Listening for Prescriptions:
A National Consultation on
Pharmaceutical Policy Issues

Ordonnance à l'écoute : consultation nationale sur les enjeux politiques sur les produits pharmaceutiques

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Abstract

Objectives and Methods: Pharmaceutical policy is an increasingly costly, essential and challenging component of health system management. We sought to identify priority pharmaceutical policy issues in Canada and to translate them into research priorities using key informant interviews, stakeholder surveys and a deliberative workshop.

Results: We found consensus on overarching policy goals: to provide all Canadians with equitable and sustainable access to necessary medicines. We also found widespread frustration that many key pharmaceutical policy issues in Canada – including improving prescription drug financing and pricing – have been persistent challenges owing to a lack of policy coordination. The coverage of extraordinarily costly medicines for serious conditions was identified as a rapidly emerging policy issue. *Conclusion:* Targeted research and knowledge translation activities can help address key policy issues and, importantly, challenges of policy coordination in Canada and thereby reduce inequity and inefficiency in policy approaches and outcomes.

Abstract

Objectifs et méthodologie : La question des politiques sur les produits pharmaceutiques constitue un des aspects de la gestion du système de santé qui présente de plus en plus de défis et qui est de plus en plus coûteux et important. Nous avons cherché à déterminer les enjeux prioritaires en matière de politiques sur les produits pharmaceutiques au Canada et à les transposer en priorités de recherche, et ce, au moyen d'entrevues auprès d'informateurs clés, de sondages auprès des intervenants et d'un atelier de discussion. *Résultats :* Nous avons observé qu'il y a consensus sur les objectifs principaux en matière de politiques, soit fournir à tous les Canadiens un accès équitable et durable aux médicaments nécessaires. Nous avons également observé un sentiment de frustration générale quant au fait que plusieurs enjeux essentiels de politiques sur les produits pharmaceutiques au Canada – notamment l'amélioration du financement et des coûts des médicaments sur ordonnance – constituent des défis constants qui découlent d'un manque de coordination des politiques. La couverture des médicaments exceptionnellement onéreux pour les états de santé graves a été désignée comme un enjeu qui émerge rapidement. *Conclusion :* La recherche ciblée et les activités de transposition de connaissances peuvent aider à cerner les principaux enjeux politiques et, ce qui est primordial, à affronter les défis en matière de coordination des politiques au Canada, permettant ainsi de réduire les iniquités et l'inefficacité des démarches politiques et de leurs résultats.

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WITH INCREASED USE AND COST OF MEDICINES OVER THE PAST HALF-century, pharmaceutical policy has become a key component of health system management. We believe a pharmaceutical policy research strategy is needed because of the prominent political and economic challenges faced in the sector and because specific features of the Canadian regime have resulted in disappointing progress towards previously identified pharmaceutical policy goals. Research

aligned with priority policy issues and related challenges may help Canada's pharmaceutical policy makers better address current and emerging challenges in this sector.

Government commissions have studied pharmaceutical policy in Canada almost every 10 years since the 1960s with the intent to make recommendations concerning priority policy actions (Canada 1963, 1965, 1985, 1998, 2002). While some of these have been extensively consultative, none has focused on identifying underlying policy issues and ways in which health research can inform pharmaceutical policy development (even the identification of pharmaceutical policy problems) in the same way that the Listening for Directions consultations of the Canadian Health Services Research Foundation and partners have done for health services and policy research more generally (CHSRF 2001; Dault et al. 2004; Law et al. 2008). We therefore set out to identify priorities for research in support of pharmaceutical policy in Canada using an interpretative priority-setting process similar to the Listening for Directions consultations (Lomas et al. 2003). With input from policy makers, researchers, health professionals, patient advocates and industry representatives, we identified the key pharmaceutical policy issues facing Canadians in the short and medium term and translated these issues into priority areas for policy research.

Methods

Our priority-setting process involved several stages of expert consultation, analysis and interpretation. As Lomas and colleagues (2003) have recommended for policy research priority-setting, we deliberately oversampled decision-makers at each consultation stage. Each stage of primary data collection was approved by the Behavioural Research Ethics Board at the University of British Columbia.

