Interview request: NML issues, for next Wed

Morrissette, Eric (HC/SC)<eric.morrissette@canada.ca>
Mon 2019-09-23 1:07 PM

To: Robertson, Dylan <Dylan.Robertson@freepress.mb.ca>

Hi Dylan,

As discussed, please find below the Agency's response to your inquiry. If you need anything else, or of there's anything that isn't clear, please let me know.

Protecting the privacy of our employees is of paramount importance, and we will not comment on any individuals or their circumstances. Our response addresses the themes of your questions and where possible, we are providing specific answers.

The Public Health Agency of Canada Canada's National Microbiology Laboratory (NML) is an international renowned, world-class institution that protects the health of the public and carries out science in the public interest. The critical work that NML employees undertake can be demanding, particularly during disease outbreaks or when conducting research to understand dangerous pathogens. NML management is committed to open dialogue with employees; our highest priorities are the physical safety and mental wellness of our staff.

NML scientists and the other experts at NML are highly qualified professionals who conduct or support leading-edge science and research according to professional and organizational codes of conduct. Our processes in our specialized laboratory environment meet the highest standards, including multiple independently verified ISO quality standards, which cover our management and operational practices.

NML employees accomplish their work in collaborative teams composed of experts that span multiple technical, scientific and administrative disciplines. This team-based approach is consistent with a scientific organization where all employees rely on each other, both in carrying out complex work and in supporting each other when workplace challenges arise.

Like any workplace, we encounter challenges and conflicts and individuals may struggle with personal issues. To support managers and employees, we use a range of processes, training and services. Mandatory training in Mental Health First Aid, among other training programs, is in place so that managers and employees have skills to help recognize wellness issues affecting themselves and others, and to connect with the range of services available to them.

We regularly communicate to employees the availability of the Employee Assistance Program—a 24-hour crisis and referral program. It is available to every employee and their immediate family members, and offers services to help individuals cope with personal difficulties that may be affecting their social, mental or physical well-being, and/or their work performance.

Specific Responses

Question 2

The Community Liaison Committee is the NML's connection with the public. The Committee helps ensure regular dialogue and information-sharing on the scientific and operational business of the lab. Transparency is key to public confidence in the NML. The work of this Committee—along with other community relations activities, including open-house events at the lab—support this relationship with the community. Personnel-related matters regarding individual employees are not part of the committee's mandate.

Question 3

The health and well-being of our employees is vital to our workplace culture and that is why we have processes in place. Employee surveys consistently tell us that employees feel that the NML is a respectful workplace and that employees are proud of the work they do. Their responses to the 2018 Public Service Employee Survey indicate that the majority feel that the organization treats them with respect (81%), that individuals in the workplace behave in a respectful manner (80%) and that the organization is doing a good job in raising awareness about mental health in the workplace (81%). Employees further indicate that they are proud of the work they do (89%), that they get a sense of satisfaction from their work (75%), and that they have the tools they need to do their jobs (90%).

In an institution of more than 600 employees charged with preparedness for and response to infectious diseases and biosecurity threats, issues of workplace wellness can arise. Protecting the physical security and mental wellness of

employees is fundamental to the NML's management priorities. Like any organization, we are continuously evolving to respond to circumstances when they arise and to support employee wellness. In recent years, we have put better tools and processes in place, and we will continue to evolve them to meet employee needs.

Based on our core values of respect, innovation, collaboration, communication, and quality and safety, the*NML's Workplace Wellness Policy Statement*—which was signed and endorsed by all directors at the NML— supports the psychological health and wellness of all employees. Our approach is based on dialogue and employee engagement, a principle of the *National Standard for Psychological Health and Safety in the Workplace*. This happens through both formal and informal advisory groups and employee-led committees, all focused on making improvements and responding to the needs of employees.

To further support employee well-being on an ongoing basis, we provide employees with resources for mental health in the workplace, prevention and resolution of harassment, and workplace wellness. Employees have access to counselling and support through the Employee Assistance Program, the Ombudsman's Office, the Informal Conflict Management Services and Internal Disclosure Services teams, the Respect in the Workplace Office, and the Values and Ethics Office. Further, training in Mental Health First Aid, Building Blocks of Respect in the Workplace, Creating a Respectful Workplace, and Values and Ethics in the Workplace for Managers is in place for employees.

