes in global demand, and fluctuating vaccine uptake and population intentions.

- The Government of Canada will continue to work closely with provincial, territorial, and Indigenous partners, as well as vaccine manufacturers to ensure vaccine supply aligns with Canada's program requirements, the most recent scientific data, and evidence- based expert advice.

Key Successes

- Overall: The successful procurement and equitable distribution of vaccines have contributed to the health and well-being of people in Canada, allowing for widespread protection against severe COVID-19 outcomes and the safe re-opening of our economy and society.

- Since the beginning of the pandemic, the Government of Canada's primary objective has been to protect the health and safety of Canadians. This included early procurement steps to ensure early and timely access to the most effective vaccines as soon as they became authorized by Health Canada and available on the international market.

- To ensure the best chance for success in a highly competitive and uncertain global market, informed by an expert-based Vaccine Task

Force, Canada built its vaccine portfolio through Advance Purchase Agreements (APAs) with seven vaccine suppliers to mitigate uncertainty risks surrounding successful product authorization, development and timely delivery.

- Canada's response to COVID-19 has involved significant and positive collaboration between the federal government, provinces, territories, Indigenous partners, health professional associations, the private sector, diverse community partners such as faith leaders and many more.

- Through the support of this broad set of partners led by PHAC, Canada's COVID-19 immunization plan successfully supported the largest vaccination campaign in our country's history.

- To date (as of Jan. 26, 2023), over 97 million doses of COVID-19 vaccines have been administered to people in Canada.

- Canada has achieved one of the highest levels of individuals

with their primary vaccine series completed in the world at 80.6% as of January 1, 2023.

- Japan and Canada have the highest proportion of fourth doses received at 44.2% and 23.4%, respectively.

- For children and youth (ages 5 to 11 and 12 to 17), Canada had the highest coverage for both the at least one dose and primary series completed categories.

- Based on a published study by PHAC, Canada's collective efforts up to April 2022, to achieve high vaccine coverage and adhering to public health measures may have saved or prevented up to an estimated:

- 800,000 lives
- 1.9 million hospitalizations
- 34 million COVID-19 cases

Looking Forward

- Of course, with any large scale and complex endeavour, further improvements can be made drawing on lessons to date to ensure continued support for the health and well-being of Canadians.

- Today, people in Canada are well protected against severe outcomes from COVID-19 through vaccination, and we continue to make this health product available to people in Canada and international partners and countries around the world through international donations and investments.

- There is still uncertainty with the COVID-19 trajectory globally and potential future variants. Our priority remains ensuring the protection of the health and safety of Canadians and we will continue to dedicate the resources necessary to respond to and manage COVID-19, including through our collective vaccination response.

- As you may have heard, on January 27, 2023, the WHO Director General determined that the global COVID-19 pandemic continues to constitute a public health emergency of international concern.

- The Government of Canada acknowledges the WHO Director General's determination that COVID-19 remains a PHEIC, as the SARS-CoV-2 virus continues to evolve and is still circulating widely across Canada and in many other countries worldwide.

- PHAC will continue to work with Provinces and Territories, Indigenous partners, health professional organizations and communities to support vaccine confidence and uptake efforts in the context of significant mis- and dis-information about COVID-19 vaccines.

- In doing this we have placed a particular focus on reaching underserved and marginalized communities through our investments in national, regional and community-based projects via the

Immunization Partnership Fund and the Vaccine Community Innovation Challenge.

2b. MRAP - key messaging by recommendation

2023-01-13

4:21 PM

- Canada's vaccine procurement was undertaken with the goal of protecting the health and safety of Canadians at a time of considerable uncertainty as to whether and which manufacturers would ultimately produce safe and effective COVID-19 vaccines.

- Given the competitive global race to obtain COVID-19 vaccines in 2020-2021, decisions on vaccine procurement needed to be made at a time when global demand was high, and there was uncertainty, over which, if any, vaccine candidates, including new technological platforms, would ultimately be safe, effective or available, and when.

- Recommendation 55: PHAC Response – complete by end of Vaccine APAs.

- Our main objective has always been to ensure that Canada has timely access to the most effective vaccines to protect the health and safety of Canadians. Canada's COVID-19 vaccine supply plans have evolved throughout the pandemic, informed by emerging scientific evidence, timing of regulatory approvals, product availability, NACI guidance, and federal/provincial/territorial needs.

- The Public Health Agency of Canada will review lessons learned and collaborate with other implicated departments and stakeholders to optimize COVID-19 vaccine supply management and reduce COVID- 19 vaccine surpluses and wastage throughout the duration of the contracts.

- Recommendation 61: PHAC Response – complete in 2023 (3 modules)

- We are actively working to advance the implementation and data quality procedures of the three modules of VaccineConnect; namely, the Intelligent Supply Chain (ISC), the Immunization Information System (IIS) and the Immunization Program Management (IPM).

- Building on investments to date in the Intelligent Supply Chain module of VaccineConnect, the Agency will work closely with other federal departments, as well as provincial and territorial partners to support supply chain management and distribution of vaccines. VaccineConnect 2.0 was successfully launched in November 2022, including an enhanced WebPortal with data quality procedures in place for submission and tracking of orders and inventory at the central level to support supply chain management.

- The Agency will continue to actively engage PT partners on identification of service gaps, data quality gaps and needs to support future integration of the systems.

- Recommendation 77: PHAC Response – FPT endorsement of PCHDS by March 31, 2023

- The Public Health Agency of Canada created the Corporate Data and Surveillance Branch in October 2020 to signal its commitment to continue improving health data collection, sharing and use as our response to recommendation 8.66 in the 2021 Report 8 of the Auditor General of Canada.

- The Agency and Health Canada have been working with provinces and territories to co-develop the Pan-Canadian Health Data Strategy since December 2020. This Strategy will address long-standing issues affecting Canada's ability to collect, share, access and use health data to support better health outcomes.

- Recommendation 78: PHAC Response – identified milestones for completion by November 30, 2023

- The Agency agrees with the OAG, that information sharing is an integral component of our public health and regulatory systems. Canada's vaccine safety surveillance system, which is a collaboration between provinces and territories, PHAC, Health Canada, and vaccine manufacturers, will continue to advance better information sharing among partners.

- To be clear, Canada's systems continue to effectively monitor,

detect, share and act on any vaccine safety signals.

- The Agency is leading consultations with provincial and territorial partners on a proposal to provide Health Canada with access to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). CAEFISS receives reports from all provincial and territorial public health authorities and from some federal departments.

- Some provinces and territories have put conditions on access to and use of the health information they provide to the Agency, for example related to protecting the privacy of personal information.

3a. September PACP 11 Progress Report

2023-02-02

3:19 PM

Mr. John Williamson, M.P. Chair

Standing Committee on Public Accounts House of Commons

Ottawa, ON September 29, 2022 Dear Mr. Williamson:

On behalf of the responding Departments and Agencies, we are pleased to provide a status update on the second recommendation from the Report of the Standing Committee on Public Accounts (PACP) on Securing Personal Protective Equipment and Medical Devices:

That, by 30 September 2022, the Public Health Agency of Canada provide the House of Commons Standing Committee on Public Accounts with a progress report in regard to enforcing the terms and conditions in its contracts with third-party warehousing and logistics service providers, with particular attention given to the provision of timely, accurate, and complete data in order to control the inventory of personal protective equipment and medical devices.

We are pleased to inform you that this recommendation has been addressed. Lessons learned from early contracts with third-party warehousing and logistics service providers have informed contracting practices. Contracts now include clear service-level expectations about the timelines and activities required for inventory intake and data reporting.

The Public Health Agency of Canada also developed a governance protocol for the long-term warehousing and logistics contracts that outlines how incidents, issues, and disputes are resolved between the third-party logistics provider and the Agency.

Since the long-term contracts were established, the Agency continues to work closely with its third-party warehousing and logistics service providers for the provision of timely, accurate, and complete data to help control the inventory of personal protective equipment and medical devices and, if required, will take appropriate actions to enforce the terms and conditions in these contracts.

The Agency continues to give priority to supporting Canada’s response to the COVID- 19 pandemic and will continue to identify and implement incremental improvements during its ongoing efforts to respond to COVID-19.

3b. October PACP 16 Progress Report

2023-02-02

3:21 PM

Mr. John Williamson, M.P. Chair

Standing Committee on Public Accounts House of Commons

Ottawa, Ontario K1A 0A6 October 18, 2022

Dear Mr. Williamson:

On behalf of the responding Departments and Agencies, we are pleased to provide electronically, in both official languages, progress reports requested by the Standing Committee on Public Accounts pursuant to the Committee's

Sixteenth Report on Enforcement of COVID-19 Quarantine and Testing Orders of June 2020.

Recommendation 1:

The Public Health Agency of Canada (PHAC) recognizes that access to timely and reliable data is a key component of successful implementation of border measures to mitigate public health risks associated with international travel.

PHAC is working to enhance existing system functionality in the near-term, while also working to establish the human and financial resources to improve data quality and tracking capabilities for the longer-term. While the COVID-19-related border measures ended on October 1, 2022, PHAC remains committed to achieving its objectives and improving data quality to ensure that it has agile and fit for purpose platforms as the developments in the current pandemic or future public health emergencies warrant.

Prior to October 1, 2022, PHAC was on a continuous improvement cycle with test providers to improve overall data quality and increase our ability to reconcile test data with traveller information received from the Canada Border Services Agency (CBSA),through the ArriveCAN app and website and/or information entered by Border Services Officers directly in their desktop apps. These improvements enhanced PHAC's data quality in the short-term.

Looking at the longer term, PHAC has established a governance committee to oversee the development of requirements for an improved end-to-end system to increase automated tracking and improve overall data quality. These requirements will be based on experiences from the past two years and will be informed by international best practices in pandemic management. An

assessment of IT systems and data requirements for border measures is underway.

PHAC is currently on track to meet its commitment captured in the Managerial Response and Action Plan developed in response to the Auditor General's fifteenth report, Enforcement of Quarantine and COVID-19 Testing Orders-Public Health Agency of Canada.

With respect to implementing sex and gender-based analysis plus (SGBA plus) considerations to mitigate any potential adverse effects of existing and future programs on diverse and vulnerable groups, PHAC notes that, notwithstanding the fact that emergency orders issued under section 58 of the Quarantine Act are not subject to the Cabinet Directive on Regulation and the requirement for an

SGBA Plus, the Government of Canada's COVID-19 border measures have been informed by SGBA Plus considerations. Key impacts for which focused border measure exemptions that have been legally enabled at various points during the existence of COVID-19 border measures, include disparate impacts due to sex and gender, age, ability/dependency and geographical location, as well as due to social, cultural or economic status.

- Sex and Gender — For example, security vulnerability in Designated Quarantine Facilities (DQF) is mitigated by controlled and monitored entry/exit, enhanced security in hallways and public areas, as well as private secured spaces with landline telephones for accommodated travellers; and, nursing assessments in DQF include consideration of sex and gender determinants of health.

