Eva Quattrini

German Pharmaceutical Policies: an example for Canada.

To achieve universal health coverage, the World Health Organization (WHO) has repeatedly stressed the importance of coherent pharmaceutical policies to provide "universal access to safe, affordable and appropriately prescribed medicines" (Morgan et al. 2016,20). Although the Canadian health care system provides universal health coverage including all necessary drugs in hospital and emergency care, universal prescription drug coverage is not extended to drugs outside the hospital setting (Daw and Morgan 2012,19) making Canada the only country with a universal healthcare system without universal prescription drug coverage.

Most Canadians therefore rely on various private drug insurances, usually provided through an employer sponsored health benefit plan, to finance their prescription drug expenditures (Morgan et al. 2013,3-4). Despite various provincial drug plans serving specific demographics such pensioners and low income individuals, close to 10% of the Canadian population find themselves without prescription drug coverage and recent national surveys indicate that in 2014 close to 14% of Canadians did not fill drug prescriptions due to cost considerations (Morgan et al. 2016, 24). Inadequate access to medicines is associated with many unfavourable healthcare outcomes including increased emergency hospitalization (Morgan et al. 2015,7) and premature death (Morgan et al. 2016,25).

In the recent years, drug prices in Canada have increased substantially compared to the OECD country average (Morgan et al. 2015,13), contributing to an overall healthcare expenditure between 11-12% of GDP per year, similar to 11% of GDP for Germany. This translated into close to $6,000 of spending per person with approximately 16% of this expenditure on pharmaceuticals (Maioni 2015, 48-50). This makes pharmaceuticals one of the top three health expenditures in

Canada (Salehi 2016,544) and importantly, on a per capita basis, the amount spent on drugs in Canada is more than in any other country apart from the United States (Lexchin 2015, 30).

Universal pharmacare policies have been discussed on a federal and provincial level since the early debates on the universal Medicare system over 50 years ago (Morgan and Daw 2012,16) and there have been three key attempts, in the early 1970s, the late 1990s and early 2000s to introduce a universal pharmacare program in Canada (Boothe 2015, 86). Due to high drug prices in the late 1950s and 1960s, commissions were established to make recommendations on drug price controls which cumulated in the 1972 Drug Price Program which proposed a 50% federal contribution to universal provincial drug coverage programs including co-payments. Although one of the primary policy aims was price control, policy makers generally regarded it as too expensive and there was limited electoral interest as drugs were not considered a major concern for the general public. In the 1960s there were only a few private drug insurance providers and most provincial drug plans were not introduced until the early 1970s (Boothe 2015, 92-95). Only in 1997 did universal pharmacare appear again on a political platform. However, comparable to the 1970s, the potential price tag of a pharmacare program in combination with the recent memory of the financial difficulties of the Canadian government in the early 1990s, obstructed concrete policy development (Boothe 2015, 98-101). The most recent proposals for nationwide pharmacare were introduced in two federally mandated reports in the early 2000s. Given the failure of the comprehensive policy initiatives in the 1990s, policy makers pushed for the introduction of only limited federal coverage for catastrophic pharmaceutical expenditures for people who experience high drug expenditures as a percentage of their income. The general idea of this limited scope was to initiate a federal drug insurance program which then could be extended over time. However,

even this limited proposal was also not successful to generate a federal pharmacare program (Boothe p.104-105).

Overall, there are a few key explanations for the past failures of universal pharmacare policy. Arguably, one of the main structural challenges in Canada is the fact that each province has its own unique healthcare administration and highly variable health requirements due to the differences in size, population, and wealth of each province (Morgan et al. 2016,20,31) which make coordination difficult. Policy makers have not regarded pharmacare as a priority due to the general belief that fixing the current services takes precedence over adding new ones. Importantly, universal pharmacare coverage has been regarded as too expensive, with no effective cost control measures and this opinion has been supported and reinforced by the public (Boothe p. 105-106). Also, there is evidence that the complexity of the analytical and policy aspects of pharmacare proposals were a major deterrent for policy makers. Furthermore, given the limited experience of directly administering health programs, there was doubt that the federal government would able to manage a complex program such as universal pharmacare on a nationwide level (Boothe p. 107).

