DISCUSSION AND DEBATE

# The Power of "Principles" in a National Pharmaceuticals Strategy

## Le rôle des "principes" dans la stratégie nationale relative aux produits pharmaceutiques

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## Abstract

The role of principles in shaping the development of public policy has garnered increasing attention. The authors explore the role of underlying principles in the development of a Canadian National Pharmaceuticals Strategy (NPS), an area in which practical policy development has been disappointing. In analyzing proposed principles for a NPS identified in government documents and by a set of major stakeholder coalitions, they find broad agreement on principles underlying a NPS, particularly regarding equity, accessibility, safety and effectiveness. However, the identification of principles for a NPS has not motivated practical policy progress in this crucial area. Some reasons

for this failure are rooted in the current state of ethics and principles in health policy and some in the value-laden, interest-dominated nature of pharmaceutical policy itself.

## Résumé

Le rôle que jouent les principes dans l'élaboration des politiques publiques suscite de plus en plus d'intérêt. Les auteurs examinent le rôle des principes sous-jacents à la stratégie nationale relative aux produits pharmaceutiques (SNPP), un secteur dans lequel l'élaboration de politiques pratiques a été décevant. L'analyse des principes proposés pour la SNPP, et définis par un groupe d'intervenants importants du monde de la santé, révèle la présence d'un large consensus, notamment pour ce qui est des principes d'équité, d'accessibilité, de sécurité et d'efficacité. Toutefois, la définition de ces principes n'a pas contribué à favoriser l'élaboration d'une politique pratique dans ce secteur important. L'échec repose en partie sur l'état actuel de l'éthique et des principes dans les politiques de la santé, et en partie dans la nature même des politiques pharmaceutiques qui sont chargées de valeurs et dominées par les intérêts.

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Pharmaceuticals occupy a central role in the Canadian healthcare system. Since 2000, public and private expenditure on drugs in Canada has risen 9% or more annually (CIHI 2007). While drug costs are soaring (Federal/Provincial/Territorial Ministerial Task Force 2006), access to public coverage for drugs varies substantially among provinces (Demers et al. 2008). This resultant cost-shifting for outpatient medications – one might say, an essential component of "medically necessary care" – is deeply problematic for the central values underlying Canadian medicare: equity, fairness and solidarity (Romanow 2002). Moreover, increasing evidence suggests that financial status affects drug affordability (Demers et al. 2008) and patient adherence to recommended drug treatment regimes, both factors that can have significant negative consequences for health outcomes (Tamblyn et al. 2001; Anis et al. 2005; Lexchin and Grootendorst 2004).

The call for a national pharmaceuticals strategy in Canada has spanned several decades. The Royal Commission on Health Services (1964) identified the need for a national strategy to provide access and coverage to prescription drugs for all Canadians. The National Forum on Health (1997) expanded the call for financial coverage to a comprehensive national pharmaceuticals strategy. The Kirby Report (2002) recognized the potentially catastrophic impact of prescription drug costs on Canadians and recommended immediate and sustainable action to protect them from undue financial hardship. Many of the same sentiments were echoed a month later when the Romanow Report (2002: 210) concluded that

> [p]rescription drugs play a growing and essential role in Canada's health care system and the health of Canadians. They are a vital component of the health care system and that reality should be reflected in how we fund, cover and ensure access to quality, safe and cost-effective prescriptions drugs.

Most recently, the Ten-Year Plan to Strengthen Health Care (First Ministers 2004) promised renewed ministerial commitment to the development of a National Pharmaceuticals Strategy (NPS). This plan committed governments to the development and implementation of a NPS and to report on their progress by June 2006. The explicit goal of a NPS was to "address the challenges and opportunities across the drug life cycle using an integrated, collaborative, multi-pronged approach to pharmaceuticals within the health care system" (F/P/T Ministerial Task Force 2006: 6). In October 2005, health ministers affirmed their commitment to a NPS and asked officials to accelerate their work on catastrophic drug coverage; extend the scope of the Common Drug Review process to include all drugs; develop a national formulary; expand the Patented Medicine Prices Review Board responsibility to monitor non-patented drug prices; and collect, integrate and disseminate information on the real-world risks and benefits of drugs (HCC 2006). Since the 2006 NPS Progress Report there has been no official communication of progress.

