INDEPENDENT VOICES FOR SAFE AND EFFECTIVE DRUGS

REPRESENTING CANADIAN ACADEMICS, RESEARCHERS, PATIENT AND CONSUMER ACTIVISTS

November 5, 2020

Submission to the Standing Committee on Health
Patented Medicine Prices Review Board's Guidelines

Independent Voices for Safe & Effective Drugs represents academics, researchers, and patient and consumer advocates with no ties to the pharmaceutical industry. We are able to speak directly to the research evidence on drug costs, safety and efficacy and we take into account the health care needs of all Canadians.

We support the PMPRB Guidelines to the newly amended Patented Medicines Regulations that will come into force in January 2021. These guidelines are the product of a five-year process that included extensive consultations with Canadians across the country. We believe the Guidelines will strengthen the PMPRB's role in protecting Canadian consumers from the excessive costs of patent medicines by introducing new requirements for determining and monitoring patented drug price ceilings.

What we support

We were glad that the new Guidelines were supported by Canada's health minister and were heartened that the federal government sees these reforms as a key building block for National Pharmacare.

We particularly welcome two reforms: the new basket of comparator countries the PMPRB will use to set drug prices in Canada, and stronger rules that allow it to assess value-for-money based on the actual price paid at the cash register, rather than the industry's inflated numbers. We also support the benchmarking of prices against countries more akin to Canada, requiring information from the pharmaceutical industry about actual prices (including rebates and discounts) paid in Canada, and incorporating a pharmacoeconomic lens to determine the therapeutic value of drugs in the context of other public health needs. We believe that these amendments lend positive support to plans for a National Pharmacare program which will need access to fairly priced essential medicines.

Room for Improvement

However, we feel that some of these amendments do not go far enough. The "basket" of countries that will be used to help set prices in Canada has been changed and the number of comparator countries has increased, but they still spend above the OECD average. And we are

concerned that the PMPRB will continue to use the highest list price for the purpose of the Maximum List Price comparison.

An assessment of pharmaco-economic value (PV) is an important new feature of the PMPRB regulations, designed to provide the patient population with the most health benefit within a limited health budget. The PV allows the PMPRB to take into account the opportunity cost of making cuts elsewhere in the system when a drug is excessively priced, using the standard measure of the Quality-Adjusted-Life-Year (QALY). In the November 2019 draft of the Guidelines, the PV threshold was established at $60,000 per QALY and, for patented medicines for rare diseases, at a 50% higher threshold. But, as the PMPRB reported, pharmaceutical manufacturers were "fundamentally opposed to the introduction of PV as a factor…in determining what constitutes an excessive price". Some rare disease groups were also opposed, arguing that these thresholds were "arbitrary and unreasonable." However, we believe this is a valuable addition to the PMPRB's powers. The clinical benefit of new drugs is often ambiguous or unknown, which has allowed companies and industry-funded patient groups to press for coverage of very expensive drugs that turn out to have limited clinical value and sometimes significant clinical harm. Unfortunately, in response to industry opposition, the new guidelines substantially weaken this valuable regulatory tool by revising the guidelines to change the PV threshold from $60,000 per QALY to $100,000 to $200,000 per QALY depending on Therapeutic Criteria Level.

We would like to see HESA recommend that the PMPRB reinstate the PV threshold of $60,000 per QALY.

We are also uncertain about how – or whether – prices of patented drugs will be weighed in relation to their impact on total population health needs and our health care system as a whole. For example, as the population ages, we have seen an increased need for other non-pharmaceutical services such as dental and vision care, audiology and other essential services. Even without taking into account these growing needs, expenditures on patented medicines already take a disproportionate share out of every health care dollar, a fact that is felt across the entire health care system where Canadians are often waiting in long queues to access services.

In spite of these concerns, we urge the House Standing Committee on Health to recommend implementation of the Guidelines in January 2021. We offer one example of how stronger powers for Canada's Patented Medicine Prices Review Board will make a difference for those who need access to reasonably priced drugs, in this case insulin.

