

September 24, 2020

## **QUESTIONS AND ANSWERS Agreements for vaccine candidates**

### **How many vaccine agreements have you signed to date?**

Including the agreement we've announced today, we have now signed agreements for six promising COVID-19 vaccine candidates.

Earlier this week, we have announced an agreement with Sanofi/GSK. We previously announced agreements with Pfizer and Moderna on August 5, 2020, as well as agreements with Novavax and Johnson & Johnson on August 31.

### **Why can't you disclose details of these agreements? Don't Canadians deserve to know how much this is costing?**

In addition to the agreements we have already signed, we are actively pursuing additional COVID-19 vaccine candidates.

As such, and in order to protect our negotiating position and commercially sensitive pricing information, we cannot disclose details of specific agreements at this time.

The Government of Canada has, to date, allocated approximately \$1 billion to secure access to vaccine candidates. This includes some upfront payments that the pharmaceutical companies require to support vaccine development, testing and at-risk manufacturing. While not recoverable, this investment guarantees Canada's earliest possible place in production runs.

Subsequent payments are contingent on the vaccines passing clinical trials and obtaining regulatory approval. These amounts will depend on which vaccine candidates are successful and the number of doses Canada decides to ultimately purchase.

In line with our commitment to transparency, we will continue to release as much information as possible on all the measures being taken to respond to COVID-19.

### **When are clinical trials going to be finished?**

Suppliers of vaccine candidates should be contacted directly for information about their clinical trials.

### **What happens if the vaccine candidate isn't approved? Do you still have to pay the company?**

The Government is taking action to ensure Canada is prepared to deliver vaccines to its citizens as quickly as possible.

Given the pace of the pandemic and the global race to secure access to a vaccine, Canada has had to make advance payments to vaccine companies to secure access to their vaccines.

These advance payments are key to securing early access to the vaccines, as they fund at-risk manufacturing of early doses that can be distributed at the moment of regulatory approval.

While some of these investments will not be recoverable if some of the vaccine candidates fail in clinical trials, making these advanced payments gives Canada a place in the early production runs.

### **Are you negotiating an agreement with Company X?**

I can confirm that we are in discussions to secure access one other vaccine candidate from Medicago. We hope to have an agreement finalized as quickly as possible.

*If pressed on more details/other companies:*

To protect our negotiating position, we cannot disclose further details at this time.

### **Why has it taken so long for the Government of Canada to sign these agreements, when other countries have been announcing similar agreements for weeks?**

We now have agreements in place for six leading COVID-19 vaccine candidates.

Our progress is similar to other countries, including the United States and the United Kingdom—both of which have secured access to a comparable number of vaccine candidates.

With that said, Canada is well positioned globally to provide Canadians with access to an approved vaccine as early as possible.

### **Who decides what to buy?**

Our approach to vaccines—as has been our entire response to COVID-19—is being directed by the best available science, recognizing that the evidence base is evolving.

In particular, the COVID-19 Vaccine Task Force, which is comprised of vaccine and immunology experts as well as industry leaders, is providing strategic

scientific and technical advice to the Government of Canada on a portfolio of leading international vaccine candidates.

### **Are you negotiating with Canadian suppliers?**

We are pursuing potential vaccines guided by advice from the Vaccine Task Force, with the goal of diversifying our supply sources so we have the best access to safe and effective COVID-19 vaccines when available.

### **What will you do when countries such as the U.S. apply export restrictions?**

We're exploring all options from working with domestic suppliers to partnering with leading international vaccine developers, while building domestic capacities to fight future pandemics.

By supporting vaccine research and development, supporting biomanufacturing requirements for large-scale production, enhancing capacity and access for clinical trials, and seeking solutions for domestic capacity, Canada will be in a better position to rapidly access a vaccine once it becomes available, and prepared for any challenges outside its control.

