



More than a dose of collaboration



What Ottawa should do if it
wants **drugs and vaccines**
to be made in Canada
and benefit patients

Nigel S B Rawson and John Adams



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Executive Summary

For many years, successive federal governments have created a policy environment harmful to innovation in the biopharmaceutical sector in this country. The COVID-19 pandemic has shone a harsh light on these shortcomings, revealing the dangerous lack of investment in pharmaceutical and vaccine research, development and manufacturing.

The Liberal government now seems set on repairing this damage and “re-establishing” Canada as a leader in drug and vaccine production. For example, the 2021 federal budget included money to stimulate pharmaceutical manufacturing in Canada.

However, it is very much in question whether Canada was ever a leader in this field, despite some potential. And there is reason for skepticism that we ever will be without a major course correction in how new drugs are regulated in this country.

In recent decades, the brand-name pharmaceutical industry has made several attempts to develop a collaborative partnership, particularly with regard to damaging proposed changes to the Patented Medicine Prices Review Board guidelines for drug pricing. But the doors and minds of the federal government were slammed so tight that multiple companies determined they had no realistic alternative but to go to court to fight. The results are mixed and appeal hearings are awaited. Quebec has joined the opposition, seeing the new rules as trespassing on provincial jurisdiction, by intervening in a constitutional appeal.

The new federal government regulations will drastically reduce the prices of medicines, in some cases possibly by 60 percent or more, which is unsustainable and will further deter developers from launching new medicines in Canada. Simply put, they will only increase the already numerous cost-containment barriers facing innovative biopharmaceutical companies, including the lack of globally competitive intellectual property protection for innovative medicines, and inhospitable government-controlled health technology assessment and price negotiation organizations.

Federal, provincial and territorial governments fail to accept the value medicines bring in producing better health outcomes for Canadians and in reducing costs in other health care areas. One creature of governments, the Canadian Agency for Drugs and Technologies in Health, regularly recommends price reductions using an outdated cost-effectiveness threshold – especially for medicines that are designed to treat patients with chronic conditions, disabilities or rare disorders.

Just the threat of the new regulations has already created a chill for new drugs coming to Canada and a significant reduction in manufacturer-funded late-stage Canadian clinical trials. Some drug developers are likely to decide that Canada is a less viable market for their products and depart, while others may downsize their investment in Canada. Significantly reducing drug prices might save money for government drug plans, but it will be at the expense of patients suffering without their health needs being met and dying prematurely.

“ *Some drug developers are likely to decide that Canada is a less viable market for their products and depart.* ”

Current plans include a possible Canada Drug Agency, which would assume part or all of the roles of the health technology assessment agencies, the price negotiating body, provincial and territorial drug decision-making committees, and some Health Canada regulatory activities. This raises questions about the wisdom of adding yet more process to a non-system that values cost-containment over health outcomes and does not measure speed to patient – how long it takes from regulatory approval to patient use. The same can also be said of plans for a national formulary of essential drugs. After all, if a formulary is established, it is unclear as to who would decide what drugs are “essential.” Will a life-saving drug for a person with cystic fibrosis or sickle cell disease, for example, make it to the list?

Less antipathy and greater collaboration between Ottawa and the innovative biopharmaceutical industry have the potential to deliver significant value not only to the health care system but to the economy as a whole. It would also provide Canadians with earlier access to new medicines and vaccines.

The federal government seems aware, to some extent, of the regulatory burden facing drug developers. In September 2020, Ottawa announced a policy to effectively exempt badly-needed COVID-19 vaccines and medicines from Patented Medicine Prices Review Board scrutiny. Dealing with COVID-19 is

important, but so are the unmet health needs of Canadians who could be denied access to new medicines by the impact of regulations scheduled to take effect on July 1, 2021.

If Ottawa is serious about stimulating biopharmaceutical research and manufacturing to establish Canada as a leader in drug and vaccine development and production, it must do much more to create a constructive working relationship with drug and vaccine developers to build a secure domestic industry. As a priority, the government must cancel or, at least, delay and reconsider the new Patented Medicine Prices Review Board regulations if it really wants to demonstrate to the industry and patients that a reset is feasible. Only then will Canada show that it is committed to making our pharmaceutical environment attractive to investment and innovation and that our patients deserve speedy access to new medicines.

Sommaire

Pendant de nombreuses années, les gouvernements fédéraux ont chacun à leur tour contribué au développement d'un environnement politique nuisible à l'innovation dans le secteur biopharmaceutique de notre pays. La pandémie de COVID-19 a mis cruellement en lumière toutes ces lacunes, révélant le dangereux manque d'investissement dans la recherche, le développement et la fabrication de produits pharmaceutiques et de vaccins.

Le gouvernement libéral semble maintenant décidé à réparer ces dommages en aidant le Canada à se « rétablir » en tant que leader dans la production de médicaments et de vaccins. Par exemple, le budget fédéral de 2021 a prévu des fonds pour favoriser la production pharmaceutique au Canada.

Toutefois, bien que le Canada possède un certain potentiel, encore faudrait-il qu'il ait déjà été un leader dans ce domaine. Et puis, il y a lieu d'être sceptique quant à la possibilité que nous exercions ce rôle un jour, à moins de remettre les pendules à l'heure quant à la façon dont les nouveaux médicaments sont réglementés dans ce pays.