Compared to other countries with a federal government, such as Germany, the highly decentralized nature of the Canadian healthcare system is unique. In particular, healthcare in Canada is not a constitutionally shared jurisdiction but primarily the responsibility of each province with the federal government only involved in a limited number of administrative or financing decisions. One of the only ways the federal government can influence provincial health policies is through the Canada Health Act (1982). The act mandates the federal government to provide a portion of healthcare funding to provincial governments which in return have to provide healthcare services that meet the conditions of the act (public administration, comprehensive coverage of services, universal eligibility, portability across the country and a guarantee of equal

access) (Maioni p. 31-35). Although the criteria provide a framework which has been effective in standardizing some healthcare services throughout provinces, there only has been little coordination on pharmacare policies. This lack of coordination has resulted in the pharmaceutical market being fragmented into a complicated "patchwork" of federal regulators, provincial healthcare providers, government and private healthcare insurance companies, many of which decide on their own course of action independent from one another (Lexchin 2015,38-39).

The principal pharmaceutical regulatory body in Canada is the Patented Medicine Prices Review Board (PMPRB) which was founded in 1988 to control the introductory price of new medicines and to limit the existing price increase over time to the rate of inflation. PMPRB is a federal agency that works at arm's length from the Ministry of Health and has authority over all patented medicines sold in Canada (close to 60% or $12.8billion per year). PMPRB assesses whether a new drug represents a new presentation of an existing product or if it is a new active substance never sold before in Canada. If the drug is an existing product, it is priced similar to the other products already available in Canada. On the other hand, if the drug is a new active substance, a variety of criteria including reference prices from seven comparator countries (France, Germany, Italy, Sweden, Switzerland, the UK and the United States) are used to establish the maximum average potential price. In the case the pharmaceutical company chooses a price above this maximum, PMPRB enters negotiations with the company and can force to lower the price in federal court (Lexchin 2015, 29-31).

PMPRB has been largely successful at limiting the prices of individual drugs in line with prices in other OECD countries. However, unlike regulatory agencies in other countries such as Germany, it allows companies to set the price of new medicines at the highest price charged in the same therapeutic market. This practice results in new drugs being almost always priced close to

the maximum price allowed in the market. Notably, PMBRB only has jurisdiction over price regulation and does not provide recommendations on prescription volume and mix of treatments which are regarded as the main contributors to the significant increases in per capita drug expenditures in Canada compared to the OECD average (Lexchin 2015, 30-31).

In addition to PMPRB, the Canadian Agency for Drugs and Technologies in Health (CADTH) was established in 1989 to provide a national organisation to coordinate the review of health technology. In particular, CADTH formed the Common Drug Review in 2003, which provides advise to the three federal and all provincial drug plans (except Quebec) on the clinical and cost effectiveness of drugs compared to other alternatives. CADTH primarily reviews submissions of new drugs from manufactures or existing classes of drugs. However, the recommendations made by CADTH are non-binding and a number of drug plans have listed drugs despite negative ratings (Lexchin 2015, 33). Notably, both PMPRB and CADTH make recommendations on drug effectiveness and prices largely independent from the buyers of drugs, the public and private insurance providers or private individuals, and the prescribers of drugs, the physicians. Although the two federal agencies communicate their findings to the responsible entities in the provinces, there is no institutionalized coordination mechanism which facilitates communication between the various provincial actors and the federal regulators.

Since 2006, the Ontario Public Drug Program (OPDP) has been proving pharmaceutical coverage to close to 3.8m Ontario residents with an estimated overall budget of $4.8billion per year. The plan covers close to 3,800 eligible drug products for persons over the age of 65, on social assistance, living in long term/special care homes or persons with high drug costs relative to their income (Trillium Drug Program). In 10 years of operation, OPDP estimates to have saved approximately $3.3billion through the promotion of appropriate drug use and by providing Ontario

with a stronger commercial position as a drug purchasing entity. Regarding the integration in the national regulatory system, OPDP reviews drugs recommendations issued by CADTH using the Committee to Evaluate Drugs (CED) in order to "filter" recommendations to Ontario specific considerations (Ontario Public Drug Program 2016, 2-4). The fact that the recommendations made by CADTH are not considered to be directly applicable to Ontario is a clear indicator that coordination and an institutionalized feedback structure is needed in order to the make the existing federal agencies more relevant to the provinces.