Questions 6 and 8

Whether in management, technical or science support roles, staff are selected for positions through processes based on public service staffing policies and procedures, which value fairness and transparency.

Qualifications for positions are explicitly defined. Some positions require PhD-trained scientists; others require skills in science or research management, or highly specialized skills such as bioinformatics, among others. The requirements of each position determine the necessary qualifications.

The specific position you referenced in Question 6 is not a research position, but rather an operational management position. It reports to a director position that requires a PhD. This ensures effective execution of operations within a scientific program.

With respect to question 8, we would like to be clear that this meeting was held to support open dialogue and awareness of the range of tools and supports available to managers and employees when workplace issues arise. No specific workplace issue was discussed. This was an opportunity for senior management of the Public Health Agency of Canada to engage directly with NML managers and staff and to show support in addressing workplace issues, as well as reinforce expectations based on the Values and Ethics Code of the Public Sector.

Question 7

All federal employees must comply with the Values and Ethics Code for the Public Sector. Employees have an obligation to perform their duties safely to protect themselves and others in the work environment from harms.

The *Non-Smokers' Health Act* has been amended to regulate and prohibit the smoking and vaping of cannabis in federally regulated workspaces, including the NML.

Question 9

All employees are supported in fulfilling their responsibilities and in developing their skills through a range of training and learning opportunities. For Research Scientists, we use a standardized Research Scientist Promotion Process, which is conducted annually. Scientists apply to this process, and an independent committee assesses each application according to pre-established criteria. The committee reviews scientists' research and management activities to determine their readiness for promotion. This promotion process is different from the competitive staffing processes used to fill vacant or new positions, including management positions. Science management positions are generally classified as either biologist, research scientist, or research manager positions, depending upon the role of the work unit, seniority of the position, and the required competencies.

Management positions require competencies that reflect the requirements of these jobs. Scientists are not promoted to these positions as a means of increasing their salaries. Rather, public health management positions require many of the same leadership competencies as scientific positions, such as the ability to forge productive collaborations within a team-based environment and to mobilize team members.

Questions 10, 11 and 12

For clarity, the workplace assessment was not an NML-wide review; it was a specific assessment of a non-scientific professional community, representing less than 10% of the NML's workforce. The goal of the assessment was to

understand employees' needs and how to support them. The workplace assessment was conducted as planned. Any adjustments in timing were made in response to requests by staff to accommodate their work schedules and enable good participation. This was worked out through discussion and input from staff, and the assessment proceeded.

The workplace assessment has been completed, and management and staff will begin the dialogue to support implementing its recommendations. This is normal practice and is consistent with our core values of respect and communication.

Exit interviews are an important management tool to identify workplace issues and to make improvements. While they are currently not mandatory, our plan is to make them a systematic part of our management approach.

We have strong and collegial relationships with the various unions representing scientists and other employees at the NML. The positive relationships with local union representatives have enabled open dialogue and joint recommendations on a number of initiatives, such as improving fairness and transparency in staffing. Senior management of the NML meets quarterly with the unions representing its employees to discuss issues and shared concerns. Issues are also raised and discussed on an ad hoc basis and informally throughout the year. Our collaboration with local union representatives is fundamental to our collective support of staff.

Question 13

As we have previously indicated, an administrative matter at the NML resulted in the initiation of an investigation. We will not comment further on this matter.

Question 14

The Government of Canada owns the patents for the rVSV vaccine technology for viral hemorrhagic fever viruses and continues to receive royalties from some of the sales of the Merck-manufactured vaccine. These royalties are deposited into the Consolidated Revenue Fund, and can be used to support other innovative research at PHAC. The NML accesses these funds through the supplementary estimates process.

The VSV-ZEBOV experimental vaccine is the product of more than 10 years of scientific research by NML scientists. The first patents for this vaccine were filed in July 2002; the first paper was published in June 2005.

The discovery of the Ebola vaccine was funded by the Public Health Agency of Canada and the Canadian Safety and Security Program and required collaboration with government departments, investment by private industry and, importantly, international partnerships.

The intellectual property rights for the vaccine belong to the Government of Canada. It has been licensed to NewLink Genetics, and on November 24, 2014, NewLink Genetics and Merck announced their collaboration on the vaccine. They have the responsibility to produce mass quantities and to complete clinical trials for the vaccine.

