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This submission is a summary of the recently published report: ***UCL Institute for Innovation and Public Purpose (2018) 'The people's prescription: Re-imagining health innovation to deliver public value', IIPP Policy Report, 2018-10. London: IIPP, Global Justice Now, Just Treatment, STOPAIDS.***
Available at: https://www.ucl.ac.uk/bartlett/public-purpose/sites/public-purpose/files/peoples_prescription_report_final_online.pdf
All references can be found in the report.

Abstract

A thriving health innovation system should generate new health technologies that improve public health and ensure access to effective treatments for the people who need them. However, our current health innovation system fails to direct innovations towards the greatest health needs, and is fraught with inefficiencies: when innovation happens, it happens more slowly and at great cost. Driven by profit rather than public health needs, the pharmaceutical sector is incentivised to set high prices and deliver short-term returns to shareholders, rather than focus on riskier, longer-term research which leads to critically needed therapeutic advances. The high prices of medicines are causing severe patient access problems worldwide, with damaging consequences for human health and wellbeing. These are symptoms of an innovation model that is broken. This submission maps the fault lines of this system and sets out principles for a new one. While it does suggest some quick fixes that policymakers can implement in the short term, crucially it proposes concrete policy actions that can be taken in the long term to actively shape and co-create a health system that delivers real public value. The transformative proposals discussed in this submission include:

- **A mission-oriented approach to improving health outcomes**
- **De-linking innovation funding from high prices**
- **Achieving public return through conditionality**
- **Changes to corporate governance: beyond shareholder value**

The proposals are further expanded in the report '*The people's prescription: Re-imagining health innovation to deliver public value', IIPP Policy Report, 2018-10. London: IIPP, Global Justice Now, Just Treatment, STOPAIDS.*

1. Diagnosis: Problems with the current health innovation system

Continuing with business as usual is not an option, as our current health innovation model is expensive, inefficient and unsustainable. The first step to addressing these problems is to diagnose the problems of the system and outline the principles for how our health innovation system can be better designed to build a health innovation model that delivers public health. Our current health innovation system is failing on multiple fronts, affecting both the rate and the direction of innovation. Such failings affect patient health, innovation and the economy:

1a. R&D priorities are not determined by public health needs

A wide range of critical health needs are either not being met or are sidelined, in high-income, middle-income and low-income countries alike. A system driven by profits ignores diseases prevalent mostly in the global south, such as tuberculosis (TB) which kills millions. It also incentivises development of 'me-too' drugs that offer little therapeutic advance and primarily serve to prolong patent protection. In Europe, an analysis of 1345 new medicine approvals between 2000 and 2014 revealed that 51% of newly approved medicines were modified versions of existing medicines and did not offer any additional health benefits. An analysis of the German health technology assessment agency came to a similar conclusion.

1b. Lack of transparency and stifled collaboration

As the major incentive for innovation in our current system, intellectual property rights (IPR) need to encourage innovation rather than stifle it. The fact that patents have been made increasingly hard to license, much broader than the downstream area of innovation, and too easy to extend, has led to patents blocking learning, diffusion and dynamic collaborations. Additionally, a systemic lack of transparency (and public accountability) in the underlying research data and methods, in both pre-clinical and clinical trial stages, has severe implications not only for the research process, but also for patient health. A 2016 meta-analysis of 28 studies documenting clinical trial results found that unpublished documents were much more likely to report the occurrence of adverse events than published ones.

1c. Out-of-reach drug prices

There are no safeguards within the current R&D model to guarantee that medicines – including those developed with public funding (**Table 1**) – are affordable for the patients who need them. Patent monopolies negate competition, allowing companies to charge the price the market will bear. High prices put pressure on national health budgets and have led to rationing of treatments, for example on breakthrough medicines for hepatitis C and cancer in the UK. Pharmaceutical companies argue that prices are proportionate to the intrinsic value of drugs – that is, the costs to society if a disease is not treated or is treated with the second-best therapy available (value-based pricing). According to this argument, higher prices represent more value, with health systems willing to pay now for better future health outcomes from a therapeutic advance. However, this argument obscures the key political-economic drivers of higher prices: short-term financial pressures to increase prices, and monopoly power to set prices at the upper limits of what health systems can bear.