### **How many doses have you procured?**

To date, we have signed agreements for six vaccine candidates that will give us access to up to 282 million doses. This includes:

Single dose:

- Johnson & Johnson – up to 38 million doses

Two dose:

- AstraZeneca – 20 million doses
- Moderna – up to 56 million doses
- Pfizer – 20 million doses, with negotiations ongoing with the company to add options for more
- Novavax – up to 76 million doses (vaccine requires two doses per person)
- Sanofi/GlaxoSmithKline (GSK) – up to 72 million doses

It's important to note that all vaccine candidates must still undergo successful clinical trials and Health Canada authorization before they can be given to Canadians. Some of the vaccines listed above may require more than one dose to be effective, to be approved by Health Canada.

### **Does one dose equal one individual?**

This depends on the particular vaccine. The majority of the vaccine candidates we have secured to date require two doses per person, with the exception of the vaccine from Johnson & Johnson, which requires one dose per person.

**What's the difference between the vaccine candidates these five companies are offering?**

With these six vaccine candidates, we have diversified our potential vaccine supply by securing access to the three main types of vaccine:

1. mRNA (Pfizer, Moderna)
2. Protein Subunit (Sanofi/GSK, Novavax)
3. Viral Vector (Johnson & Johnson, AstraZeneca)

**How does the partnership with Sanofi/GSK work?**

This particular vaccine candidate uses the same recombinant protein-based technology as one of Sanofi's seasonal influenza vaccines, with GSK's established pandemic adjuvant technology. Adjuvants are vaccine components which help to produce a stronger immune response.

In July, Sanofi and GSK announced a collaborative effort with the U.S. government to accelerate the development and manufacturing of this vaccine.

**When will Canada start receiving deliveries of vaccines?**

Globally, we are in the discovery and development stage, but moving toward the formulation, scale-up and production stage. We are all anxious to deliver safe and effective vaccines to Canadians as soon as possible, and that is exactly what we are working on every single day.

As you are aware, clinical trials, which are in the development phase, are ongoing and any vaccines require Health Canada approval. While Health Canada will be expediting the review of vaccines for COVID-19, this will be done without sacrificing standards for safety, efficacy and quality. In particular, it will be important that there is evidence from large clinical trials to demonstrate that the vaccines can provide protection from infection.

We are working on all possible fronts, with a diverse range of leading developers and varying vaccine types, while getting involved in the vaccine development process at the trial stage to secure Canada's position.

**Q. Did the government buy any VanRx machines? If so, where and when will these machines go?**

One machine was purchased by the National Research Council of Canada (NRC) and two machines were purchased by the Public Health Agency of

Canada (PHAC). The NRC machine has already been delivered and is being installed. It was purchased before the Vaccine Task Force was established. The PHAC machines will be delivered in 2021, between the end of January and May. The Vaccine Task Force provided advice on these machines. Where these machines will go will be determined in the months ahead. Chris Procyshyn recused himself from all discussions, deliberations and recommendations related to the purchase of the fill and finish machines.

**Did any members of the Vaccine Task Force recuse themselves from the Sanofi recommendation due to a conflict of interest? (Vaccine Task Force Lead)**

At prior meetings, Co-chair Mark Lievonen declared he was previously employed by Sanofi Pasteur (past president, retired in 2016) and that he holds shares, with a current value of only \$500. Mr. Lievonen is no longer active with the company and, in an abundance of caution recused himself from any discussions, deliberations, and recommendations related to Sanofi Pasteur.

Mr. Rovinski worked for Sanofi Pasteur over 20 years ago. Once again, in an abundance of caution, he recused himself from any discussions, deliberations, and recommendations related to Sanofi Pasteur.

Member Michel de Wilde, who has previously worked for Sanofi Pasteur, did not attend the meeting where the Sanofi recommendation was made.

Other interests were identified that members agreed were not considered conflicts:

- Dalhousie University, where Co-chair Joanne Langley is a Professor of Pediatrics and Community Health and Epidemiology, has received funds from Sanofi Pasteur in the past for vaccine studies, and has a challenge unit named after Sanofi Pasteur. She has no personal financial interests in the arrangement.
- Ten years ago, member Sylvia van den Hurk held a small contract with Sanofi Pasteur regarding preclinical studies.

**Q. How are the Vaccine Task Force's recommendations made to the Government of Canada? (ISED Lead)**

The Vaccine Task Force (VTF) has been providing advice on prioritizing leading vaccine projects in Canada; identifying international vaccine candidates of interest to Canada and considering options to manufacture the most promising COVID-19 vaccines.