- Age — For example, an exemption for travellers less than five years of age from border testing; and, an exemption for unaccompanied minors from the former requirement stay in a government-authorized accommodation (GAA) pending receipt of a negative on-arrival test.

- Ability/Dependency — For example, an exemption for dependent adults from the former requirement to stay in a GAA pending receipt of a negative on-arrival test; exemptions from prohibition of entry and for limited release from quarantine for travellers who must provide support/care to another person; and, exemptions from the requirement to use the ArriveCAN mobile application due to cognitive or physical impairments.

- Geographical Location — For example, exemptions for persons in certain remote locations from the prohibitions of entry and/or from quarantine and other obligations who need to cross the Canada-U.S. land border in order to access essential services/necessities life, or to fulfill child custody obligations.

- Social, Cultural or Economic Status — For example, self-administered testing instructions available in multiple languages (written and video); alternative border testing protocols for seasonal agricultural temporary

foreign workers; and, to the extent possible, tailored accommodations for families/caregivers who were subject to the former requirement to stay in a GAA or DQF.

Recommendation 3:

PHAC is committed to implementing processes to assess PHAC's enforcement

approach to border measures.

PHAC will work collaboratively with our law enforcement partners to reduce the administrative burden associated with reporting to facilitate timely reporting of outcomes by law enforcement partners to PHAC. This work will ensure that PHAC is well-prepared should the enforcement of border measures be required again in the future.

On January 19 and 21, 2022, PHAC held an initial meeting with a group of police partners (RCMP, Sûreté Québec and the Ontario Provincial Police) to discuss hurdles that police forces may face regarding the outcome of referrals and to brainstorm solutions to improve reporting.

In June 2022, PHAC began reducing the number of daily referrals to police. Previously, PHAC sent police partners a daily list of all travellers required to quarantine or isolate, including those rated as low priority for follow-up compliance verification and enforcement activities. As of July 1, 2022, PHAC discontinued the practice of sending daily lists and only sent referrals for high risk travellers to police as urgent verification requests (UVRs). PHAC requested that the officer conducting the visit submit a Traveller Visit Report form to provide information on the outcome of the visit.

Travellers rated as "high" risk were those who were suspected of non- compliance, following either a compliance verification call or during an in-person visit conducted by contracted security companies who were screened to ensure the safety of the Canadian population. PHAC requested that police make at least one physical visit to these travellers as soon as possible. UVRs occurred when PHAC was seeking a time-sensitive physical verification on a traveller. Traveller history of non-compliance, behaviour of the traveller, and the nature of suspected non-compliance were key factors in determining whether to send a UVR.

This approach had the potential to lead to a higher rate of police reporting on referral outcomes. Although data regarding the impact of this change on reporting rates is still preliminary, early indications

do not show the anticipated positive impact on reporting rates. Notwithstanding the reduction of total referrals, the percentage of reports received by PHAC remains comparable to the rate before the July 2022 changes. PHAC will continue collaborating with police partners to identify and implement other changes that may improve reporting

rates, if the epidemiological context makes it necessary for the Government of Canada to reinstitute quarantine requirements.

Recommendation 4:

PHAC will continue exploring mechanisms to make the potential future enforcement of non-compliance with border measures more consistent across all jurisdictions in Canada.

PHAC had a nationally consistent compliance and enforcement program, wherein all travellers, regardless of where they arrived in Canada, were subject to the same compliance and enforcement activities. The compliance and enforcement program ranged from compliance promotion and education, through warnings, ticketing, and possible criminal prosecution.

All travellers entering Canada, regardless of where they enter, received:

- Compliance promotion emails and robocalls;
- Compliance verification calls (including discussion of testing requirements);
- Referrals to security companies for in-person compliance verification visits; and
- Referrals to law enforcement for in-person verification visits if suspected of non-compliance.

The issue identified by the Auditor General relates to the fact that PHAC primarily used the ticketing regime set out in the Contraventions Act and Regulations as its enforcement mechanism of last resort. Due to the nature of the Act, each provincial government must agree to its application in their jurisdictions and Alberta, Saskatchewan, and the three territories have not agreed to the use of this contraventions regime in their jurisdictions.

Identifying and, if appropriate, introducing other enforcement mechanisms that can be utilized to support potential future public health-related border measures will require significant time and analysis to ensure that PHAC lands on the best approach. In addition, this analysis will ensure that the enforcement of non- compliance is done in a fair and unbiased manner for all travellers.

While PHAC undertakes this longer-term exercise, in parallel, it had taken several steps to put in place processes and mechanisms that made its enforcement approach more consistent across Canada. For example, PHAC developed standardized notebooks for PHAC officers with instructions on the documentation of enforcement actions (e.g., tickets issued) in a consistent and thorough manner, to improve the overall quality of the enforcement actions taken. Notebooks were developed to include Standard Operating Procedures to provide consistency of operations and ensure a smooth workflow.

In addition, PHAC has been working with the Public Prosecution Service of Canada (PPSC) in various jurisdictions to determine the PPSC's evidentiary needs in each jurisdiction to successfully support the prosecution of travellers who contest their tickets. Similarly, in jurisdictions where PHAC could not issue tickets (i.e., Alberta, Saskatchewan, and the territories), the Agency has been working with the PPSC to support prosecutions under the Criminal Code for violations of the Quarantine Act. In doing so, PHAC has helped ensure that the outcomes of its enforcement approach were consistent across the country by ensuring prosecutors had the tools they needed to make enforcement actions stand up to legal challenges.

3c. December PACP 16 Progress Report

2023-02-02

3:23 PM

Mr. John Williamson, M.P. Chair

Standing Committee on Public Accounts House of Commons

Ottawa, Ontario K1A 0A6 December 19, 2022

Dear Mr. Williamson:

The Public Health Agency of Canada (PHAC) is pleased to provide electronically, in both official languages, progress reports requested by the Standing Committee on Public Accounts pursuant to the Committee's Sixteenth Report on Enforcement of COVID-19 Quarantine and Testing Orders of June 2022.

Recommendation 3:

PHAC remains committed to implementing processes to assess PHAC's enforcement approach to border measures. Prior to all border measures being lifted on October 1, 2022, PHAC continuously evaluated the

outcomes of referrals to police that were reported back to the Agency and used these results to inform its overall enforcement approach.

The estimated rate of compliance from the information received by PHAC was high throughout the pandemic; however, because police were not obligated to report on the outcomes of referrals, these compliance rates were estimates only. To address this issue, PHAC implemented a Compliance Verification (CV) Visits program using contracted security guards to visit travellers during their 14-day quarantine period. This program added an additional layer to the Agency's enforcement approach, and the reported results from these CV Visits provided PHAC an additional data set to use when assessing whether the Agency's enforcement approach was working.

PHAC is committed to maintaining and improving the relationships it has developed with police partners through a process of continuous and ongoing engagement and dialogue, education and training. The outcomes of this ongoing engagement will be documented and incorporated in future planning and reporting.

Recommendation 4:

As noted in our previous report to the Committee, early in the pandemic, PHAC established a nationally consistent compliance and enforcement regime, wherein all travellers, regardless of where they arrived in Canada, were subject to the same compliance verification activities and the risk-based enforcement continuum. The compliance and enforcement program ranged from compliance promotion and education, to warnings, ticketing, and possible criminal prosecution.

The issue identified by the Auditor General related to the fact that PHAC used the ticketing regime set out in the Contraventions Act and regulations as its enforcement mechanism of last resort. Due to the nature of the Act, each provincial government must agree to its application in their jurisdictions. Alberta, Saskatchewan, and the three Territories did not agree to the use of contraventions tickets in their jurisdictions, meaning PHAC and police officers were not able to issue tickets to non-compliant travellers in these jurisdictions.

The Auditor General noted that, without agreement from Alberta, Saskatchewan, and the Territories to accede to the contraventions regime, there was no equivalent alternative enforcement mechanism that could be implemented quickly during the COVID-19 public health emergency. Recognizing the limitations of the contraventions regime, PHAC took several steps to put in place processes and mechanisms to make its enforcement approach more consistent across Canada.

In addition to the various ongoing activities described in our previous report to the Committee, and in alignment with the timing and scope of various lessons learned exercises, PHAC is initiating internal conversations regarding the Quarantine Act with the objective to establish the policy foundations needed to design and implement a nationally consistent penalty structure under the Quarantine Act (as opposed to a nationally consistent compliance and enforcement program with potential penalties that vary by jurisdiction).

As noted previously, identifying and, if appropriate, introducing other enforcement mechanisms will require significant time and analysis to ensure that the Agency lands on the best approach. In addition, analysis will be conducted to ensure that the enforcement of non-compliance is done in a fair and unbiased manner for all travellers.

PHAC remains on track to meet its commitments captured in the Managerial Response and Action Plan developed in response to the Auditor General's Fifteenth Report, Enforcement of Quarantine and COVID-19 Testing Orders - Public Health Agency of Canada.

3d. December PACP 8 Progress Report

2023-02-02

1:35 PM

Mr. John Williamson, M.P. Chair

Standing Committee on Public Accounts House of Commons

Ottawa, Ontario K1A 0A6

December 19, 2022

Dear Mr. Williamson:

The Public Health Agency of Canada (PHAC) is pleased to provide electronically, in both official languages, progress reports requested by the Standing Committee on Public Accounts pursuant to the

Committee's Eighth Report on Pandemic Preparedness, Surveillance, and Border Control Measure of February 2022.

Recommendation 3:

PHAC recognizes that the collection of timely, accurate, and complete surveillance information from provinces and territories, during and after the COVID-19 pandemic, is a key component to protecting the health and well-being of Canadians. PHAC is committed to building a world-class health data system by working to enhance collaboration and strengthen health data foundations across jurisdictions, including renewing its information technology (IT) infrastructure.

PHAC has built, and continues to build, custom features into its data ecosystem to enhance the quality of the infrastructure such that it supports the needs of the Agency and the broader health ecosystem. This renewed data ecosystem has already demonstrated progress towards improving the three areas identified in the 2021 Office of the Auditor General of Canada Pandemic Preparedness, Surveillance and Border Control Measures Report: manual data processing, data formatting, and storage capacity, as demonstrated in recent efforts to counter the spread of monkeypox/mpox.

For instance, PHAC has created and managed a protected B cloud-based environment that securely collects, stores, analyzes and disseminates data including disaggregated and de-identified information. Public health partners, including other federal government departments, provinces and territories, academia and Indigenous organizations, can work with PHAC through this

secure cloud environment on relevant, timely and novel data sources to support their public health needs.

This work is grounded in PHAC's commitment to protecting the privacy of Canadians, ensuring that both PHAC and its public health partners only have access to data in alignment with the Privacy Act and Regulations. As PHAC's data ecosystem evolves, ensuring the security and privacy of public health data, including the use of disaggregated and anonymized data, remains the priority.

