Pharmaceutical Pricing and Reimbursement: Canada
Before starting a clinical trial in Canada, manufacturer needs to file CTA or Clinical Trial Application with Health Canada. Health Canada reviews the application for its completeness. Applications must be submitted for phase 1, 2 and 3 trial or if the sponsor wishes to conduct a clinical trial for a new indication. Phase 4 trials do not require CTA filing.

Sponsors are invited to have Pre-CTA consultation meeting with Health Canada to discuss drug development plan and to obtain any guidance, for which they are supposed to submit pre-CTA information package/modules to Health Canada before meeting. In case of any change in protocol or manufacturing process, sponsor can submit CTA amendment to Health Canada. Health Canada itself can issue either a request for clarification (called as Clarifax) or a screening rejection letter in case of major concerns in the application. If no deficiencies are identified, a NOL or No Objection Letter is issued by Health Canada. Subsequently, sponsors are supposed to submit details like clinical trial information site, ethics committee approval documents, participating investigators etc. to Health Canada. The CTA is required to be regularly updated with information relating to research ethics boards, premature discontinuation of trial, adverse drug reactions and information on investigator’s brochure.
The Therapeutic Products Directorate (TPD) of the Health Products and Food Branch (HPFB), a branch of the Department of Health (Health Canada), is in charge of reviewing new drugs for licensing and labeling. TPD is the national authority that regulates, evaluates and monitors the safety, efficacy and quality of pharmaceutical drugs available to Canadians.

A marketing application for a new drug in Canada is called as NDS or New Drug Submission. Sponsors file market licensing applications and supporting documentation for proposed new products. Drugs are reviewed by HPFB in-house experts, who collaborate with outside experts to assess their safety, efficacy and quality. At the end of the review process, Health Canada may grant a marketing authorization or “Notice of Compliance (NOC)”, which indicates that the drug under review has met its safety, efficacy and quality requirements.

Sponsors can also have pre-submission meetings with Health Canada to discuss the presentation of data for the forthcoming submissions. Post submission filing, screening of all the documents is done. Minor issues that arise during the TPD review are usually dealt with by issuing a Claifax.

Following are the possible outcomes post NDS review process.

1. **Notice of Deficiency (NOD):**
   The review cannot continue due to deficiencies or significant omissions in the file

2. **Notice of Deficiency–Withdrawal (NOD/w):**
   If the response to an NOD is inadequate, the TPD will issue an NOD/w letter, indicating the company must withdraw the submission

3. **Notice of Non-compliance (NON):**
   Indicates the review is complete and the submission is deficient or incomplete

4. **Notice of Non-compliance–Withdrawal (NON/w):**
   If the response to a NON is inadequate, the company must withdraw the submission

5. **Notice of Compliance (NOC):**
   Once all issues have been resolved, the TPD will issue an NOC. This identifies the Drug Identification Number (DIN) which permits the sponsor to market the drug in Canada and indicates the drug’s official approval. All drugs granted marketing authorization in Canada are reviewed to ensure that they meet the requirements of the Foods and Drugs Act.

- TPD also has a Priority Review Process which allows for faster review to make available promising drug products for life-threatening or severely debilitating conditions, such as cancer, AIDS, or PD, for which there are few effective therapies already on the market.

- In certain circumstances, conditional approval for marketing may be granted to expedite access to potentially life-saving drugs (with the same eligibility criteria as priority review drugs) under the Notice of Compliance with Conditions (NOC/c) policy. An NOC/c authorizes the manufacturer to market a drug on condition that the manufacturer undertakes additional studies to demonstrate the drug is clinical benefit. Conditions associated with approval allow the HPFB to monitor the safety and effectiveness of the drug through enhanced post-market surveillance.
Health Canada also administers a Special Access Programme (SAP), which authorises the sale of drugs that have not been licensed in Canada, including drugs that are available in other countries or are still in development. This program is reserved for patients with a serious or life-threatening disease, when alternatives have failed or are not available in the Canadian market.

An abbreviated procedure is used to assess generic products, mainly based on comparative bioavailability studies aimed at showing that the generic product is as safe and as effective as the brand name product.