Recommendations from the VTF are made to the Government of Canada via the Minister of Health and the Minister of Innovation, Science and Industry.

The VTF has also reviewed the most advanced international vaccine candidates and related available data and recommended to the Minister of Health, Minister of Innovation, Science and Industry, and Minister of Public Services and Procurement Canada a prioritized list for procurement. This advice has been used to inform Ministers' decisions on Canada's procurement strategy for COVID-19 vaccines.

**Q. Did Chris Procyshyn, Chief Executive Officer and co-founder of Vanrx Pharmasystems, recuse himself from discussions around the recommendation of the purchase of the Vanrx biomanufacturing machinery?**

Vaccine Task Force member Chris Procyshyn, Chief Executive Officer and co-founder of Vanrx Pharmasystems, formally recused himself from the discussion related to the potential purchase of Vanrx biomanufacturing machinery. He did not participate in any discussions related to the drafting, review or approval of the recommendation related to the purchase.

The Task Force has a robust conflict of interest process in place, which is consistent with the practices of other volunteer external advisory bodies to government and embodies international best practices. When assessing projects for funding, members are required to be transparent about their interests and potential for conflict. Those with conflicts must formally recuse themselves. Each Task Force member signed a Conflict of Interest and Confidentiality Agreement, and completed and signed a Conflict of Interest Declaration form. At the start of each meeting, the co-Chairs ask members to declare any conflicts with the agenda items of that meeting and ask members who have a disqualifying conflict to recuse themselves from that discussion. The conflict of interest protocol is publicly available on the National Research Council's (NRC) website.

Given the significant interest in the Vaccine Task Force's process, the Task Force is taking the exceptional step of publishing a [registry of declared interests](#). The registry will be updated on the NRC's website following each vaccine announcement by the government that is based on a Task Force recommendation.

**Q. Dr. Gary Kobinger recently resigned from the Vaccine Task Force, saying the Government of Canada is not being transparent in its decision making? How do you respond to this?**

The government thanks Dr. Kobinger for his participation and public service as a member of the COVID-19 Vaccine Task Force.

As experts and industry leaders, Task Force members provide invaluable insight -- all on a volunteer basis -- to help the government make sound evidence-based decisions to protect the health and safety of Canadians during the pandemic.

Since June 2020, the Task Force and its Bio-manufacturing Sub-Committee have reviewed and provided advice on numerous domestic vaccine and bio-manufacturing proposals and international vaccine candidates.

Task Force members have committed to ensuring transparency and to recusing themselves from providing advice on projects where there is a conflict.

In 23 instances, a member of the Task Force declared a conflict of interest pertaining to a specific proposal, or candidate, and formally recused themselves - - not participating in deliberations or the formulation of advice.

The conflict of interest protocol available on the NRC website is in line with standards for other volunteer external advisory bodies across government, and embodies international best practices.

**Are you worried that because other nations like the U.S., the UK and Australia are further advanced in the vaccine procurement process and have promising domestic candidates, Canada will be as far behind in receiving the allocation of vaccines as we were with PPE?**

I can tell you that we are currently working quickly to negotiate advanced purchase agreements with a range of leading vaccine developers to secure supply for Canadians as quickly as possible.

We have already secured agreements for six vaccine candidates from Pfizer, Moderna, Novavax, Johnson & Johnson, Sanofi/GSK and AstraZeneca, and at this time we are actively pursuing another vaccine candidate from Medicago.

By supporting vaccine research and development at this stage in the process, supporting biomanufacturing requirements for large-scale production, enhancing capacity and access for clinical trials, as well as seeking solutions for domestic capacity, we are securing Canada's position and ensuring that we are ready.

**Are you considering contracting for the Russian vaccine?**

We are not in discussions for this particular vaccine at this time.

**On September 16, the Head of the Chinese Center for Disease Control and Prevention (CDC) declared that coronavirus vaccines being developed in China could be ready for use by the population in November 2020. Are you considering contracting for Chinese vaccines?**

We are not in discussions for these particular vaccines at this time.