Telephone interviews

In February 2009, we conducted a series of telephone interviews with individuals identified as important potential users of pharmaceutical policy research. Potential interviewees were purposively selected from federal and provincial government branches directly related to general health policy, pharmaceutical policy and industry policy; public agencies in health and the pharmaceutical sector; professional associations of pharmacy, medicine and nursing; patient advocacy organizations; private sector consultancies; the generic and brand-name pharmaceutical industries; and the private health insurance industry. Aiming for representation across stakeholder groups and geographic regions, we invited 42 key informants to participate in a telephone interview. A total of 24 participated (57% response rate): 14 government decision-makers; three employees of public agencies; four representatives of health professions; three patient/consumer advocates; one private consultant; and one pharmaceutical indus-

try representative. Interviews involved open-ended questions organized around three themes: (a) leading pharmaceutical policy issues today and in the near future, (b) areas where new policy research would have the greatest impact and (c) recommendations on how to improve pharmaceutical policy research in Canada. Interviews were conducted by both authors, lasted from 20 to 40 minutes and were digitally recorded and professionally transcribed.

Online survey

Also in February 2009, we e-mailed invitations to participate in an online survey to 225 purposively selected individuals from across stakeholder groups and regions. The survey consisted of short-answer questions organized around the same themes as the telephone interviews. We received 82 completed surveys (~33% response rate): 26 from university-based researchers; 22 from policy makers and employees of public agencies; 13 from health professionals; seven from private consultants; five from patient advocates; three from the pharmaceutical industry; three from drug plan sponsors; and three from persons who did not identify their role in the sector.

Deliberative workshop

In November 2009, we hosted a workshop with 10 policy makers, seven employees of public agencies and 13 university-based researchers to refine and prioritize findings. The meeting involved presentations and discussions around leading themes from the initial stages of our consultation. In small groups, participants reviewed a summary of consultation themes and identified what they viewed as priority areas for new pharmaceutical policy research. After small-group work and large-group discussions, participants were given six stickers to use as "votes" for what they believed were the top priorities (and allowing them to cast multiple votes for a single research area). Stickers were colour-coded so that researcher and policy maker/analyst votes could be tallied separately.

Interpretive analysis and final review

We independently read all interview transcripts to develop draft theme codes, which we revised based on discussion and review of online survey data. We sent initial themes to workshop participants and then finalized a draft set of research priorities based on grouping and prioritizing themes from all stages of consultation. In February 2010, we sent a draft of the findings for validation and comment to the 48 people who participated in the telephone interviews, the deliberative workshop or both. Thirteen (27%) responded with comments and suggestions, all of which were taken into consideration when preparing this manuscript.

Results

Emergence of themes

We began to see saturation of themes related to overarching policy goals and key policy challenges early in the interview process and observed remarkable consensus on these overarching themes throughout our consultation stages. Specifically, participants from all stakeholder groups suggested that a central policy goal is to provide all Canadians with equitable and sustainable access to safe and effective treatments when needed. However, this suggestion was often expressed in terms of frustration with the status quo: that access to medicines is not equitable within and across provinces, and that existing systems for drug pricing, financing and coverage are not adequate for dealing with financial pressures in a sustainable way. This was put most clearly by a provincial decision-maker in a telephone interview: "until we have a consistent approach to how we deal with pharmaceuticals across the country, until we have a reimbursement system that is consistent across the country, until we have an eligibility criteria and product selection across the country that's consistent, our pharmaceutical programs will never be sustainable."

From our telephone interviews, three specific policy issues and one cross-cutting challenge emerged as dominant. The first dominant issue was the pricing of both new and generic medicines given the increased availability of generic versions of blockbuster drugs and the trend towards extraordinarily high prices for new, specialized medicines. The second dominant issue was equity and sustainability of prescription drug financing systems given historically rapid growth in costs and concerns about the effects of population aging. The third dominant issue was a concern about inter- and intra-provincial disparities in drug coverage given the challenges in assessing extraordinarily costly medicines for serious and often-rare diseases. A further cross-cutting theme raised by all types of stakeholders interviewed was concern about the lack of pharmaceutical policy coordination and cooperation in Canada.

Survey results were largely consistent with telephone interview themes. Table 1 lists the frequency with which specific themes were identified as priority challenges or priority areas for future policy research in our online survey. Recognizing that some of the narrow themes in our coding system related to others – e.g., a theme of "value for money" is related to the themes of pricing policy and coverage decisions – the general themes of financing, coverage and pricing were among the most commonly mentioned in the online survey. Results from our deliberative workshop – summarized in Table 2 – were also comparable to those of the telephone interviews and online survey, with financing- and pricing-related policy research receiving the most "votes" as priority areas for policy research.

