UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

Universities Allied for Essential Medicines (UAEM)'s Submission to the Standing Committee on Health for their study on increasing the benefits resulting from federally funded health research, with the goals of lowering drug costs and increasing access to medicines, both in Canada and abroad (M-132).

UAEM is a global, student-driven organisation that promotes systemic reform of intellectual property in biomedical research as a solution to achieve affordable and equitable access to medicines. This brief will outline the role of federally funded health research in Canadian innovation today, the access to medicines crisis in Canada and internationally, and UAEM's approach and proposed solutions for increasing public benefit from federally funded health research.

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The Role of Federally Funded Health Research in Canadian Innovation

Publicly funded research drives the discovery of the most innovative, life-saving medicines. In 2014, Canadian universities invested $13 billion in research and development (R&D), accounting for 40 percent of total Canadian R&D.[1] Canadian research undertaken at publicly funded institutions has led to some of the most important pharmaceutical discoveries of the 20th century, including insulin (life-saving treatment for diabetes), lamivudine (key antiretroviral HIV/AIDS drug) and Rh immunoglobulin (treatment for Rh disease, which is fatal for infants).[2] As the primary generators of scientific research, publicly funded institutions can and must ensure that all Canadians can afford to access the results of their scientific discoveries. Universities especially have the mandate to serve the public good and their policies should reflect that. By changing their licensing practices and placing patients above profits, universities and other publicly funded institutions can choose to commercialize their biomedical discoveries in ways that promote access, not prohibit it.

The Canadian Institutes for Health Research (CIHR) is Canada's main funder of biomedical research. Every year, the CIHR invests $1 billion into more than 13,000 health science researchers and trainees to fund innovative research into both basic and applied science.[3] In April 2017, Canada's Fundamental Science Review Panel released a report calling for the government to increase funding for Canadian research.[4] The government responded by making a bold investment in research in the 2018 budget, with $354.7 million in new funding for the CIHR over the next 5 years.[5] This is a public investment. If Canadians cannot access the results of this investment, it has not served its purpose. Investment in Canadian biomedical research should advance the health of Canadians, not increase the profit margins of pharmaceutical corporations exploiting taxpayer dollars.

As it stands, there are no policies attached to the results of federally-funded innovation that mandate access to affordably-priced products, promote follow-on innovation, and ensure that the value of taxpayers dollars invested ensures returns that benefit society.

Despite the existence of the *Tri-Agency Open Access Policy on Publications*, (CIHR, the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Science and Humanities Research Council (SSHRC)), there is no harmonized policy addressing Global

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[1] "Facts and Stats." Universities Canada. Accessed Feb 8. 2018. Source: https://www.univcan.ca/universities/facts-and-stats/

[2] "Milestones in Canadian Health Research." CIHR. March 2017. Source: http://www.cihr-irsc.gc.ca/e/35216.html

[3] "Health Research for Canadians." Canadian Institutes of Health Research. November 2016. Source: https://www.youtube.com/watch?v=tBL8PJBgbo4

[4] "Investing in Canada's Future - Strengthening the Foundations of Canadian Research." Advisory Panel for the Review of Federal Support for Fundamental Science." 2017. Source: http://www.sciencereview.ca/eic/site/059.nsf/vwapj/ExecSummary_April2017-EN.pdf/$file/ExecSummary_April2017-EN.pdf

[5] "Significant Investments in Budget 2018 will Revitalize Canadian Scientific Research." U15 Group of Canadian Research Universities. February 2017. Source: http://u15.ca/sites/default/files/u15_press_release_-_budget_2018_revitalize_final_0.pdf.

Access Licensing (GAL) of biomedical research. These existing federal agencies do not retain or claim any ownership of intellectual property. Thus, universities and other publicly funded institutions currently commercialize the results of taxpayer-funded research with little transparency, accountability, or oversight.

The federal government's commitment to open access publishing is critical and serves as a basis for extending this commitment downstream, to the translation of the results of publicly funded research. Open access publishing and data sharing enable rapid, widespread dissemination of research results, reduce research duplication and waste, and encourage collaboration, all of which speed scientific advancement. But what is the point of rapid and efficient scientific research, if the resulting products are not accessible to the people who would benefit from them? With no conditions to protect access and promote follow-on innovation attached to the products of federally-funded biomedical research, the risk remains that biomedical innovations developed in our own country will be out of reach for the average Canadian.

Canada's Position in the Access to Medicines Crisis

The World Health Organization (WHO) defines access to medicines as "having drugs continuously available and affordable at public or private health facilities or drug outlets that are within one hour's walk of the population."[6] One-third of the world's population lacks access to basic essential medicines, and the most frequently cited reason for lack of access to essential medicines is unaffordability.[7] Canada must act to lower drug prices, enable competition and accountability for end-product affordability of the results of taxpayer funded research. Here, we provide two current examples of the severe lack of access to life-saving drugs and describe how their patents block patients from accessing the treatment they need.