Canada has faced criticism for lengthy approval times which is usually around 19 months. In 2003, Health Canada launched the Therapeutics Access Strategy, the major focus of which was improving the performance, efficiency and timeliness of the drug review process. Consequently, average and median review times in Canada have declined significantly.

HTA (Health Technology Assessment) roadmap of Canada

HTA is a multi-disciplinary process of policy analysis that aims to bridge the world of research with the world of decision-making. It examines the medical, economic, social and ethical implications of the use of a medical technology, including pharmaceuticals, in healthcare, and uses the evidence to inform decision-making. In this context, the results of HTA are applied to pharmaceuticals to define, capture, and reward value creation, with the goal of making decisions that are fiscally responsible without sacrificing patient health.

The Canada Health Act (CHA) is Canada's federal legislation for publicly funded health care insurance that aims to ensure that all eligible residents of Canada have reasonable access to necessary health services. Furthermore, the CHA mandates that health insurance be administered by a public authority, reasonably comprehensive, non-exclusive (universal), portable across provinces, and allow for equity of access.

Canada has Medicare, a universal (publicly funded) healthcare insurance since the 1960s; however, medication, except drugs administered in hospitals and for certain special populations, is not covered through this program. Thus, the majority of the population (about 66%) obtains drug coverage through private insurers, either through their employers or purchased individually. For public funding, each Canadian province and territory operates its own drug plan, which primarily covers seniors, welfare recipients, and other groups for whom drug costs represent a significant financial burden. Some provinces (such as Alberta, British Columbia, Saskatchewan and Quebec) make their drug plans available to all residents who choose to join the plan (Alberta, British Columbia, Saskatchewan) or lack private drug coverage (Quebec). Moreover, the federal government has established drug plans for First Nations (Non-Insured Health Benefits), veterans, penitentiary inmates, armed services personnel, and the federal police. Altogether, approximately 10 million Canadians are covered by publicly funded drug plans, nine million through the provincial plans and another million through the federal one while 10 percent of Canadians lack basic drug coverage.
A drug’s inclusion in a formulary, or list of medicines eligible for reimbursement by a third-party payer, is an important determinant of the accessibility of that medicine to persons covered by the insurance. In Canada, where hospital care - including medicines furnished to hospital patients on an inpatient basis - is covered by Medicare, individual hospitals are responsible for developing their own formularies. Private insurers are free to draw up their own formularies. Provinces make their own decisions regarding the formularies used by provincial drug plans.

Health Canada, the federal health is responsible for product licensure while provincial bodies control healthcare funding. However, national bodies are important in advising formulary decision making. Quebec, predominately French speaking, does not, for the most part, participate in such pan-Canadian processes that serve the rest of the country (English speaking). Formulary decisions are rendered province by province, hospital by hospital and in some cases, separately for diseases such as cancer and HIV/AIDS.

The Canadian Agency for Drugs and Technologies in Health (CADTH) is an independent, not-for-profit agency funded by federal, provincial, and territorial governments, to provide evidence-based information about the effectiveness of drugs and other health technologies to Canadian healthcare decision makers. HTAs of the selected technologies are either carried out in-house or commissioned to external public or private research organization. CADTH fulfils its mandate through the Health Technology Assessment (HTA) program, the Common Drug Review (CDR) process, and the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) which identifies and promotes optimal drug therapy. CADTH also conducts Optimal Use Projects to encourage ideal prescribing, purchasing and use of drugs and health technologies by healthcare providers, policy makers and consumers. These projects are often large projects involving systematic reviews of clinical evidence, cost effectiveness and development of recommendations and guidelines.

As part of the CDR process, Canadian Expert Drug Advisory Committee (CEDAC) is composed of drug therapy and evaluation experts, who make formulary listing recommendations to participating drug plans based on scientific evidence and current clinical practice. CEDAC is appointed by and accountable to the CADTH Board of Directors.