### **Medicago Vaccine Trials (*Health Canada lead*)**

We knew it was critical to invest in research, so that our best and brightest can find therapies, treatments, and a possible vaccine for COVID-19.

On July 9, Health Canada approved a Phase 1 trial of Medicago's vaccine and on July 14, clinical testing of this vaccine began in Canada.

This is the first vaccine from a Canadian company to enter human trials, and we are pleased to support such important research in Canada.

We continue to support the Canadian and international scientific community in their research for treatments and vaccines of COVID-19

*If pressed on Health Canada review:*

This approval followed careful review of the application by Health Canada, and met the necessary requirements for safety and quality.

Health Canada reviewed the submission through its expedited review process for all clinical trials for COVID-19 products.

The department has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

**Which Canadians are going to get the vaccine first? How will you determine priority groups - will you prioritize students and teachers, since schools have reopened, before other sectors fully open up? (*PHAC lead*)**

As has been the case with the distribution of personal protective equipment (PPE) to the healthcare system, we are guided by the direction of public health experts. The Public Health Agency of Canada's National Advisory Committee on Immunization will provide guidance on key populations for early vaccination in the early fall.

**Will the federal government make vaccination mandatory? (*PHAC lead*)**

Although there is currently no vaccine for COVID-19, we are committed to safe and effective vaccines that prevent disease and disability.

Health Canada has a rigorous scientific review system in place to ensure vaccines are safe and effective.



While vaccine recommendations are made at the federal level, the primary responsibility for their administration and delivery falls within provincial and territorial jurisdiction.

None of Canada's provinces or territories currently have a policy of mandatory vaccination for any disease, and mandatory vaccination has never been an approach used in Canada.

*If pressed on mandatory reporting of vaccination:*

Some provinces and territories require mandatory reporting of vaccinations, where parents are required to submit their children's vaccination records.

This provides local public health officials with the information necessary to respond during an outbreak.

**What is the status of procurement for the equipment needed to administer the vaccines?**

The Government of Canada has recently purchased three fill and finish vaccine systems through two contracts with Vanrx, a Canadian manufacturer. These systems are the last portion of a vaccine production line which allows the vials to be filled and finished without human intervention, thus allowing a rapid roll out of vaccines while minimizing waste.

On the recommendation of the Joint Biomanufacturing Subcommittee of the COVID-19 Vaccine Task Force and the COVID-19 Therapeutics Task Force, the Government of Canada has also issued Letters of Intent to SIO2 Materials Science (USA) and Schott-Kaisha (India) for vials and pre-filled syringes, and to ARaymond (France) for vial stoppers and adapters.

We recently signed two contracts with SiO2 for syringes and vials for use in filling vaccines. The vials are anticipated to provide filling for up to 80 million doses.

PSPC is currently in contract negotiation with the other two suppliers.

**Criticism has been levelled at the Government of Canada for engaging in "vaccine nationalism" by engaging in bilateral advance purchase agreements at the expense of greater contributions to multilateral, global solutions, such as the COVAX Facility. How do you respond?**

Canada is committed to global collaboration to end this pandemic. The COVAX Facility is an example of how multilateral cooperation can allow us to accomplish together what none of us could accomplish alone.

The Government of Canada has been engaging with Gavi and other supporting countries on the COVAX Facility, with the aim of developing a mechanism that works for all countries and supports equitable global access to safe, effective, and affordable COVID-19 vaccines, once developed.

On September 18, Canada signed an agreement to participate in the COVAX Facility. This will allow us to diversify our portfolio of vaccine candidates, provide an additional mechanism to donate or sell surplus doses to other nations, potentially secure earlier access to vaccine doses, and reduce the risk of export controls preventing delivery of doses to Canada. This facility allows us to accomplish together what none of us could accomplish alone.

Through this agreement, Canada will also have access to up to 15 million vaccine doses, if required, while supporting equitable global access to safe, effective, and affordable COVID-19 vaccines.

Though we may not end up purchasing vaccines for Canada through the Facility, it is valuable to have this additional option. Ultimately, our decisions to procure vaccine doses for our own use through the COVAX Facility will be informed by the recommendations of the Vaccine Task Force.