1d. Short-termism and financialisation

Pharmaceutical companies are increasingly focused on maximising short-term financial returns to shareholders. A common tactic is companies buying back their own shares to boost the value of the remaining ones, hence also boosting the value of stock options. From 2007 to 2016, the 19 pharmaceutical companies included in the S&P 500 Index in January 2017 spent US$297 billion repurchasing their own shares, equivalent to 61% of their combined R&D expenditures over this period. The use of these funds to boost shares and options, rather than investing in technology and production, leads to value capture by shareholders at the expense of health advances in the public interest.

Table 1. Key contributions of the Canadian public sector to health innovation

- This year, the Canadian government has taken significant steps to support leading-edge science, by allocating $4 billion to a range of science programs over the next several years, the single largest investment in fundamental and discovery research in Canadian history.[1]
- The Ebola vaccine used to control the 2014 outbreak in West Africa was discovered by researchers at the Public Health Agency of Canada's National Microbiology Laboratory. The Public Health Agency of Canada and Defence Research and Development Canada were the direct funders of the research and development of the Ebola vaccine, with a total government funding of $5.3 million over a period of more than 10 years. This figure does not include the costs covered under the regular operating budget of the National Microbiology Laboratory.[2]
- Promising drugs for the treatment of osteoarthritis, the most common form of arthritis affecting about five million Canadians and for which there is currently no treatment available, have been recently developed by the Krembil Research Institute, part of the Canadian University Health Network (UHN).[3]

2. Principles for a health innovation model that delivers public value

Recognising the deep dysfunctionality of the current model, we have drawn up core principles that could nurture a better health innovation ecosystem:

2a. Directed innovation and mission setting

Innovation should be directed towards public health outcomes. This means designing an incentive structure that rewards public health advances rather than market return. This can be achieved through a 'mission-oriented' approach, in which public actors set the directions for innovation aimed at key public health milestones, and policy levers are used to welcome bottom-up experimentation to achieve those goals. Indeed, these are the processes that got us to the moon!

2b. Collaboration and transparency

Tackling public health needs requires a collaborative environment where actors – public, private and civil society – work together and share knowledge in new and dynamic ways to accelerate innovation. This requires transparency as well as an intellectual property system that incentivises innovation rather than blocking it (eg, the use of narrow patents that are easily licensed).

2c. Affordability and access

Affordable and accessible medicines are fundamental to the realisation of the human right to health. There is also a clear socio-economic case for supporting these actions in terms of securing a healthy workforce and the positive ripple effects on the economy as well as tax revenues.

2d. Long-term horizons and patient finance

Innovation is uncertain and can take time; public and private actors thus need to commit to long-term goals. It is also necessary to identify forms of finance that are 'patient' and capable of providing reliable funding to

[1] Government of Canada. Canadians are innovators. Available at: https://www.budget.gc.ca/2018/docs/plan/chap-02-en.html (Accessed 17 October 2018)

[2] Plummer, F. A. and Jones, S. M. (2017). The story of Canada's Ebola vaccine. *CMAJ,* 189(43), E1326-E1327

[3] University Health Network. Potential treatment could stop knew and spine osteoarthritis, Krembil scientists say. Available at: https://www.uhn.ca/corporate/News/PressReleases/Pages/Potential_treatment_could_stop_knee_and_spine_osteoarthritis.aspx (Accessed 17 October 2018)

sustain the innovation process, allowing collective learning to accumulate over time while at the same time bearing high risks and inevitable failures.

3. Immediate policy actions: Getting better prices today

In the short term, immediate actions are needed to address the ongoing crises of access to medicines. Governments should urgently implement pricing strategies and measures based on managing intellectual property rights (IPR) to improve the affordability of vital medicines. These include pooled and volume-based procurement, and increasing transparency around prices – both these measures can improve the bargaining power of public buyers. To get around the high price of the hepatitis C drug sofosbuvir (brand name Sovaldi), the Australian government entered into a unique volume-based price agreement with Gilead to treat 62,000 people at a cost of AUS$1 billion over five years – an average price per treatment of AUS$16,129 (US$11,715 / £8,234) if all 62,000 people are treated.161 This compares with the list price of £34,982 for a 12-week course and £69,965 for 24-week course (excluding VAT) in England.

Policy makers can also make intellectual property work for public health by ensuring that stringent patentability criteria are applied to prevent overly broad patents, as well as making information on patents accessible to increase transparency. Governments can also negotiate agreements around voluntary licenses to improve access to affordable medicines. When this is not possible, compulsory licenses (and government or Crown use) should be actively used. Governments should not implement intellectual property rules that go beyond what is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

4. Transformational change: Re-imagining our health innovation system to deliver public value

In the longer term, governments must do more than simply treat the symptoms of this fundamentally flawed system, and should instead adopt transformative approaches aimed at a radical shift in the innovation ecosystem to better serve public needs.