Au cours des dernières décennies, l'industrie des médicaments brevetés a tenté à plusieurs reprises de mettre en place une collaboration entre partenaires, notamment face à l'effet préjudiciable des nouvelles lignes directrices proposées en matière de fixation des prix du Conseil d'examen du prix des médicaments brevetés. Or, le gouvernement fédéral a claqué la porte et est resté si peu réceptif que plusieurs entreprises ont estimé qu'elles n'avaient pas d'autres choix réalistes que de faire appel aux tribunaux. Les résultats sont mitigés et des audiences d'appel sont attendues. Le Québec s'est joint à l'opposition par l'intermédiaire d'un recours constitutionnel, voyant les nouvelles règles comme un empiètement sur les compétences provinciales.

Les nouvelles réglementations du gouvernement fédéral réduiront drastiquement les prix des médicaments, possiblement dans certains cas jusqu'à plus de 60 pour cent, une mesure qui est impossible à satisfaire et qui dissuadera encore davantage les développeurs. En d'autres termes, ces réglementations ne feront qu'accroître les limitations déjà nombreuses sur les coûts aux-

quelles font face les entreprises biopharmaceutiques novatrices, notamment en lien avec la protection insuffisante de la propriété intellectuelle sur les médicaments novateurs, qui empêche le Canada d'être compétitif à l'échelle mondiale, et l'indifférence des instances gouvernementales d'évaluation des technologies de la santé et de fixation des prix.

Les gouvernements aux paliers fédéral, provincial et territorial ne reconnaissent pas la valeur apportée par les médicaments sur les résultats en santé des Canadiens et la réduction de coûts dans d'autres domaines des soins de santé. Un organisme gouvernemental particulier, l'Agence canadienne des médicaments et des technologies de la santé, recommande régulièrement des réductions de prix en utilisant un seuil de rentabilité dépassé – tout spécialement en ce qui concerne les médicaments conçus pour traiter les patients atteints de maladies chroniques, de handicaps ou de troubles rares.



Certains développeurs décideront probablement que le Canada est un marché moins viable pour leurs produits et y renonceront.

La simple menace de nouvelles réglementations a déjà retardé l'arrivée de nouveaux médicaments au Canada et a entraîné une réduction importante des essais cliniques canadiens de stade avancé financés par les fabricants. Certains développeurs décideront probablement que le Canada est un marché moins viable pour leurs produits et y renonceront, tandis que d'autres pourraient diminuer leurs investissements. Si une réduction importante du prix des médicaments permet aux régimes d'assurance médicaments gouvernementaux de réaliser des économies, ce sera au détriment des patients qui souffriront sans que leurs besoins en matière de santé soient satisfaits et qui mourront prématurément.

Les plans actuels prévoient la création d'une éventuelle Agence canadienne des médicaments, qui assumerait une partie ou la totalité des rôles présentement dévolus aux organismes gouvernementaux d'évaluation des technologies de la santé et de fixation des prix, aux comités provinciaux et territoriaux de prise de décision en matière de médicaments et à certaines activités de réglementation de Santé Canada. Cela soulève des questions quant à la pertinence de superposer un nouveau processus à un « non-système » qui privilégie la limitation des coûts plutôt que les résultats en santé et qui ne mesure pas la rapidité de l'accès au patient, c'est-à-dire le temps qui s'écoule entre l'approbation réglementaire et l'utilisation par le patient. On peut également

dire la même chose des plans pour une Liste nationale de médicaments essentiels. Après tout, si une liste est établie, il n'est pas clair qui déciderait quels médicaments sont « essentiels ». Un médicament vital pour une personne atteinte de fibrose kystique ou de drépanocytose, par exemple, sera-t-il inscrit sur la liste?

Moins d'antipathie et plus de collaboration entre Ottawa et l'industrie biopharmaceutique innovatrice pourraient non seulement contribuer positivement au système de soins de santé, mais à l'économie dans son ensemble. Cela permettrait également aux Canadiens d'avoir un accès plus rapide aux nouveaux médicaments et vaccins.

Le gouvernement fédéral semble conscient, dans une certaine mesure, du fardeau réglementaire auquel se heurtent les développeurs de médicaments. En septembre 2020, Ottawa a annoncé une politique visant à écarter les vaccins et les médicaments contre la COVID-19, dont on a cruellement besoin, du champ d'application du Conseil d'examen du prix des médicaments brevetés. Il est important de s'occuper de la COVID-19, mais il en va de même pour les besoins de santé non satisfaits des Canadiens qui pourraient se voir refuser l'accès à de nouveaux médicaments en raison de l'impact de la réglementation qui doit entrer en vigueur le 1er juillet 2021.

Si Ottawa veut vraiment stimuler la recherche et la fabrication biopharmaceutiques afin de faire du Canada un leader dans le développement et la production de médicaments et de vaccins, il doit déployer beaucoup plus d'efforts pour instaurer des relations constructives avec les développeurs de médicaments et de vaccins afin de bâtir une industrie nationale sûre. En priorité, le gouvernement doit annuler ou, à tout le moins, retarder et revoir le nouveau règlement du Conseil d'examen du prix des médicaments brevetés s'il veut vraiment démontrer à l'industrie et aux patients qu'une réinitialisation est possible. C'est de cette manière seulement que le Canada montrera qu'il est déterminé à rendre notre environnement pharmaceutique attrayant pour l'investissement et l'innovation et que nos patients méritent un accès rapide aux nouveaux médicaments.