In addition to federal, provincial and territorial governments, key stakeholders in the pharmaceutical life cycle, from those who manufacture pharmaceutical products to those who prescribe and use them, have articulated their visions of an effective NPS: and have all contributed their views on the need for a NPS:

- Canadian Health Coalition (CHC), representing 11 national organizations consisting primarily of Canadian labour unions (CHC 2006);
- Canada's Research Based Pharmaceutical Companies (CRBPC), an association representing over 50 member organizations involved in pharmaceutical research and development in Canada (Williams 2006);
- Coalition for a Canadian Pharmaceuticals Strategy (CCPS), an alliance representing the Best Medicines Coalition, Canadian Medical Association, Canadian Nurses Association, Canadian Pharmacists Association and Canadian Healthcare Association (CCPS 2006); and
- Health Charities Coalition of Canada (HCCC), representing 20 national health charities spanning the continuum of care (HCCC 2006).

However, despite apparent broad agreement on the need for a NPS, we have failed to meet identified targets: progress on implementing catastrophic drug coverage is disappointing; public coverage of very expensive drugs remains ad hoc; progress on a national formulary is limited; and attention to improved prescribing behaviour

has been deferred. There is some progress on improved drug information systems; e-prescribing projects are in development in eight of the provinces and territories and several jurisdictions have developed centralized drug data systems (HCC 2006). Nonetheless, in 2008 the Health Council of Canada concluded that "there is no sense of an overall cohesive national strategy" (HCC 2008).

**The explicit goal of a National Pharmaceuticals Strategy was to "address the challenges and opportunities across the drug life cycle using an integrated, collaborative, multi-pronged approach to pharmaceuticals within the health care system".**

Why have we had so little success here? Is it because of fundamental differences in underlying values and principles, or something else? We believe an ethical analysis can reveal some of the reasons for the lack of progress. In this paper, we review a set of government documents as well as the four published NPS proposals identified above to identify principles underlying a NPS, analyze the description of these principles, assess their role in a NPS and identify the possibilities and limits to statements of principles in motivating health system change.

## Identified Principles for a National Pharmaceuticals Strategy

In defining their vision for a NPS, First Ministers and stakeholder groups identified not only practical objectives, but also principles that are "normative action guides" (Beauchamp and Childress 2001). For example, the NPS Progress Report (F/P/T Ministerial Task Force 2006) identifies sustainability as a key principle for directing policy development and the pursuit of purchasing strategies in order to obtain optimal prices for drugs and vaccines as a practical example of how this principle may be applied. Some documents identified principles explicitly, while others used such terms as "criteria" or "values" (Table 1). All terms identified for this purpose are referred to herein as "principles."

All four coalition reports, as well as the Ten-Year Plan to Strengthen Healthcare and the NPS Progress Report, identified the principles of *accessibility*, *effectiveness*, *equity* and *safety* as central to a NPS. *Affordability* and *transparency* were named by five publications, while *appropriateness*, *cost-effectiveness* and *evidence-based decisions* were named by four; *accountability*, *participation* and *sustainability* were named by three. *Impartiality* was named twice, and *inclusiveness*, *innovation* and *patient-centred care* were

each identified once. Principles were not prioritized, and none of the reports provided guidance for balancing them.

**TABLE 1.** Proposed NPS principles

| | Ten-Year Plan to Strengthen Health Care | NPS Progress Report | Canadian Health Coalition | Canada's Research Based Pharmaceutical Companies | Coalition for a Canadian Pharmaceutical Strategy | Health Charities Coalition of Canada |
|---|---|---|---|---|---|---|
| Accessibility | X | X | X | X | X | X |
| Effectiveness | X | X | X | X | X | X |
| Equity | X | X | X | X | X | X |
| Safety | X | X | X | X | X | X |
| Affordability | X | | X | X | X | X |
| Transparency | | X | X | X | X | X |
| Appropriateness | X | X | | X | X | |
| Cost-effectiveness | X | X | X | | X | |
| Evidence-based decisions | | X | X | X | X | X |
| Accountability | | | X | | X | X |
| Participation | | | X | X | X | |
| Sustainability | | X | | X | X | |
| Impartiality | | | X | | X | |
| Inclusiveness | | | | | | X |
| Innovation | | | | X | | |
| Patient-centred care | | | | | X | |

Despite an apparent high level of agreement on the terms used, we found great diversity in meaning and usage.