To date, almost $6 million has been received in royalties.

Question 15

As a part of the Public Health Agency of Canada, the NML supports PHAC in its mandate under the *Public Health Agency of Canada Act* to assist the Minister of Health in exercising or performing the Minister's powers, duties and functions under the *Department of Health Act* in relation to public health (see section 3 of *Public Health Agency of Canada Act*). These public health responsibilities include the protection of the people of Canada against the spreading of diseases; investigation and research into public health, including the monitoring of diseases; and cooperation with provincial authorities, foreign governments, and international organizations with a view to coordinating efforts for preserving and improving public health (see preamble of *Public Health Agency of Canada Act*).

The core activities of the NML are to offer diagnostic and reference testing services, to be national leaders in infectious disease surveillance and outbreak response activities, and to conduct research to better understand diseases. We greatly benefit from having the mandate to conduct research alongside our public health activities, as the knowledge gained or technologies developed in one area can quickly flow into and improve other areas of work for our specialized teams.

Question 16

Like any organization, we are continuously evolving to respond to circumstances when they arise and to support employee wellness. In recent years, we have better tools and processes in place and will continue to change them as new needs emerge. The information we have from employees tells us that the NML is a valued institution and a source of pride for those who work there. While isolated workplace problems occur and are expected within any place of work, there is no evidence that these reflect systemic workplace issues.

Purpose

At the National Microbiology Laboratory (NML) we believe that people are our most important asset and thus their psychological health and wellness is crucial to our organizational success.

The purpose of this policy statement is to illustrate our commitment to establishing a workplace environment that promotes the psychological health and wellness of all employees through the implementation of the Canadian Standard on Psychological Health and Safety in the Workplace in alignment with the NML's core values.

Scope

- This policy statement applies to all those employed by the NML including contractors, students and casual staff.

Goals

- To establish and maintain a workplace environment and culture that supports wellness by decreasing the negative effects of workplace-related psychosocial risk factors.
- To increase employees' knowledge and awareness of psychological health and wellness.
- To reduce stigma around mental unwellness and illness in the workplace.
- To facilitate active participation in initiatives that support psychological health and wellness.

Responsibility

NML Management has a responsibility to:

- Ensure that all employees are made aware of this policy statement.
- Actively support and contribute to the implementation of this policy statement, including its goals.
- Encourage employees to participate in initiatives that support psychological health and wellness.
- Support the Steering Committee in achieving its goals for implementation of the Canadian Standard on Psychological Health and Safety in the Workplace.
- Make suitable learning and training opportunities that support this policy available to employees.

The focus of the NML's workplace wellness initiative is on organizational factors affecting wellness rather than individual wellness. Therefore, individuals are responsible for the following:

- Understanding this policy statement and seeking clarification from management where required.
- Considering this policy statement while completing work-related duties and at any time while representing the NML.
- Supporting fellow employees in their awareness of this policy statement.
- Supporting and contributing to the NML's goal of providing a psychologically healthy and supportive environment for all those employed within all facilities of the NML.
- Taking reasonable care of their own psychological health and wellbeing, including physical health.
- Taking reasonable care that their actions do not affect the psychological health and safety of other people in the workplace.

Monitoring and Review

The NML Workplace Wellness Initiative Steering Committee will review this policy statement annually. Effectiveness of the policy statement will be assessed through regular engagement with employees, Workplace Wellness Initiative Advisory Committee and NML Management.

Signatures

By signing this document I am acknowledging my support for the NML Workplace Wellness Policy Statement.

Name	Signature	Title
Matthew Gilmour		Director General
Steven Guercio		Executive Director
Mette Cornelisse		Deputy Executive Director
Anil Nichani		Director Enteric Diseases
Catherine Robertson		Biorisk & Occupational Safety Services
Cindi Corbett		Director Bacterial Pathogens
Dorothea Blandford		Director Office of Intellectual Property Management & Business Development
Florence Lopuck		Director Program Service & Support
Garrett Sorensen		Director Scientific Informatic Services
Grant McClarty		Director Science Technology Core & Services
Guillaume Poliquin		Senior Medical Advisor
Jan Trumble Waddell		Director Risk Management
Kelly Keith		Director Science Support & Client Services
Michael Drebot		Director Zoonotic Diseases & Special Pathogens
Nick Ogden		Director Public Health Risk Sciences
Paul Sandstrom		Director National HIV & Retrovirology Laboratory
Shamir Nizar Mukhi		Director Canadian Network for Public Health Intelligence
Ted Kuschak		Director Network & Resilience Development
Tim Booth		Director Viral Diseases
Todd Coulter		Director Facility & Property Management Division