Introduction

The COVID-19 pandemic has unequivocally demonstrated the lack of investment in pharmaceutical and vaccine research, development and manufacturing in Canada. This is the result of many years of successive federal governments creating a pharmaceutical policy environment that discourages investment in innovations in pharmaceutical research, development and manufacturing in this country (Field 2021; Lucas 2020; Rawson et al. 2020).

However, the current federal government says it is now trying to repair the damage. Industry Minister François-Philippe Champagne confidently claims that drug and vaccine developers and the government can work together to “re-establish” Canada as a leader in drug and vaccine production (Tumilty 2021).

The biopharmaceutical industry is pleased that Ottawa is at last re-engaging after a cold war of sorts and offering support. Nevertheless, it remains concerned that, starting in July, the federal government still intends to regulate medicine prices that will lead to significant price reductions – an outcome that will discourage private investment in research, manufacturing, well-paid jobs and the launching of new medicines in Canada to the detriment of patients with unmet needs.

Are the federal government and the biopharmaceutical industry simply posturing? What are the facts? We examine the issues.

The Federal Government

Notwithstanding national pride, it is questionable whether Canada has ever been a leader in drug and vaccine manufacturing. Facilities such as the Connaught Laboratories did exist (Walmsley 1989). Yet, like the discovery of insulin, this has been the rare exception. There have been and continue to be few Canadian world players in the pharmaceutical field. Most global companies have affiliates in Canada, but their footprint has decreased over many years,

with manufacturing, research and high-paid jobs moving to other countries.

The reasons for this brain-drain are numerous. They date back more than 50 years to the government of Pierre Trudeau and its move to eliminate pharmaceutical patents when it introduced compulsory licensing – a price control mechanism much-loved by anti-industry activists (Lexchin 2020) – with the aim of lowering drug prices and fostering a Canadian domestic industry. However, rather than encouraging a Canadian industry, this government policy choice resulted in the opposite. Several global brand-name companies closed their research centres in this country and the ill-considered policy of rewarding generic drug manufacturers led to the establishment of an oligopoly of these companies that perform little innovative research but accumulate great personal and corporate wealth by charging Canadians high generic prices.

Most brand-name pharmaceutical companies in Canada are affiliates of multi-national organizations. As such, they compete with counterparts in other countries for a finite amount of global research and manufacturing opportunities. When Ottawa's decades-long actions result in the Canadian market being viewed with uncertainty, or worse negatively, by international pharmaceutical businesses, Canadian affiliates are put in a weak position when trying to attract interest in investment from their head offices (Lucas 2020). As a consequence, research and manufacturing capacity often goes to more collaborative countries. The lack of investment in COVID-19 vaccine research, development and manufacturing in Canada has unambiguously demonstrated this reality (Rawson and Adams 2021a).

“Canadian affiliates are put in a weak position when trying to attract interest in investment from their head offices.”

Conservative governments have supported the innovative pharmaceutical industry by improving intellectual property rights as part of multinational trade considerations, but Canada still does not have globally competitive intellectual property protection for innovative medicines (Owens 2017; Raffoul 2021; US Chamber of Commerce 2021). Left-of-centre politicians and bureaucrats, some labour unions and anti-industry activists in academia are opposed to changing the situation. Unfortunately, Ottawa heeds them.

The antipathy goes beyond research, development and manufacturing. Canada's processes for reviewing new medicines and making them accessible to Canadians who need them further disincentivize developers from launching their innovative products. The timeliness of Health Canada's regulatory re-

view process for evaluating the efficacy, safety and quality of new medicines has improved since the 1980s and 1990s when it was badly needed (Rawson 2018). Even so, its efficiency could be improved further by using assessments done by agencies in peer countries (e.g., the United States Food and Drug Administration, the European Medicines Agency and the Australian Therapeutic Goods Administration) instead of re-inventing the wheel for each review (Barua et al. 2021). There is no evidence of any value added by Canadian federal officials re-reviewing the evidence of safety, efficacy and quality of a medicine already reviewed by peer regulators and the results made public.

Of more pressing concern to biopharmaceutical innovators are the processes for health technology assessments and price negotiations/coercion performed by the Canadian Agency for Drugs and Technologies in Health (CADTH) and the pan-Canadian Pharmaceutical Alliance (pCPA) (Rawson 2019, 2021a). These non-public, non-transparent and non-accountable organizations have been aligning their processes allegedly to improve access for Canadians. In reality, this alignment seems designed more as budget management, not health care improvement, to deter new medicines from being brought to Canada, or at least to delay them to contain costs. So much for getting new therapies to suffering patients as speedily as possible.



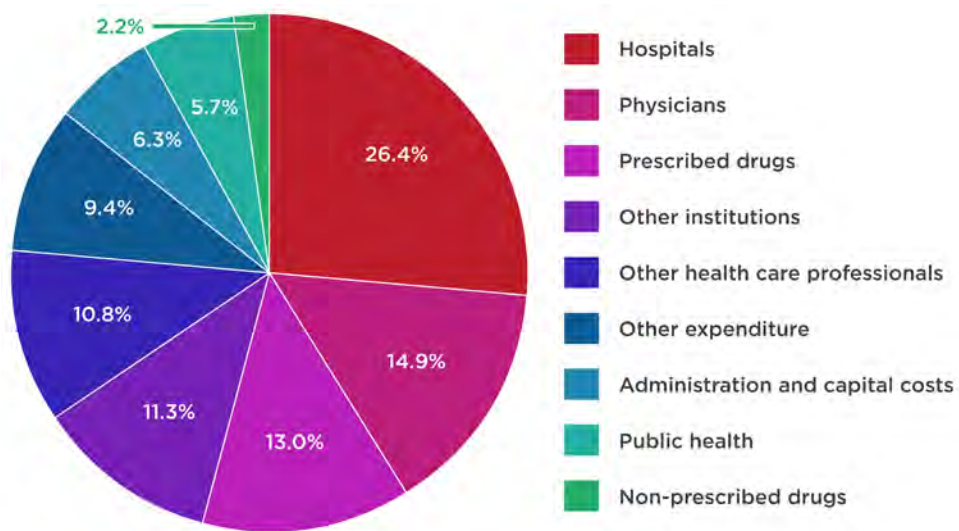
Medicines and vaccines are too often seen by federal, provincial and territorial governments as just a cost to the health care system.