OPDP joined the pan-Canadian Pharmaceutical Alliance (pCPA) which has provided significant benefits to OPDP and other provincial drug plans through coordination of pharmaceutical purchases (WHO 2015). In particular, coordinated purchases provided OPDP with a favorable commercial position which enabled it to reduce the price of a number of the most common generic drugs to 18% of the brand name product price, which resulted in close to $100m of savings for Ontario annually (Ontario Public Drug Program 2016, 7-8). Furthermore, a number of provincial drug plans have entered product listing arrangements (PLA) with drug companies, agreeing to list their products in return for unpublished discounts. These discounts are reported to have reduced expenditures to the benefit of tax payers, however, since the prices are not published, there is no direct evidence of the extend of the reductions (Lexchin 2015,34).

Private insurance companies provide some form of drug insurance to close to 68% of the Canadian population (approximately 23million people) and therefore incur a large portion of the overall drug expenses. Contrary to the provincial drug plans who operate on a limited tax funded budget, private insurance companies have little incentives to curtail costs. The primary reason is that the majority of the expenditure is passed through to other insurance companies or to the employers who provide their employees with group benefit plans. Private insurers are therefore

found to be more likely to list new and usually more expensive drugs than public plans (Lexchin 2015, 36-37). Despite the low incentives for cost reduction, even private insurance companies have attempted to increase coordination and cooperation by joining the Canadian Drug Insurance Pooling Corporation which was established by the Canadian Life and Health Insurance Association in 2012. In particular, the pooling corporation was created for insurance providers to share the costs of the number of recently developed high priced pharmaceuticals for diseases such as hepatitis C, some forms of cancer, and rare conditions which have put a significant burden on insurance companies and consequently on the companies paying for insurance cover for their employees (Canadian Life and Health Insurance Association 2012). Nonetheless, this cooperation does not confront the underlying issue of high prices but only helps to manage the resulting financial burden.

Apart from the federal regulators and the public and private insurance providers, other key actors in the pharmaceutical market are the physicians, who are the primary decision makers on the choice of treatment plans and consequently on which drugs are chosen and purchased. In Ontario, licensing and regulation of physicians, including treatment guidelines, are overseen by the College of Physicians and Surgeons of Ontario (CPSO). The CPSO formulates a variety of healthcare policies focused on treatment experience and quality, however it appears to largely disregard monetary value considerations. For example, the recently updated policy statement on prescribing drugs, which is the guideline for physicians in Ontario for filling prescriptions, does not mention the word “price” or “value” in the context of a monetary consideration (CPSO 2012).

Although many of the key aspects of Canadian pharmaceutical policies are unique, including the divisions between the federal and provincial jurisdictions and the fragmentation in private and public drug insurance providers, it is nevertheless worthwhile to analyze the

approaches and solutions in other federal systems, such as Germany. Most notably, the German healthcare system, which faces many challenges similar to Canada regarding high costs and countless actors and stakeholders, forces all key actors to make decisions in a combined effort. While the result is a fairly complicated and convoluted structure, the coordinated approach of the German system has been effective in improving affordability of medicine (Maioni 2015,83) while providing R&D incentives for pharmaceutical companies (Sieler et all. 2015,26).