Canadian Drug Expert Committee (CDEC) is an appointed, national, independent body of physicians, pharmacists and other health care professionals and public members - uses the Clinical and Pharmacoeconomic Drug Reviews to evaluate the comparative benefits and costs of the Drugs under consideration and Patient Input to make common formulary listing recommendations to participating F/P/T Drug Plans (federal, provincial and territorial). As of September 2011, CDEC replaced the CEDAC. In addition to making listing recommendations, CDEC also provides other drug-related recommendations or advice, based on CADTH reviews, to inform decisions and strategies.
The pricing and reimbursement of pharmaceuticals in Canada is controlled at three levels: by the federal Patented Medicine Prices Review Board, by the 17 federal, provincial and territorial public drug plans and by the Common Drug Review. This system means that an innovative manufacturer must obtain the approval of 19 different bodies for the price of a new drug in Canada (decentralized system). Decisions regarding which new technologies to include in the basket of publicly funded services, therefore, rest with individual provinces and territories, and the role of the federal government remains primarily limited to premarket approval and, in the case of patented pharmaceuticals, price regulation.

Health Canada

In Canada, drugs are federally regulated under the Food and Drugs Act within Health Canada, the federal health department. Health Canada reviews new drug submissions for the purposes of safety, efficacy and quality of manufacture, and issues marketing authorizations – known in Canada as notices of compliance (NOC). The regulatory review by Health Canada does not include a pharmacotherapy or pharmacoeconomic analysis relative to other marketed drug products. Following the issuance of an NOC, Health Canada’s role is essentially limited to post-market surveillance, inspections, and investigations of the safety and efficacy of the drug. It is also responsible for promoting healthy living to Canadians by communicating information on disease prevention, drug safety, and other health-related issues. Reports of suspected problems can be received from manufacturers, health care professionals and consumers, which Health Canada evaluates to determine appropriate action if a serious health risk is identified. Such actions can range from issuing warnings to the public and the health care community, to removing a product from the market. Contrary to popular belief, Health Canada is not involved in the regulation of drug prices in Canada.

Patented Medicine Prices Review Board (PMPRB)

The PMPRB is an independent body within the federal health portfolio, which also includes Health Canada, and is responsible for regulating drug prices for all prescription and non-prescription patented drugs sold in Canada. It was created because of concern that patentee might abuse the increased patent protection provided by the Patent Act of 1987; it is therefore the consumer protection component of the 1987 amendments. Patents pertaining to active ingredients, processes of manufacture, delivery systems, dosage forms, and indications for are some of the patents that fall within the jurisdiction of the PMPRB. It also submits to the federal parliament, an annual report including analyses of patented drug prices, price trends, and research and development expenditures of patent-holding drug manufacturers.

The PMPRB regulates the price at which patentees or their licensees sell patented medicines to wholesalers, hospitals or pharmacies – commonly referred to as the “factory gate” or “ex-factory” price. It does not, however, have jurisdiction to regulate the prices of patented medicines throughout the distribution chain (i.e., from the wholesaler to pharmacies) or to the eventual customer, the patient. Nor does it have jurisdiction to review the prices negotiated with the F/P/T Drug Plans.

For the PMPRB to review the prices of patented medicines, patentees must submit specified pricing information at introduction and on a semi-annual basis. The Board then undertakes both a scientific and an economic review to establish whether the price of the patented medicine is an appropriate benchmark price or whether it is excessive.
PMPRB approach involves concepts of comparing the price of a new drug with the prices of existing drugs and to prices in other countries. In principle, the board guidelines mention that:

- The prices of most new patented drugs cannot exceed the price of the most expensive drug that treats the same disease
- The prices of breakthrough or substantial improvement drugs cannot exceed the median of the price in other industrialized countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States)
- Prices cannot increase more than the Consumer Price Index; and
- The price of a patented drug in Canada can never be the highest in the world

The “excessive price” criterion used in assessing the price of a new drug depends on the degree of innovation of the new product, as categorised by the PMPRB using a three-tiered scale. Drugs are classified in these three categories by experts of the Human Drug Advisory Panel (HDAP), which reviews all the available information on the drug and its comparators, with reference to documents provided by the manufacturer and to published literature.