This objective is not surprising when one considers who owns, manages and funds CADTH and the pCPA – the federal, provincial and territorial governments and their drug insurance plans – whose interest is in keeping drug costs down, rather than improving health outcomes. This is in accordance with Health Canada’s departmental plan, which measures success not by metrics that would show improved health outcomes but by how it manages to control budgets, including keeping drug spending at 1 to 2 percent of the gross domestic product (Health Canada 2021a). Thus, CADTH and the pCPA have major conflicts of interest and duty when they carry out their work (Rawson and Adams 2017).

Medicines and vaccines are too often seen by federal, provincial and territorial governments as just a cost to the health care system. It is often cited, particularly by anti-biopharmaceutical industry activists, that drug expenditure is higher than expenditure on physicians, but this is based on expenditure on

both prescribed and non-prescribed drugs. The per capita spending on prescribed drugs (\$916) was 13 percent of total health expenditure in Canada in 2019 (CIHI 2020), compared with over 26 percent for hospitals and almost 15 percent for physicians (Figure 1). However, the per capita spending on patented medicines was \$458 (PMPRB 2020a), which comprises only half of the reported expenditure on prescribed drugs – 6.5 percent of total health expenditure. Furthermore, since the figure of \$458 is based on manufacturers’ list prices, it does not account for rebates offered to government and private drug plans and, consequently, significantly overstates the real cost of innovative medicines to the Canadian health care system.

FIGURE 1: TOTAL HEALTH EXPENDITURE PER CAPITA, 2019



Source:
Adapted from CIHI 2020

Federal, provincial and territorial governments fail to appreciate the value medicines bring in producing better health outcomes for Canadians and in reducing costs in other health care areas (Buxbaum et al. 2020). This is due in no small measure to the siloed mandates, budgets and structures of the government health care systems. Governments and their agencies track dollars spent, but not one of them tracks how long patients wait to be able to use a new drug, something that could be called “speed to patient.”

For decades, governments have also failed to adequately recognize the comprehensive benefits brought to the economy by new scientific discoveries made by innovative pharmaceutical companies. In 2018, Innovative Medicines Canada members added almost \$8 billion to the gross domestic product and supported either directly or indirectly more than 54,000 full-time-equivalent jobs in Canada (Statistics Canada 2021).

One of the Trudeau government's objectives is to replace the current provincial and territorial drug plans with something it calls national pharmacare. Although no new money was allocated to it in the 2021 federal budget (Government of Canada 2021), national pharmacare continues to be part of the Liberals' re-election program. As a component of the initiative, the government intends to establish a new entity called the Canada Drug Agency, which would assume part or all of the roles of the health technology assessment agencies, the pCPA, provincial and territorial drug decision-making committees, and some Health Canada regulatory activities (Advisory Council on the Implementation of National Pharmacare 2019). The question is: will red tape be cut or will the Canada Drug Agency add yet more process to a non-system that values process and cost-containment over health outcomes?

Considerable alignment between CADTH and the pCPA is already in place (Rawson 2020a). For example, representatives from each organization are observers and undoubtedly commentators, formally or informally, at the others' meetings behind closed doors away from independent input or public scrutiny. One can observe a parliamentary health committee, provincial legislative committee or municipal council on a topic of interest, but no concerned citizen or journalist can observe a CADTH committee as it decides whether to recommend for or against a new drug, including its price and conditions of use.

“*Elements of the federal government continue to view the innovative pharmaceutical industry with hostility.*”

CADTH reviews regularly include a recommendation for a price reduction (Rawson 2021a) – often a specific percentage – to achieve cost-effectiveness at an arbitrary and outdated threshold that for many medicines, especially those for rare disorders, is too low. It is not CADTH's role to set prices, but including price reduction recommendations in an assessment report allows CADTH to set up an initial negotiating position for the pCPA if it chooses to negotiate with the manufacturer (the pCPA is not even required to try to negotiate).

Two other features of the Liberal government's plan for national pharmacare are the creation of a national formulary of covered medicines and a national strategy for expensive drugs for rare disorders. If the government follows the recommendation of the Advisory Council on the Implementation of National Pharmacare, the formulary will initially only include a limited list of so-called essential drugs (Taglione et al. 2017), but it is unclear who would decide what drugs are “essential.” Will recommendations and decisions be made behind

closed doors? Will a life-saving drug for a person with cystic fibrosis or sickle cell disease, for example, make it to the list? Such drugs do not appear on any proposed lists of “essential” drugs.

Health Canada recently produced a discussion paper on its “strategy” for expensive drugs for rare disorders (Health Canada 2021b). Unfortunately, the discussion paper demonstrates that it is just a plan for cost-containment, not a real strategy to improve the health and wellbeing of Canadians living with rare disorders (Rawson and Adams 2021b).