Final Date of Approval: _____

ORDER/ADDRESS OF THE HOUSE OF COMMONS
ORDRE/ADRESSE DE LA CHAMBRE DES COMMUNES

NO.-N°	BY / DE	DATE
Q-1155	Ms. Duncan (Etobicoke North)	April 16, 2015 / 16 avril 2015

RETURN BY THE LEADER OF THE GOVERNMENT IN THE HOUSE OF COMMONS
DÉPÔT DU LEADER DU GOUVERNEMENT À LA CHAMBRE DES COMMUNES

Signed by Mr. Tom Lukiwski
PRINT NAME OF SIGNATORY
INSCRIRE LE NOM DU SIGNATAIRE

SIGNATURE
MINISTER OR PARLIAMENTARY SECRETARY
MINISTRE OU SECRÉTAIRE PARLEMENTAIRE

JUN 0 3 2015

(TABLED FORTHWITH / DÉPOSÉ AUSSITÔT)

JUNE 3, 2015

SESSIONAL PAPER
DOCUMENT PARLEMENTAIRE
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HOUSE OF COMMONS
CHAMBRE DES COMMUNES

Q-1155 — April 16, 2015 — Ms. Duncan (Etobicoke North) — With respect to the Ebola vaccine developed at the National Microbiology Laboratory (NML): (a) on what date did research for the vaccine begin; (b) what are the names of the scientists involved in the research, and what are their positions; (c) why was the vaccine research initially being undertaken; (d) was the research undertaken at any time in relation to anti-bioterrorism, and, if so, during what periods and with what specific mandate; (e) who provided funding for the research and development of the vaccine; (f) was the Government of Canada the only contributor to the research and development fund; (g) how much funding did the government provide, broken down by (i) percentage, (ii) department, (iii) date, (iv) dollar amount of contribution; (h) on what date was a robust immune response demonstrated to the vaccine; (i) on what date were research findings published and in what journal, and, if not, why not; (j) on what date was the vaccine patented and when was the initial patent application brought; (k) in which countries is the vaccine patented; (l) during what specific time period was the vaccine produced, (i) how many vials were produced, (ii) who was informed of this production, (iii) how were they informed; (m) was there a competitive process to sell the licensing rights or other entitlements relating to the vaccine; (n) if the process in (m) was created, (i) who developed the criteria for the licensing rights or other entitlements, broken down by position and department, (ii) what were the criteria to obtain the licensing rights or other entitlements, (iii) on what date was the competitive process launched, (iv) how many companies bid for the rights, (v) which companies bid for the rights and on what dates, (vi) how did NewLink Genetics (including Bioprotection Systems Corporation) meet the criteria for the licensing rights or other entitlements; (o) on what date was NewLink Genetics awarded the rights or entitlements; (p) what specific experience did NewLink Genetics have with vaccines, specifically when it comes to manufacturing capacity; (q) what of NewLink Genetics products had reached the point of commercial production at the time of its bidding and purchase of the rights; (r) on what date did NewLink Genetics purchase the rights or entitlements from the Public Health Agency of Canada (PHAC), and for what cost; (s) as part of the licensing agreement, was NewLink Genetics expected to meet any milestones by any particular dates, if so, when, and, if not, why not; (t) as part of the licensing agreement, what percentage royalties would NewLink Genetics pay Canada on any sales of the vaccine; (u) to date, how much income has the government obtained from licensing the vaccine, broken down by (i) up-front payments, (ii) milestone payments, (iii) any other payments; (v) did any of the NML or PHAC scientists/staff have any associations or links or monetary or proprietary interests or any other association with NewLink Genetics, and, if so, what are they; (w) did Canadian officials and the licensee meet annually in face-to-face meetings as required by Article 7.9 of the license agreement, and, if so, for all meetings, what is (i) the date, (ii) location, (iii) the name of all persons in attendance; (x) on what date did NewLink Genetics begin clinical trials of the vaccine; (y) how long was the delay between the onset of the commercial relationship with NewLink Genetics and start of clinical trials, broken down by (i) days, (ii) months, (iii) years; (z) what reason was given for the delay in (y); (aa) did the government question the progress of the clinical trials, if so, on what specific dates, and, if not, why not; (bb) in Canada's licensing agreement with NewLink Genetics, did Canada have the right to let other manufacturers make the vaccine for use in other countries "for compassionate care purposes" if NewLink had not received regulatory approval for the vaccine in the target country; (cc) did anyone in Canada urge the government to terminate its agreement with NewLink Genetics, and, if so, (i) who did so, (ii) on what dates, (iii) why; (dd) did anyone outside Canada request that Canada cancel NewLink's rights under the license, and, if so, (i) who did so, (ii) on what dates, (iii) why; (ee) did the government terminate the agreement, if so, why, and, if not, why not; (ff) if the government terminated the agreement with NewLink Genetics, would Merck have paid the government the $30 million up front and $20 million once larger formal trials begun that went to NewLink Genetics, and would the government have been eligible to receive royalties on sales in certain markets; (gg) did the government approve of NewLink Genetics sub-licensing the vaccine to Merck; (hh) on what date did the government pay for IDT Biologika, to manufacture approximately 1 500 vials of the vaccine suitable for human trials, (i) how much was paid, (ii) was the Department of Defence involved, and, if so, why, (iii) did the Department of Defence contribute any funds; (ii) on what date did the Ebola outbreak begin in West Africa; (jj) on what date did the government reveal it had in storage an experimental vaccine that might be of use in combating the epidemic; (kk) on what date did the government offer vaccine to the World Health Organization (WHO); (ll) how many vials were sent to the WHO by the government, (i) on what date did the vials arrive, (ii) were there any delays; (mm) what are the results of the eight, phase I clinical trials in terms of (i) safety, (ii) immunogenic response, (iii) dose strength for phase 2/3 clinical trials; (nn) on what date did phase 2/3 clinical trials begin in Guinea, Liberia, and Sierra Leone; and (oo) what was the government's involvement overall, broken down by (i) expertise, (ii) funding, (iii) personnel, (iv) other?

