The Payer/Reimbursement Environment in Canada: Current and Future

JUDITH GLENNIE

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A BRIEF HISTORY OF TIME

From a reimbursement perspective, Canada has long been seen as one of the more challenging environments in which to achieve product funding. As an "early HTA" country, economic evaluations became part of the decision making framework for government funded drug programs in the early 1990's along with other countries like Australia. This explicit approach to assessing a product's value is the foundation upon which recent developments have occurred in the area of reimbursement.

RECENT DEVELOPMENTS

1) Risk Sharing Agreements[1,2]

Also known as managed entry agreements, product listing agreements, or performance- or value-based reimbursement schemes, all are intended as tools for managing the uncertainty (i.e., clinical, economic, health-related quality of life) associated with funding of new products. In the Canadian context financial agreements have predominated in many parts of the country, with little to no attention being paid to the clinical/health outcome side of the equation. From both a public policy and an industry perspective, this focus on financials is short-sighted. It does not address the fundamental question of whether a product really performed or brought value to the health care system as anticipated. In addition, it shifts the discussion away from the core principles of data-driven decision making and, thus, undermines the value of future innovative products.

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One exception to this was the introduction of the Evidence Building Program (EBP)[3] for oncology products in Ontario, a program founded in the principles of coverage with evidence development.[4] The EBP is a pilot program which seeks to resolve uncertainty around clinical- and cost-effectiveness data related to the expansion of cancer-drug coverage. Funding is provided for a fixed period to allow the collection of real-world data about a product's clinical and cost-effectiveness, to help inform a final funding decision. While concerns of complexity and expertise are very real, good policy would dictate that payers should push for performance-based agreements when relevant to addressing the data issues that form the foundation of their decision-making frameworks.

2) Patient Input Processes

In contrast to the EU and UK, the move towards patient engagement in various aspects of pharmaceutical policy in Canada has been slow. In 2010, the Canadian Agency for Drugs and Technology and Health (CADTH) introduced a patient group input process for drugs being evaluated under the Common Drug Review (CDR) process.[5] The provinces of Ontario[6] and British Columbia[7] followed suit in the same year. The level of patient engagement in the design, execution and evaluation of these processes has paled in comparison to the very comprehensive and inclusive approach taken by the Patient-Centered Outcomes Research Institute (PCORI)[8] in the US. Patient groups have expressed particular concern related to how their input is being used as part of the evidence evaluation process. While all 3 input processes underwent program evaluation in 2011, results have yet to be made public.

3) pCODR

Last year (2011) saw the introduction of a national oncology drug review process, separate from the CDR process whose focus is non-oncology pharmaceuticals.[9] As with the CDR, the pan-Canadian Oncology Drug Review (pCODR)[10] is intended to bring consistency and clarity to the clinical and cost-effectiveness evidence review process, to provide individual jurisdictions and agencies with an analysis that facilitates their final drug funding decisions.

The creation of a separate agency for oncology sets an important precedent, with de facto recognition of a need for different approaches to evaluate evidence for oncology products. Clinical expertise is front and centre in the pCODR process, proving that it is possible to work around issues of perceived conflict in order to get clinical expert engagement.

As with the agencies noted above, pCODR has also introduced a patient input process. Theirs stands out, however, in that patient input is sought both at the front end (to inform the process) as well in response to the initial recommendation. In addition, how patient input has been incorporated into the review recommendations is much clearer. These reflect the distinctively constructive and collaborative approach that has been taken throughout the launch of pCODR.

With the introduction of pCODR came a distinct shift in disclosure procedures that were a first for the Canadian environment. Under pCODR the intent is to make public the vast majority of information provided by stakeholders (with some caveats), as part of their commitment to transparency of the evidence evaluation process. This is aligned to the approach of some major regulators (i.e., FDA, EMA) and HTA bodies (NICE). It is, however, a major adjustment for Canadian industry and it will be important to monitor progress to ensure that there are no unintended impacts.

IMPLICATIONS FOR DRUG DEVELOPMENT

The need for understanding payer-related data needs as a cornerstone of drug development has never been clearer. International efforts are underway to create means of communicating these needs, with some being driven by those in HTA (e.g., HTAi Green Park Collaborative)[11] while others have evolved from regulatory-industry discussions (e.g., European Healthcare Innovation Leadership Network)[12]. In the Canadian context, the challenge is in obtaining "real" payer input, as opposed to that of intermediaries (i.e., CADTH, pCODR), who do not have the same accountabilities and/or priorities. Ultimately, evolution in the approaches to both early and late-stage development (i.e., Phase IV and CED-type approaches) will be necessary - to address payer needs to ensure that funded products provide good value to the system, and to ensure value from a patient perspective. ●

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