Despite claims to the contrary, elements of the federal government continue to view the innovative pharmaceutical industry with hostility. The barriers that they, together with the provincial and territorial governments, have built over many years already lead to drug and vaccine developers launching their products in Canada later than the United States and the European Union or not marketing them here at all (Barua et al. 2021; Rawson 2013, 2018), which harms patients and the health care system.

The biopharmaceutical industry in Canada

As previously mentioned, most patented medicine pharmaceutical companies in Canada are affiliates of multinational organizations. While they have a degree of autonomy in their activities in this country, they must accept the authority of the head office in many areas. The head offices of these organizations take a wider business view and, should Canadian government initiatives endanger the enterprise in other countries, global business activities take priority. After all, Canada constitutes less than 2 percent of the world marketplace. Two percent is not even the tip of the dog’s tail.

Drug developers face numerous barriers that must be overcome before their innovations can be accessed by Canadian patients who need them. In particular, CADTH takes a narrow public health system perspective in its health technology assessments that ignore wider benefits to Canadian society. Similar agencies in several European countries take a more holistic point of view.

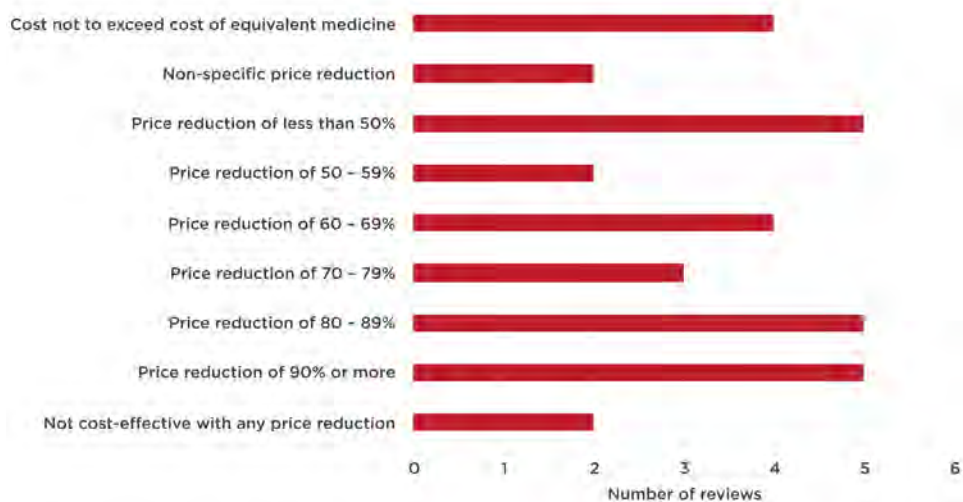
Like most health technology assessment agencies, CADTH prefers cost-utility economic analyses that use a metric known as a quality-adjusted life year (QALY). A QALY is a measure of disease burden that attempts to include both the quality and quantity of life lived. QALYs use a linear scale between zero and one, with zero and one being arbitrary values for death and full health, respectively. This is a one-dimensional and inadequate measure of an individual’s quality of health that, in reality, is a complex, multi-faceted and

non-linear physical, psychological and social state (Pettitt et al. 2016; Prieto and Sacristán 2003). QALYs fail to fully capture the social value of a medicine (Rowen et al. 2017) and are an inadequate and inequitable measure of health quality for assessing the value of treatments for people with disabilities, chronic conditions or rare disorders (National Council on Disability 2019; Richter et al. 2018).

Although QALYs may give the false impression of pseudo-precision, they have serious limitations because health economic analyses are based on modelling techniques that require numerous assumptions and frequently use less than ideal, incomplete data. Sophisticated methods have been developed in an attempt to overcome these issues, but they can never overcome problems caused by unrealistic or illogical assumptions and inadequate data. As a consequence, results can vary widely, even between different health technology assessment agencies using the same data (Rawson 2021a).

As previously stated, CADTH reviews commonly include a recommendation for a price reduction. In 2020, CADTH produced 59 final recommendations – 27 for oncology therapies and 32 for other medicines – taking an average of 8.5 months for the reviews. Six (almost 19 percent) of the non-oncology reviews stated either that the price should be reduced or the drug plan cost should not exceed that of an equivalent medicine, while two (just over 6 percent) noted that no price reduction would allow the drug to attain cost-effectiveness at a threshold of \$50,000 per QALY. The other 24 non-oncology reviews (75 percent) had recommendations for price reductions of between 9 and 96 percent (Figure 2) – all but one based on a \$50,000 per QALY threshold, the other on a \$100,000 per QALY threshold.