Impact of pricing regulation on Canadian drug prices

According to PMPRB estimates, Canadian prices have moved closer to median international prices since price regulation commenced in 1987. In 1987, Canadian prices for patented medicines exceeded the international median by more than 20%. After a fairly consistent annual decrease until 1994, the prices have since stabilized at or up to 10% below the median in seven comparator countries. In 2005, prices of patented drugs in Canada were about 8% lower than the median prices of the seven comparator countries. These data suggest that Canadian price regulation has had a dampening effect on relative price levels in Canada, bringing them closer to the median price paid in a selected set of countries.

In 2004, as part of the National Pharmaceutical Strategy, the federal and provincial ministers of health directed that the PMPRB monitor and report on the prices of non-patented drugs in Canada as well. While the establishment of the PMPRB has arguably resulted in the over-regulation of patented medicines, it appears that the prices of generic medicines have escaped any formal price regulation and are excessively priced in Canada. Patentees are concerned that the PMPRB is continually expanding its jurisdiction. The marked increase in payments reflects the Board's ever-proliferating jurisdiction and increased enforcement activities.

Public Drug Plans

The reimbursement process in Canada is governed by a combination of federal, provincial and private plans. Through the publically-funded Medicare system, all Canadians and residents have free access to coverage for drugs, procedures, and physician services provided in hospitals.

At the federal level, various prescription drug plans are available to certain regulated groups. All provinces and territories, meanwhile, have implemented publicly funded drug plans for specific subpopulations. In general, the provincial and territorial governments provide drug coverage for individuals over the age of 65, individuals receiving social assistance or disability benefits and individuals with “catastrophic” drug needs (defined as “high drug cost in relation to income”).

Consequences of excessive price

When the PMPRB considers a price to be excessive according to the criteria defined above, there are two alternatives:

1. If the company agrees to cut its price and to pay to the government of Canada some compensation for the excess revenues earned, it must submit a Voluntary Compliance Undertaking (VCU)

2. If the company does not agree with the PMPRB, the Board holds a public hearing to reconsider the conclusion of excessive price and, if affirmed, make a judgment regarding penalty. If the public hearing confirms that the price is excessive, the company may appeal to the Federal Court of Canada to ask that the Board decision be overruled.
Following a manufacturer’s submission, a drug plan will conduct a separate pharmacotherapy and pharmacoeconomic review to determine whether a new drug will be included in its formulary and the conditions for reimbursement. What is meant by economic considerations ranges from simple budget impact analysis to more elaborate cost-effectiveness studies provided by the manufacturer.

As PMPRB jurisdiction is limited to the ex-factory price charged by a manufacturer, some provinces have enacted legislation restricting payments by manufacturers, including rebates and professional allowances, to pharmacies and wholesalers. This, to some extent, regulates the prices of patented and non-patented medicines. Furthermore, provincial legislation has been enacted requiring manufacturers to provide volume discounts or similar payments as a condition of listing on the provincial formularies. It should be noted that such payments are kept confidential. The practical effect of the legislation, however, is for the provinces to assume price regulation at the point where the jurisdiction of the PMPRB ends, and to establish a maximum price for manufacturers to comply with to be included in the provincial drug plans.

Common Drug Review (CDR)

The Common Drug Review (CDR), at the Canadian Agency for Drugs and Technologies in Health (CADTH), was launched in 2003. It is an intergovernmental collaborative body which aims at evaluating new chemical entities (NCEs) and new combinations to inform an official recommendation as to whether a drug should be included in the formularies of participating publicly financed drug plans. It is also a pan-Canadian process for conducting objective, rigorous reviews of the clinical, cost-effectiveness, and patient evidence for drugs. CDR was initiated to harmonize the drug review process across the country, in an attempt to optimize the use of healthcare resources and reduce duplication of effort. A CDR submission represents a submission to all participating institutions, including all federal, provincial (all provinces, except Quebec) and territorial drug plans.

The goal of the CDR is to provide participating drug plans with formulary listing recommendations based on a consistent, scientifically rigorous, evidence-based review. Manufacturers submit a dossier to CDR. A review of each product submission is performed by internal reviewers (CDR staff) and external clinical and health economic experts, and sent to the manufacturer for comment.