In parallel, PHAC has undertaken the Health Surveillance IT Infrastructure Renewal (SITIR), which addresses enterprise-wide related IT needs for public health surveillance activities, such as collecting and analyzing wastewater samples or anonymized hospital records of illnesses or virus outbreaks, and will serve as a guide for the development and implementation phase of PHAC's surveillance infrastructure renewal effort. Surveillance activities undertaken at PHAC are intended for detecting and forecasting health threats and emerging diseases through the collection, analysis, and reporting of health data to

better understand and respond to public health issues affecting Canadians. PHAC is committed to safeguarding the privacy of Canadians to achieve better health outcomes, and the insights gained from collected data does not contain any personal information.

Through SITIR, Agency-wide consultations were conducted to evaluate the state of PHAC's IT infrastructure to support public health activities and inform its evolution. Based on consultations and third-party assessments, the Agency validated its operational needs and infrastructure gaps. This work is happening in parallel with work on effective data management policy, standards and governance.

PHAC is using the results of SITIR and parallel policy work to determine a path towards an agile, secure, and effective data ecosystem to support internal and external (including Provincial/Territorial) public health outcomes. This path will include the adoption of additional technical capabilities and associated tools, expanding the list of IT support roles and enhancing business capabilities required to address IT stakeholder needs.

A Task Force has been created in partnership with Health Canada to develop a roadmap for IT improvements, and to begin work on implementing a modernized infrastructure. As an immediate next step, PHAC will launch a challenge-based procurement initiative to leverage innovation in the Canadian marketplace to inform the Agency's data infrastructure.

PHAC will continuously improve its information technology and data infrastructure by including additional functionalities and tools to continue building a world-class public health surveillance and data system.

Recommendation 6:

PHAC recognizes the importance of a robust risk assessment process to guide public health responses to limit the spread of infectious diseases that can cause a pandemic.

In December 2021, the Standing Committee on Public Accounts (PACP) was informed of a Baseline Review of risk assessment activities at PHAC that engaged leaders and experts across the Agency and included a high-level summary of existing practices and challenges related to integrated risk assessment, with a particular focus on governance, methodologies, and data. The Baseline Review informed the mandate, priorities, and early development of a new Centre for Integrated Risk Assessment (CIRA) created in December 2021.

CIRA began operations in mid-2022 with a mandate to coordinate and oversee integrated public health risk assessment activities across the Agency, from signal detection to public health action. The integration of risk assessment activities

from across the Agency will optimize PHAC's ability to anticipate, understand,

and act on public health risks to protect the health of Canadians.

Specific improvements within PHAC since the last report to PACP include:

- Signal Detection and Assessment: Branch programs continue to detect and verify public health signals arising from event-based surveillance, such as the Global Public Health Information Network (GPHIN), and indicator-based surveillance. Since June 2022, branch programs use criteria developed by CIRA to determine if the signals pose a threat to Canadians.
-

Coordinated Threat Assessment: Branch programs report these public health signals centrally through the Scientific Committee for Coordinated Threat Assessment (SCCTA). Introduced by CIRA in June 2022, the SCCTA is comprised of risk and content experts from across the Agency representing all public health hazards. The SCCTA meets weekly to assess all public health signals to determine their potential threat to, and impact on Canadians and public health actions for consideration. Public health threats identified by SCCTA are presented for discussion once weekly to the PHAC Daily meeting attended by senior management and Directors General responsible for key program areas.

This includes a description of the threat and its importance, as well as the actions being taken or recommended to respond or monitor the threat.

- Risk Assessments for Infectious Diseases: In November 2022, after international review and consultation and through extensive piloting of methods and tools, PHAC began implementing a consistent, scientifically sound approach to public health risk assessments for infectious disease. Through collaborative efforts, the process, methods, and governance have

been tested and improved through assessments undertaken in 2022 on acute hepatitis in children, SARS-CoV variants, avian influenza, monkeypox/mpox; and Sudan virus disease (Ebola). Risk assessments measure the likelihood and impact of infection on the Canadian population. Risk assessments are triggered from SCCTA-monitored public health threats.

- Agency Coordination of Risk Assessment and Pandemic Response Planning: The work of CIRA is recognized as an integral part of PHAC's pandemic response preparedness and plans. PHAC is dedicated

to coordinating these efforts to guide public health response to limit the spread of infectious disease that can cause a pandemic.

Recommendation 8:

PHAC is currently developing a Quality Manual that will document the operational framework necessary to facilitate future operational program delivery in support of Quarantine Act measures. The Quality Manual will also act as a foundational document / plan for the administration and enforcement of future mandatory quarantines, should they be required.

The Quality Manual will:

- Act as a how-to document of the organization's operational processes;
- Support on-going improvements of the program;
- Support evidence gathering in response to internal and external audits; and
- Provide an operational framework and tools for future public health events.

Work on the Quality Manual is progressing: a gap analysis has been completed; existing reviews and lessons learned exercises from the early part of the pandemic (2020-21) are being consolidated; and problem statements that will be addressed in the document have been developed.

An important milestone that the Agency committed to in the Management Response to the Auditor General's report is performing Lessons Learned exercises. These began in earnest following the decision to lift all border measures on October 1, 2022. This commitment will be met in the timelines stated, as the Agency is diligently working to capture and preserve the knowledge of employees who are departing the Agency following the decision to lift all border measures.

With the objective of being better prepared to respond to a future pandemic, PHAC is conducting an internal lessons learned exercise to review and document the lessons learned from the processes stood up to promote, verify, and enforce compliance with the border measures in place.

With a focus on program inception and evolution, the information gathered is intended to help PHAC better understand areas of strength, pain points, and potential improvement, thus supporting the development of future emergency plans.

PHAC will continue documenting lessons learned as employees are offboarded or as they transition to new positions within the Agency. PHAC will then synthesize these lessons learned into an actionable document (i.e. the Quality Manual) that can be used to develop Emergency Plans for use in the event of a future public health crisis.

Planning for the Quality Manual continued throughout 2022. Despite some resources being temporarily redirected to address other priorities, such as moving COVID-19 testing out of airports, and a delay in completing the first draft, PHAC remains on track to fulfill this commitment within 18 months of the end of the pandemic.

4a. Doses administered to date

2023-01-13

4:23 PM

- Cumulative doses administered: 97,083,209 (as of Feb 3, 2023)

4b. Vaccine supply in federal inventory

2023-01-13

4:24 PM

- As of January 31, 2023, there are 22,035,010 doses within the federal central inventory.

4c. Vaccine donations to date

2023-01-13

4:24 PM

- Canada has donated the equivalent of 196 million doses, including at least 41.5 million doses deemed surplus from Canada's domestic supply.

4d. Expired vaccine doses

2023-01-13

4:24 PM

- Overall, approximately 25.6M doses have expired to date in federal holdings. Breakdown as follows:

- As of December 31, 2022, a total of 12,061,760 doses held domestically in federal inventory have been disposed of or are awaiting disposal due to expiry.

- A total of 13.6M doses held off-shore (AstraZeneca) have been disposed of due to expiry as of December 31, 2022.

Note that provinces and territories are responsible for disposal of expired vaccine product held at PT DEL and non-DEL facilities, as per provincial guidelines.

International Donations

- Due to limited demand for the AstraZeneca vaccine and recipient country challenges with distribution and absorption, of approximately 21.8M AstraZeneca doses offered to COVAX, only 8.2M were donated, and 13.6M doses could not be used and expired.

- Canada continues to support international donations and is working closely with COVAX to ensure surplus Canadian doses are made available for donation with the longest shelf-life possible.

FPT Coordination of Inventory

- The number of vaccine doses (12M) expired presented above is reflective of vaccines maintained by the federal central inventory.

While PHAC makes every effort to track wastage in the jurisdictions, notably closed vial or avoidable wastage to monitor the integrity of the supply chain, this is contingent on accurate, frequent reporting from local levels to PTs to PHAC.

- While Canada's largest vaccination campaign benefitted in terms of broad vaccination accessibility from a significant increase in the breadth and diversity of sites administering vaccination including through mobile, pop-up, mass clinics, pharmacies and community sites, this diffuse approach to vaccination has made data sharing and reporting on dose expiries, wastage, etc. within jurisdictions quite challenging for provinces and territories. These challenges within PT systems also affect their ability to share quality and timely information to PHAC on wastage, expiries, etc..

- As outlined in the OAG report, strengthening the ability to monitor inventory including wastage in addition to streamlining reporting and data sharing will facilitate more accurate capture of vaccine wastage in Canada.

- The Government of Canada has ongoing collaboration with Provinces and Territories to limit wastage throughout the vaccination campaign, through detailed demand planning and forecasting, based on evolving scientific evidence, product changes in terms of formulations and shelf life, and NACI recommendations, to effectively manage the supply needs for campaigns in progress and to determine supply requirements for future campaigns.

- Additionally, PHAC works closely with Public Services and Procurement Canada and vaccine suppliers to adjust contractual commitments and delivery schedules, where possible.

- PHAC also works closely with vaccine manufacturers, to monitor vaccine shelf-life/expiry date extensions and approvals by Health Canada to maximize the use of doses delivered in Canada.

- Canada continues to actively manage vaccine supplies by seeking to extend shelf-life where possible and examining options to reduce/adjust firm contractual commitments in 2023 and 2024 to align with future evolving public health need based on available science.

4e. Biomanufacturing: actions to support planning for future domestic manufacturing and supply of vaccines

2023-01-13

4:24 PM

- The COVID-19 pandemic has reinforced the importance of strengthening domestic capacity to rapidly access vaccines to protect all people in Canada against pandemics and other health emergencies.

- With support from the Government, the Canadian biomanufacturing landscape is actively evolving. For example, Moderna is in the process of building a state-of-the art mRNA vaccine production facility in Quebec and Sanofi Pasteur is establishing an influenza vaccine manufacturing facility in Ontario.

- The Government of Canada continues to explore opportunities to grow the domestic life sciences sector and biomanufacturing capacity and, at the same time, augment Canada's ability to access international vaccine supply for ongoing routine immunization programs and outbreak response to emerging or re-emerging infectious diseases.

- Further, strengthening of supply chains leveraging domestically

produced and international products will further leverage Canada's ability to respond to a future pandemic or national health emergency response.

- The Government of Canada is aware of the situation with Mitsubishi and Medicago. Together with other federal departments, we are evaluating the impact this will have on our existing Advance Purchase Agreement with Medicago and will work closely with Public Services and Procurement Canada and the supplier to determine future steps. More information will be provided as it becomes available.

4f. Medicago

2023-02-03

1:24 PM

STATUS OF DOMESTIC BIOMANUFACTURING CAPACITY

ISSUE

- Canada is implementing the Biomanufacturing and Life Sciences Strategy, which aims to grow a strong, competitive, and resilient domestic life sciences ecosystem, with cutting-edge biomanufacturing capabilities, and to ensure Canada is prepared for future pandemics and health priorities.

- The Strategy's funding opportunities are underway through the Strategic Innovation Fund, the integrated Canada Biomedical Research Fund/Bioscience Research Infrastructure Fund, and the Clinical Trials Fund, which intend to stimulate growth and innovation and strengthen talent in Canada's life sciences and biomanufacturing ecosystem.