1) Lack of generic competition keeps life-saving insulin unaffordable for world's majority, 100 years later

Insulin, a life-saving and essential diabetes medication, was developed at the University of Toronto, a publicly-funded Canadian university, yet this essential medication is unaffordable for 50% of people who depend on it to live.[8] The Canadian discoverers sold the insulin patent to their university for a symbolic $1 each, with the vision of ensuring access to this essential medicine.[9] However, the University of Toronto exclusively licensed the right to manufacture insulin to Eli Lilly. Eli Lilly, along with two other major pharmaceutical corporations, have since

[6] "Access To Essential Medicines As Part Of The Right To Health." 2017. World health Organization. Source: http://www.who.int/medicines/areas/human_rights/en/
[7] "2000–2003 Framework For Action In Essential Drugs And Medicines Policy." World Health Organization. 2000. Source: http://apps.who.int/medicinedocs/pdf/whozip16e/whozip16e.pdf
[8] "Fact Sheet 1: Inequities and Inefficiencies in the Global Insulin Market". 2015. Health Action International. Source: http://haiweb.org/wp-content/uploads/2015/11/ACCISS-Fact-Sheet-1-Inequalities-in-Insulin-Market.pdf
[9] "Discovery of Insulin at University of Toronto." 2012. Source: http://heritage.utoronto.ca/insulin

made successive reformulations to maintain patent monopolies on this drug. Today, nearly a century after this transformative discovery was made, 57% of Canadians with diabetes report not adhering to their prescribed treatment because they cannot afford their medication.[10] Globally, the most common cause of death for a child with type 1 diabetes is a lack of access to insulin.[11] The example of insulin pricing is indicative of a broader issue: rapidly increasing cost of medications leads to unaffordability and a lack of access to essential medicines.

2) Patent exclusivity stymies timely development of Ebola vaccine

As the Ebola epidemic raged in West Africa in 2014, the most promising vaccine candidate, developed by Canadian researchers at the Public Health Agency of Canada's National Microbiology Laboratory, sat on a shelf. If the vaccine candidate, now known to be 100% effective in preventing Ebola infection in humans, had been non-exclusively licensed, other manufacturers could have begun testing and developing the vaccine earlier -- even while the original licensee did not respond.

Given that CIHR's mandate is to "*excel...in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system*",[12] Canada needs to rethink its patenting and licensing processes to ensure that citizens--both domestic and international--have access to the essential medicines they need. We can do this by ensuring that all CIHR research grants require end-product affordability where the technologies have been developed using taxpayer funds, and require non-exclusive patent licensing in the majority of licensing situations to promote more rapid and collaborative innovation in Canada, while ensuring a competitive supply of affordable medicines to Canadian patients.

The Health Committee has been tasked with the mission to study ways of increasing public benefit from federally funded health research. In order to do this, we will identify parts of the R&D process that can be improved to elicit significant nationwide and global effects.

What Needs to be Changed and Why

As many as 1 in 10 Canadians cannot afford their prescription medicines.[13] On average, Canadians pay 30% more for medications (both generic and patented) than other OECD countries, excluding the United States.[14] Many of these medicines, unaffordable to both patients

[10] "The Burden of Out-of-Pocket Costs for Canadians With Diabetes." Canadian Diabetes Association. Source: https://www.diabetes.ca/CDA/media/documents/publications-and-newsletters/advocacy-reports/burden-of-out-of-pocket-costs-for-canadians-with-diabetes.pdf

[11] Gale EA. Dying of diabetes. *Lancet*. 2006; 368:1626–1628.

[12] "Funding Overview." CIHR. Source: http://www.cihr-irsc.gc.ca/e/37788.html

[13] "The effect of cost on adherence to prescription medications in Canada." Canadian Medical Association Journal. 2012. Source: http://www.cmaj.ca/ content/184/3/297.

[14] "Comparison of Canadian prices to foreign prices," in Annual Report 2013. Patented Medicine Prices Review Board. 2014. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=938#1765

and governments, were developed in whole or in part with public funds at universities and other publicly-funded research institutions.[15] Despite the vast amount of public capital that contributes to the development of effective and lifesaving treatments, the end products of our research are currently privatized and monopolized. When a new biomedical innovation shows promise, institutions often licence the rights to a biotech company, which typically acquires exclusive rights to further develop and sell the resulting product. This exclusivity is one factor that is driving the price of medicines by limiting competition which typically lowers prices. Exclusive licensing of medications and lack of genetic competition means that patent holders can arbitrarily inflate drug prices, regardless of the cost of R&D (the R&D-to-sales ratio of the pharmaceutical industry in Canada hovers around a shockingly low 5%) and regardless of the effect on Canadians.[16] This increases financial burden on Canada's healthcare system and is an unjust use of valuable taxpayer dollars.