The review, manufacturer comments and reviewer replies to the comments are then submitted to CEDAC, who meet monthly for deliberation and recommendation. CEDAC may recommend a drug (a) be listed, (b) be listed with restrictions, or (c) not be listed at all. The listing recommendation is posted on CADTH’s website. The final listing decision rests with each public drug plan, which considers the CDR recommendation and arrives at its own decision about formulary listing and criteria for reimbursement.

Patient Groups are also invited to submit information related to a Drug Submission under review by CDR. Patient Group Input is used in the review of Drug Submissions and by CDEC in the development of recommendations. The information, provided by Patient Groups, should describe the experiences and perspectives of patients living with the condition for which the Drug under review is indicated and the impact of drug therapy (existing and new, if available) on the lives of those with the illness or condition.

To facilitate an efficient submission preparation and filing process, pharmaceutical manufacturers may request a pre-submission meeting with CADTH. These meetings provide an opportunity for the manufacturer to introduce the drug to CADTH and seek information about the CDR submission, requirements of the drug, including the approach to economic evaluation.

The CDR does not review products used for the active treatment of cancer; these are submitted to the pan-Canadian Oncology Drug Review (pCODR). Quebec’s public drug plan requires separate formulary submissions, independent of CDR or pCODR. In addition, the province of Ontario has established a Rapid Review Process that is independent of the CDR Process.
The pan-Canadian Oncology Drug Review (pCODR) process (all provinces except Quebec)

Submissions for drug products for active treatment of cancer that may potentially be funded by the participating provincial and territorial drug plans (i.e., federal, provincial and territorial drug plans, except Quebec) are directed to pCODR who will make a listing recommendation. pCODR is a newly established evidence based cancer drug review process with the role of assessing clinical evidence and cost-effectiveness of new cancer drugs. Manufacturers submit a dossier to the pCODR expert review committee, which also takes into account input by patients and clinician-based tumor groups.

Ontario's Rapid Review Process

Ontario is participating in the CDR and the pCODR processes. However, a product may qualify for the Rapid Review Process, which is independent of the CDR, if evidence is submitted showing that the new chemical entity will either fill a significant unmet medical need or that listing will result in significant savings for the drug plan or the Province.

Quebec

Quebec’s Régime Public D’Assurance Médicaments (Public Drug Insurance Program) provides drug coverage to seniors, welfare recipients, and residents without private drug insurance. The last are required to join the public plan (universal coverage). To obtain listing on the Quebec formulary (i.e., Liste de Médicaments Assurés) for any potentially covered drug, manufacturers submit a dossier to the Conseil du Médicament, which makes a listing recommendation.

Hospitals

Hospitals maintain their own formularies through Pharmaceuticals and Therapeutics Committees (P&T committee) which are under provincial purview. Dossiers must be submitted to individual hospitals or hospital consortia.

Private Payers

Given the absence of a national insurance plan for outpatient prescription drugs, many employers provide private drug insurance for employees and their dependants. About 1,000 private plans cover two-thirds of the Canadian population. Private plans may be national, regional, or local in coverage, and enrolment tends to cater to those affiliated with particular employers, or through membership in a professional order or association. Individual subscriptions to private drug insurance plans are not common. In Québec, individual coverage is even prohibited.
The level of coverage by private insurance varies from one province to another, together with employment conditions; high-wage workers are more likely to have access to employer-sponsored private insurance. Private plans are financed by premiums from their sponsors and from beneficiaries. According to recent estimates, employers normally pay about 70% of premiums; however, employers are not required to offer this benefit. If an employer offers coverage, an employee may be required to enrol (along with spouse and children). The majority of public and private plans require patients to bear some of the financial burden in the form of co-payments, deductibles and premiums.