TABLE 1. Frequency of policy issue themes identified in an online survey of stakeholders, by question posed

	Most pressing pharmaceutical policy issues/ challenges	Area where new pharmaceutical policy research would have the greatest impact
Financing: providing an equitable and sustainable system of financing necessary medicines	39	9
Regulation: ensuring that available medicines are safe and effective	32	5
Value: ensuring that pharmaceuticals purchased produce benefits to patient and population health that are commensurate with benefits from alternate uses of equivalent resources	23	9
Expensive drugs for rare diseases (EDRD): appropriately managing evaluations, expectations and costs of treatments for rare and serious diseases	20	2
Pricing: achieving fair and competitive prices for brand and generic drugs	17	5
Information: ensuring that balanced and complete information about diseases and treatment options is readily available to prescribers and patients in formats appropriate to their use	17	4
Policy coordination: effectively coordinating pharmaceutical policies within and across jurisdictions and organizations	16	5
Coverage: allocating resources in an equitable, efficient and acceptable way	15	6
Quality use of medicines (QUM): ensuring that patients seek and take pharmaceuticals in ways that are optimal by comparison to alternatives, including non-drug options	12	5
Prescribing: optimizing the quality of prescribing in primary care	12	2
Dispensing: making efficient use of pharmacists' professional skills while generating welfare-enhancing competition among retailers and distributors of prescription drugs	10	3
Innovation: promoting the development of treatments that address previously unmet needs and/or stimulate welfare-enhancing competition	10	1
Engagement: generating public understanding, engagement and ownership related to pharmaceutical policies as health system policies	5	3

Note: Based on the survey design, three items could be mentioned as pressing challenges, whereas only one could be mentioned as an area where more research would have the greatest impact.

TABLE 2. Percentage of "votes" cast for further research, by theme coding and role of voter

	University-based researchers	Policy makers and analysts at public agencies	Total
Financing: providing an equitable and sustainable system of financing necessary medicines	28%	26%	27%
Pricing: achieving fair and competitive prices for brand and generic drugs	19%	26%	23%
Prescribing: optimizing the quality of prescribing in primary care	17%	14%	15%
Coverage: allocating resources in an equitable, efficient and acceptable way	11%	12%	12%
Policy coordination: effectively coordinating pharmaceutical policies within and across jurisdictions and organizations	11%	11%	11%
Dispensing: making efficient use of pharmacists' professional skills while generating welfare-enhancing competition among retailers and distributors of prescription drugs	11%	9%	10%
Expensive drugs for rare diseases (EDRD): appropriately managing evaluations, expectations and costs of treatments for rare and serious diseases	2%	2%	2%

Final priority research areas

By synthesizing the results from all consultation stages, we identified six key issues – stated in terms of policy objectives – that form our final priority areas for pharmaceutical policy research in Canada: (1) coordinated policies within and across jurisdictions, (2) equitable and sustainable financing, (3) fair pricing for value and competition, (4) high-quality prescribing and medicine use in primary care, (5) reasonable and accountable coverage policy and processes and (6) regulation for ongoing safety and effectiveness. These are listed in terms of research priority, finalized based on deliberation and interpretation of data collected at each stage of consultation. Even though it was not singled out as frequently as some other issues, the theme of policy coordination is our top priority because it is a cross-cutting theme and because inter-jurisdictional challenges were specifically identified by participants in relation to many other key priority issues – such as financing, pricing, coverage and safety. In the sections that follow, we briefly discuss each policy objective, place it in context, and provide examples of the types of research that could help inform related policy processes.