Insulin: an example of weak price controls

Insulin prices in Canada have been on an upward trajectory since the introduction of recombinant DNA human insulin in the mid-1980s. At the time, the average annual cost for insulin was estimated at about $250 – about $540 in current Canadian dollars.[1] Then in the mid-1990s, manufacturers began to heavily promote insulin analogues, and in 1995 initiated a withdrawal of up to 27 low-cost insulin products derived mainly from cows and pigs. By 2017, a vial of the

[1] Christopher J. Rutty, "'Couldn't Live Without It': Diabetes, the Costs of Innovation and the Price of Insulin in Canada, 1922-1984," Canadian Bulletin of Medical History 25, 2 (2008): 414-416.

most commonly used insulins ranged in price from $60 to $130 a vial[2] with an average cost of between $1080 and $2340 a year.

In April 2002, Sanofi received market authorization for insulin glargine, a long acting insulin analogue with the brand-name Lantus. This approval was welcomed among diabetics who experienced harm or lack of benefit from the existing stock of insulin products then available in Canada and who responded with hope and anticipation to news that a safer and better insulin might soon be available. Unfortunately, the evidence was not as robust as the company's marketing campaign and two years later, Lantus was still not available in Canada because Sanofi had not come to an agreement with the PMPRB on price. Many physicians voiced concern that Sanofi was aiming for a price in Canada that would match what it cost in the United States. As Dr Christopher Kovacs, an endocrinologist in St. John's, put it, "Many of my colleagues in endocrinology and diabetes from across Canada have received a consistent message about the status of Lantus. That is: [Sanofi] Aventis is pushing to have Lantus at the same price as in the U.S., or close enough to it that there is no big advantage for an American to buy it in Canada."[3]

Sanofi's asking price was on par with what it sold for in the United States – but three times higher than the highest priced insulin then on the market. Yet most studies indicated Lantus was not much better, a fact that could not be missed.[4] While the PMPRB struggled with this issue, Sanofi was threatening to pull jobs out of Germany – a comparator country – in protest against a new policy on drug pricing which placed branded and generic drugs into the same reference price groups. The company's chair, Jean-Francois Dehecq, said the policies were "disastrous" and warned that Sanofi had no interest in investing in countries where it couldn't make a profit.[5] Two years later, the Institut für Qualität und Effizienz im Gesundheitswesen (Institute for Quality and Efficiency in Healthcare) reported that "insulin analogues have not shown superiority over human insulin; hence no higher price is justifiable."[6] When the regulator, Gemeinsame Bundesausschuss, announced public reimbursement for analogues would be restricted until the price was no higher than human insulin, patient groups and the pharmaceutical industry responded with anger, with Sanofi threatening to bring legal action.[7]

In its 2005 report on insulin glargine, the PMPRB, echoing scientists and regulatory authorities around the world, concluded that Lantus was not the breakthrough drug its manufacturer claimed it was and gave it a Category 3 designation (provides moderate, little or no therapeutic advantage over comparable medicines). Nonetheless, Sanofi proposed that the introductory price of $5.507 per mL was justified in spite of the fact it was nearly triple the cost of conventional insulins with similar safety and efficacy profiles. After a tense negotiation with the company that took many months, the PMPRB announced that the introductory price for Lantus insulin "did not exceed the

---

[2] Price Comparison of Commonly Prescribed Pharmaceuticals in Alberta 2017. https://www.acfp.ca/wp-content/uploads/2017/03/ACFPPricingDoc2017.pdf.
[3] "Wait still on for Lantus," Cheryl LaRocque, Medical Post. Vol 40; No. 22, June 1, 2004. Sanofi denied this claim.
[4] Holleman F, Gale E. Nice insulins, pity about the evidence. Diabetologia 2007;50:1783-90
[5] "Sanofi-Aventis to shed jobs in Germany," Pharma Marketletter, December 20, 2004.
[6] Cohen D, Carter P. How small changes led to big profits for insulin manufacturers . BMJ 2010 ;341: c7139. 2. Diabetes UK (2010).
[7] "Anger Builds in Germany Over Insulin Analogues," Gustav Ando. IHS Global Insight, July 20, 2006.