FIGURE 2: CADTH RECOMMENDED PRICE REDUCTIONS FOR NON-ONCOLOGY MEDICINES, 2020

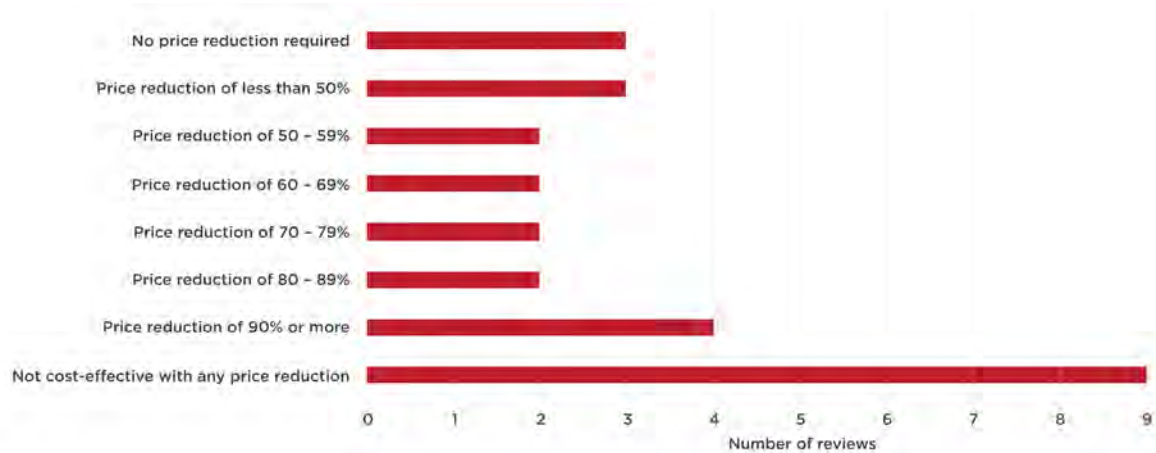


Source:

Author calculations based on reimbursement review reports issued in 2020 (CADTH 2021)

In the oncology drug reviews, a price decrease was not recommended in three reviews (11 percent), while at the other extreme, nine (33 percent) stated that no price reduction would allow the drug to be cost-effective at \$50,000 per QALY (Figure 3). In the remaining reviews, 11 (41 percent) had recommendations for price reductions of more than 30 percent to over 90 percent to achieve cost-effectiveness at \$50,000 per QALY and four (15 percent) had recommendations for price reductions of 75 percent to over 95 percent to attain cost-effectiveness at \$100,000 per QALY.

FIGURE 3: CADTH RECOMMENDED PRICE REDUCTIONS FOR ONCOLOGY MEDICINES, 2020



Source:

Author calculations based on reimbursement review reports issued in 2020 (CADTH 2021)

The situation for the seven drugs for rare non-oncology disorders with CADTH recommendations in 2020 is more dire. First, the CADTH reviews for these drugs recommended huge price reductions of between 75 and 96 percent to attain cost-effectiveness at \$50,000 per QALY (an absurdly low threshold for such medicines) and, second, only one had a successful price negotiation.

The use of a \$50,000 per QALY threshold for some drugs and a \$100,000 per QALY threshold for others is evidence of arbitrariness and a lack of nuance in evaluations. Recommendations for price reductions of 60 percent or much more are unrealistic as reductions of this magnitude would be unsustainable and a major deterrent to launching new drugs in Canada.

Although nine oncology medicine reviews stated no price reduction would allow the drug to achieve cost-effectiveness, a successful price negotiation had been accomplished by the end of April 2021 for five, indicating the priority given to these drugs. The precedence given to oncology medicines by the pCPA is also seen in the fact that the median time between CADTH’s final recommendation and the start of the pCPA negotiation was 74 days, compared with 176 days for non-oncology drugs, and that, by the end of April 2021, a successful price negotiation had been completed for 52 percent of the on-

cology medicines, compared with just 12 percent of the non-oncology drugs. Where completed, price negotiations took an average of 4 months.

Paying “experts” and bureaucrats to take an average of more than 12 months to review a medicine and negotiate its price, while patients who need the drug suffer and die, is appalling. But it is intolerable that, even if a medicine has a positive CADTH recommendation and a successful price negotiation, government drug plans are not mandated to cover it. Only one of the oncology medicines – pembrolizumab (Keytruda) for squamous non-small-cell lung cancer – is funded in eight of the nine provinces that support CADTH and just one non-oncology drug – vedolizumab (Entyvio) for ulcerative colitis – has coverage via special access in more than half of the nine provinces outside Quebec.

Given the numerous barriers confronting brand-name pharmaceutical companies, one might expect greater response from the industry, especially through their trade associations. The brand-name association in Australia regularly publishes a “Facts Book” that demonstrates the health and economic benefits its members bring to Australia and reports that compare the access and reimbursement environment in Australia with 19 other Organization for Economic Cooperation and Development countries (Medicines Australia 2021a, 2021b). These reports show that Canada is 17th out of the 20 countries on a market access index, ahead of only South Korea, Portugal and New Zealand. The biopharmaceutical industry’s associations in Canada could provide similar data-based evidence illustrating the impact of regulatory, reimbursement and pricing obstacles in this country for patients, clinicians and government decision-makers.

Discussion

The federal government has been on a political track to try to significantly reduce medicine prices for some time. This is built on a false premise. Federal claims of high drug prices fail to note that they are based on comparisons of list prices, without taking into account discounts and rebates negotiated with government and private drug plans.

Since health care is predominantly a provincial and territorial responsibility, the federal government has few means with which to achieve its goal of reducing drug prices, however flawed. One instrument it can use is under exclusive federal jurisdiction. This is the Patented Medicine Prices Review Board (PMPRB), a little-known tribunal that ensures prices for patented medicines sold in Canada are not excessive. Evidence for the government’s use of the PMPRB can be seen in the ongoing proceedings against Alexion and Horizon Therapeutics for allegations of excessive pricing for two drugs used to treat

life-threatening rare disorders: eculizumab (Soliris) for atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria, and cysteamine bitartrate (Procysbi) for nephropathic cystinosis (PMPRB 2021).