KEY FACTS

- Canada announced the creation of the Biomanufacturing and Life Sciences Strategy on July 28, 2021 to re-build a strong and resilient domestic biomanufacturing and life sciences sector.

- Investments in biomanufacturing capacity can reduce our reliance on imported products and strengthen our domestic industrial capacity.

- The Government will work with provinces, territories, and other partners to deliver real results for Canadians.

- The strategy is supported by existing resources and Budget 2021 investments, including support of $2.2 billion for the revitalization of Canada's biomanufacturing and life science sector.

- Health Portfolio explicit work includes:

- $250 million, over three years, for the Canadian Institutes of Health Research to establish a new Clinical Trials Fund.

- Advancing regulatory modernization efforts, including: modernized clinical trial regulations, a new pathway for advanced therapeutic products; agile regulations for the licensing of drugs and medical devices

- The objective of the Biomanufacturing and Life Sciences Strategy is to grow the domestic life sciences ecosystem, and prepare Canada for future pandemics and health priorities. In order to improve Canada's pandemic vaccine preparedness, the Biomanufacturing and Life Sciences Strategy proposes increasing domestic biomanufacturing capacity across multiple platforms, including those that represent the latest in vaccine technology, such as mRNA.

KEY MESSAGES

- The government continues to work to position Canada to develop and produce safe and effective vaccines and therapies that respond to COVID-19.

- Canada is investing to establish world-class end-to-end domestic biomanufacturing capacity – from research and development to fill and finish.
- Canada's Biomanufacturing and Life Science Strategy is focusing on growing our domestic life science ecosystem to prepare Canada for future pandemics and other health priorities.
- Budget 2021 provided $2.2 billion over seven years towards growing a vibrant domestic biomanufacturing and life sciences sector.

IF PRESSED on THE DOMESTIC CAPACITY TO DEVELOP mRNA VACCINES…

- To date, mRNA vaccines have proven to be highly effective in preventing severe disease, and they represent an alternative to traditional vaccines, with potential for rapid development and scaling of production.
- Canada is prioritizing mRNA technology for the important and innovative role it is anticipated to play in future vaccine development and preparedness for future pandemics, outside of the COVID-19 context.
- This includes partnerships with leading mRNA vaccine developers like Moderna who is building a state-of-the-art mRNA vaccine manufacturing facility in Quebec.

IF PRESSED on THE MOdeRna FACILITY…

- Moderna is a leading mRNA vaccine developer that has demonstrated, through its response to the COVID-19 pandemic, its benefit as a flexible solution to unanticipated health events.
- In 2022, the Government of Canada and Moderna announced that Moderna is building a state-of-the-art mRNA vaccine manufacturing facility in Quebec. When completed, it will produce up to 100 million pandemic vaccine doses annually.
- Moderna's new facility will not only strengthen Canada's preparedness for future pandemics but will also help position Canada as an mRNA centre of excellence.

IF PRESSED ON MITSUBISHI TANABE PHARMA CORPORATION'S DECISION TO CEASE OPERATIONS AT MEDICAGO INC. …

- Our Government was disappointed to learn of Mitsubishi's recent decision to begin the process to wind-down its support for Medicago's operations.

- Medicago remains the only Canadian-based company to have received market authorization by Health Canada for its COVID-19 vaccine. Its innovative, plant-based vaccine platform technology remains highly regarded by experts.

- Canadians can be assured that we are in contact with both Medicago and Mitsubishi to ensure an orderly transition process, and make sure Canadian interests are protected.

- Protecting the health and safety of Canadians is our government's top priority, including ensuring we have sufficient domestic vaccine production capacity to protect against future infectious disease threats and pandemics.

IF PRESSED on VACCINE investments …

- Canada is working to re-establish domestic capacity across key vaccine platforms, to be better prepared for future health emergencies.

- This includes the National Research Council's new Biologics Manufacturing Centre in Montreal, which has partnered with Novavax to produce its COVID-19 vaccine, and investments in companies like Biovectra and Sanofi Pasteur.

- It also includes partnering with Moderna, who is building a state-of- the-art mRNA vaccine manufacturing facility in Quebec, and significant investment to Sanofi Pasteur who is establishing an influenza vaccine manufacturing facility in Ontario.

IF PRESSED on PANDEMIC VACCINE PREPAREDNESS …

- The COVID-19 pandemic has reinforced the importance of strengthening domestic capacity to rapidly develop vaccines to

protect all people in Canada against pandemics and other health emergencies.

- Through strategic investments and partnerships, the Government of Canada is working to grow Canada's domestic life sciences sector and biomanufacturing capacity. These include those with Moderna who is in the process of building a state-of-the-art mRNA vaccine production facility in Quebec, and Sanofi Pasteur who is establishing an influenza vaccine manufacturing facility in Ontario.

IF PRESSED ON THE VACCINE TASK FORCE AND COUNCIL OF

EXPERT ADVISORS…

- We thank the COVID-19 Vaccine Task Force for their critical role in advising on the Government of Canada's COVID-19 vaccine response efforts.
- As the scope of the Task Force's work has expanded, the Council of Expert Advisors was established to transition from the Vaccine Task Force and assume a long-term advisory function.
- The expertise on the Council of Expert Advisors is broad – advising on scientific, health, public health, and industrial matters – supporting the Government's goal of a revitalized Canadian life- science sector and improved pandemic preparedness.

The five pillars of the Strategy are:

- Coordinating Governance;
- Strengthening Research Systems and the Talent Pipeline;
- Growing Canada's Life Sciences and Biomanufacturing Sector;
- Operationalizing National Research Council's Biologics Manufacturing

Centre (BMC) and Considering a National Centre; and,

- Ensuring Best-in-Class Regulation & World-Class Clinical Trials Systems.

Increasing domestic capacity and building a robust life sciences sector will require dedicated efforts to connect and mobilize federal investments and assets in collaboration with academia and industry to the broader life sciences ecosystem.

The emergency regulatory measures put in place during COVID-19 aim to make the system more agile, and enable prompt access within Canada to health products needed to diagnose, treat and slow the spread of the virus without compromising safety, efficacy and quality. Going forward, it will be important to maintain this level of agility (especially during non-pandemic times) to ensure Canadians receive access to needed health products. Efforts are underway to modernize regulations in areas such as agile licensing for drugs and medical devices, clinical trials, and advanced therapeutics.

The COVID-19 Vaccine Task Force and Council of Expert Advisors (CEA)

One of the main focuses on the Biomanufacturing and Life Sciences Strategy is establishing dedicated governance to ensure the Government's actions across the entire life sciences ecosystem are coordinated and expertly guided to ensure alignment and the achievement of the Strategy's objectives.

While the COVID-19 Therapeutics Task Force and the COVID-19 Vaccine Task Force were formed at the onset of the pandemic and played a foundational role in, providing invaluable insights and scientific validation in Government of Canada's pandemic response tactics, the Task Forces were not established to be permanent. As the scope of pandemic response efforts shift towards more enduring operational structures, Canada requires a permanent advisory body with broader expertise to provide guidance during pandemic and interpandemic settings. The Council of Expert Advisors (CEA) was established to take on this longer-term role.

The CEA brings together leading experts across biomanufacturing and life sciences to advise the Government on overall strategic priorities, specific project proposals, funding opportunities and other proposed actions. The CEA will also monitor progress on the Strategy's initiatives and advise on ways to

adapt approaches and strategies to respond to new technologies and changing conditions in the marketplace.

Investments under the Biomanufacturing and Life Sciences Strategy

Budget 2021 committed $1B over seven years through the Strategic Innovation Fund to support life science firms to innovate and expand in Canada. Thus far, one (1) project, Biovectra in Charlottetown, Prince Edward Island, has been funded while the remaining projects are moving through the evaluation process.

Supported through Budget 2021 commitments, the Government of Canada has launched two (2) funds to help strengthen Canada's talent pipeline and research systems, including the Canada Biomedical Research Fund ($250M over four years) which supports transitional and applied research, training and talent development, to drive downstream manufacturing capacity, and the Bioscience Research Infrastructure Fund ($500M over seven years), which will support the bioscience capital and infrastructure needs of post-secondary institutions and research hospitals.

- These funds are administered through Canada's three federal research agencies, the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the

Social Sciences and Humanities Research Council of Canada along with the Canadian Foundation for Innovation (CFI).

The first of these investments has been made by CFI in November 2022, with

$127 million distributed through the Bioscience Research Infrastructure Fund. This investment responds to urgent and essential needs of postsecondary institutions and research hospitals by supporting biocontainment facilities capable of working with pathogens.

The Canadian Institutes of Health Research has launched three funding opportunities under the Clinical Trials Fund (pan-Canadian clinical trials consortium, clinical trials training platforms, clinical trials projects) in May 2022 and are under peer review, with funding set to begin this Fall.

Canadian Biomanufacturing Capacity Since 2020

In addition to Budget 2021 funding, the government has announced a number of investments to bolster domestic production capacity through the Strategic Innovation Fund, Next Generation Manufacturing Canada Supercluster, the National Research Council, Regional Development Agencies, and other government partners, including in:

- National Research Council (NRC) (Montréal, QC) - $126 million to establish the new Biologics Manufacturing Centre;

- Medicago (Quebec City, QC) - $173 million to develop a plant-based virus-like-particle vaccine and for the construction of a Good Manufacturing Practice facility.
- AbCellera (Vancouver, BC) - $175.6 million in government support of antibody discovery for clinical testing and for the construction of a GMP antibody production facility;
- Vaccine and Infectious Disease Organization (VIDO) (Saskatoon, SK) –

$59.2M, over three years, starting in 2021-22, to support the development of its vaccine candidates and expand its Saskatoon facility;

- Precision Nanosystems (Vancouver, BC) - $25.1 million in government support to build a biomanufacturing centre for production of RNA vaccines;
- KABS Laboratories (St-Hubert and Val des Sources, QC) - $54.25 million toward a biologics production facility with a focus on antibody therapies and new fill-finish capabilities;
- Novocol (Cambridge, ON) - $32.7 million contribution for expanded fill- finish capacity;

- Providence Therapeutics and Northern RNA Inc. - $5 million through the Next Generation Manufacturing Supercluster to expand their operations in Calgary to design and manufacture COVID-19 vaccines and build a pipeline of mRNA vaccines;
- Sanofi Pasteur (Toronto campus) – up to $415 million support towards building an end-to-end influenza vaccine manufacturing facility; and,
- Resilience Biotechnologies (Mississauga, ON) - $199 million to increase manufacturing and fill/finish capacity for a number of vaccines and therapeutics including mRNA technologies.

Moderna's Canadian Facility

In 2022, the Government of Canada and Moderna announced that Moderna would build a state-of-the-art mRNA vaccine manufacturing facility in Quebec. Construction of the facility is underway, and when completed, will be able to produce up to 30 million mRNA vaccine doses per year in non-pandemic times and up to 100 million doses per year during a pandemic.