- *Equity* was not defined as a particular concept of justice in any of the documents. Rather, it applied to two distinct but related issues: equitable access to drugs and equitable health outcomes resulting from access to drugs. The four stakeholder reports relate equity to the goal of access regardless of location of residence or ability to pay (CHC 2006; CCPS 2006; Williams 2006; HCCC 2006). While

several reports discuss the importance of pharmaceuticals for improving health outcomes in general, only the Ten-Year Plan and the NPS Progress Report identified the role of a NPS in contributing to equitable distribution of health outcomes among Canadians (First Ministers 2004; F/P/T Ministerial Task Force 2006). The Ten-Year Plan states that "[a]ffordable access to drugs is essential for equitable health outcomes for all our citizens" (First Ministers 2004).

- *Accessibility* was also used in two distinct ways: individual access to approved drugs and accessibility to a speedy new drug approval process. All reports agree that Canadians are "not [to be] denied access to the best available medicines and vaccines based on income or place of residence" (Williams 2006: 1). Some reports called for accelerated drug review processes, particularly for breakthrough drugs (F/P/T Ministerial Task Force 2006; CCPS 2006; Williams 2006). The CCPS recommends that the federal government "continue to reduce the time required for regulatory review to the fastest level consistent with ensuring optimal health outcomes and the safety of the drug supply" (CCPS 2006: 3), thereby linking accessibility and safety.

**All four coalition reports, as well as the Ten-Year Plan to Strengthen Healthcare and the NPS Progress Report, identified the principles of *accessibility*, *effectiveness*, *equity* and *safety* as central to a NPS.**

- *Safety* was identified in all reports as an essential principle for a NPS. Several (CHC 2006; CCPS 2006; F/P/T Ministerial Task Force 2006) explicitly note that safety requires appropriate pre-market evaluation and post-market surveillance. The NPS Progress Report recommends "a stronger system for gathering, interpreting and applying" drug safety information in the real world (F/P/T Ministerial Task Force 2006: 13).
- *Effectiveness* was generally agreed as essential, specifically, the importance of making decisions "for which evidence indicates effectiveness in the treatment, management and prevention of disease and/or significant benefits for quality of life" (CCPS 2006: 2). *Cost-effectiveness* was identified by two groups as an essential component of effectiveness, though neither defined how it ought to be measured (CHC 2006; CCPS 2006). The CHC called for "a national drug formulary that would focus on providing essential drugs that are both medically necessary and cost effective" (CHC 2006: 9).
- *Affordability* was identified as a principle applicable to both individuals and the health system. All stakeholder groups agreed with the NPS Progress Report that

"no Canadian should suffer undue financial hardship in accessing needed drug therapies" (F/P/T Ministerial Task Force 2006: 4). It was also suggested that a NPS ought to include coverage for catastrophic drugs but that "[a]s a first step, governments should adopt a common operational definition of 'catastrophic'" (CCPS 2006: 2). The necessity of system-level affordability to ensure the responsible use of government funds was named by two stakeholder groups (CHC 2006; HCCC 2006), thus linking affordability with sustainability.