median of the prices of the same drug product" in the comparator countries listed in the Regulations.[8]

This was an unfortunate retreat on the part of the Price Review Board, but one that mirrored the tug-of-war in Europe between regulators and the pharmaceutical industry. Manufacturers criticized the emergence of what were described as "third hurdles in the form of health-technology assessments (HTAs) in the post-licensing phase to determine the value of new drugs to the healthcare system." This had led to ongoing stand-offs in the U.K. and other jurisdictions that, as was the case with insulin analogues, attracted considerable media attention. Moreover, as Global Insight, an economics forecasting group pointed out, "the human-interest angle of patients denied access to potentially life-saving therapies has generated an unusual level of support for a pharmaceutical industry often regarded with deep suspicion."[9] But the PMPRB's decision to rubberstamp a price tag on insulin that showed no additional benefit to existing and much less expensive alternatives put the evidence of safety, effectiveness and value for money on the backburner.

The action shifts to the payer

The greatest burden for this decision was carried by patients who were prescribed Lantus insulin but who lacked any kind of insurance coverage, public or private. Shortly after the PMPRB's decision, the matter went to the Common Drug Review which, after reviewing 20 clinical trials, concluded that "studies did not find statistically or clinically significant differences between insulin glargine and NPH (or ultralente)…in patients with either Type 1 or Type 2 diabetes."[10] It recommended that insulin glargine not be listed in provincial formularies. This was followed by an aggressive lobby by the manufacturer and the Canadian Diabetes Association (now Diabetes Canada) whose Clinical Practice Guidelines (co-sponsored by Sanofi) had recommended Lantus insulin in 2003 – a year before it was available on the market.

In a letter to then-Minister of Health Ujjal Dosanjh, the industry-funded diabetes group protested that the CDR's recommendation contradicted "Health Canada's scientists and international experts at the Therapeutic Products Directorate [who] reviewed, evaluated and approved the safety and efficacy of insulin glargine." It also pointed to the PMPRB which, it said, had "approved insulin glargine for sale in Canada, thereby making it available to those Canadians who could personally afford it."[11] Against a backdrop of aggressive promotion of Lantus insulin by Sanofi, provincial CDA groups and patients demanded that provincial drug plans list the insulin. The organization did not publicly lobby Sanofi to lower the price, focusing instead on mobilizing its members to force provinces to list Lantus.

---

[8] *Report on new patented drugs -- Lantus*. Ottawa: Patented Medicine Prices Review Board; 2005.

[9] "Germany's GBA committee has decided that the cost of short-acting insulin analogues should only be borne by the statutory sick funds when these products are no more expensive than human insulin," IHS Global Insight. July 19, 2006.

[10] Canadian Coordinating Office for Health Technology Assessment. CEDAC final recommendation on reconsideration and reasons for recommendation. Insulin glargine (Lantus® — Aventis Phrama Inc.). 2005. Available: www.ccohta.ca/CDR/cdr_pdf/cdr_submissions/Complete/cdr_complete_Lantus_2005Sept28.pdf

[11] Letter to the Honourable Ujjal Dosanjh, Minister of Health, from Michael Howlett, President and CEO of the Canadian Diabetes Association, October 11, 2005.

In 2007, a systematic review and meta-analysis by the Canadian Agency for Drugs & Technologies in Health found that "the total budget required by drug plans for insulin products increases when long-acting insulin analogues [LAIAs] are listed, because of the higher cost of the analogues." Based on rising numbers of insulin users switching from lower-cost conventional insulin to analogues, it estimated the increased cost to provinces over three years (2006 to 2008) "would range from C$605,708 to C$13,921,951 (if 10% switched) and from C$3,534,906 to C$79,115,423 (if 100% switched), depending on the province." It cautioned that publicly funding these analogues "will require significant additional investment largely because they are based on unproven assumptions about the long-term benefit of therapy."[12] But in 2007, one paper estimated the annual growth in sales of insulin glargine at 37%. Today, Lantus is the top-selling insulin on the Canadian market reaching total sales of $273 million In 2018.[13] And while a 10ml vial costs about $71 in Canada, according to a 2018 study in BMJ Global Health the estimated cost of production for to be between USD$3.69 and USD$6.16. The same study suggested that, including profits, transport and other costs, a fair selling price for analogues, including glargine, would be between US$78 and US$98 per person per year.