Just as Canada, Germany has a universal health care system which provides comprehensive health care coverage through mandatory health insurance, however including prescription drug coverage. Contrary to the Canadian system, in Germany patients are provided with a number of choices regarding their statutory (government) health insurance plans and coverage. Given a certain income threshold, there also exists an option to choose a private insurance provider instead of one of the statutory insurance plans. In addition, patients have a choice of healthcare providers and universal access to all healthcare facilities. Just as in Canada, healthcare policy decisions in Germany are shared between the federal government and the state governments (provinces). However, a significant number of healthcare decisions are made by self-governing associations, the most notable of which are those of accredited physicians (the providers) and the statutory health insurance funds (SHI), called the sickness funds (the payers). With oversight by the Federal Ministry of Health and state governments, these associations make decisions on financing and delivery of all aspects of healthcare benefits including coverage and pricing of prescription pharmaceuticals (Busse and Blümel 2014,17-20). In contrast to the general revenue financing in Canada, the German system is financed through mandated payroll taxes shared by employers and employees (Maioni 2015, 83).

Importantly, healthcare decisions in Germany are formulated by a plenary, self-governing body called the Federal Joint Committee which consists of representatives of each of the associations, including the sickness funds, the physicians and patients (see Figure 1 in the annex) (Busse and Blümel 2014,43). The Federal Joint Committee issues directives which are communicated to all actors and organizations in the healthcare system. Due to the complexity of the decisions regarding a multitude of subjects, there are several specialized subcommittees. Most importantly, the Federal Joint Committee is advised by the Institute for Quality and Efficiency in Health Care which was established in its current form in 2004. The institute evaluates drugs according to their therapeutic benefits and is one of the central authority for pharmaceutical policy in Germany (Busse and Blümel 2014,63-66), comparable to the Canadian Agency for Drugs and Technologies in Health (CADTH) (PMPRB 2016,14). The actual reference prices for pharmaceuticals in Germany are set by the Federal Association of Sickness Funds, the association of the statutory insurance bodies (Busse and Blümel 2014,209). Conversely, in Canada the majority of pharmaceutical price regulation is not decided by private insurance providers or provincial healthcare providers who incur the costs of pharmaceuticals, but by the independent quasi-judicial Patented Medicine Prices Review Board (PMPRB) (Lexchin 2015,29-30).

German pharmaceutical policy aims at striking a balance between healthcare and industrial interests through providing quality, safety, and cost control measures for the public insurance system, and protection for the national labor market while ensuring international competitiveness of the German pharmaceutical industry. Germany is the largest producer of pharmaceuticals in Europe and the third largest in the world, after the United States and Japan. Therefore, the pharmaceutical industry exerts strong institutional pressure on policy making which historically has prevented price regulations to be implemented. Indirect price controls through reference prices

were only introduced in 1989 and regional spending caps in early 1990s. Only starting in 2002, Germany initiated a number of more aggressive cost containment measures (Busse and Blümel 2014, 200-201). Nevertheless, up to today there are no direct price regulations for "ex-factory" prices charged by pharmaceutical companies (Busse and Blümel 2014, 205). Most importantly, close to 73% of all medication sold in 2011 was covered by statutory health insurance (SHI) and due to this large volume and market share, the set maximum reimbursement limits of SHI serve as a powerful indirect price regulator for pharmaceuticals (Busse and Blümel 2014, 202). Similar to the method used by PMPRB in Canada (PMPRB 2016,9-10), the majority of SHI reimbursement limits on new drugs are set using reference prices. However, in simple terms, the limits set in Germany using reference prices cannot exceed the highest price in the lower third of the market for drugs with the same or similar active ingredients and effectiveness (Busse and Blümel 2014, 209-212) which is much more restrictive compared to the highest price limit used by PMPRB. Furthermore, the reimbursement limits are combined with a complex system of rebates, discounts, price freezes and co-payments, which are constructed in a way to give incentives to pharmaceutical companies to lower their prices in order to increase their profits. For example, a mandatory flat-rate co-payment by the patient is waived if pharmaceuticals are priced 30% below the reference price. Although in theory pharmaceutical companies could charge any ex-factory price with the amount above the reimbursement limit to be paid by the patient, in practice only very few drugs are priced above the reimbursement limit. Therefore, the reference-price scheme used in Germany is generally considered to be an effective cost-containment instrument. In the most recent years the methods used for reference prices and reimbursement limits have been further refined, most notably in 2010 with the introduction of the Pharmaceuticals Market Reorganisation Act (AMNOG) (Busse and Blümel 2014,205-212). In particular, AMNOG requires pharmaceutical