Private coverage tends to be more inclusive in terms of the number of products covered for reimbursement, as compared with the publicly financed plans. Many private plans offer open access to all drugs licensed for marketing by Health Canada, while others cover only drugs listed on a more restrictive formulary, reflecting growing concerns from employers about growth in benefit cost. Some private plans are reportedly beginning to experiment with the use of formularies which mirror those of public drug plans, while others offer employers various options in terms of formularies. Generally speaking, private plans have the option to reference public plan formularies for coverage decisions, or to maintain their own. However, in Québec all plans are required to offer coverage at least equal to the public formulary.

Private health plans can be regulated by the provinces and territories, resulting in different policies across Canada. For instance, while risk selection (health insurers are authorised to accept or refuse enrolment according to characteristics of the candidate and to vary the premium according to these characteristics) is allowed in most provinces, it is prohibited in Québec. Overall, regulation of private insurance is more stringent in Québec than in other provinces.

Recommendations for a common national formulary are a recurring item in Canadian public debates. It has been asserted that a national drug review and formulary would avoid duplicative work of formulary management; increase negotiating power of buyers, ensure an adequate investment in formulary management, impede strategic behaviours from manufacturers and provinces harming other provinces, eliminate the differences in ‘available’ drugs between provinces, and reduce marketing delays by increasing collaboration between Health Canada and the PMPRB.
Data requirements are specific to each jurisdiction for which listing status is sought. However, there are requirements that are common to all or most jurisdictions; these include:

a) The price to be charged for all dosage forms
b) Product characteristics (from the Product Monograph)
c) Clinical efficacy and safety data
e) Economic evaluation
f) Budget impact assessment.

Below specific data requirements are outlined for a CDR submission and for a submission to Quebec’s Conseil du médicament.

**CDR Submission**

Key requirements for a CDR submission are evidence for the efficacy, effectiveness and safety of a product along with an appropriate economic evaluation.

Cost-effectiveness or cost-utility analyses are required if the drug: a) is the first available (no other products listed) to treat a disease or disorder or has established a new therapeutic class; b) has demonstrated differences in safety or efficacy versus comparators in head-to-head randomized controlled trials; or c) in the absence of head-to-head trials, the manufacturer assumes that such differences exist. (Evidence to support this claim must be provided.) Cost-effectiveness or cost-utility analyses must be based on final outcomes, such as life-years, QALYs or important events (e.g., fracture, stroke, or myocardial infarction), or validated surrogate outcomes.

Products demonstrating benefits in other outcomes (e.g. patient-reported, non-clinical, or surrogate) only require cost-consequence analyses. For all other products, only detailed price comparison and cost tables are to be submitted.

Budget impact analyses (BIAs) are also required for CDR submissions for most of the participating drug plans. Each BIA must meet the specifications of its respective drug plan, and be supported by current market data and regional information. Product information approved by Health Canada, local epidemiological data (prevalence or incidence) where available, and detailed pricing information are also required.

**Quebec Submission**

With regard to evidence of clinical efficacy and safety, Quebec stipulates that a maximum of five clinical studies can be submitted, including at least one randomized controlled trial published or accepted for publication in a peer-reviewed biomedical journal. In addition to an economic evaluation according to CADTH guidelines, Quebec’s Conseil du médicament requires a detailed price justification. Information about the disease of interest — including duration, progression and stages — and the projected impact of the product on the healthcare system also needs to be included in the dossier.
Therapeutic reviews are another type of review, in addition to the Common Drug Review (CDR) process, to support evidence-based decision-making. An important characteristic of a therapeutic review is that it is conducted to coincide with a CDR submission review and thus, informs the CDR submission review and listing recommendation and informs drug plan decisions.

The final outputs of the therapeutic review include one of the following:

1. A recommendation(s) from the Canadian Drug Expert Committee (CDEC); The drug plans generally prefer recommendations
2. Advice from CDEC (based on analysis and synthesis of information)
3. A report and conclusions

CADTH - with input from jurisdictions and CDEC - will consider the most feasible of a range of options for conducting the therapeutic review. These may include simply adapting or supplementing an existing drug class review, or undertaking a CADTH systematic review and/or meta-analysis of available data and a CADTH-generated pharmacoeconomic evaluation or other approaches.