Despite CADTH's recommendation and its estimate of the impact on provincial budgets, all provinces and territories listed Lantus insulin, three with restrictions. This reflected a full-blown campaign to pressure provinces to include Lantus in their drug plan formularies. In 2019, B.C. became the first province to remove the product from the Pharmacare formulary, replaced by Basaglar, a more cost-effective biosimilar.

Stronger Guidelines are one essential step to ensure that the scenario outlined above – and which is similar for many other new drugs in Canada – is not repeated over and over again. Without stronger guidelines, Canadians will continue to be held to ransom by companies whose main concern is the bottom line, not the health and well-being of people who need medicine.

Conclusions and Recommendations

Insulin manufacturers have been part of two court cases challenging the Constitutional authority of the Government of Canada to protect Canadians from excessive and unjustified drug prices. They have manipulated patient groups, some of which they fund, to join them in an aggressive lobby to ensure the Guidelines which are the subject of HESA's study are either delayed indefinitely or never introduced at all. In the United States, manufacturers are suing the state of Minnesota for passage of the Alec Smith Insulin Affordability Act. The bill passed almost three years after the death of 26-year old Alec Smith who was unable to pay the $1300 a month it cost him to buy insulin and who died as a consequence. The effort to get the new law enacted was led by the young man's mother and backed by a group called T1International which spurns funding from the pharmaceutical industry.

The industry manipulates patients whose lives depend on and have a right to expect unhindered access to safe and effective medicines. Many of us, frankly, are fed up that this continues without

[12] Tran K, Banerjee S, Li H, Cimon K, Daneman D, Simpson S, Campbell K. Long-acting insulin analogues for diabetes mellitus: meta-analysis of clinical outcomes and assessment of cost-effectiveness [Technology Report number 92]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2007.

[13] Generics and Biosimilars Initiative. The Cost of biologicals in Canada, October 10, 2020. Available at: http://www.gabionline.net/Reports/The-cost-of-biologicals-in-Canada

hindrance in Canada. Any relationship with the industry comes, we believe, with a very high moral and ethical cost. Many patient advocacy groups lack any substantial funding and struggle to ensure that views which represent their interests, as opposed to the interests of drug company investors and shareholders, are part of the discussion.

We ask the Standing Committee on Health to recommend that the government undertake to study the financial links between charitable groups that purport to represent patients and the pharmaceutical industry. This would be of more value than yet another study of the PMPRB Guidelines.

We ask that the Standing Committee on Health recommend to the federal government that they enable the PMPRB to implement the Guidelines in January 2021.

We also ask that that HESA recommend the PMPRB reinstate the PV threshold of $60,000 per QALY.

The pharmaceutical industry threatens that it won't introduce new medicines to Canada if the new Guidelines go into effect. This isn't the first time this has happened, and nor is Canada the first country to confront this kind of intimidation. A project on Access to Insulin managed by Amsterdam-based Health Action International found that a growing number of children in low-income countries are unable to obtain insulin. A diagnosis of Type 1 diabetes for these children is a death sentence and most will die within a year. A report by the group in 2016 noted that "Worldwide, 100 million people need access to the insulin, yet currently one in two of these people cannot rely on an adequate supply due to a multitude of barriers to affordability and availability."[14]

Companies not only make decisions about when and whether to introduce medicines, they also withdraw drugs that may no longer be profitable for them or because they disagree with regulatory measures they disagree with. As mentioned above, Eli Lilly and Novo Nordisk withdrew up to 27 lower-cost, effective and safe insulin products between 1995 and 2006. In 1985, Eli Lilly, whose Argentine plant produced 1000 litres of insulin per month, demanded an exemption from across-the-board government price controls so they could hike insulin prices. When the government refused, Lilly closed its plant, leaving 73,500 people stranded. The government hastily arranged for the importation of insulin from BioBras, based in Brazil, and moved to establish a national producer.[15]