- *Sustainability* was identified as a fundamental principle for publicly funded drugs. A NPS ought to ensure that "[p]harmaceuticals are evaluated not in isolation but as an integral part of the health system. They are assessed in the context of the overall burden of illness, and of their impact on direct and indirect illness costs and health system sustainability" (CCPS 2006: 2). CRBPC indicated that innovative pharmaceuticals accessed through the NPS are likely to contribute to maintaining system sustainability by reducing costs in the acute care sector (Williams 2006).
- *Evidence-based decisions* were identified as a principle by three groups (CHC 2006; CCPS 2006; HCCC 2006). One group called specifically for an environment in which "[a]ll policy decisions, including drug approval and program coverage, are based on an impartial review of the best available scientific evidence" (CCPS 2006: 2).
- *Transparency* and *impartiality* are two aspects of the same procedural principle. Three reports cited the importance of transparency in the development, implementation and evaluation of a NPS (Williams 2006; HCCC 2006; F/P/T Ministerial Task Force 2006). Another three specified that research evidence used in the drug evaluation process ought to be made available to health professionals and to the public once a drug has been approved (CHC 2006; HCCC 2006; CCPS 2006). The CHC states that "[b]oth health care practitioners and the general public should have access to all information used to make decisions on drug approvals" (CHC 2006: 16) and that this transparency ought to carry over into post-market surveillance of drugs for real-world safety and effectiveness. In addition to the reliance on evidence in decision-making, two groups highlighted the need to eliminate bias in this context (CHC 2006; CCPS 2006).
- *Appropriateness* was recommended as a principle by two stakeholder groups (Williams 2006; CCPS 2006) and both government reports. All stakeholders are encouraged to collaborate in order to "find the best ways to promote healthy living, appropriate utilization of medicines and management of chronic disease" (Williams 2006: 1), though the elements of appropriateness are not identified.
- *Patient-centred care* is a recommended principle at the clinical interface. Decisions ought to be patient-centred, "taking account of the unique needs and therapeutic outcomes of individual patients and respecting the relationship between patients and their health-care providers" (CCPS 2006: 2). These goals are linked to effec-

tive knowledge translation from the pharmaceutical evaluation process to all those responsible for prescribing.

- *Participation* and *inclusiveness* were identified as important procedural principles by all stakeholder reports. Some (CCPS 2006; CHC 2006) called for identified engagement of health professionals, patients and the public, stating that the "process must provide all interested Canadians opportunities for meaningful involvement in the development, implementation and ongoing evaluation of the NPS" (HCCC 2006: 3). CRBPC advocated specifically for increased industry participation in the development of the NPS as a necessary condition for success (Williams 2006).
- *Accountability* was considered an essential principle by three of four stakeholder groups (CCPS 2006; CHC 2006; HCCC 2006). The HCCC explicitly recommended that "[t]he health, economic and social outcomes of the NPS must be regularly reported to Canadians" (HCCC 2006).
- *Innovation* was cited only by the CRBPC as important for a NPS, expressing its support for a strategy that would "ensure that Canada has a vibrant, robust, research-based pharmaceutical industry" (Williams 2006: 1).

## Discussion

There appears to be a high level of agreement on four key principles for a NPS: *equity, accessibility, safety* and *effectiveness*. Moreover, because *appropriateness* and *evidence-based decisions* can be considered elements of *effectiveness*, and *affordability* and *sustainability* are facets of *accessibility*, there is an even stronger apparent agreement on substantive principles, i.e., those functioning as criteria for decision-making and action. Furthermore, *participation/inclusiveness, transparency, impartiality* and *accountability* are understood to be components of *an equitable process*, so there is a high degree of consistency regarding procedural principles as well. Only *cost-effectiveness* and *innovation* appear to lack broad agreement.

So, why has this high degree of apparent agreement on principles not facilitated the realization of a NPS? We believe the answer lies in both the current state of principles in health policy and in the particular dynamics of pharmaceutical policy.

The inclusion of principles, values and ethical frameworks has become a common feature of health policy documents in Canada (Giacomini et al. 2004, 2009) and internationally (Daniels 1994; Hoedemaekers and Dekkers 2003; Kenny and Joffres 2008). This trend is a manifestation of the new convergence of healthcare ethics and policy sciences (Fischer and Forester 1987; Danis et al. 2002; Kenny and Giacomini 2005). However, as demonstrated in these documents, much confusion surrounds these terms, their interrelationships and their practical use in public policy (Giacomini et al. 2004, 2009; Kenny and Joffres 2008).