companies to prove that new drugs have an additional therapeutic benefit that would justify a price above comparable drugs and therefore represent a material innovation (Sieler et all. 2015,23). This stands in stark contrast to the regulation methods used by PMPRB in Canada. If a drug price charged is found to be excessive, PMPRB has to investigate rather than the pharmaceutical company having to prove their innovation and rationale for the higher price as in the case of AMNOG (PMPRB 2016,9-10).

In addition to reference pricing, German pharmaceutical policies also include various measures which track and guide prescription behavior of physicians including guidelines on the average prescription volume per patient in each clinical discipline. Physicians are notified and asked to explain when their prescription volume is found to be significantly above guidelines. If the increased prescription volume is not justified, physicians will have to repay the price of the pharmaceuticals above the guideline to the SHI. Furthermore, the SHI performs regular audits of physicians and provides feedback and information on prescription behavior (Busse and Blümel 2014,215-216). The prescription behavior of physicians is currently not tracked and supervised in a comparable manner in Canada (Furlan et all. 2014,102).

Overall, the German healthcare and pharmaceutical system provides a number of interesting solutions to the challenges faced by policy makers for pharmaceutical policy formulation in Canada. In particular, the coordination method of using a plenary body such as the Federal Joint Committee is a valuable tool for providing a more efficient overall structure which appears to be necessary for sustainable universal pharmaceutical coverage. The fact that the federal regulators in Canada do not closely collaborate with the public and private insurance companies and the associations of physicians greatly reduces their effectiveness and applicability of recommendations. Each actor in the healthcare system has to make conscious policy decisions

looking at the whole system rather than at an isolated part. A good example of this is the fact that CPSO does not take price into consideration in its prescription guidelines. Therefore, Canada should introduce a plenary body to meet on regular intervals consisting of representatives from key private, provincial and federal institutions. It is particularly important to include the private insurance providers due to their potentially large market power in the case that coordination can be achieved. The physicians should become key actors in the pharmaceutical regulatory effort, which should include tracking of prescription behavior and an incentive structure for physicians to prescribe according to cost in addition to treatment experience and quality. PMPRB should be refined by putting the burden of proof of additional therapeutic benefit of medicines on the pharmaceutical companies and by introducing supplementary incentive structures for them to reduce prices.

Many actors in the Canadian pharmaceutical system have demonstrated a willingness to reform and an understanding that cooperation is imperative in the operation of sustainable pharmaceutical policies. PMPRB has considered a number of reforms including increasingly incorporating therapeutic benefit analysis into their price regulation efforts (PMPRB 2016,14-15). In the absence of government policy, private insurance companies have come together and established a cooperative body to share the burden of high cost pharmaceuticals and the Ontario provincial drug program has called on unified action to reform pharmaceutical policies. In the words of Suzanne McGurn, the assistant deputy minister and executive officer of the OPDP in the most recent annual report, “the Ontario Public Drug Program has reached a critical turning point where we cannot continue to keep growing at the rate we have. Simply put, it is not financially sustainable.” However, “it is within our power to deal with this reality” and a way forward has to include collaboration between all stakeholders including patient groups, practitioners and

pharmacies and the pan-Canadian Pharmaceutical Alliance to "think about drugs in new ways, so that we can all better understand the practical and clinical value of what is being offered and its financial worth" (Ontario Public Drug Program 2016, 1). There currently appears to be a favorable political climate with reform minded liberal governments at both federal and Ontario provincial levels and the policy initiative "Pharmacare 2020" has gained wide ranging support. Unfortunately, universal pharmacare did not appear on the political platform of the Trudeau administration and a lack of strong political backing has been detrimental to the past attempts to introduce universal pharmacare policy in Canada (Boothe p. 102).

Sources

Boothe, Katherine. 2015. *Ideas and the Pace of Change: National Pharmaceutical Insurance in Canada, Australia, and the United Kingdom*. Toronto: University of Toronto Press.