The attempt to foster investments in pharmaceutical R&D in Canada, with the provisions of Canada's Patent Act, did not lead to any actual increase in R&D spending. Under the former North American Free Trade Agreement (NAFTA) brand-name pharmaceutical companies committed to reinvest 10% of their domestic profits in domestic R&D in exchange for longer patent monopolies, but in reality the R&D-to-sales by pharmaceutical patentees in Canada has been falling since the late 1990's and has been under the agreed-upon target of 10% since 2003,[4] while pharmaceutical IP protections have increased eight times in Canada in between 1987 and 2013.[5]

This demonstrates how fundamental it is to rethink our current system rather than focusing on trying to fix a system that is inefficient, expensive and unsustainable. The transformative proposals listed below are built on the principles of how innovation flourishes**.**

4.1. A mission-oriented approach to improving health outcomes

Governments can set the direction of health innovation by focusing the energy of state, civil society and private sector actors on clearly articulated public health goals. This 'mission-oriented' approach has been successful in other areas, driving everything from technological advances in aviation and aerospace to the creation of the internet. We believe the same approach can marshal unprecedented coordination in innovation for health. Government advocacy for long-term targets can also help secure the long-term financial investment required to support complex research and development processes. Mission-driven

[4] Patented medicine prices review board. Annual report 2017. Available at: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en#a8 (Accessed 17 October 2018)

[5] Financial Post (2013). Letters to the Editor: Proposed EU drug rules would cost billions. Re: "Canada needs CETA IP changes," Henry Friesen and Calvin Stiller, Jan. 25. Available at: https://business.financialpost.com/opinion/fp-letters-to-the-editor-proposed-eu-drug-rules-would-cost-billions (Accessed 17 October 2018)

organisations can also collaborate internationally to address global health challenges. Social movements can play a key role in fostering mission-driven innovation contributing to meeting health challenges.

4.2. Delinking incentives from high prices

The current incentive system for drug development is failing to deliver optimal health outcomes and must be reformed. A critical first step is to 'delink' the cost of R&D from the price of any resulting product. Innovation can instead be supported through grants or subsidies and rewarded by a variety of prizes, including innovation inducement prizes, market entry rewards, or open source dividends. Because these financing options are public in nature, they can be used to reward the achievement of R&D milestones and stipulate that results be made affordable, creating an innovation system driven by agreed health priorities and dedicated to access. The potential savings from this delinked system, in which new medicines enter the market at non-monopoly generic prices, are vast. We propose steps that can help transition health innovation towards such a model.

In Canada, spending on prescribed drugs continues to rise since 2014 and is forecast to have reached $33.9 billion in 2017, an increase of 5.5% over the previous year. The introduction of new and expensive hepatitis C medicines has contributed significantly to this increased spending in recent years.[6]

4.3. Achieving public return through conditionality

If value is created collectively through the involvement of different actors, then the rewards should also be shared to ensure sustainable capital and resources for continued innovation. Instead, under the current system, the public sector plays an essential role in funding the upstream high-risk research, while the downstream profits disproportionately go to the private sector. A more just sharing of rewards needs to be based on a reinvigorated concept of 'public value' – in other words value that is both created and shared by the public. This could happen in various ways, including attaching conditions on public funding such as:

a) Conditions for reinvestment, requiring a company to reinvest a share of their profits into productive economic activities or a public innovation fund, or with the public receiving a share of the financial returns from successful innovations in which public funding played a major role. Royalties can be used to finance future innovation or to help cover the losses that inevitably arise when investing in high-risk areas.

b) Conditions for sharing knowledge, supporting and stipulating participation in open data repositories, open access publishing and collaborative research initiatives. Governments could also retain a 'golden share' of patents developed with public funding, with patents governed in such a way to allow companies to recover their costs while spurring greater use of that specific innovation.