Canada is vulnerable to this kind of unethical behaviour because we are so dependent on companies that have no allegiance to anyone or anything except an ever-increasing rate of return. This hasn't always been the case. In 1913, the University of Toronto created Connaught Laboratories to produce a low-cost vaccine for diphtheria. Toronto was facing an outbreak of the disease which, at the time, was the leading cause of death for children aged 2 to 14 years. Many people could not afford the American vaccine, which cost $25, the equivalent of two weeks'

[14] Ewen, M., Beran, D. "Access to insulin: current status and global policy implications," Submission to the UN Secretary-General's High-Level Panel on Access to Medicines, February 25, 2016. http://www.unsgaccessmeds.org/inbox/2016/2/25/margaret-ewen-and-david-beran.
[15] "Latins' Narrow View of Trade," Eric Ehrmann, Journal of Commerce, 3 November 1987.

wages for most working families. The University's goal was to produce the antitoxin, as well as other essential medicines and vaccines, as a public service, to be made available free of charge to provincial boards of health across the country. In May 1914, the University agreed to form the Connaught AntiToxin Laboratories to provide a complete range of essential medicines and vaccines to all Canadians for free, regardless of income.[16] In 1985, Connaught was privatized by the federal government and subsequently sold to what is now Sanofi.

The re-establishment of a public manufacturer would assure that Canadians have access to low-cost essential medicines. It also would support the creation of a National Pharmacare program. We urge the Standing Committee on Health to recommend that the federal government move to establish a public manufacturer of generic medicines and vaccines in Canada.

And finally, it is time to re-institute a national system of compulsory licencing. This would strengthen the ability of the PMPRB to more effectively control the cost of medicine, something that is essential to plans for a National Pharmacare program which the federal government has indicated it is committed to pursuing. Compulsory licensing would shift the power over price from the patent holder to government while at the same time protecting the patent holder's right to make a profit.[17] This would strengthen both federal and provincial negotiators with manufacturers over bulk purchasing of essential medicines. And as Sean Flynn, Aidan Hollis and Mike Palmedo have pointed out, "The right of countries to use compulsory licenses to promote access to medicines has been repeatedly reaffirmed in international law, including through the Doha Declaration on the TRIPS Agreement and Public Health, issued at the 2001 WTO Ministerial Meeting."[18] There is nothing holding us back from taking this important step to exert greater control over the price that Canadians pay for the medicines they need.

We ask that the Standing Committee on Health recommend that the federal government identify options to pro-actively utilize a system of compulsory licencing. If a manufacturer has not patented a drug in Canada, we ask that other avenues be explored, including support for public patents on innovative medicines.

---

[16] James FitzGerald, "Dr. John Gerald FitzGerald: The Troubled Healer," University of Toronto Magazine, Spring 2002. Sanofi, the corporation that bought Connaught in 1989, asserts that FitzGerald's goal "was to provide life-saving public health products in Canada at a price that was within the reach of everyone" – rather than free of charge. See http://www.sanofipasteur.ca/node/17302.

[17] Hollis A. The link between publicly funded health care and compulsory licencing. CMAJ 2002 Oct. 1; 167(7): 765-766.

[18] S. Flynn, A. Hollis, and M. Palmedo, "An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries," Journal of Law, Medicine & Ethics 37, no. 2 (2009): 184-209

Thank you for allowing Independent Voices for Safe & Effective Drugs to submit this brief to the Committee and we hope we have made a contribution to your deliberations. We have appended our February 2020 submission to the PMPRB for further information.

Submitted by:

Colleen Fuller, Vancouver
Wendy Armstrong, Edmonton
Sharon Batt, Halifax
Janet Currie, Edmonton
Linda Furlini, Montreal

Contact:
Colleen Fuller
Email: colleenfuller3@me.com
Telephone: (604) 255-6601; (604) 441-6296 (cell)

INDEPENDENT VOICES FOR SAFE AND EFFECTIVE DRUGS

REPRESENTING CANADIAN ACADEMICS, RESEARCHERS, PATIENT AND CONSUMER ACTIVISTS

February 8, 2020

Patented Medicine Prices Review Board
Consultation on Draft Guidelines

To the Patented Medicines Prices Review Board:

We are academics, researchers, and patient and consumer advocates with no ties to the pharmaceutical industry. We are able to speak directly to the research evidence on drug costs, safety and efficacy and to take into account the health care needs of all Canadians.