Busse Reinhard, Miriam Blümel. 2014. "Germany: Health System Review." *Health Systems in Transition,* 16(2):1–296.

Canadian Life and Health Insurance Association. 2012. "Canadian Life and Health Insurance Industry Launches Industry Initiative to Protect Canadians' Drug Coverage." News Release April, 3. https://www.clhia.ca/domino/html/clhia/CLHIA_LP4W_LND_Webstation.nsf/resources/Drug_Protection/$file/News_Release_drug_coverage.pdf.

College of Physicians and Surgeons of Ontario (CPSO). 2012. *Policy Statement #7-16: Prescribing Drugs.* http://www.cpso.on.ca/CPSO/media/documents/Policies/Policy-Items/PrescribingDrugs.pdf?ext=.pdf.

Daw, Jamie R., and Steven G. Morgan. 2012. "Stitching the gaps in the Canadian public drug coverage patchwork? A review of provincial pharmacare policy changes from 2000 to 2010." *Health Policy,* 104(1): 19-26. doi:10.1016/j.healthpol.2011.08.015.

Furlan, Andrea D., Peter MacDougall, Denise Pellerin, Karen Shaw, Doug Spitzig, Galt Wilson, and Janet Wright. 2014. "Overview of four prescription monitoring/review programs in Canada." *Pain Research & Management: The Journal of the Canadian Pain Society,* 19(2): 102-106.

Lexchin, Joel. 2015. "Drug Pricing in Canada.". In *Pharmaceutical Prices in the 21st Century*, edited by Zaheer-Ud-Din Babar, 25-41. Cham: Springer International Publishing: Imprint: Adis. [electronic resource].

Maioni, Antonia. 2015. *Health care in Canada*. Don Mills, Ont., Canada: Oxford University Press.

Morgan, Steven G., Danielle Martin, Marc-André Gagnon, Barbara Mintzes, Jamie R. Daw, and Joel Lexchin. 2015. "*Pharmacare 2020: The future of drug coverage in Canada.*" Vancouver, Pharmaceutical Policy Research Collaboration, University of British Columbia.

Morgan, Steven G., Jamie R. Daw. 2012. "Canadian Pharmacare: Looking Back, Looking Forward." *Healthcare Policy 8*(1): 14–23. doi:10.12927/hcpol.2012.23017.

Morgan, Steven G., Jamie R. Daw, and Michael R. Law. 2013. "*Rethinking Pharmacare in Canada*." Toronto, Ont.: C.D. Howe Institute.

Morgan, Steven G., Marc-André Gagnon, Barbara Mintzes, and Joel Lexchin. 2016."A Better Prescription: Advice for a National Strategy on Pharmaceutical Policy in Canada." *Healthcare Policy | Politiques De Santé* 12(1): 18-36. doi:10.12927/hcpol.2016.24637. http://simplelink.library.utoronto.ca/url.cfm/512144.

OECD. 2015. *Health at a Glance 2015: OECD Indicators*, OECD Publishing, Paris. *http://dx.doi.org/10.1787/health_glance-2015-en.*

Ontario Public Drug Program. 2016. *Working Together for Change. Annual Report 2014-2015*. Queen's Printer for Ontario. http://www.health.gov.on.ca/en/public/programs/drugs/publications/opdp/docs/odb_report_14_15.pdf.

Panteli Dimitra, Francis Arickx, Irina Cleemput , Guillaume Dedet, Helene Eckhardt, Emer Fogarty, Sophie Gerkens, Cornelia Henschke, Jennifer Hislop, Claudio Jommi, Daphne Kaitelidou, Pawel Kawalec, Ilmo Keskimäki, Madelon Kroneman, Julio Lopez Bastida, Pedro Pita Barros, Joakim Ramsberg, Peter Schneider, Susan Spillane, Sabine Vogler, Lauri Vuorenkoski, Helle Wallach Kildemoes, Olivier Wouters, and Reinhard Busse. 2016. "Pharmaceutical regulation in 15 European countries: Review." *Health Systems in Transition*, 18(5):1–118.