UAEM's Approach and Proposed Solutions for Increasing Public Benefit from Federally Funded Research

We now present UAEM's approach to the problem, using the two lenses of access and innovation.

a. Access

The Health Committee aims to lower drug costs and increase access to medicines, both in Canada and globally. Generally speaking, lowering drug costs will require changes at the licensing level or at the market level, or both. A licensing change is an upstream change in the drug development pipeline. Market price controls, on the other hand, are downstream changes. A licensing change would require non-exclusivity to ensure affordability of the final product. Price controls require imposing limits at the market level that go beyond the work of the Patented Medicines Prices Review Board (PMPRB), the body in charge of regulating Canada's patented drug prices, requiring and taking into account data regarding national public investment in the development of new medicines.

UAEM recommends the adoption and implementation of a "Global Access Licensing" (GAL) framework as a solution to the high prices of publicly funded medicines. This framework is already in use at many Canadian institutions and worldwide. This type of framework would challenge the patent exclusivity and monopoly-based model that is promoted by pharmaceutical corporporations, which currently takes advantage of publicly funded discoveries and drives high drug prices. Adoption of a GAL framework would involve incorporating requirements into funding such as grants for federally funded research, ensuring that the final product is made available at

[15] "Addressing Global Health Inequities: An Open Licensing Approach for University Innovations." Yochai Benkler. Berkeley Technology Law Journal. January 2005. Source: http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=4057&context=fss_papers

[16] "Annual Report 2015." Patented Medicines Prices Review Board. p47. Source: http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2015/2015_Annual_Report_Final_EN.pdf

an affordable price to the public, and providing a mechanism for enforcement.

In Canada, strengthening requirements of federally-funded research grants could help make many medicines more affordable. We recommend that the CIHR make grant funding conditional on the inclusion of patent clauses that guarantee end-product affordability in Canada, with prices no higher than those determined by the PMPRB comparative standards. For products already on the market, or already in development with public R&D funding, conditions should be created that trigger march-in rights, royalty-free rights, or government use in cases where there is exorbitant pricing, anticompetitive, abusive or unfair practices by a patent holder or licensee.

For patients beyond Canada's borders, federally-funded biomedical R&D grants should include terms and conditions that require affordability and availability of products in low- and middle-income countries, such as non-enforcement of patents in these countries so as to allow local, generic competition.

These conditions would have two immediate benefits:

- First, other researchers and innovators, or even organizations and institutions would be able to use the biomedical research to develop the same product. Non-exclusive licensing ensures that several companies can make use of the biomedical research while preventing monopolies that enable the price gouging practices currently seen in Canada and abroad.
- Second, other researchers would be able to use the biomedical research to continue to innovate, using the information to continue to push the research landscape further, potentially developing more treatments at a faster rate than our current system allows.

A GAL condition would be a large stride for Canada in removing cost-related barriers to access to biomedical innovations for the Canadian public. It would also allow Canada to contribute to reducing drug prices outside of Canada, achieving the government goals of increasing the presence of Canadian products in foreign markets and improving the quality of development assistance and aid.

b. Innovation

Biomedical innovation is an essential focus of the federal government's investment in science and technology. A GAL framework would play a part not only in improving access to the health technologies developed with federal public research dollars, but also in ensuring that patents and other intellectual property monopolies do not act as a barrier to further biomedical innovation. While a simple reform, a GAL framework has the potential to positively affect the lives of millions of Canadians and people worldwide by ensuring that they benefit fully from publicly-funded research.

UAEM's second proposed solution is regular assessment of the distribution of CIHR research dollars. This would help ensure that Canada's research priorities are in line with Canadian and global disease burdens. This would better equip Canada's health systems to make progress in challenging national areas like tuberculosis and to improve Canada's standing as an international health champion in providing solutions to international epidemics like Ebola and

antimicrobial resistance.

Given the Canadian government's historical commitment to addressing the access to medicines crisis, including examples such as the Canadian Access to Medicines Regime, this would mark an important point of leadership by Canada on both the domestic and international stage.

Our Solutions in Practice (Global Access Licensing Spotlight)

The solutions that UAEM proposes above are already in practice both nationally and internationally. To effect meaningful change, they require more broad scale implementation by the Canadian federal government.

