Access to therapies is one of the more important issues in cancer care today, taking up an increasing amount of everyone’s time and energy. There have been rumblings of new processes to address some of the more pressing issues in the approval and reimbursement of therapies, but to date, little concrete action.

The Market Access Summit, a Canadian conference put on annually by the Strategy Institute in Toronto, this year focused unprecedented attention on access issues in oncology. Participants were from government agencies involved in drug regulation and funding, the pharmaceutical industry and third-party consultants to these groups. All are responsible for key decisions that determine whether a drug will be accessible and what options will be available to help patients to pay for it.

The present situation across Canada causes enormous problems for oncologists. Navigating the disjointed system requires a clear view of current issues. Here we present some highlights from the discussions at the Market Access Summit, and some of the suggestions for improvement heard over the course of the conference.

**Suggestion: Streamline the number of departments and agencies involved in government-supported funding**

The Canadian drug-funding system is complex, dysfunctional and outdated. The number of departments and agencies involved in drug funding is staggering. This results in inconsistent, uneven access to therapies, which affects drug developers, the oncology care team and patients. Each of these groups spends huge amounts of time and resources manoeuvring through the system to obtain funding for drugs.

To understand this situation, it helps to step back and note that the system developed with little coordination or planning for current circumstances. Among the many contributing factors:

**The Growing Role of Medications in Healthcare**

In 1957, when the federal government passed the Hospital Insurance and Diagnostic Services Act, the average cost to fill a prescription was about $1.50, according to conference speaker George Wyatt of Wyatt Health Management. In 2007, the average cost was $50.00.1 When the Canada Health Act was enacted in 1984 to insure citizens by paying for healthcare via general taxation, drugs provided to hospital in-patients were included under universal coverage, but drugs taken outside hospital were not. At that time, drugs represented a smaller proportion of health spending (9.5% of total spending in 1985), and most healthcare was delivered in hospitals. Today, more care is provided on an outpatient or day-hospital basis and drugs play a much larger role in treatment. By 2007, drugs made up almost 17% of total healthcare spending.2 Some of the newer drugs, notably in oncology, are prohibitively expensive and an increasing number of these are taken outside hospital, therefore outside medicare’s reach.

**Provincial vs Federal Responsibilities**

Healthcare, including drug coverage, falls under provincial jurisdiction. Each province develops its own formulary, the list of drugs it pays for during hospital stays and for those covered by provincial outpatient drug plans. Private insurers also offer outpatient drug insurance, usually as part of an employee benefits package, and create their own formularies.

An important consequence of this fragmented system is that people with more wealth and/or more generous insurance plans can make treatment choices not available to all Canadians. Often the differences pertain to geography alone: where a patient lives makes a big difference in what treatment options are covered.

A centralized process has been developed to help provinces determine what to include on their formularies and reduce duplication of effort in evaluating drugs. All provinces (except Quebec) and the federally-funded public plans’ participate in the Common Drug Review (CDR) process developed by the Canadian Agency for Drugs and Technologies in Health (CADTH). Oncology treatment drugs are currently excluded from this process (see below), but drugs used in supportive care continue to undergo CDR assessment. The CDR reviews evidence of the clinical and cost effectiveness of drugs, and makes recommendations on drug funding. The key CDR committee making recommendations is the Canadian Expert Drug Advisory Committee (CEDAC).4 CDR evaluation takes at least 7 months, and it has recommended funding for roughly half the drugs reviewed to date.
CEDAC/CDR recommendations are not binding on provinces, and another 4 months after CDR decisions are rendered usually go by before a province decides on coverage. Local factors – from economic strength to patient advocacy to disease burden – have been seen to play an important role in whether a province adopts a CDR recommendation.

The information burden on pharmaceutical companies should have been streamlined in the CDR process, but provincial variations in the adoption of CDR recommendations (and the disappointing positive recommendation rate) mean that regional efforts are still important in gaining provincial reimbursement. However, companies often find it difficult to get support from their own central management to invest the time and manpower required to meet the information needs of decision-makers and payers in 12 provinces and territories and the 6 federal programs. The complexities of the system for obtaining public reimbursement have led a few companies to ignore the Canadian publicly funded market altogether for some of their drugs, and there are fears that this trend may grow.

The variation in coverage decisions between provinces is also partly attributable to deal-making between provinces and drug manufacturers.

**ONCOLOGY DRUG REVIEW**

A separate review process, the Joint Oncology Drug Review (JODR), was developed after CDR capacity to handle oncology drugs came into question. Initiated in 2006, it is now completing an interim phase that is being evaluated as a possible model for a permanent body. Leadership of the interim phase was granted to Cancer Care Ontario (CCO), with representatives from participating provinces observing discussions and meetings. The JODR receives input from several outside groups including the Canadian Partnership Against Cancer, the pharmaceutical industry’s Industry Oncology Working Group and the Canadian Association of Provincial Cancer Agencies (CAPCA). Drugs used in the active treatment of cancer are submitted to the Committee to Evaluate Drugs of Cancer Care Ontario (CED-CCO), following the Ontario Guidelines for Drug Submission and Evaluation. A list of the drugs reviewed from March 2007 to October 2008 is available on Health Canada’s website. A third party has been contracted to evaluate what components of the interim process can be used for a future, more permanent JODR, and to develop a business plan; a report and recommendations to deputy ministers is expected in early 2009. Decisions regarding continuation of the JODR and its potential form should follow that report.