INQUIRY OF MINISTRY
DEMANDE DE RENSEIGNEMENT AU GOUVERNEMENT

PREPARE IN ENGLISH AND FRENCH MARKING "ORIGINAL TEXT" OR "TRANSLATION"
PRÉPARER EN ANGLAIS ET EN FRANÇAIS EN INDIQUANT "TEXTE ORIGINAL" OU "TRADUCTION"

QUESTION NO./Nº DE LA QUESTION	BY / DE	DATE
Q-1155	Ms. Duncan (Etobicoke North)	April 16, 2015

REPLY BY THE MINISTER OF HEALTH
RÉPONSE DE LA MINISTRE DE LA SANTÉ

Signed by the Honourable Rona Ambrose

PRINT NAME OF SIGNATORY
INSCRIRE LE NOM DU SIGNATAIRE

Rona Ambrose

SIGNATURE
MINISTER OR PARLIAMENTARY SECRETARY
MINISTRE OU SECRÉTAIRE PARLEMENTAIRE

QUESTION

With respect to the Ebola vaccine developed at the National Microbiology Laboratory (NML): (a) on what date did research for the vaccine begin; (b) what are the names of the scientists involved in the research, and what are their positions; (c) why was the vaccine research initially being undertaken; (d) was the research undertaken at any time in relation to anti-bioterrorism, and, if so, during what periods and with what specific mandate; (e) who provided funding for the research and development of the vaccine; (f) — **See full text of the question attached.**

REPLY / RÉPONSE

ORIGINAL TEXT / TEXTE ORIGINAL [X]
TRANSLATION / TRADUCTION [ ]

Public Health Agency of Canada and Canadian Institutes of Health Research

(a) Research on the VSV Ebola vaccine began at the National Microbiology Laboratory in 1999.

(b) Over the years, there have been many scientists involved in the development and testing of the VSV Ebola vaccine. The three original scientists named on the patent were Drs. Heinz Feldmann, Steven Jones and Ute Stroeher.