Therapeutic reviews may be updated as required based on, but not limited to, the following: new information about the safety and/or effectiveness of the drugs within the class, changes in drug policies, and changes in pricing.

Current issues in HTA in Canada

Which technology to assess and in what order

Although this challenge has been minimized with the creation of the CDR, there is still a need to set priorities when “priority reviews” emerge and disrupt the “first-come-first-served” system.

Lack of real world data

For pharmaceuticals, data are frequently limited to that required for market approval by Health Canada (i.e., evidence of safety and efficacy). As a result, they typically comprise placebo-controlled randomized trials of efficacy, rather than effectiveness, with relatively short follow-up periods. In the absence of the effectiveness data, HTA producers resort to using modeling techniques and sensitivity analyses to examine parameters such as longer time frames and possible variations in efficacy.

However, even the most rigorous models often fail short of capturing not only important aspects of a drug when introduced into the “real world” (e.g., therapeutic benefit in the presence of co-morbidities, adverse effects caused by poly-pharmacy, etc.), but also outcomes of value to patients and payers, as trials conducted for regulatory purposes typically focus on narrower clinical measures (e.g., change in blood pressure or length of survival).

Incorporating values-based data

HTA relies on values-based data from studies measuring health-related quality of life (HRQOL). This information is then input into cost-utility analyses, which offers a means of establishing the value of a technology as seen by the payer. However, for some technologies, HRQOL data are not available, precluding the assessment of their value from the patient's perspective.
Transferability of economic information

Canadian costing information for economic evaluation is primarily obtained from administrative databases. In the case of new technologies for which no Canadian data are available, costs are generally extracted from sources that most closely reflect the Canadian context (i.e., public health-care system in a westernized country) and then converted into Canadian dollars. In compliance with CADTH's economic evaluation guidelines, sensitivity analyses are carried out around estimates to account for any uncertainties in them.

Generating and using real-world data

HTA in Canada usually relies on the form of secondary research i.e. on existing data from various kinds of scientific studies. However, lack of sufficient evidence regarding the effectiveness of many health technologies has resulted in the establishment of Field Evaluation system by the federal government, a mechanism for obtaining evidence to support decision-making through primary research on the effectiveness of promising new technologies for which no "real-world" data exist. The field evaluation concept is akin to that of Coverage with Evidence Development.

Timelines

HTA producers continue to face criticism over the turnaround times for assessments, which have often been well over a year. Nationally, CADTH has responded by creating a Health Technology Information Service, designed to provide information to decision-makers based on the "best available evidence" within 1 to 30 business days, depending on the urgency of the request.

Transparency in decision-making

The lack of transparency has become particularly frustrating for patients and manufacturers searching for answers to why certain technologies received negative recommendations or decisions.

Silo budgeting

Health economists believe that economic evaluations of health-care services should be conducted from the societal perspective, but unfortunately no single "societal" budget exists. As a result, technologies shown to be cost-effective through evaluations conducted from the societal perspective are deemed inefficient.

Parallel trade

Because of price differences for pharmaceuticals between Canada and the United States, parallel trade for these products exists.

Patient and provider choice

For pharmaceuticals, there are three groups of payers in Canada: 1) the federal, provincial, and territorial governments, 2) insurance companies, and 3) individuals who do not fall into at least one of the first two categories. In the first two groups, patient choice is limited to pharmaceuticals included in formularies or benefit lists, the contents of which are determined by government or the insurance company. Because HTA—through the CDR—is part of all government-based decision-making processes, it has the potential to influence patient access. Insurance companies typically base their coverage decisions on those already made by government. However, physicians may prescribe any product that has received market approval from the federal government.

Quality-adjusted life year (QALY) thresholds

The proposed figure was $20,000 per QALY for the threshold below which a new technology ought to be adopted, and $100,000 per QALY for the threshold above which a new technology should not be adopted. A threshold figure that is cited now is US $50,000 per QALY. However, there is no formal evidence that any of these boundaries has ever been accepted or implemented by any Canadian decision-making body. Thus, although QALY thresholds might exist in an implicit sense, there is no explicit evidence that they have been used during decision-making.
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