**Suggestion: Provide a stable regulatory environment that encourages companies to bring their products to Canada, and to bring them early**

Prior to reimbursement, the approval process for new oncology drugs and indications is also fraught with problems. Drug developers at the conference described requirements for evidence that changed midstream during an application, and review periods that extended well beyond reasonable delays. The prolonged period between submission of a drug to Health Canada for approval and a decision leads oncology drug manufacturers to make frequent use of Special Access and Compassionate Use programs, often for prolonged periods, especially following completion of clinical trials. A number of independent companies have evolved that provide infusion services on behalf of pharmaceutical companies offering such programs.

There is a pressing need to balance the desire to get oncology drugs that have performed well in clinical trials to patients quickly, against the need for additional study and cost considerations.

It is expected that these problems will be alleviated by the adoption of a “progressive licensing” framework for drug regulation in Canada, which is now in development. A Progressive Licensing Framework is expected to support faster access to promising new drugs and continuous monitoring of safety, quality and efficacy, with enough flexibility to incorporate new scientific developments. Much of the initial information-gathering has been completed, but the time frame for resulting legislation is unknown.

**Suggestion: Improve collection and analysis of efficacy, safety and economic data for drugs on the market, particularly drugs with conditional approvals**

The data needed to support approval and reimbursement decisions is often not available at the time drug submissions are reviewed, especially when clinical studies are stopped early due to unforeseen levels of benefit. There was some discussion among conference delegates about the possibility of introducing more efficient data-gathering at drug administration sites that would permit long-term monitoring of efficacy and toxicity and the collection of economic data. This issue clearly ties in with the Progressive Licensing framework for drug regulation discussed above.

**Suggestion: Develop an explicit ethical framework to guide clinical trial design, approval and reimbursement decisions**

Several speakers and conference delegates pointed to a lack of transparency around the ethics guiding drug approval and reimbursement decisions. Without a common and clear understanding of how different outcomes — improved quality of life, disease-free survival, overall survival — are weighted in economic analysis, lengthy and expensive clinical studies can be wasteful if the endpoints selected at the outset of the study do not match the reviewers’ priorities at the time drug approval and reimbursement recommendations are made.

Further ethical issues surround the differential standards applied to drugs likely to be used by a small number of patients vs those with wider application and therefore greater overall cost implications for the public purse. Denis Morrice, co-chair of the Best Medicines Coalition, pointed out that societal discussions are needed on these issues. Partial ethical frameworks have been developed at the CDR and JODR, but clear guidelines on these issues are lacking. It is not known what type of ethical framework will be proposed in the upcoming report on the JODR. Finally, some suggested that
ethicists needed to be involved in every decision, not just in developing a framework, to ensure thorough consideration of particular ethical issues surrounding a new drug.

**Suggestion:** Formulate explicit pharmacoeconomic standards to be used in reports delivered to decision-making bodies, and include consideration of cost savings made possible by appropriate drug therapies

Drug reimbursement decisions are often made on the basis of comparisons with other drugs and/or consideration of expected overall costs. The pharmacoeconomic models used generally do not incorporate consideration of the impact on other components of the healthcare system. Denis Morrice pointed to a Quebec study conducted after copayments were introduced for lower-income and elderly residents that showed a decrease in the use of essential drugs and a concurrent increase in associated adverse events and emergency department visits.

Morrice reported that government-funded research often displayed a bias toward containing short-term costs.

On the other hand, Jeffrey Hoch, Head of the Pharmacoeconomics Research Unit at Cancer Care Ontario reported findings that pharmacoeconomic studies sponsored by industry were more likely to use modeling than administrative data and to arrive at more favourable cost estimates per quality-adjusted life year (QALY) than research funded by non-profit government agencies. It is obvious that funding sources for pharmacoeconomic research need to be stated clearly, just as for clinical research. Many participants called into question the value of pharmacoeconomic research in decision-making, as the results are so dependent on the selection of patient variables, time frames and contexts in calculating QALYs. The onus has been on the pharmaceutical industry to conduct pharmacoeconomic research, but there is some debate as to how much can be determined with the limited amount of data available at the time this research is conducted.

**Suggestion:** Develop more cost-effective logistics for administration of infusions to outpatients

Even when an intravenous drug is inexpensive, there are significant costs associated with infusions, including an appropriate infusion clinic and skilled personnel. The logistics of ordering and stocking these drugs are complex, and differ substantially between provinces. Conference participants debated whether drug manufacturers could consider jointly setting up and staffing infusion clinics, rather than individually attempting to provide designated facilities for a few specific drugs. It was suggested that allowing Canadian physicians to be reimbursed under the publicly funded system for administering intravenous drugs in their offices, as is done in the US, be considered.

**What next?**

Canada’s processes and programs for bringing oncology drugs to market and making them available to patients is disjointed, inconsistent and in need of very significant change. Initiatives are underway, including the JODR assessment and Health Canada’s Progressive Licensing Project. However, the time frames in which we can expect real guidance from these government initiatives is unknown.

In the meantime, Special Access programs may enable some patients to access new oncology drugs, and cancer centres are likewise developing innovative strategies to secure funding for patients who lack coverage (see page 23 of this issue of Oncology Exchange). These stopgap measures warrant close attention: they are what now determines access for many patients.

**References**

3. Information available on www.drugcoverage.ca and www.drugcover-age.org
5. More information is available at www.health.gov.on.ca > Health Care Providers > Ontario Public Drug Programs > Drug Submissions > Submission Guidelines For Oncology Drugs
7. More information is available at www.hc-sc.gc.ca > Drugs & Health Products > Progressive Licensing

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