Further evidence lies in the new federal government regulations regarding the PMPRB that are planned to take legal effect in July 2021. These will change the so-called basket of countries currently used to compare a drug's proposed Canadian price (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). The high-cost countries of Switzerland and the United States will be replaced with the lower-cost countries of Australia, Belgium, Japan, the Netherlands, Norway and Spain to bring down list prices by about 20 percent (PMPRB 2020b). The new rules will have a ripple effect into other jurisdictions changing the basis of international comparisons of prices.

In addition, in the new regulations, the PMPRB will, in certain circumstances, use CADTH's health technology assessment recommendations to assess whether the manufacturer's price is excessive and, if so, will lower prices even further. In these situations, it would seem an educated guess that the PMPRB will use CADTH's low threshold of \$50,000 per QALY for cost-effectiveness to establish a maximum price. The \$50,000 per quality-adjusted life-year was first proposed in the early 1990s (Grosse 2014); 30 years later, it is an absurdly low figure for the value of today's drugs for oncology and rare disorders and, even if only adjusted for consumer inflation, should be close to \$100,000. But most importantly, cost-effectiveness estimates are not designed to set prices – only to assist in assessing the value of a medicine – and the use of QALYs has been shown to intrinsically discriminate against the value of the life of a person with a disability, chronic condition or rare disorder.

Repeatedly, Ottawa officials have blithely and falsely denied the negative impact of the new PMPRB regulations. Instead, talking points based on ideology, rather than thought or evidence, are repeated via social media as mantras, while real-world evidence to the contrary grows. The new rules are already having a disturbing effect on innovation for Canadian patients. Published case studies demonstrate that the new rules may require manufacturers to reduce prices to unsustainable levels (Rawson and Lawrence 2020). In addition, the numbers of new drugs approved in Canada and clinical trials funded by drug developers, which give desperate patients earlier access to promising therapies, have decreased (IMC 2021; Rawson 2020b, 2021b). Between 2015 and 2020, the number of late-stage manufacturer-funded trials of therapeutic medicines fell by 22 percent in Canada, compared with only 11 percent in the United States. The overall decrease in Canada hides a 25 percent reduction in late-stage trials of non-oncology drugs between 2015 and 2020 and a 23 percent decrease in oncology trials between 2019 and 2020 after an increase of 20 percent between 2016 and 2019.

Late-stage clinical trials are not undertaken lightly because they are expensive, since they involve thousands of patient volunteers, and the *Declaration of Helsinki* places an ethical obligation on developers to “make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial,” which could be for years (*Declaration of Helsinki* 2021). When trials of this type are performed in Canada, it is commonly an indication that developers intend to launch their products in this country. Whether the reduction in Canada is caused by the approaching change in the PMPRB rules, the COVID-19 pandemic, a general decrease in clinical trials or a combination of these factors is impossible to determine at this point but, within the current pharmaceutical policy environment, the trend is of concern to patients and health care providers.

“*Officials in Ottawa have blithely and falsely denied the negative impact of the new PMPRB regulations.*”

The federal government seems aware, to some extent, that elements of the pricing revisions are a regulatory burden on drug developers and a barrier to meeting patients’ needs. In September 2020, Ottawa announced a policy to exempt, in effect, badly-needed COVID-19 vaccines and medicines from PMPRB scrutiny as part of a “government wide effort to provisionally ease the regulatory pathway” for COVID-19 therapeutics (Government of Canada 2020). Manufacturers can provide these products at their list price unless the PMPRB receives a complaint from a federal or provincial minister of health. Dealing with COVID-19 is important, but so are meeting the unmet health needs of Canadians including those with chronic conditions, disabilities and rare disorders.

Nevertheless, the federal government intends to proceed with changes in the PMPRB’s regulations, unless legal challenges delay or halt them (Bellavance 2021; Smith 2021). This, together with the integration of the roles of the health technology assessment agencies, the pCPA, provincial and territorial drug decision-making committees and some Health Canada regulatory activities into the Canadian Drug Agency, a limited national formulary restricted to a short list of so-called essential medicines, and a strategy for expensive drugs for rare disorders that is only a cost-containment plan, strongly demonstrate that Ottawa aims to drastically control drug prices so that it can fund a limited national pharmacare program with meager benefits for Canadians. It is possible that many Canadians could lose coverage of drugs not on the national formulary under the contemplated changes.

Innovative advances are commonly undervalued in Canada (Cross 2020) and new medicines are no exception. Presently, Canada is a commercially viable market for new medicines and vaccines, despite the barriers created by governments that limit, delay or deny access to new drugs, especially costly ones. However, the new federal price controls will prevent many new medicines from coming to Canada at all. Instead of heeding a recommendation from industry leaders on its own Health and Bioscience Economic Strategy Table to reduce the complex “processes that stifle innovation and hinder the adoption of promising innovations in the health care system” to advance Canada’s global competitiveness (Health and Biosciences Table 2018), Ottawa is creating more impediments and greater complexity.

Overtures to biopharmaceutical companies (Scofield 2021) are unlikely to succeed without a reversal of the PMPRB changes. In fact, drug developers are more likely to decide that Canada is not a viable market for their products. Some can be expected to leave Canada – Providence Therapeutics, which has been developing mRNA vaccines for cancers and COVID-19 (like those of Pfizer-BioNTech and Moderna) but found little interest in Ottawa in funding a home-grown initiative, is leaving (Tasker 2021) – while other businesses may downsize their investment in Canada. Significantly reducing drug prices might save money for government drug plans, but it will be at the expense of patients suffering without their health needs being met and dying prematurely.