We welcome the opportunity to comment on the Draft Guidelines to the newly amended Patented Medicines Regulations that will come into force July 1, 2020. These amendments are intended to strengthen the PMPRB's role in protecting Canadian consumers from the excessive costs of patent medicines by introducing new requirements for determining and monitoring patented drug price ceilings.

We strongly support the mandate of the PMPRB in terms of researching, monitoring and setting price ceilings for patented drugs. Canada's patented drug prices are the third highest among OECD countries and much of this cost burden is carried by 23% of Canadians who pay out of pocket for their medications. The high cost of patented medicines not only affects patients directly but also draws money out of the health care system that could be used to enhance access to medically necessary health care services that are vital to Canadians.

In addition to these direct opportunity costs, unseen ripple effects have an impact on access to prescription medicines. For example, high drug costs are pushing insurance premiums up and extended health benefits out the door. Up to 80% of the cost of extended health benefits are going to pharmaceuticals, and as drug costs increase many small and mid-sized employers have cancelled coverage. Both public and private employers have moved to outsourcing, contract and part-time jobs to avoid the high costs of employer-funded health benefit plans. One group that has felt the full weight of cancelled benefits are seniors: a majority of employers no longer provide benefits to retirees at all.

We support many of the regulatory amendments proposed by the PMPRB, including benchmarking prices against countries more akin to Canada, requiring information from the pharmaceutical industry about actual prices (including rebates and discounts) paid in Canada,

and incorporating a pharmacoeconomic lens to determine the therapeutic value of drugs in the context of other public health needs. We believe that these amendments lend positive support to plans for a National Pharmacare program which will need access to fairly priced essential medicines.

However, we feel that some of these amendments do not go far enough. The "basket" of countries that will be used to help set prices in Canada has been changed and the number of comparator countries has increased, but they still spend above the OECD average. And we are concerned that the PMPRB will continue to use the highest list price for the purpose of the Maximum List Price comparison.

We are also uncertain about how – or whether – prices of patented drugs will be weighed in relation to their impact on total population health needs and our health care system as a whole. For example, the population of elderly Canadians is increasing and we must consider how we will respond to the growing need for home support and home care. As the population ages, we have seen an increased need for other non-pharmaceutical services such as dental and vision care, audiology and other essential services. Even without taking into account these growing needs, expenditures on patented medicines already take a disproportionate share out of every health care dollar, a fact that is felt across the entire health care system where Canadians are often waiting in long queues to access services. Our health care system is already strained.

We believe that the PMPRB is an essential tool in Canada's efforts to effectively control the cost of prescription medicines. As the Minister's office has stated before, the regulatory changes will help "lay the foundation for National Pharmacare," something that Canadians are anxious to see. However, we believe there are additional tools that Canada needs to support the work of the PMPRB and the potential role it can play in a National Pharmacare program. One of these is compulsory licencing.

Beginning in 1923, Canada's patent laws allowed compulsory licensing of pharmaceuticals. After amendments in 1969, compulsory licencing saved Canadians an estimated $100 million dollars a year ($679 million in 2020 dollars) and created the conditions for a thriving domestic generic drug manufacturing industry. Under this system, Canadians paid among the lowest drug prices for prescription medicines in the world.

In 1987, the government passed Bill C-22, limiting compulsory licensing and creating the Patented Medicine Prices Review Board to ensure prices of patented medicines were not excessive as a consequence of the new law. But six years later compulsory licencing was eliminated altogether, a move that had a dramatic and negative impact on domestic generic drug manufacturing and on our ability to control the cost of drugs. Today, brand-name pharmaceuticals account for just under 80% of domestic sales in Canada[1], up from 43.9% in 1995.[2] Canada's trade deficit in pharmaceuticals has also skyrocketed, from $1.6 billion in 1993, to $4 billion in 2000[3] and $8.5 billion by 2018.