(c) While viral haemorrhagic fevers (Ebola, Marburg, Crimean-Congo, etc.) are not endemic to Canada, international travel provides the opportunity for the introduction of these diseases via infected individuals. Canadian researchers understood that having a safe and effective treatment at the ready would be important for better Canadian public health and security in addition to helping address these outbreaks at source. Moreover, the novel technologies and methods used to create treatments and vaccines against aggressive viruses such as Ebola could potentially be applied to less virulent pathogens. The cascading effects of Ebola research at the Agency's National Microbiology Laboratory may help Canada stop the next pandemic and could directly contribute and help shape the future development of better therapeutics to fight a range of new and emerging pathogens.

(d) Beginning in 2005, the Defence Research and Development Canada (DRDC)-led Research and Technology Initiative (CRTI) provided the Public Health Agency of Canada with funding to further develop and then manufacture a pharmaceutical grade version of the vaccine for use in clinical trials. The Chemical, Biological, Radiological-Nuclear (CBRN) CRTI was a federal program led by DRDC, which has now been integrated as part of the Canadian Safety and Security Program, also led by DRDC in partnership with Public Safety Canada. This initiative was tasked with seeking out science and technology solutions to help defeat CBRN threats. This included investigating medical countermeasures against threats such as Ebola.

(e) The Public Health Agency of Canada and DRDC.

(f) The Government of Canada (Public Health Agency of Canada and DRDC) were the direct funders. However, other organizations also undertook research that contributed to the development of the vaccine.

(g) (i) 100%
(ii) Public Health Agency of Canada $3.5M; DRDC $1.8M
(iii) over a period of more than 10 years
(iv) $5.3M

(h) Published research in 2005 showed that early animal trials showed a robust immune response as early as 14 days after vaccination.

(i) Research findings were published in *Nature Medicine* on June 5, 2005 and have been published in multiple scientific publications since.

(j) The provisional patent was filed on July 26, 2002 and issued on January 13, 2010 (Europe), September 6, 2011 (USA) and November 12, 2013 (Canada).

(k) The Public Health Agency of Canada has been granted Canadian, European and U.S. patents.

(l) The vaccine was released in January 2014; development work was ongoing from 2008 to 2013.

(i) 1506
(ii) Departments involved in the CRTI (referred to in response to (d))
(iii) Through the CRTI update meetings

(m) A solicitation process was undertaken to identify possible licensees in accordance with the Guiding Principles for the Management of Intellectual Property established within the Government of Canada through the Federal Partners in Technology Transfer[a].

(n) (i) The criteria for licensing the rights were developed by the Public Health Agency of Canada in conjunction with Justice Canada.

(ii) In keeping with the Guiding Principles for the Management of Intellectual Property in accordance with the Guiding Principles for the Management of Intellectual Property, the criteria for licensing rights were based on maximizing socioeconomic benefits to Canadians, on advancing government priorities and on fulfilling the mandate of the Public Health Agency of Canada.

(iv) The process used for facilitation of licensing VSV-EBOV began upon the filing of the provisional application for the patent (July 2002).

(v) One.

(vi) BioProtection Systems (now a wholly-owned subsidiary of New Link Genetics) was the sole entity that approached the Agency with a request to license the rights in May 2007.

(vii) As per standard practice, a prospective licensee needs to both agree to the terms of a license established by the Public Health Agency of Canada, as well as have a business plan which shows a probability of operationalizing the product / technology being licensed. BioProtection Systems met both of these criteria, as well as the ability, in a period of time where there was no demand for the product, to collaborate with the Agency in further developing the technology, pursuing regulatory approval and establishing conditions for vaccine lot production.

(o) This technology was licensed to BioProtection Systems Corporation in May 2010.

(p) BioProtection Systems Corporation had the corporate capabilities to develop the VSV-EBOV vaccine into a fully regulatory-approved product. BioProtection Systems Corporation had a seasoned, experienced executive team with vast experience in biotechnology research. Further, the company had experienced staff in the field of special pathogens.

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[a] See *Federal Partners in Technology Transfer Annual Report 1997* at http://www.fptt-pftt.gc.ca/pdf/annual_report97_e.pdf for the full list of Guiding Principles for the Management of Intellectual Property.