Moderna is a leading mRNA vaccine developer that has demonstrated, through its response to the COVID-19 pandemic, its benefit as a flexible solution to unanticipated health events—not only by rapidly developing a successful COVID-19 vaccine, but also by producing and distributing it at commercial scale. Having an mRNA developer producing vaccines at scale in Canada represents one important piece in Canada's plan to rebuild the life sciences sector, and will better protect Canadians for whatever the future holds.

Moderna's new facility in Canada will not only help strengthen our biomanufacturing sector and pandemic preparedness, but will also help position Canada as an mRNA centre of excellence and a global mRNA research and

development (R&D) hub. As part of the agreement with the Government of Canada, Moderna is committed to building a robust R&D Workplan, which will include Pandemic Preparedness R&D projects along with development of partnerships with Canada's leading research universities and institutions to help advance research and development here at home. For example, Moderna has already partnered with McGill University through Moderna's mRNA Access program to accelerate vaccine innovation, as well as with the University of Toronto to do research across a range of scientific disciplines to develop new ways to treat infectious diseases.

The facility will boost the Canadian economy through the creation of hundreds of jobs during construction and operation of the facility, including direct and indirect biomanufacturing and research jobs. Moderna's facility will also mean domestic opportunities for the brightest young minds in the field

through internships, co-op positions, and other Moderna-supported training and development opportunities. In this way, the facility will enhance Canada's talent pipeline by attracting, developing and retaining a highly skilled workforce. The facility will also offer the potential for Canadian companies to work with Moderna, and, where possible, opportunities to comprise part of Moderna's supply chain.

In November 2022, Prime Minister Justin Trudeau Participated in the facility's ground-breaking ceremony. The facility is expected to be operational in 2024 at the earliest, subject to planning and regulatory approvals. In addition to COVID- 19 vaccines, the facility is expected to be able to produce vaccines for other respiratory diseases, such as influenza – pending their ongoing development by Moderna and approval by Health Canada.

Medicago

Medicago is the only Canadian-based company to have received market authorization for Covifenz COVID-19 vaccine. Covifenz is the product of years of scientific efforts that began with public science collaboration between Agriculture and Agri-Food Canada and the Université Laval in the late 1990s. Since then, Medicago has established itself as an innovative global leader in plant-based vaccines, using living plants as bioreactors for the production of virus-like particles (VLP).

In 2020, Canada entered in to an advance purchase agreement (APA) with Medicago to secure access to up to 76 million doses of its COVID-19 vaccine (20M firm doses and 56M optional doses). Due to unanticipated manufacturing issues, Medicago has not marketed any lots of its COVID-19 vaccine for commercial use.

On February 3, 2023, Mitsubishi Tanabe Pharma Corporation announced that it has decided to cease all operations with Medicago Inc. That same day Health

Canada's Health Products and Food Branch were informed that Mitsubishi Tanabe will be cancelling their vaccine authorization and withdrawing the submission currently under review (which would had been filed to extend the use of the vaccine to the elderly population). Health Canada will work with Medicago to close out their files.

Medicago, whose headquarters is in Quebec City and operates an additional facility in North Carolina, employs roughly 550 people (about 400 in Canada). The company has been 100% owned by Mitsubishi Tanabe Pharma since December 2022. Before the decision, global tobacco giant Philip Morris

International owned 21 per cent of the company's shares. Medicago's plant- based COVID-19 vaccine, Covifenz, was initially rejected by the World Health Organization over its ties with the tobacco industry.

Inspection and Licensing – Oversight of Drug Manufacturing in Canada

Health Canada's role in regulating drugs is to evaluate and approve products, set requirements, monitor safety and enforce compliance and communicate health risks. Further, Health Canada approves establishments involved in the manufacturing of drugs marketed for use in Canada.

To ensure drugs are safe, effective and of high quality, all drug producing facilities in Canada, including those supporting domestic biomanufacturing efforts, must hold a Drug Establishment License and be inspected by Health Canada to demonstrate it meets Good Manufacturing Practices, known as "GMPs".

Health Canada continues to remain supportive in strengthening Canada's drug manufacturing capacity and prioritizing new and continued COVID-19 drug manufacturing, enabling industry with responsive and flexible regulations to mobilize and support current needs of the domestic market.

Health Canada is committed in providing regulatory advice and guidance in the planning and development of operations to support domestic biomanufacturing in Canada now and into the future.

As part of Health Canada's role in ensuring a safe and effective drug supply, inspection and other regulatory experts will continue to promote and enforce Canada's high standards for drug manufacturing.

4g. NACI QP note

2022-10-17

3:04 PM

Issue

NACI may make recommendations that are broader or narrower than the conditions of use approved by Health Canada (known as 'off-label' recommendations). As the regulator, Health Canada rigorously evaluates safety and efficacy data from clinical trials before authorizing vaccines but does not dictate practice of medicine or make recommendations on how the vaccines should be used for public health impact.

Key Facts

- The National Advisory Committee on Immunization (NACI) is an external body of experts that provides recommendations to the Public Health Agency of Canada on the use of authorized COVID-19 vaccines to support provinces and territories in planning COVID-19 vaccine programs in Canada.

Key Messages

- Canada's National Advisory Committee on Immunization (NACI) updates its recommendations on COVID-19 vaccines based on the latest scientific evidence and its expert opinion.

- COVID-19 vaccines authorized for use in Canada have been essential in saving lives and protecting the health of Canadians, and reducing the burden on the health care system.

- At this point in the pandemic, it is important for individuals to receive a booster dose when recommended to continue to protect themselves against severe outcomes from COVID-19.

- In addition to keeping up to date with vaccination, wearing a well- fitting mask, hand hygiene and physical distancing, continue to be

strategies individuals can employ to help lower their individual risk of contracting COVID-19.

If pressed on 2023 guidance on booster doses

- NACI strongly recommends that all individuals 18 years of age and older, and adolescents 12 to 17 years of age who are at increased risk of severe illness from COVID-19 should receive at least one booster dose following completion of the primary series.

- NACI strongly recommends that all individuals 65 years of age and older and individuals 5 to 64 years of age who are at increased risk of severe illness from COVID-19 and have not yet received a fall 2022 COVID-19 vaccine booster dose, should be offered one.

- NACI recommends that all other individuals 5 to 64 years of age who have not yet received a fall 2022 COVID-19 vaccine booster dose may be offered one.

- NACI recommends that bivalent Omicron-containing mRNA COVID-19 vaccines are the preferred products for booster doses.

- NACI recommends that when COVID-19 booster doses are offered, they should be provided at an interval of 6 months since the previous COVID-19 vaccine dose or infection.

- Based on the variability of fall 2022 booster program start dates across jurisdictions, some individuals will have exceeded 6 months since receiving their last booster dose later this winter. Currently, NACI is not issuing guidance on an additional booster dose for these individuals.

- For children 5 to 11 years of age, NACI is currently recommending only one booster dose after the primary series. At the discretion of a healthcare provider, a bivalent booster dose may be offered at the recommended interval to children considered at high risk of severe

COVID-19 who have previously received a booster dose of the original Pfizer-BioNTech (Comirnaty) vaccine.

- At this time, there are no booster dose products authorized for children 6 months up to 5 years of age and NACI is not making any booster dose recommendations for this age group.

- There may be variability in how each province, territory or community assesses risk and responds to the needs of their respective jurisdictions.

- NACI plans to continue to monitor the evidence and evolving epidemiology and provide updated guidance in the coming months.

If pressed on primary series for children 6 months to 5 years of age

- Most children who get COVID-19 have mild or no symptoms; however, some children, including previously healthy children, experience severe disease and require hospitalization. Children who have an underlying medical condition may be at higher risk of severe outcomes from COVID-19.

- NACI recommends a 2-dose primary series of the Moderna Spikevax COVID-19 vaccine (25 mcg) may be offered to children 6 months to 5 years of age, while a 3-dose primary series of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (3 mcg) may be offered to children 6 months to 4 years of age.

- NACI recommends that children 6 months to 4 years of age who are moderately to severely immunocompromised may be offered a primary series that consists of an additional dose of an mRNA COVID- 19 vaccine (three doses of the Moderna Spikevax [25 mcg] vaccine for those 6 months to 5 years of age or four doses of the Pfizer- BioNTech Comirnaty [3 mcg] vaccine for those 6 months to 4 years of age). Moderna Spikevax (25 mcg) is the recommended product for this population, given the fewer number of doses in the schedule.

- It is essential that children and their caregivers are supported and respected during the decision-making process so they are able to make an informed decision about COVID-19 vaccination.

If pressed on boosters for children 5 to 11 years of age

- NACI recommends a booster dose of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine should be offered at least 6 months after the completion of a primary series or SARS-CoV-2 infection to children 5 to 11 years of age who have an underlying medical condition, including children who are moderately to severely immunocompromised, that places them at high-risk for severe COVID-19 outcomes.

- For all other children 5 to 11 years of age, NACI recommends that a booster dose of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg) may be offered at least 6 months after the completion of a primary series or SARS-CoV-2 infection.

- A bivalent Omicron-containing mRNA COVID-19 vaccine is the preferred vaccine product for children aged 5 to 11 years who are receiving a booster dose.

- It is essential that children and their caregivers are supported and respected during the decision-making process so they are able to make an informed decision about COVID-19 vaccination.

Background

- NACI guidance is based on current evidence and expert opinion. NACI continues to closely monitor the evolving evidence on COVID-19 and COVID-19 vaccines, including safety and effectiveness, and updates recommendations as needed.

Strong versus discretionary NACI recommendations

- NACI makes two types of recommendations—strong recommendations and discretionary recommendations. A strong

recommendation uses the words “should / should not be offered” and applies to most individuals in a population unless a compelling alternative is available. A discretionary recommendation uses the words “may / may not be offered” and means that the vaccine may be considered for individuals in a population, but that the decision should be made considering factors, such as individual benefits and risks, or local epidemiology.

Concurrent administration of COVID-19 vaccines and other vaccines

- NACI recommends that individuals 6 months of age and older may be offered COVID-19 vaccines concurrently with (i.e., same day), or any time before or after, non-COVID-19 vaccines (including live and non- live vaccines). (Discretionary NACI recommendation)

COVID-19 vaccination for children

- Most children who get COVID-19 have mild or no symptoms; however, some children, including previously healthy children, experience severe disease and require hospitalization. Children who have an underlying medical condition may be at higher risk of severe outcomes from COVID-19.

Primary series for children 6 months to 5 years of age

- Two vaccines are approved for use in this population: the Moderna Spikevax mRNA (25 mcg) vaccine is authorized for children 6 months to 5 years (2 dose primary series) and the Pfizer-BioNTech Comirnaty mRNA (3 mcg) vaccine is authorized for children 6 months to 4 years (3 dose primary series).

- NACI recommends that a primary series of an mRNA COVID-19 vaccine may be offered to children in the authorized age groups without contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose (Discretionary NACI recommendation).