COORDINATED POLICIES WITHIN AND ACROSS JURISDICTIONS

> One of the difficulties we have is that a lot of the patent issues are federal and are looked at from Industry Canada's perspective … whereas a lot of the pricing issues are provincial issues and looked at from a whole different perspective, and we don't always get good coordination there. [Industry representative]

> Having limited [budgets] and being beside the largest unregulated marketplace has its own challenges. But I think our bigger challenge really is for us to be consistent across jurisdictions. … The fact is there needs to be cohesion and coordination across jurisdictions, but people are just disengaged. [Government decision-maker]

Owing to the distribution of legislative powers in Canada's *Constitution Acts* (1867 and 1982), healthcare and the regulation of health professionals are provincial responsibilities while the regulation of trade, commerce and intellectual property rights are federal responsibilities. This division of jurisdictional authority is a significant challenge for pharmaceutical policy making because pharmaceutical policy is ultimately a system of interdependent policies, including commercial regulation, intellectual property law, healthcare financing, professional regulation and more (WHO 2001; Morgan, Kennedy et al. 2009). Coordination is therefore fundamental to achieving desired goals effectively and efficiently. Yet, as noted by consultation participants from all stakeholder groups, there has been no sustained mechanism for coordinating the policy efforts of different governments in Canada.

While there are examples of pharmaceutical policy collaboration in Canada around specific policy areas – such as the Common Drug Review – the National Pharmaceuticals Strategy that was launched in 2004 with the 10-Year Plan to Strengthen Health Care in Canada has not translated into an effective and coordinated policy system (Health Council of Canada 2009). With possible renewal of the 10-Year Plan fast approaching, research in this area may assist in developing plans and processes for better coordinating pharmaceutical policies in Canada. For example, comparative and historical analyses of politics, law and public opinion may illustrate ways to overcome challenges of pharmaceutical policy coordination in federations such as Canada.

SUSTAINABLE AND EQUITABLE FINANCING

> [With] the economic downturn that's happening now, the access to proper medication will be even harder for medium-to-low income groups. And that comes to the argument of having a public pharmacare program. [Health professional]

> What are the issues around equity, or lack of equity, in access … issues related to efficiency, or lack thereof, that are associated with and arise from the

fact that we've got multiple payers and multiple benefit regimes for drugs? [Government decision-maker]

While the financing of medical and hospital care is reasonably well harmonized in Canada through federal cost-sharing arrangements that date back to the 1950s and 1960s (Taylor 2009), there is no equivalent act for coordinating prescription drug benefits in the community setting. Federal and provincial financing policies have therefore evolved independently: the federal government provides drug benefits for specific populations – status Indians, military, etc. – and provinces generally provide coverage for select groups defined by age, income, employment, health status or some combination of these (CIHI 2010). Remarkably few data regarding private drug benefits are systematically collected in Canada; however, previous research suggests that many Canadians experience financial barriers to accessing necessary medicines (Kennedy and Morgan 2009).

In provinces where public coverage is targeted towards senior citizens, the aging of the baby-boomer generation is an increasingly apparent fiscal pressure because government liability for (though not the total level of) drug costs will increase dramatically once boomers reach age 65. In provinces where public drug benefits are set based on income, economic downturns and related cutbacks in employment- and retirement-based private insurance put increasing financial strain on households and, ultimately, on public programs. As noted by many experts with whom we consulted, financing systems and financial pressures in Canada create a classic dilemma: universal pharmacare is a difficult political sell when costs are out of control, yet effective tools for controlling costs depend on such systems of financing (Evans and Williamson 1978; Evans et al. 2007). Policy research can help provide governments with a coherent and principled basis for financing reforms. As a starting point, policy makers need high-quality data on the nature, cost (both private and public) and trends of private drug coverage in Canada. Moreover, provincial pharmacare models should be carefully evaluated and compared with domestic and international alternatives. Research should aim to identify the design, expected performance and viability of financing options for Canada in light of Canadian law, politics and public expectations.

FAIR PRICING FOR VALUE AND COMPETITION

I think there should be one [generic drug] price for the country, but that's not happening. Everybody has a different policy for generic pricing. [Government decision-maker]

[The] lack of pan-Canadian price negotiation … means the smaller provinces never quite know what the prices are across the country, and they don't have

> access to the same prices. … I think that's fundamentally wrong. [Employee of a public agency]

Canada has relatively uncoordinated pharmaceutical pricing policies as a consequence of its fragmented financing system and past policy decisions by federal and provincial governments. To help address what were thought to be excessive drug prices in the 1960s (Canada 1963), the federal government allowed generics to compete directly with patented medicines under a policy known as compulsory licensing (Lexchin 1993). As generic versions of patented medicines were generally not available in other countries, provinces were content to pay for generics at modest discounts relative to patent-holding brands. In the late 1980s, the federal government began a process of eliminating the compulsory licensing provision for drug patents, but provinces did not update their generic pricing policies. The historic policy of covering any generic priced at specified discounts (e.g., 30% less than the brand) gives retailers little or no incentive to compete on generic prices. Because the cost of producing generics is often a small fraction of the retail price of brands, generic manufacturers still compete with one another by paying rebates to retail pharmacies; however, these rebates are not passed on to patients or drug plans (Hollis 2002; Competition Bureau 2007). With patents expiring for many of the world's blockbuster drugs in the current era (IMS 2010), provincial governments are now looking to update their policies to better capture the potential savings from generic competition.