(q) The products had not reached the point of commercialization at the time of bidding.

(r) This technology was licensed to BioProtection Systems Corporation in May 2010. It has been publicly reported that $205,000 was paid for the license. BioProtection Systems Corporation did not purchase the rights or entitlements; they licensed the rights. The Government of Canada maintained full intellectual property rights.

(s) Yes, BioProtection Systems Corporation was expected to meet milestones over the term of the license agreement.

(t) The percentage of royalties is based on both commonly accepted industry practices as well as on market conditions at the time the license was negotiated. The Government of Canada maintained full intellectual property rights and royalties received would be reinvested in the Public Health Agency of Canada's scientific researchers.

(u) To date, the Agency has received in excess of $6.0 M. The specific details are subject to confidentiality obligations.

(v) No.

(w) As per Article 7.9 of the license agreement, annual meetings took place between Canadian officials and the licensee.

(x) The Public Health Agency of Canada's Ebola vaccine, VSV-EBOV, began Phase I clinical trials on October 13, 2014 at the Walter Reed Army Institute of Research and the Clinical Trials Center of the Translational Medicine Branch in Silver Spring, Maryland, United States.

A parallel Canadian Phase I clinical trial for the same vaccine (VSV-EBOV) began on November 12, 2014. The trial is being led by the Canadian Immunization Research Network and is taking place in Halifax, Nova Scotia. Additional clinical trials are taking place in Africa and Europe and also started in late 2014.

(y) Clinical trials began 4 years, 5 months and 9 days after the establishment of the commercial relationship. The Government of Canada does not characterize this period of time as a delay; rather it is the outcome of much work to develop a manufacturing process and produce clinical grade vaccine, which ultimately enabled a response to global circumstances urgently requiring vaccines and treatments.

(z) Please refer to the response to (y).

(aa) The government worked very closely with BioProtection Systems Corporation and IDT Biologika in respect of the development of the manufacturing process and subsequent manufacture of clinical trial lot of vaccine. The Public Health Agency of Canada was aware of the timelines and progress, and the technical reasons for the time it took to undertake trials.

(bb) Canada retained carve-out provisions under the license agreement that enabled it to make or use the vaccine for specific compassionate care purposes in the event the vaccine had not received regulatory approval for its use in target countries.

(cc) (i) and (ii) As reported in media, in the fall of 2014, Professor Amir Attaran, Canada Research Chair in Law, Population Health and Global Development Policy, Faculties of Law and Medicine, University of Ottawa urged the government to terminate the agreement. See articles at: http://www.macleans.ca/news/canada/canada-urged-to-end-ebola-vaccine-licence-transfer-rights-to-bigger-firm/ and http://www.ctvnews.ca/health/canada-urged-to-cancel-ebola-vaccine-licence-transfer-rights-to-bigger-company-1.2062134.

(iii) Please refer to the response to (cc) (i) and (ii).

(dd) Not to the knowledge of the Government of Canada.

(ee) The government did not terminate the agreement because the company was not in breach of contract.

(ff) The government cannot speculate on this response.

(gg) The government supported the sub-licensing of rights by BioProtection Systems Corporation.

(hh) As the manufacturing of the vaccine was funded by DND, the Public Health Agency of Canada cannot provide an answer to this question.

(i) $877,422.48 CAD
(ii) Yes, as per response to question (d), the DRDC-led CRTI program provided the Public Health Agency of Canada with funding to further develop and then manufacture a pharmaceutical grade version of the vaccine for use in clinical trials.
(iii) Yes, the Department of National Defence provided the total funding for the manufacture of the clinical grade vaccine.

(ii) Retrospective studies indicate that the index case in the West Africa Ebola epidemic developed symptoms on December 26, 2013, in Guinea. The World Health Organization (WHO) publicly announced the outbreak of Ebola virus disease in Guinea on its website on March 23, 2014. On August 8, 2014, the Director General of the WHO declared the Ebola outbreak in West Africa a Public Health Emergency of International Concern.

(jj) On August 12, 2014, the Government of Canada announced that it was donating 800 – 1000 vials of its experimental Ebola vaccine held at the National Microbiology Laboratory in Winnipeg to the WHO in its role as the international coordinating body in response to the Ebola outbreak in West Africa.