- NACI recommends that children 6 months to 4 years of age who are moderately to severely immunocompromised may be offered a primary series that consists of an additional dose of an mRNA COVID- 19 vaccine

- Three doses of Moderna Spikevax [25 mcg] for those 6 months to 5 years of age, or

- Four doses of the Pfizer-BioNTech Comirnaty [3 mcg] vaccine for those 6 months to 4 years of age)

- Intervals of 4 to 8 weeks between each dose (Discretionary NACI recommendation).

- With regard to the product offered to children 6 months to 4 years of age who are moderately to severely immunocompromised, NACI recommends that

- Moderna Spikevax (25 mcg) should be offered, due to potential feasibility challenges of a four-dose primary series.

- The Pfizer-BioNTech (3 mcg) vaccine may be offered as an alternative primary series if Moderna Spikevax (25 mcg) is unavailable.

Primary series for children 5 to 11 years of age

- Two COVID-19 vaccines are approved for use as a primary series in this population: the Pfizer-BioNTech Comirnaty mRNA (10 mcg) vaccine is authorized for children 5 to 11 years of age and the Moderna Spikevax mRNA (50 mcg) vaccine is authorized for children 6 to 11 years of age.

- NACI recommends that a 2-dose primary series of an mRNA COVID- 19 vaccine should be offered to children in the authorized age groups without contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose (Strong NACI recommendation).

- For children 6 to 11 years of age, the Pfizer-BioNTech Comirnaty (10 mcg) vaccine is preferred to the Moderna Spikevax (50 mcg) vaccine to start or continue the primary vaccine series. This is due to the well-known safety profile of the Pfizer-BioNTech Comirnaty (10 mcg) vaccine in this age group. The Moderna Spikevax vaccine may be offered as an alternative.

- NACI recommends that children 5 to 11 years of age who are moderately to severely immunocompromised should be offered a 3- dose primary series of an mRNA COVID-19 vaccine with an interval of 4 to 8 weeks between each dose. (Strong NACI recommendation).

- For children 6 to 11 years of age who are moderately to severely immunocompromised, a primary series of the Moderna Spikevax (25 mcg) vaccine may be considered given the potential benefit

of a better immune response that has been observed in adults with immunocompromising conditions when comparing Moderna Spikevax (100mcg) and Pfizer-BioNTech Comirnaty (30 mcg).

Primary series for adolescents 12 to 17 years of age

- Two COVID-19 vaccines are approved for use as a primary series in this population: the Pfizer-BioNTech Comirnaty mRNA (30 mcg) vaccine and the Moderna Spikevax mRNA (50 mcg) vaccine.

- NACI recommends a complete primary series of an mRNA COVID-19 vaccine should be offered to adolescents 12 to 17 years of age who do not have contraindications to the vaccine with a dosing interval of 8 weeks between the first and second dose (Strong NACI Recommendation).

- The Pfizer-BioNTech Comirnaty (30 mcg) vaccine is preferred to start or continue a primary series.

- NACI recommends adolescents 12 to 17 years of age who are moderately to severely immunocompromised should be offered a 3- dose primary series of an mRNA COVID-19 vaccine. (Strong NACI recommendation)

Primary series for adults 18 years of age and over

- Six COVID-19 vaccines are authorized for use in this population: Pfizer-BioNTech Comirnaty mRNA (30 mcg), Moderna Spikevax mRNA (100 mcg), Medicago Covifenz (18 to 64 years), Novavax Nuvaxovid, AstraZeneca Vaxzevria and Janssen Jcovden.

- NACI recommends that a complete primary series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine, with a dosing interval of 8 weeks between the first and second dose (Strong NACI Recommendation).

- NACI recommends that adults who are moderately to severely immunocompromised should be offered a 3-dose primary series of an authorized mRNA COVID-19 vaccine with an interval of 4 to 8 weeks between each dose (Strong NACI Recommendation).

- For individuals 18 to 29 years of age, the Pfizer-BioNTech Comirnaty (30 mcg) vaccine is preferred to start or continue the primary series due to a lower reported rate of myocarditis/pericarditis compared to the Moderna Spikevax (100 mcg) vaccine.

- NACI recommends a primary series of a protein subunit COVID-19 vaccine (Novavax Nuvaxovid) or a virus-like particle COVID-19 vaccine (Medicago Covifenz) may be offered to individuals in the authorized age groups without contraindications to the vaccine who are unable or unwilling to receive an mRNA COVID-19 vaccine (Discretionary NACI Recommendation).

- NACI recommends that a primary series of a viral vector COVID-19 vaccine (AstraZeneca Vaxzevria, Janssen Jcovden) may be offered to individuals in the authorized age groups without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated (Discretionary NACI Recommendation).

Booster doses for children 6 months up to 5 years of age

- At this time, there are no booster dose products authorized for children 6 months up to 5 years of age and NACI is not making any booster dose recommendations for this age group.

Booster doses for individuals 5 years of age and over

- At least one booster dose should be offered to all adults 18 years of age and over and adolescents 12 to 17 years of age who are at increased risk of severe illness. (Strong NACI recommendation)

- All adults 65 years of age and older and individuals 5 to 64 years of age who are at increased risk of severe illness from COVID-19 should have received a booster dose since the start of fall 2022. For individuals who have not yet received a fall 2022 booster, it should be offered, as per the recommended interval. (Strong NACI recommendation)

- Individuals 5 to 64 years of age without risk factors for severe illness from COVID-19 may have been offered a booster dose since the start of fall 2022. Individuals who have not yet received a fall 2022 booster may still be offered one, as per the recommended interval. (Discretionary NACI recommendation)

- NACI recommends bivalent Omicron-containing mRNA COVID-19 vaccines are preferred for booster doses for all individuals 5 years of age and older. (Strong NACI Recommendation).

- NACI is currently recommending only one booster dose after the primary series for children 5 to 11 years of age. At the discretion of a healthcare provider, a bivalent booster dose could be offered at

the recommended interval to children considered at high risk of severe COVID-19 who have previously received a booster dose with the original Pfizer-BioNTech Comirnaty mRNA vaccine.

- Individuals 12 years of age and older who are not able or willing to receive a bivalent vaccine may be offered an original mRNA vaccine. Booster doses of original mRNA COVID-19 vaccines continue to provide good protection against severe outcomes from COVID-19, including from Omicron infection.

- NACI continues to recommend that when COVID-19 booster doses are offered they should be provided at an interval of 6 months after a previous COVID-19 vaccine dose or 6 months after SARS-CoV-2 infection.

Recommendations related to myocarditis and/or pericarditis

- Rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the heart lining) have been reported following vaccination with mRNA COVID-19 vaccines.

- Cases have occurred more frequently in males 12 to 29 years of age after a second dose of an mRNA COVID-19 vaccine. Most cases have been mild and resolved quickly.

- Based on data from the United States, the risk of myocarditis/pericarditis may be much lower in children 5 to 11 years of age than adolescents 12 to 17 years of age.

- To further minimize the rare risk of adolescents and young adults experiencing myocarditis and/or pericarditis, the Pfizer-BioNTech Comirnaty COVID-19 (30 mcg) vaccine is preferred for use in

adolescents and young adults 12 to 29 years of age for the primary series.

- Canadian and international data suggest a lower reported rate of myocarditis following vaccination with the Pfizer-BioNTech Comirnaty (30 mcg) vaccine compared to the Moderna Spikevax (100 mcg) COVID-19 vaccine.

- The Pfizer-BioNTech Comirnaty (10 mcg) vaccine is also preferred to start or continue the primary vaccines series in children 5 to 11 years of age.

- Based on clinical judgement, the Moderna Spikevax (100 mcg) vaccine may be considered for adolescents and adults 12 to 29 years of age who are moderately to severely immunocompromised given evidence that this vaccine may have a slightly higher vaccine effectiveness and may provide longer protection against infection and severe COVID-19 outcomes compared to the Pfizer-BioNTech Comirnaty (30 mcg) vaccine.

- Out of precaution, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.

- Some people who experienced myocarditis with or without pericarditis after a first dose of an mRNA COVID-19 vaccine may choose to receive another dose of vaccine after discussing the risks and benefits with their healthcare provider.

- If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech Comirnaty (30 mcg) vaccine due to the lower reported rate of myocarditis and/or pericarditis following this vaccine compared to the Moderna Spikevax (100 mcg) vaccine.

- Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. People previously diagnosed

with myocarditis but who are no longer being followed by a medical professional for heart issues should receive the vaccine.

COVID-19 vaccination following SARS-COV-2 infection

- NACI continues to recommend COVID-19 vaccination for individuals who have had COVID-19. While infection alone provides some protection, hybrid immunity (i.e., conferred by vaccination and infection) may provide better and longer lasting protection. Suggested intervals may change as evidence evolves.

- At this time, NACI suggests that individuals 6 months of age and older who are not considered moderately to severely immunocompromised and with no history of MIS-C or MIS-A who experience SARS-CoV-2 infection before starting or completing their primary COVID-19 vaccine series receive their next dose 8 weeks after symptoms started or after testing positive (if no symptoms were experienced).

- For individuals 6 months of age and older who are moderately to severely immunocompromised and without a history of MIS-C or MIS-A, who experience SARS-CoV-2 infection before starting or completing their primary COVID-19 vaccine series receive their next dose 4 to 8 weeks after symptoms started or after testing positive (if no symptoms were experienced).

- For individuals 5 years of age and over who are recommended to receive a booster dose, the booster dose may be offered at an interval of 6 months after SARS-CoV-2 infection (or 6 months from a previous COVID-19 vaccine dose). A shorter interval of at least 3 months may be considered particularly in the context of heightened epidemiologic risk, evolving epidemiology and operational considerations for the efficient deployment of vaccine programs.

4h. Vaccine Equity (P/T)

2023-02-05

2:01 PM

- Throughout the immunization campaigns for COVID-19, focused actions were undertaken to ensure vaccine equity across Canada, through FPTI engagement, communications efforts, as well as targeted efforts working with community-based groups.

- PHAC invested in projects with trusted community-based partners through grants and contributions to support vaccine confidence and uptake efforts especially in regionally diverse, marginalized communities such as racialized groups, children/youth, faith communities, and others.

- Ahead of vaccine rollout in December 2020, NACI issued recommendations for prioritization of initial vaccines to 4 groups:

- Residents and staff of congregate living settings that provide care for seniors

- Adults 70 years of age and older, beginning with adults 80 years of age and older and decreasing in 5-year increments

- Health care workers

- Adults in Indigenous communities

- This advice was critical to align PT priority populations during the first phase of the rollout, and allowed the focus of limited initial supply toward the protection of the most vulnerable, with the aim of preventing severe outcomes like hospitalization and deaths.

- Working together with Indigenous Services Canada, PHAC engaged with First Nations, Inuit and Métis partners to provide an integrated and coordinated approach to the administration and planning process for COVID-19 vaccines in communities.