At the other end of the pricing spectrum – involving new drugs protected by patent – policy challenges are emerging in price negotiation and the transparency thereof. Provincial drug plans (like drug plans around the world) are both considering and using contracts as mechanisms for setting prices for new medicines. These contracts may involve secret rebates, volume-based price reductions and payment based on clinical outcomes. The outcomes-based contracts raise particular scientific challenges, such as how to generate real-world effectiveness evidence strong enough for contract enforcement; however, all contract-based pricing policies pose equity and efficiency challenges in multi-payer environments. The main challenges arise because fragmentation of financing reduces the purchasing power of individual drug plans and tends to result in the highest prices being charged to those with the least ability to pay (e.g., uninsured patients). Research drawing on ethical, legal, political and economic theory and evidence can help identify pricing models – including contracting and regulatory systems – that are best suited for pharmaceuticals in the Canadian context. Moreover, specific research that draws on theory, evidence and international experience concerning generic drug pricing and retail pharmacy markets may help policy makers realize the full potential of generic competition.

HIGH-QUALITY PRESCRIBING AND MEDICINE USE IN PRIMARY CARE

> We need to figure some way of getting [the public] appropriate information because, otherwise, they're just getting everything off the Internet. [Government decision-maker]

> A challenge that has been on our plate [as health professionals] for at least 20 years now is the relationship with industry. [Health professional]

Ensuring that the right drugs are prescribed to, and used appropriately by, the right patients is both a central goal and a major challenge for pharmaceutical policy (Sansom 1999). Challenges are particularly great in the community setting, where the lack of institutional structures makes pharmaceutical management and communication more difficult than in hospitals and other care facilities. Policy aimed at optimizing the use of medicines in primary care settings requires a combination of regulation, education, remuneration and infrastructure development – policy levers that are divided between jurisdictions in Canada (MacKinnon and Canadian Pharmacists Association 2007). Although provinces have undertaken various initiatives to encourage appropriate prescribing, Canada as a whole has not coordinated the many policy instruments that affect medicine prescribing and use.

At the clinical encounter, Canadian doctors have far less access to electronic medical records, electronic prescribing and prescribing aids than doctors in other countries (Schoen et al. 2009). Moreover, the dominant model of primary care in Canada encourages high-volume, physician-only primary care practice, which increases risks of potentially inappropriate prescribing (Hutchinson and Foley 1999; Tamblyn et al. 2003; Cadieux et al. 2007). There are also growing concerns about whether the public has and uses information that is complete, balanced and accurate given increases in a variety of forms of consumer-targeted pharmaceutical marketing (Bell et al. 2000; Gahart et al. 2003; Kaphingst et al. 2004; Frosch et al. 2007). Provinces are also currently experimenting with new prescribing privileges for pharmacists that may have significant effects on the quality of medicine use. Existing research on quality improvement initiatives has been gathered together in the Rx for Change database (CADTH 2010). Findings need to be contextualized to Canadian settings based on sound behavioural and organizational theories; moreover – given the varied quality of previous studies – the body of existing evidence should be used to guide the implementation and rigorous evaluation of quality improvement initiatives that appear fit for Canadian contexts. With rapid changes in marketing activities and Web-based information seeking, there is an increased need for high-quality research on the effects of these information sources on professionals, patients and health systems. Primary care research on impacts of prescribing roles and privileges for different health professionals is also needed to inform emerging policies in this area.