---

[1] Industry Canada, Pharmaceutical industry profile. Available at https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html.

[2] Canadian Drug Manufacturers Association, "PMPRB Annual Report shows increase in market share for Big Pharma as Canadians' drug costs continue exponential rise," in Drug Costs News Update, July/August 2001

[3] Canadian Drug Manufacturers Association, "PMPRB Annual Report shows increase in market share for Big Pharma as Canadians' drug costs continue exponential rise," in Drug Costs News Update, July/August 2001

As Sean Flynn, Aidan Hollis and Mike Palmedo have pointed out, "The right of countries to use compulsory licenses to promote access to medicines has been repeatedly reaffirmed in international law, including through the Doha Declaration on the TRIPS Agreement and Public Health, issued at the 2001 WTO Ministerial Meeting."[4] Since it was introduced, the "Doha Declaration solution," has only been used once. This occurred in 2007 when Apotex was granted a compulsory licence by Canada to export antiretroviral drugs to Rwanda.[5]

Canada is facing growing pressures to manage the costs of Expensive Drugs for Rare Disease (EDRDs), including biologics, which in 2018 comprised 26.2% of Canada's pharmaceutical sales. Lower cost strategies, including the use of less expensive biosimilars, have had limited success in Canada and lag far behind European countries. We believe that compulsory licencing within the terms permitted by the WTO under the Doha Declaration is possible and would support access to cost-effective biosimilars in Canada. It also would complement the regulatory mandate of the PMPRB, contributing to a strong foundation for a cost-effective National Pharmacare program.

We therefore urge the PMPRB to explore the viability of using compulsory licencing, possibly in alliance with other countries such as The Netherlands who may also be interested in developing policies that meet population needs while upholding obligations undertaken in the WTO. Compulsory licensing – or even the possibility of compulsory licencing – would shift the power over price from the patent holder to government while at the same time protecting the patent holder's right to make a profit. This would strengthen negotiations with manufacturers over bulk purchasing of essential medicines and strengthen the role of the Patented Medicine Prices Review Board in medicine pricing.

We congratulate the PMPRB for including a range of voices and backgrounds in their recent consultation processes. We are disturbed, however, by the dominant role that patient groups funded by the pharmaceutical industry have played within the PMPRB, most notably when three individuals, all from organizations heavily funded by the drug industry, were named to represent patients on a steering committee of the Review Board. At the same time, members of patient and health advocacy organizations independent of the industry were entirely missing from the same committee.

We have to wonder on what basis individuals were chosen to sit on the steering committee, since the selection criteria are not, to our knowledge, on the record. Furthermore, some of the views of these committee members on drug prices and related drug policy matters are contested within the patient and health advocacy community. In future, we recommend that individuals selected to represent patients and the public interest on drug policy agencies be chosen through a transparent process, grounded in a system accountable to patients and to the public interest. This would help ensure that the range and diversity of views and experiences among Canadians better informs public policy.

Many countries are grappling with the dilemma of industry-funded patient advocacy organizations. The process of implementing a new drug policy regimen is an opportunity for Canada to establish a system of "best practices" for engaging with patient and public interest

[4] S. Flynn, A. Hollis, and M. Palmedo, "An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries," Journal of Law, Medicine & Ethics 37, no. 2 (2009): 184-209

[5] Ooms Gorik, Hanefeld Johanna. Threat of compulsory licences could increase access to essential medicines BMJ 2019; 365 :l2098

groups. A good starting point, we believe, would be to require independence from the pharmaceutical industry.

We look forward to working in the future with the PMPRB to achieve our common goals of an effective patented medicines pricing regime and a National Pharmacare program.

Submitted by:

Janet Currie, Edmonton, janetcurrie1@shaw.ca

Colleen Fuller, Vancouver, colleen_fuller@telus.net

Sharon Batt, Halifax, sharon.batt@dal.ca

Linda Furlini, Montreal, furlinil@bell.net

Wendy Armstrong, Edmonton, wlarmstrong@shaw.ca