5. Key Messages

2023-01-20

10:17 AM

- Launched in June 2021, VaccineConnect is an agile, modular digital platform developed to address the urgent need to manage distribution and administration of COVID-19 vaccines and laid the foundation for an integrated pan-Canadian vaccine supply management system.
- It is made up of three main modules, namely, the Intelligent Supply Chain (ISC), the Immunization Information System (IIS) and the Immunization Program Management (IPM).
- The ISC module was developed in partnership with the Canadian Armed Forces (CAF), PHAC and HC, in collaboration with federal, provincial and territorial jurisdictions responsible for immunization delivery, vaccine manufacturers and logistical partners.
- ISC 2.0 successfully launched in November 2022 including an enhanced WebPortal with data quality procedures in place for submission and tracking of orders and inventory at the central level to support supply chain management.
- It focuses on standardizing processes, providing users with additional reporting capabilities and ensuring a stronger foundation for sustainable management of the medical countermeasures supply chain and inventory management, including and beyond COVID-19 vaccines
- PHAC is actively working to advance the implementation and data quality procedures of the three modules of VaccineConnect. The Agency will continue to actively engage jurisdictional partners on identification of service and data quality gaps and needs to support future integration of the systems.
- Provinces and territories report on vaccine wastage and inventory; however, not all have an inventory tracking system that electronically

monitors and rolls up supply at the local level across diverse vaccination administration sites.

- The limited functionality of VaccineConnect in tracking vaccine wastage was largely due to the inability of provinces and territories to track and share usage and wastage data at the local level once COVID-19 vaccines had been distributed to pharmacies, diverse community sites and primary care providers.

6a. Vaccine safety to date

2023-02-02

9:37 AM

- Up to and including January 6, 2023:

- 53,611 reports of adverse events following COVID-19 vaccinations have been submitted to PHAC or Health Canada, representing 0.056% of COVID-19 vaccine doses administered.

- Over 10,000 of the reported adverse events were considered serious, representing 0.011% of COVID-19 vaccine doses administered.

- PHAC, Health Canada, provincial and territorial public health authorities work collaboratively to investigate statistical signals detected within Canadian data or identified internationally. To date, statistical safety issues identified in Canada have been communicated to the public using an online report.

- Safety issues have related to Thrombosis with thrombocytopenia syndrome (blood clots with low platelets) and myocarditis/ pericarditis (inflammation of the heart muscle/lining around the heart).

- 400 reports with an outcome of death had been submitted to PHAC or HC. These deaths are not necessarily related to the vaccine.

- All reports of death are reviewed by medical doctors at PHAC or Health Canada.

- The breakdown of results of causality assessment is provided in the online report on Canada.ca, with 4 determined to be consistent with a causal association to immunization.

- These 4 reports are individuals reported to have experienced blood clots with low platelets following vaccination with a viral vector vaccine.

- For public transparency, there is a report on Canada.ca providing information on the expert causality assessment conducted on case reports for blood clots and low platelets

- Safety signals/issues

- Earlier in 2022, Guillain-Barré Syndrome had been noted as a safety signal.

- In May 2022, to align with standard reporting practices, Guillain- Barré Syndrome (GBS) reports were adjusted to exclude reports with insufficient information to confirm diagnosis. With this adjustment, Guillain-Barré Syndrome no longer met the criteria to be considered a safety signal.

6b. VISP - Vaccine Injury Support Program

2022-10-14

10:00 AM

- The Government of Canada is committed to ensuring that Canadians who support public health by being vaccinated are supported, should they experience a serious and permanent injury as a result of vaccination.

- PHAC has established a pan-Canadian no-fault Vaccine Injury Support Program (VISP), in consultation with the provinces and territories.

- The pan-Canadian program, which launched on June 1, 2021, is being administered independently by RCGT Consulting, which oversees all aspects of claims intake, assessment and reporting.

- The province of Quebec continues to administer its existing provincial program, the Vaccine Injury Compensation Program (VICP), for people vaccinated in Quebec with federal funding. Individuals vaccinated in all other provinces and territories are eligible under the pan-Canadian program, VISP.

- $75 million has been earmarked for the first five years of the program, starting in FY 2021/22. Currently, $37.2 million over 5 years has been allocated to RCGT Consulting for administration and claim payments. In addition, up to $7.75M over 5 years has also been allocated to the Government of Quebec for the continued delivery of its provincial vaccine injury compensation program.

- The overall cost of the program is dependent on the volume of claims and compensation awarded over time. Remaining funds are available to adapt to the demand for financial support. As the volume of claims has been higher than originally anticipated, amounts are likely to change upwards.

- Information on the number of claims received, and the number of claims resulting in compensation, can be found on the RCGT website.

- Health Canada and PHAC continue to advise that the benefits of vaccination with a vaccine approved in Canada outweigh the potential risk of disease.

- The VISP strengthens our national immunization programs by ensuring fair and equitable access to support for all individuals vaccinated in Canada.

The Vaccine Injury Support Program began accepting claims on June 1, 2021.

Table: Program statistics for the period from the start of the program until December 1, 2022.

1299

Total number of claims received

23

Number of claims pending administrative review for eligibility

These claims have been received by the VISP but have

not been reviewed by a Case Manager to determine eligibility.

1276

Number of claims with administrative review completed These claims have had their initial preliminary review by a Case Manager and have been deemed eligible to

continue.

209

Number of claims that are inadmissible

These claims do not meet the eligibility criteria or are unable to move forward in the process due to incomplete information or ineligibility.

1067

Number of claims that are admissible

These claims are in the process of being depersonalized

and prepared to move forward to a preliminary medical review.

662

Number of claims in process of collecting medical records Each health care provider is contacted individually in order to retrieve relevant medical records. This is often

the longest step in the claims assessment process.

48

Number of claims pending Medical Review Board assessment

These claims are considered complete and are awaiting review by the Medical Review Board, which will be comprised of physicians with relevant experience who will determine if there is an association between the injury and the vaccine. The claims have been

depersonalized.

221

Number of claims that have been assessed by the Medical Review Board

These claims have been assessed by the Medical Review

Board. If a probable link between the injury and the

vaccine is determined, the severity of the injury is also established to calculate the financial support to be awarded. NOTE: The Medical Review Board may decide that more information or time is required to properly

assess the claim.

50

Number of claims approved by Medical Review Board These claims represent cases where it has been determined by the Medical Review Board that there is a probable link between the injury and the vaccine, and

that the injury is serious and permanent.

18

Number of appeals received

These claims have been reviewed by a Medical Review Board and an appeal of the decision for either causality or severity has been requested. The VISP has received 13

appeals for causality, and 5 for severity.

$2,779,277

Total amount of compensation approved

This is the total amount of compensation approved or paid since the inception of the VISP.

6c. Improving data sharing (with WHO, Vaccine manufacturers and HC)

2023-01-13

4:32 PM

Information Sharing with the WHO and vaccine manufacturers

- Canada and PHAC are in good standing with the WHO and have maintained good relationships with international partners throughout the pandemic. PHAC shares aggregate patient data with the WHO on a monthly basis, as requested, and this has not been a problem. To date, the WHO has made no requests to PHAC for more reporting, nor expressed any complaint or concern on the existing arrangement.

- Nevertheless, PHAC and P/Ts are supportive of enhancements to data- sharing with the WHO in the interest of supporting global pharmacovigilance efforts.

- PHAC intends to facilitate consultations with HC and F/P/T immunization programs on options to share more granular vaccine safety data with the WHO and vaccine manufacturers, with a focus on addressing barriers identified by F/P/T immunization programs.

- Established barriers to expanded data-sharing arrangements include existing Health Canada policy around the default publication of patient- level Adverse Events Following Immunization (AEFI) data on Canada Vigilance Database (CVD), an online public access database.

- This also impacted data-sharing with the WHO Uppsala Monitoring Center, as patient-level data entered into the WHO's Vigibase is accessible to vaccine manufacturers, who are then compelled by Health Canada regulation to submit that data into CVD.

- Provincial and territorial immunization programs have cited concerns related to: the risk associated with public disclosure of personal information; and lack of patient consent. In collecting this data for

surveillance purposes, provinces and territories have not obtained patient consent to post, albeit depersonalized, AEFI medical information online.

Information Sharing with Health Canada

- PHAC shares detailed vaccine safety data and analyses with Health Canada on an ongoing basis, in an arrangement that respects provincial and territorial requirements while ensuring that Health Canada officials have the information required to effectively conduct ongoing regulatory monitoring and reviews.

- PHAC is committed to addressing barriers that prevent the sharing of patient-level AEFI data with Health Canada and other partners, with a focus on facilitating collaboration and consensus, in alignment with its mandate.

- The Agency continues to lead consultations, begun in February 2022, with provincial and territorial partners on a proposal to address data sharing barriers, including to provide Health Canada with access to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). This aligns with Agency commitments made in the Audit of COVID-19 Vaccines Management Response Action Plan.

6d. Detect, Understand, Act (DUA) investments in data systems to support data sharing

2023-01-13

4:32 PM

- The COVID-19 pandemic has shown how important it is to be able to effectively anticipate and respond to public health risks that threaten the health and safety of Canadians.

- While the Public Health Agency of Canada responded well throughout the pandemic, it is crucial to take immediate steps to improve our monitoring [surveillance] capabilities so we are better able to detect and respond to public health events and emergencies in the future.

- As FPT conversations on advancing health system priorities, – including health data – continue, Budget 2022 will provide $436.2 million over five years, starting in 2022-23, with $15.5 million in remaining amortization, to PHAC to strengthen key monitoring [surveillance] and risk assessment capacities within the Agency.

- There are many examples where the funding proposed by Budget 2022 will tangibly improve our monitoring [surveillance] and risk assessment capabilities so we are better able to detect and respond to public health events and emergencies in the future.

- This funding will strengthen PHAC's early warning monitoring and reporting system. This includes policy, operational and infrastructure improvements for the Global Public Health Intelligence Network (GPHIN with a focus on joining up event-based monitoring [surveillance] with risk assessment processes and enhancing linkages with the security and intelligence community.

o This will address findings of the Auditor General of Canada (Report #8; 2021) and the 2021 Independent Review Panel on GPHIN.

- This funding will advance our ability to support near-real time detection of emerging infectious disease threats through genome sequencing and wastewater monitoring [surveillance], especially as we expand the scope of

these activities to more municipalities and to other known and emerging pathogens.

- This funding will stabilize and enhance the new Centre for Integrated Risk Assessment (CIRA) at PHAC. Through CIRA, we have been able to produce weekly threat reports as well as more targeted rapid-risk assessments. In this way, the establishment of CIRA has increased our capabilities to assess immediate and future public health risks to Canadians through a rigorous, evidence-based process.

- Through predictive modelling, we will further strengthen our risk assessment capacity regarding different types of infectious diseases, including new strains of flu, emerging respiratory infections, diseases spread by food or water, those spread via animals, and those spread in the environment.

- This funding will stabilize and strengthen key monitoring [surveillance] programs and risk assessment capacity/infrastructure. For instance, we will be able to better understand the wider impacts of the COVID-19 pandemic on the health of Canadians, including on chronic diseases, mental health, substance abuse, and other issues.