REASONABLE AND ACCOUNTABLE COVERAGE POLICY AND PROCESSES

> There's got to be some way that we can capture the data and evaluate when a drug is cost-effective and when it isn't cost-effective … we don't want the drug plans wasting taxpayers' money on drugs that aren't working for people. [Patient]

> The more we move into the future, and we start looking at very, very targeted therapies … we're going to be really struggling as a society trying to figure out how to actually put a dollar value on a life or a quality of life. [Government decision-maker]

Coverage policy involves deciding what treatments will, and will not, be paid for – decisions that are challenging at the best of times (Maynard 1999). Even though a Common Drug Review coordinates the critical assessment of clinical and economic evidence for all provinces but Quebec, there is widespread concern about variation in the drugs that are covered across provinces. Research had demonstrated that virtually all of the most commonly prescribed drugs are covered by all provinces (Morgan, Hanley et al. 2009); however, the popular concerns about drug coverage pertain to those medicines used to treat more serious conditions such as cancer (Menon et al. 2005). Regardless of the drug in question, coverage decisions often must be made with limited evidence about what actual utilization levels, costs and (most importantly) health outcomes will result if a product is listed on a drug formulary. Coverage policy for expensive drugs for rare diseases is further complicated by sparse evidence, extraordinary prices and (regardless of the quality of evidence) choices that may be portrayed as life-or-death decisions (Hollis 2005; McCabe et al. 2005). These challenges will likely be heightened in coming years because many of the new drugs in development today are treatments for relatively serious conditions (including many cancers), and many are being targeted to specific populations that have specific genetic or biologic markers.

In light of the tensions in drug coverage decision-making, the process of making coverage decisions is emerging as critically important (Syrett 2003; Mitton et al. 2006; Milewa 2008). Agreement on all decisions is unlikely in a world of scarce resources and clinical uncertainty; however, a well-designed process can give decisions a form of legitimacy that, as one decision-maker noted in our telephone interviews, "is meaningful in that people can say, 'Okay, I disagree with you but I understand your reasons.'" Comparative policy research on international best practices for making resource allocation decisions – especially concerning expensive drugs for rare and serious diseases – may help make Canadian processes publicly acceptable, scientifically defensible and able to withstand various external and political pressures. Research regarding inter-provincial variations in drug coverage should specifically focus on the rationale behind such variations and the extent to which they produce measurable differences in health outcomes.

REGULATION FOR ONGOING SAFETY AND EFFECTIVENESS

> We see clinical trials being done on populations where the drugs aren't going to be used … we need systems that are better at closing those information gaps. [Health professional]

> The approval process really emphasizes the speed of drug approvals, rather than ensuring that the evidence that is submitted by manufacturers is carefully scrutinized. [Patient advocate]

With the federal government clearly responsible for consumer protection, product regulation is arguably the aspect of pharmaceutical policy in Canada that is most easily coordinated. It is not without significant challenges, however, because regulatory policies must balance the competing objectives of ensuring that drugs sold on the market are safe and effective while trying not to impede access or discourage valued innovation. The history of the pharmaceutical industry is punctuated by tragic examples of what can go wrong if protections are not in place and enforced, followed by regulatory changes implemented to prevent recurrence of such outcomes (Temin 1980; Avorn 2004). Piqued by high-profile drug withdrawals – such as the 2004 withdrawal of Vioxx® – there is increased awareness of the need for rigorous evaluations of medicines before and after market approval.

More effective post-market evaluation is sought, in part, because there are often significant differences between populations enrolled in clinical trials (the young and relatively healthy) and those who use medicines in real-world contexts (Sherr 2000; Deyo 2004; Lippman 2006). Furthermore, important information about drug safety and effectiveness emerges only when large numbers of patients have used medicines over long periods of time. Increased emphasis on post-market drug evaluation creates new opportunities and challenges in policy and new needs for inter-jurisdictional cooperation in Canada. Governments are now establishing processes for ongoing assessments of pharmaceuticals to facilitate continued evaluation. A key example is Health Canada's investment in the Drug Safety and Effectiveness Network. Research on real-world evaluation methods and systems – including research on governance and accountability – can help to inform regulatory policy development and implementation. Research also can help inform pre-market regulatory policy by addressing such questions as ways to increase the quality and transparency of drug safety and efficacy studies and by evaluating the extent to which changes in regulatory standards might alter the quantity and quality of new drugs brought to market.