This review helps us identify three main reasons for the impotence of principles

in facilitating a NPS. First, there is a lack of definitional clarity. Fundamental concepts such as *equity*, *effectiveness*, *participation*, *accountability*, *affordability* and *cost-effectiveness* are not defined, but rather are named in reference to their application, e.g., equity of access to drugs. Equity is a particular conception of justice as fairness. There are many different philosophical conceptualizations of equity, including libertarian, utilitarian and Rawlesian, and they express very different views of justice (Bayer et al. 1983). Getting agreement may be difficult, but woolly, undefined terms do not motivate.

Second, no document identified a priority of principles or rules for balancing them, in light of potential fundamental conflicts – for example, between equity and affordability; safety and accessibility; effectiveness and patient-centred care; or innovation and safety. The introduction of Bill C-51, An *Act to Amend the Food and Drugs Act*, has highlighted the safety-versus-accessibility conflict. Defining the principles more clearly in relation to goals would allow the development of a process to assess trade-offs.

**Pharmaceutical policy is replete with competing interests: patient interests are different from citizens' interests, providers' interests are different from public officials', politicians' interests are different from pharmaceutical companies', and so on.**

Finally, there is little indication that these principles play any meaningful role in directing the practical elements of a NPS. In these documents, as elsewhere, principles seem to float independently of their practical and political consequences (Giacomini et al. 2009). Their role in directing policy in the practical elements of a NPS is not made explicit. Thus, it is not surprising that the principles do little to advance a coherent strategy with a clear goal, a fair process and a set of well-understood principles and practical criteria that establish priorities for action.

Definitional clarity will be insufficient if the principles fail as successful motivators for change. Even when there is general agreement on commonly understood principles, there are significant obstacles to acting on them. Federal–provincial jurisdictional and funding issues may, in fact, be the major obstacles to achievement of a NPS. So, robust ethical analysis requires the clarification of interests as well as values and principles. Competing and conflicting interests can use the same language of principle yet mean very different things. Pharmaceutical policy is replete with competing interests: patient interests are different from citizens' interests, providers' interests are different from public officials', politicians' interests are different from pharmaceutical companies', and so on. Nonetheless, having apparent agreement from various sources and interests is an essential step.

## Conclusions

Principles are value-based, normative guides that ought to direct decision and action (Beauchamp and Childress 2001). Genuine consensus on principles forces the issue of using them as criteria for decision-making and action. As part of the broad "spectrum of ethical considerations in policy making" (Kenny and Giacomini 2005: 255), which also includes careful attention to interests and to institutional and systemic constraints inherent in Canadian pharmaceutical funding, we believe these principles could do just that. For example, excellent work on explicating the meaning of transparency as a principle for a NPS has demonstrated how much work could be done in directing practical choice and action (Dhalla and Laupacis 2008). A principle of equity could galvanize the crucial prioritizing of catastrophic coverage because it requires that similar cases be treated similarly and directs our attention to the ethical significance of relevant dissimilarities and the worst off. Equity recognizes that treating persons "equally" can be profoundly unjust if there are substantive differences that should be taken into account in order for outcomes to be just. If safety is a core value, then it must work to balance access and effectiveness. Effectiveness demands clarification and distinction from efficacy. A NPS must address directly the role of economic considerations such as cost-effectiveness (Tierney and Manns 2008) in decisions regarding shared public resources if effectiveness, affordability and sustainability are to be balanced. Clarity regarding the meaning of these principles is essential.

**Principles can be powerful motivators for choice and action, and demanding criteria for assessment.**

Principles can be powerful motivators for choice and action, and demanding criteria for assessment. There appears to be agreement on the foundational principles for a NPS. However, to date, these principles have done no meaningful work for us, but rather appear to function as we have seen elsewhere (Giacomini et al. 2009) – as conventional, politically correct decorations. Collaborative work on robust, coherent and meaningful principles is urgently needed. Such effort may hold the key to real progress on this crucial area of health policy. It is time for all Canadians to use these statements of principle as powerful tools in public and policy discourse.

ACKNOWLEDGEMENTS

This work was supported by grants from the Canadian Institutes for Health Research and the Canadian Health Services Research Foundation.

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