(kk) On August 12, 2014, the Minister of Health spoke to Dr. Margaret Chan, Director General of the WHO, and offered the experimental vaccine as part of Canada's ongoing commitment to support its international partners in responding to the outbreak. The experimental vaccine was donated to the WHO in its role as the international coordinating body in response to the Ebola outbreak in West Africa. The WHO, in consultation with partners, including the health authorities from the affected countries, is guiding and facilitating the distribution of the vaccine.

(ll) In October 2014, the Government of Canada shipped 800 vials of its experimental Ebola vaccine to the WHO in Geneva, fulfilling the Government's vaccine donation commitment to the ongoing Ebola outbreak in West Africa.

(i) The vaccine was sent in three separate shipments as a precautionary measure in the event that there was an accident during shipping, such as a temperature control failure. The vaccine must be packed in dry ice and kept at -80 degrees Celsius.
- The first shipment of the vaccine arrived in Geneva on October 22, 2014.
- The second shipment arrived on October 23, 2014.
- The last shipment was sent on October 28, 2014.

(ii) There was no delay in shipping the vaccine. The vials were the property of the WHO on the date of this donation and the Government of Canada shipped them as soon as requested.

(mm) (i) Phase I clinical trials showed that the vaccine is well tolerated. No serious adverse events have been reported. A few volunteers in the trials in Geneva, Switzerland, reported temporary arthritis with no evidence of auto-immunity. This resulted in a halt to the Geneva trial so that safety monitoring and oversight could be strengthened. The trial restarted in January 2015.

(ii) Phase I clinical trials showed that the vaccine does create an immune response, with higher doses creating a stronger immune response.

(iii) The dose strength being used in the Phase 2/3 studies was recommended based on some of the published results (http://www.ncbi.nlm.nih.gov/pubmed/25830322). Final dose strength decisions for Phase 2/3 studies have been and will continue to be informed by Phase 1 trials.

(nn) The phase 2/3 study, Partnership for Research on Ebola Vaccines in Liberia (PREVAIL), has been open to volunteers since February 2, 2015. The phase 2/3 study in Guinea was launched on March 7, 2015. On April 14, 2015, Merck confirmed that the phase 2/3 Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE) had been initiated.

(oo) Since 2006-07, the Government of Canada, through the Canadian Institutes of Health Research (CIHR), has invested $661.9K in Ebola research, including $70K in 2013-14 alone.

(i), (iii) and (iv) Expertise, Personnel and Other:

- In response to the Ebola outbreak, Canada is providing expertise in clinical trials (phase I and III), and in developing, administering and launching research funding opportunities and international collaborations.
- In addition to developing Canada's VSV-EBOV vaccine, researchers at the PHAC's National Microbiology Laboratory conducted pre-clinical research which is required for a vaccine candidate to move into clinical trials.
- The National Microbiology Laboratory also provided laboratory support to the Phase 1 clinical trial in Halifax by testing biological samples from study volunteers.
- Currently, Dr. John Spika, from PHAC, serves as the Co-Chair of the Scientific Advisory Group (SAG) for the randomized trial to evaluate Ebola vaccine efficacy and safety in Guinea, West Africa. This group provides advice to the trial sponsor and its primary investigator. The SAG provides external scientific and technical input in the planning, prioritization and review of project activities. Dr. Spika had no role in the trial design and, as is true for all members of the SAG, is blinded to the study results. SAG members are asked to declare any conflicts of interest and are bound by confidentiality.
- Health Canada is the regulatory authority responsible for the review and authorization of vaccines for human use in Canada. To conduct a clinical trial in Canada a sponsor must file a clinical trial application to Health Canada. Health Canada reviews clinical trial protocols to assess the protection and safety of the participants; assesses the quality of the drugs; assures review by Research Ethics Boards; verifies the qualifications of Principal Investigators and monitors and reviews Adverse Drug Reactions.
- As part of the response to the Ebola outbreak, Health Canada has also been assisting the WHO and other national regulatory authorities in the design and review of clinical trials for Ebola vaccines.

(ii) Funding over and above government R&D costs (explained in responses to (e) and(g): Approximately $423K for the phase I trial (CIHR and PHAC) was provided as well as $2.6M for the phase III trial (IDRC, CIHR and DFATD) and $2.4M for the Innovative Ebola Research grants.