Recommendations for pharmaceutical policy research

In addition to asking about key policy issues, we also asked participants about how pharmaceutical policy research and knowledge translation could be improved in

Canada. This consultation involved questions concerning what they would change about pharmaceutical policy research in Canada today and how they would invest a hypothetical $5 million per year to improve related research and knowledge translation. Respondents consistently identified a few key recommendations, some of which mirrored concerns about pharmaceutical policy making in Canada. For example, several participants argued for a more coordinated approach to research, just as in policy (see above). Coordination was seen as a means to ensure that necessary capacity is developed, that key information needs are met, and that policy experiments are evaluated in relevant jurisdictions, compared against others, and then communicated appropriately.

> It seems to us that everybody is running and doing their own thing and setting up their own studies – and sometimes it's kind of a cacophony of noise. We would like to see much better coordination in the research program. [Government decision-maker]

> The policy makers are trying very hard to come up with a national approach for certain things ... and I really do think that pharmaceutical policy researchers have got to do the same thing in this country. [Government decision-maker]

Participants from all stakeholder groups also argued for a consistent strategy for developing and utilizing databases on the use, cost and outcomes of medicines used by all persons in all provinces:

> We need to have linked data so that the physician database, the lab database, the pharmacy database are all more readily accessible to support research. [Government decision-maker]

Several participants noted that many priority issues in pharmaceutical policy cannot be effectively addressed without access to such information.

Finally, communications and knowledge translation were a commonly cited area for improvement in pharmaceutical policy research. Many participants noted that there was no "go-to" source of information on pharmaceutical policy issues – no equivalent of the Canadian Agency for Drugs and Technologies in Health with a reputation for credible expertise in pharmaceutical policy issues and timely and responsible policy analysis. Participants also argued for investments in mechanisms that would regularly get key stakeholders together to talk about what is known, what is not known and where more information is needed:

> It's the perennial issue of when and how, with what frequency do people who are in the pharmaceutical policy and research sectors get together and seri-

ously exchange views about what's known, what would be useful to know, and what kinds of research – at what levels of intensity – would actually be worthwhile. [Government decision-maker]

Conclusion

Through the first extensive consultation of its kind, we uncovered a consensus on overarching policy objectives and priority policy issues in Canada. Several of the priority policy issues identified here – particularly those related to financing, pricing and coverage – are consistent with priority actions called for by the National Pharmaceuticals Strategy in 2004 and by government commissions dating back to the 1960s (Canada 1963, 1965, 1985, 1998, 2002, 2004). The continued prominence of key pharmaceutical policy issues highlights an overarching challenge regarding pharmaceutical policy in Canada, one that was articulated by the experts with whom we spoke: pharmaceutical policy in Canada is uniquely challenging because different levels of government are responsible for critical elements of the pharmaceutical policy system.

Although national pharmaceutical policies have been proposed as far back as the 1960s (Canada 1965), none has been implemented in a significant and sustained fashion. Pharmaceutical policies of federal and provincial governments have therefore evolved in a relatively independent and uncoordinated fashion. Meanwhile, the pharmaceutical sector also developed into an increasingly important, costly and complex component of the healthcare system. This development has resulted in a significant policy dilemma. The refrain "no cost control without pharmacare; no pharmacare without cost control" has become all too familiar in pharmaceutical policy debates, suggesting that Canada's lack of coordination may have created a negatively reinforcing policy trap: uncoordinated policies create system inefficiencies and regional inequities, and those outcomes create inter-jurisdictional tensions that, in turn, reinforce barriers to cooperation and coordination.

Effective policy reform in this sector will require political support and something perhaps overlooked in the past: a principled basis for policy action, or shared understanding of both why and how reforms should take place (Boothe 2010). There already appears to be a common understanding about the goal of reforms in Canada: providing all Canadians with equitable and sustainable access to necessary medicines. Because there are many challenges to achieving this goal, understanding the "how" of policy reform in Canada is critical. The research community can play an important role in this regard. This role will require greater efforts on the part of investigators and funders to coordinate and target research and knowledge translation activities. Researchers can and should help to identify creative policy solutions, based on sound theory and international experience; generate evidence of policy effectiveness, based on careful evaluation of policy experiences; and provide insight about the factors that

influence policy processes, based on legal, political and ethical scholarship. If well coordinated and communicated, such work may help develop a foundation of shared knowledge upon which reforms can be built to reduce inequities and inefficiencies in pharmaceutical policy approaches and outcomes in Canada.

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