The open access policy developed by the Natural Sciences and Engineering Research Council of Canada (NSERC), the Social Sciences and Humanities Research Council of Canada (SSHRC), and the Canadian Institutes of Health Research (CIHR) promotes the availability of findings that result from the research they fund, including research publications and data, "to the widest possible audience, and at the earliest possible opportunity".[7]

Genome Canada's policy for data release and sharing for recipient of funding is very comprehensive, requiring applicants to provide a 'Data release and resource sharing plan' as part of the application and, if granted with funding, to "share data and resources in a timely fashion with no restrictions". Interestingly, the policy states that for large data sets collected over several discrete time periods or phrases, it is expected that the data be release in phases as they become available.[8]

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[6] Canadian Institute for Health Information. (2017) National Health Expenditure Trends, 1975 to 2017.

[7] Government of Canada. Tri-agency open access policy on publications. Available at: http://www.science.gc.ca/eic/site/063.nsf/eng/h_F6765465.html?OpenDocument (Accessed 17 October 2018).

[8] Genome Canada data release and sharing policies. Available at: https://www.genomecanada.ca/sites/default/files/publications/gcdatasharingpolicies16-09-23.pdf (Accessed 17 October 2018).

As well as the requirement to have an access plan in place for applicants/recipient of public funding, the request for a Data release and sharing plan could be included to promote data be available for the wider scientific community.
Considering the alarming threat posed by antimicrobial resistance (AMR) worldwide, it is particularly important to implement open data repositories of molecules with promising antimicrobial actions at very early stages, so that we can create a suitable, efficient environment for delivering affordable treatment regimen effective against drug-resistant infections, such as TB, requiring more antibiotics, rather than focusing on single drug development.

c) Conditions for transparency of R&D costs to inform national and international discussions on what constitutes a fair price, empowering procuring entities in price negotiations, for example through standardised financial reporting measures for each medicine (branded and generic).

d) Conditions for access and affordability, adopting fair pricing regulations or requiring companies/institutions to have an access plan in place to be eligible to receive public funds (ie, from CIHR). When a regulation is already in place (eg, the Bayh-Dole Act in the US), governments should actively use these tools to control drug price inflation.
Although the CIHR has the clear objective of "contributing to the global advancement of health research to improve the health of Canadians and of the wider global community", the Act establishing CIHR does not include any condition to guarantee that products developed by/in collaboration with CIHR are accessible and affordable for all. The requirement to have an access plan in place could be included among the Institutional Funding Eligibility Criteria of the three federal granting agencies – the CIHR, the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC).[9] *For example, the University of British Columbia (UBC) has been implementing a strategy to ensure global access to its technologies since 2007. "In measuring the success of technology transfer activities at UBC, societal impact has become a key metric alongside standard throughput, financial and economic measurements". This strategy - promoting the use of non-exclusive licensing of research tools, open source platforms for data sharing and the design of patent strategies that do not hinder access for those in need of the final products - could be expanded and adopted by any recipient of public funding.*

4.4. Changes to corporate governance: Beyond shareholder value

Transforming innovation requires rethinking the role of the public sector beyond its 'market failure' box – acknowledging its role in actively creating markets, not just fixing them. Additionally, the private sector can be better structured. Corporate governance is key. The assumption that companies must maximise shareholder value can be rethought. We should consider, for example: limiting share buybacks that extract value out of healthcare systems to reward shareholders; tying executive compensation to the delivery of therapeutic advances rather than stock price increases; giving taxpayers and patients a voice on corporate boards at pharmaceutical companies; and promoting alternative governance models such as co-operatives, 'B-Corporations', community interest companies, and other models with an explicit public value orientation.

5. Conclusions

Governments can ensure the direction of health innovation is set toward public health needs while maximising the public value of private-sector contributions. This can be done by setting up mission-oriented organisations, by implementing delinked models, setting conditions on public investment and changing the rules of corporate governance.
A beneficial situation for all actors can be achieved if we can balance risk taking with adequate rewards, and incentivise what is socially optimal. A key aspect of the proposals discussed above is the way they

[9] Government of Canada. Institutional eligibility requirements. Available at: http://www.science.gc.ca/eic/site/063.nsf/eng/h_3D5FA603.html?OpenDocument (Accessed 17 October 2018)

steer and incentivise research investments that deliver public value, through a dynamic network of public, private and non-profit organisations across the entire innovation chain from the supply side to the market-creating demand side (eg, procurement). We propose a system of developing and ensuring access to medicines that increases the rate of innovation while also directing it towards health needs, and ultimately creates better value for money than the model we have today. As the number of countries struggling to afford new medicines grows, and patients are increasingly denied access to treatments that could heal them, the question for policymakers, including Canadian policymakers, is not whether they should initiate action to deliver a public-value-centred health innovation model, but when.