Conclusion

Over the past 30 years or so, the brand-name pharmaceutical industry has made several attempts to develop a collaborative partnership with successive governments to institute a more favourable pharmaceutical policy environment. But elements in Ottawa, supported by some provinces, left-of-centre politicians, some labour unions and academic anti-industry activists, have snubbed these efforts. In 2020, the antipathy was so bad that repeated letters to the Prime Minister from chief executive officers of global drug developers did not receive even an acknowledgement, let alone a response or discussion (Wells 2021). The doors and minds of the federal government were slammed so tight that multiple companies determined they had no realistic alternative but to go to court to fight the new price controls (Smith 2021). The results are mixed and appeal hearings are awaited. The province of Quebec has now joined the opposition and is intervening in an appeal arguing that the *Patent Act* is not a tool for price regulation and the new PMPRB rules are a Trojan Horse trespassing into provincial jurisdiction (Bellavance 2021). Other provinces may think the same.

The already numerous cost-containment barriers – a lack of globally com-

petitive intellectual property protection for innovative medicines, and inhospitable government-controlled health technology assessment and price negotiation organizations – faced by innovative pharmaceutical companies when launching their products in Canada will be increased in July 2021. At that time, new federal government regulations will drastically reduce the prices of medicines, in some cases possibly by as much as 60 to 95 percent, further deterring developers from launching new medicines in this country. Just the threat of the new regulations has already chilled the landscape for manufacturer-funded late-stage clinical trials and new drugs. Reduced access to clinical trials and new drugs raises much concern among Canadians with unmet health needs. Instead of even more cost-containment plans, the Trudeau government should be working on the metric of “speed to patient” to accelerate the processes of getting approved medicines to patients who need them.

Less antagonism and greater collaboration between Ottawa and the innovative biopharmaceutical industry have the potential to deliver significant value not only to the health care system but to the economy as a whole. It would also provide Canadians with earlier access to new medicines and vaccines. Speedier access to new biopharmaceutical therapies, not just COVID-19 vaccines, is a crucial priority for patients.

If Ottawa is serious about stimulating biopharmaceutical research and manufacturing to establish Canada as a leader in drug and vaccine development and production, it must do much more to create a constructive working relationship with drug and vaccine developers to build a secure domestic industry. As a priority, the government must cancel or, at least, delay and reconsider the new PMPRB regulations if it really wants to demonstrate to the industry that things have changed and it is committed to a pharmaceutical environment that will make Canada globally competitive to attract investment and innovation and provide speedy access to new drugs and vaccines.

The federal government can no longer speak out of both sides of its collective mouth on its relationship with the biopharmaceutical industry. What shall it be? Continued antipathy, or the start of a new era of collaboration to benefit Canadians?

About the authors



Dr. Nigel Rawson is a pharmacoepidemiologist and pharmaceutical policy researcher based in Saskatoon, Saskatchewan. He is also a Senior Fellow with the Fraser Institute and an Affiliate Scholar at the Canadian Health Policy Institute. He holds an MSc in statistics and a PhD in pharmacoepidemiology. Dr. Rawson has performed epidemiologic studies of the use of drugs and their outcomes and pharmaceutical policy issues for over 40 years, and published more than 140 articles in peer-reviewed journals and book chapters. He is also the author of the monograph “Drug Safety: Problems, Pitfalls and Solutions in Identifying and Evaluating Risk.” He has held academic positions in the

United Kingdom and Canada, been a senior researcher in an independent research centre in one of the United States’ largest health insurers collaborating with the Food and Drug Administration on drug safety studies, and GlaxoSmithKline’s only epidemiologist in Canada. Between 2012 and 2020, Dr. Rawson was President of Eastlake Research Group whose mission was to create data-driven responses to pharmaceutical policy issues. He continues this work as an independent researcher.



John Adams is a seasoned management consultant with a current focus on advocacy for unmet patient health needs. He has extensive experience in public policy, governance and senior management.

He volunteers as the Board Chair of the Best Medicines Coalition (BMC), a national non-profit of 29 patient organizations, which together represent millions of Canadian patients. The mission of BMC is to help ensure timely access to medicines that meet patient needs and that are safe and effective. BMC is engaged in current issues of national pharmacare, drug supplies and shortages, COVID-19 issues including therapeutic scams, price controls on medicines, health technologies assessment and regulatory reform.

Previously he served ten years on the board of the Canadian Organization for Rare Disorders. He has a son with a rare genetic disorder phenylketonuria (PKU) which is a brain-threatening disorder and is co-founder and President of both a Canadian non-profit and a global charity for that rare disease. That son participated in a clinical trial for the first drug to treat PKU, and is an example of a person outside the USA who benefits from the US Orphan Drug Act.

He graduated from York University in Toronto with a degree in political science, 1970; first worked as a reporter for The Globe and Mail, 1971-1975; then as chief of staff to an Ontario Cabinet Minister (1977-1981), was elected to Toronto City Council three times (years 1991-2000) including serving as Budget Chief (1993). His track record includes being the only Budget Chief in+ 60 years to reduce property taxes in Toronto. While on Council, he served on a large number of boards, including Toronto Public Health, Toronto Economic Development, Toronto District Heating Corporation, Toronto and Region Conservation Authority, Toronto Harbour Commission and as a trustee of Canada's largest health sciences centre, University Health Network.

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