- We will also be able to continue enhanced monitoring [surveillance] of vaccine coverage, safety and effectiveness, including working with partners across the country to fill monitoring and reporting gaps and better understand the perspectives of racialized communities and other vulnerable populations.

- We are also making investments to improve our ability to communicate essential information to Canadians. As two examples, the Public Health Infobase enables Canadians to view:

o Vaccine data: the number and percentage of people that have received a COVID-19 vaccine in Canada by province or territory, vaccination status, sex, age group, and vaccine series.

o Wastewater monitoring: Canadians are able to view trend data about the levels of COVID-19 in the wastewater (sewage) of different communities and settings across Canada.

- This funding will support enhanced FPT collaboration on health data collection, access, sharing, use and protection, and strengthen consultation with the public.

o Approximately $7 million of this funding will be used over three years to support the implementation of PHAC-led activities under the Pan- Canadian Health Data Strategy (PCHDS). The activities funded through this investment will be used to support a health data governance structure reporting through the Public Health Network Council.

o Funding will also be used for the creation of a public advisory body for ongoing consultations with people in Canada on the collection, use and sharing of their health data for the public good.

- Finally, in addition to supporting the PCHDS, this funding will help us build the health data infrastructure and tools required to support our important role in protecting the health of Canadians.

6e. PHAC Role in Public Health Surveillance

2023-01-20

9:26 AM

- Responsibility for public health monitoring [surveillance] shared by regional health authorities, PTs, and federal agencies.
- PHAC conducts a wide range of monitoring [surveillance] activities related to specific diseases and threats to public health. These include:
- Event-based monitoring [surveillance], through the Global Public Health Intelligence Network (GPHIN) – searching reports, media coverage, other open sources for events that could pose a serious risk to public health.
- Indicator-based monitoring [surveillance] – systematic collection, monitoring, analysis, and interpretation of public health data from formal sources and data standards. E.g., reports received on the number of lab-confirmed cases of influenza reported by PTs.
- Public health monitoring [surveillance] activities are conducted in five branches of PHAC: the Infectious Disease Program Branch, the Health Promotion and Chronic Disease Prevention Branch, the National Microbiology Laboratory, the Corporate Data and Surveillance Branch, and the Emergency Management Branch.

6f. PCHDS QP Note

2023-01-24

10:43 AM

PAN-CANADIAN HEALTH DATA STRATEGY

Issue

On November 8, 2022, federal, provincial, and territorial Health Ministers met to discuss the draft co-developed Pan-Canadian Health Data Strategy. The provinces and territories were unwilling to endorse the Strategy, pending further discussions on health transfers to the provinces and territories (PTs) to support priority work. Endorsement of the Strategy continues to be considered as part of broader conversations on advancing health system priorities with PTs.

Key Facts

- There are persistent and important gaps in data collection, protection, access, sharing and use that cost lives and negatively impact personal, health professional and system-wide health decision-making.

- These gaps impair public health responses, reduce health outcomes for Canadians, and contribute to health inequities.

- The pandemic revealed the critical importance of timely health data. Public health decision-making is impeded when health data are uncoordinated, contain incomplete information, and are not linked across various points of care and across jurisdictions. Ultimately, this negatively impacts the health outcomes of Canadians.

- The draft co-developed Strategy does not envision or create a single large technology system. Rather, it would facilitate the creation of a new enabling environment where collaborative work in common areas would support the creation of a world-class health data system, enabling Canadians to harness health data to achieve better health outcomes.

Key Messages

- A strong health data foundation, based on federal, provincial, territorial collaboration, is needed to responsibly harness the power of health data to strengthen our public health responses, reduce health inequities, and modernize our health system.

- To achieve this, the Government of Canada is committed to working with the provinces and territories to improve Canada's collection, protection, access, sharing, and use of health data, and lay the foundation for a world-class health data system.

- Strategy co-development with provinces and territories was informed by expert advice, with the desired end goal of making it easier for Canadians to access and use their own data, helping health providers deliver better quality care, and making it easier for data to be used to support critical decisions on improving health systems and public health.

If pressed on working with provinces and territories

- Our health system is experiencing significant challenges. It's important that we work together to support improved health data management to achieve better outcomes for Canadians, and to strengthen public health responses.

- There are numerous barriers to achieving a much-needed world-class health data system that can only be addressed through federal, provincial and territorial governments working together. For example, when someone moves from one province or territory to another, they should be able to bring their health data with them, so that their healthcare providers have the information they need to provide the quality of care that everyone in Canada deserves.

- The Government of Canada intensively collaborated with provinces and territories to finalize the draft Pan-Canadian Health Data Strategy and identify common commitments and actions that can advance the use of health data and digital health tools to meet Canadians' needs.

- We are disappointed by the outcome of the November Health

Ministers' meeting and subsequent statements made by provincial

and territorial Premiers. However, our government remains ready to work with provincial and territorial governments to further discuss health priorities, actions and measurable results to improve our health system using health data more effectively.

If pressed on links to health priorities and health data

- The five priorities announced by the Minister of Health in March 2022 included using modern health data and digital health more effectively in Canada. Health data was reiterated as a priority at the November 2022 FPT Health Ministers Meeting.

- Our Government is committed to advancing health priorities, actions and measurable results to improve public health responses and health services for all Canadians.

- Reliable, timely, and relevant health data are crucial to inform decision-making during public health events and drive progress in improving access to care. What is measured matters.

- Our Government remains committed to working with provinces and territories to overcome health data management barriers that slow progress on these priorities, and to improve long-term health benefits for people in Canada.

If pressed on public engagement

- Canadians should have a say in how their health data is used, so consultation and engagement are key for this work.

- Our Government has and will continue to engage with Canadians to solicit their views on how health data can serve them better, both during and between public health events.

If pressed on recommendations in the final report of the Expert Advisory Group

- In its final report, the Expert Advisory Group (EAG) recommended governments work together to expedite the creation of a person- centred, world-class health data system.

- The advice contained in the latest report of the EAG has been considered by the Government of Canada, provinces and territories

and our health data partners throughout the co-development of the Pan-Canadian Health Data Strategy.

If pressed on privacy

- Our Government knows that Canadians value the privacy of their health information and want it to be appropriately safeguarded.
- Canadians also expect that their data be used to inform public health measures, stimulate research on new treatments, and improve our health care systems.
- Our Government's approach to strengthening health data collection, access, sharing and use recognizes Canadians' rights to have their personal information protected while benefiting from the insights that can be generated by sharing it.

If pressed on Budget 2022 commitments

- Our government recognizes how important it is to be able to effectively

anticipate and respond to public health risks that threaten the health and safety

of Canadians. It is crucial to take immediate steps to improve our surveillance and data capabilities so we are better able to detect and respond to public health events and emergencies in the future.

- That is why the federal government has committed to supporting the Public Health Agency of Canada to strengthen key surveillance and risk assessment capacities.
- In addition, the federal government has committed to work with provinces and territories to ensure that the health care system is underpinned by health data that supports system improvements and Canadians' access to their own personal health records.

Background

Pan-Canadian Health Data Strategy

Health data (which encompasses public health, health system and population health data) are collected by numerous organizations and governments. However, as SARS and COVID-19 have demonstrated, there are persistent and important gaps in data collection, access, sharing and use that cost lives and negatively impact personal, health professional and system-wide health decision-making. Overall, these impacts reduce health outcomes for Canadians.

In December 2020, the Government of Canada, in collaboration with provinces and territories, began developing a Pan-Canadian Health Data Strategy. In the May 2021 Office of the Auditor General report it was recommended that Canada create a Pan-Canadian Health Data Strategy (PCHDS) to address foundational issues related to health data in Canada. The November 2021 Speech from the Throne underlined the importance of improving data collection across health systems to inform future decisions and ensure the best possible health results for Canadians. In the December 2021 Office of the Chief Public Health Officer report, A Vision to Transform Canada's Public Health System, it was recommended that Canada create a world-class public health system and noted that the PCHDS is an actionable idea to improve public health tools. The December 2021 Mandate Letter for the Minister of Health acknowledged the need for a health data system that is timely, usable, open-by-default, connected, and comprehensive.

Most recently, the Minister of Health was tasked through the mandate letter and the Federal Budget 2022 to establish the foundation of a world- class health data system so that all Canadians have meaningful, timely access to their own health information.

The goal of the Strategy was to identify commonly-supported, implementable solutions to address persistent barriers to the use of critical health data. Once identified, and when supported by provinces and territories, Canadians would be better served by their own health data, accelerating the transformation towards person-centred health care systems and strengthening public health decision-making during and between health emergencies.

At the November 8, 2022 FPT Health Ministers Meeting, the Federal and PT Ministers of Health were unwilling to endorse the Strategy. The Federal

Minister of Health reiterated the Government of Canada's commitment to

improve health services for all Canadians, including using health data and digital health more effectively.

Pan-Canadian Health Data Strategy Engagement

Canadians should have a say on how their health data is used, therefore engagement is key for this work. The Government of Canada has engaged with experts and patient advisors during the development of the Strategy. Informed stakeholder consultations started in summer 2021 and continued into fall 2021. Engagement sessions focused on overcoming the identified root causes impeding the better use of data. We will continue to ask Canadians for their feedback as we implement the Strategy across the country.

The Government of Canada will also continue to work with First Nations, Inuit and Métis partners, as well as provinces and territories, to support Indigenous data sovereignty by building connections between national and regional Indigenous health data governance and the Strategy.

Expert Advisory Group

A PCHDS Expert Advisory Group (EAG) was established in fall 2020 to provide advice and guidance to inform F/P/T co-development work. Specifically, the EAG was mandated to provide advice on:

- strategic direction for the use of health systems, population, and public health data to improve the health of Canadians;
- principles to guide the creation, collection, storage, and use of data; and
- a practical and phased roadmap for the implementation of measures to sustainably address areas of greatest opportunity and impact.

The EAG published two reports in 2021. The first report described the systemic barriers to effective health data management while the second report contained recommendations on how to overcome these barriers to optimize the use of data for better health outcomes and more effective public health event management.

The EAG published their third, and final report on May 3, 2022. In the report, the EAG recommends adopting a person-centric approach to health data that gives patients, and their healthcare providers, access to health information in an integrated system – leading to better comprehensive care and an integrated health data system that supports robust public health responses. These recommendations are reflected in the draft PCHDS co-

developed with provinces and territories. The EAG's work has now been

completed.

Indigenous Services Canada (ISC) Health Data Investments

PHAC is working directly with ISC to find alignment and synergies with Indigenous health data initiatives announced in Budget 2021. Access to reliable and culturally relevant data on Indigenous peoples is critical to building a complete portrait of Indigenous lived experiences, unmasking inequalities, and ensuring delivery of effective policies and programs.

Engagement will enable alignment with Indigenous-led data strategies, which can further self-determination by providing First Nations, Inuit, and Métis Nation governments and organizations with the data they need to support their communities.