Patented Medicine Prices Review Board (PMPRB). 2016. "*PMPRB Guidelines Modernization: Discussion Paper*." http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper.

Salehi, Leila. 2016. “National pharmacare: Time to move forward.” *Canadian Family Physician*, 62 (7): 544-546.

Sieler, Sebastian, Thomas Rudolph, Carola Brinkmann-Sass, and Richard Sear. 2015. “How has German health reform impacted pharma pricing and market access, and what can the industry learn from the experience?” *PharmaTimes,* May. Accessed November 5, 2016. http://www.pharmatimes.com/magazine/2015/may_2015.

Vogler, Sabine, Nina Zimmermann, Alessandra Ferrario, Veronika J. Wirtz, Kees de Joncheere, Hanne Bak Pedersen, Guillaume Dedet, Valnrie Paris, Aukje K. Mantel-Teeuwisse, and Zaheer-Ud-Din Babar. 2016. “Pharmaceutical policies in a crisis? Challenges and solutions identified at the PPRI Conference.” *Journal of Pharmaceutical Policy and Practice* 9(9):1-5. DOI 10.1186/s40545-016-0056-8.

White, Julie, and Keith Newman. 2016. “Submission to the Patented Medicine Prices Review Board.” *Canadian Health Coalition*. http://www.healthcoalition.ca/national-public-drug-plan/.

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. 2015. “Pharmaceutical Pricing and Reimbursement Policies: Challenges Beyond the Financial Crisis Country: Poster Book.” http://whocc.goeg.at/Downloads/Conference2015/0_Country%20Poster%20Book_v3_online.pdf.

Annex

Canada (Ontario)	Germany
Patented Medicine Prices Review Board (PMPRB)	*Federal Joint Committee*
The primary price regulatory body in Canada which sets the introductory price of new medicines and limits the existing price increase over time to the rate of inflation, nationwide.	The highest decision-making body of the joint self-government of physicians, dentists, psychotherapists, hospitals, and health insurance funds in Germany. It issues directives on all aspects of healthcare including prescription of medicines.
Canadian Agency for Drugs and Technologies in Health (CADTH)	*Institute for Quality and Efficiency in Health Care*
It advises the three federal and all provincial drug plans (except Quebec) on the clinical and cost effectiveness of drugs compared to other alternatives using a rating methodology. However, the recommendations made by CADTH are non-binding and a number of drug plans have listed drugs despite negative ratings.	It is an independent scientific institute, which advises the Federal Joint Committee. It examines the benefits and harms of medical interventions for patients. It provides information about the advantages and disadvantages of examination and treatment methods.
Ontario Public Drug program (OPDP)	*Central Federal Association of Health Insurance Funds (Sickness Funds)*
It provided drugs for close to 3.8m Ontario residents with an estimated overall budget of $4.8billion in 2015. The plan covers close to 3800 eligible drug products for persons over the age of 65, on social assistance, living in long term/special care homes, or persons with high drug costs relative to their income who are registered with the Trillium Drug program.	The central association of the health insurance funds covering close to 70 million people. It makes decisions on a variety of health aspects through the federal joint committee including decisions on drug coverage and pricing.
Canadian Life and Health Insurance Association	
The private insurance companies who cover the majority of the Canadian population and a large portion of the overall drug expense. However, they have little incentives to curtail costs.	
College of Physicians and Surgeons of Ontario	*National Associations of Statutory Health Insurance Physicians and Dentists*
A self-regulated body that regulates the practice of medicine to protect and serve the public interest. All doctors in Ontario must be members of the College in order to practice medicine.	The association representing about 165 000 physicians. It makes decisions on medical standards and range of services in the Federal Joint Committee.
Patients' Association of Canada	*Accredited Patient Organizations*
It is a national, independent NGO promoting patient focused medicine. It is not formally integrated in the healthcare system.	The patients organization accredited to participate in the Federal Joint Committee.

Figure 1 (Busse and Blümel 2014,18).