Canadian institutions have already adopted a GAL framework. Since 2007, the University of British Columbia has committed to implementing Global Access Principles (resembling UAEM's proposed Global Access Licensing Framework)[17],[18]. The University states that improving fair access to technologies will "generate significant social impact" of the research that is being done at the University, extending the impact of research findings to all socioeconomic classes. In this case, the use of GAL in biomedical research enables the equitable pricing of medicines, easing the burden on our healthcare system and promoting access to medicines for all Canadians. Grand Challenges Canada implemented a Global Access Policy in 2012 to protect patient access to end products by ensuring that intellectual property does not act as a barrier to further research. Their Global Access Policy requires one of: "a) a non-exclusive license agreement for the use of intellectual property and other outputs related to the grant; b) a general commitment to global access; and/or, c) a separate global access agreement that will detail how knowledge will be disseminated broadly, how intellectual property and other know-how will be protected in furtherance of global access, and how commercialization will be achieved in accordance with global access, among other things."[19]

GAL is also used outside of Canada. More than 30 universities worldwide have adopted policies on global access licensing, including Yale University and Johns Hopkins in the US, and the University of Oxford and Charité-Berlin in Europe. In Brazil, the province of São Paulo has implemented the São Paulo Provincial Innovation Law, requiring publicly-funded institutions to ensure that inventions relevant to the public interest are not monopolized via exclusive licensing and technology transfer agreements.

As a Champion of Global Access Licensing, Canada Can Take the Global Lead on Public Benefits of Federally-Funded Research

[17] "UBC Global Access Principles." The University of British Columbia. Source: https://uilo.ubc.ca/technology-transfer/ubc-global-access-principles

[18] "Global Access Licensing Framework." Universities Allied for Essential Medicines. Source: https://uaem.org/our-work/global-access-licensing-framework/

[19] "Global Access Policy." Grand Challenges Canada. Source: http://www.grandchallenges.ca/wp-content/uploads/globalaccesspolicy_2012Apr04_EN.pdf

Internationally, the practice of non-exclusive licensing is supported by the World Health Organization (WHO) and, most recently, the UN Secretary-General's High-Level Panel on Access to Medicines. As per UAEM's recommendation, the 2016 High-Level Panel report endorses non-exclusive licensing and strongly encourages national public interest conditions on public grants to research institutions.[20] As one indicator of a specific opportunity where Canada can lead, the 2018 World Health Assembly agenda addressed the global shortage of, and access to, medicines and vaccines.[21] It was decided at the meeting in May that the WHO would draft a "roadmap" to increase access to medicines and vaccines globally, taking into account the impact of intellectual property protection on prices.[22]

UAEM asserts that reform that incorporates a global access licensing policy for publicly funded research would be well received by the international community. This is an unparalleled opportunity for Canada to set a precedent on the international stage, as it would be the first country to legislate that federally funded biomedical research is conditional on non-exclusive, global-access licensing, prioritising affordability. This would demonstrate Canada's commitment to and leadership in equitable access to medicines, starting in Canada and spreading worldwide. Canadian innovation would be affordable to Canadians and people all around the world, with life-saving impact.

Closing Remarks

From the development of insulin in 1922, to the production of an Ebola vaccine in 2014, Canadian labs and researchers have a long legacy of producing groundbreaking biomedical research with international implications. While these discoveries contribute to an ever-growing body of research in Canada, if constituents do not benefit from the CIHR's investments in health research, the work done by our scientists is limited to only those who have the luxury to afford it, despite their taxpayer dollar investments. But life-saving medicines are not a luxury.

The solution to inflated drug prices is clear: non-exclusive global access licensing provides a mechanism for universities and other research institutions to allow multiple developers open access to federally funded biomedical research. This means that medications are produced more cost effectively, distributed to populations more quickly, and ultimately, delivered to Canadians to improve health outcomes. Global access licensing drives down the cost of medications via competition in the drug development space, while keeping patient needs at the

[20] The United Nations Secretary General's High Level Panel on Access to Medicines Report. September 2016. Source: http://www.unsgaccessmeds.org/final-report/

[21] "Agenda." World Health Organisation. May 2018. Source: http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_1Rev2-en.pdf

[22] "WHA Agrees on Drafting of Roadmap for Access to Medicines and Vaccines." May 2018. IP Watch. Source: http://www.ip-watch.org/2018/05/24/wha-agrees-drafting-roadmap-access-medicines-vaccines-us-blasts-compulsory-licences/

forefront. While there are many changes the HESA can make to improve health outcomes for Canadians, integrating global access licensing into the biomedical research landscape fulfils the mandate to, "*increas[e] benefits to the public resulting from federally funded health research, with the goals of lowering drugs costs and increasing access to medicines, both in Canada and globally."* These changes would provide Canadians with increased access to affordable medications, ultimately lowering cost and raising quality of care, within Canada's health care system.