Pharmaceutical policies in Canada: another example of federal–provincial discord

Review

Synthèse

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Abstract

PHARMACEUTICAL POLICY IN CANADA IS SET AT both the federal and provincial levels of government. The federal government is responsible for intellectual property rights of manufacturers (patents) and the initial approval and labelling of prescription drugs and for ensuring overall market competitiveness. The provincial government has responsibility and jurisdiction over the funding of all health care services, including pharmaceuticals. Various interactions between the pharmaceutical industry, the federal and provincial governments and consumers have shaped the current landscape for prescription drugs in Canada. One key failing of the system is that the federal government is almost completely insulated from the impact of its policies because, although it regulates drug prices, it does not buy any drugs. In contrast, provincial governments have no jurisdiction over market competitiveness or pricing, yet end up paying for most of the drug expenditures incurred.

Most Canadians will proudly admit that our publicly funded, universal access medicare system is worth a lot. Canadians seem willing to accept higher taxes, lower wages and a weaker dollar as the price to pay for having everyone in insured — unlike the situation in the United States. Moreover, Canadians appreciate that no one will ever lose their house or life savings because they are ill. Nonetheless, there are growing concerns, as evidenced by frequent media reports, that our health care system is falling behind in its ability to adopt new expensive medical technologies and meet the increasing demands of an aging population.

Under the Canada Health Act, a "near-universal" system of coverage has evolved that is remarkably similar in scope across the provinces. One exception, however, is the coverage provided for prescription pharmaceuticals. Although all drugs needed for treatment in hospitals are provided free of charge, outpatient prescriptions or prescriptions written in physicians' offices are not universally covered. The type and level of outpatient drug coverage is determined by individual provincial legislatures and therefore varies by province. It was forecasted that the percentage of total health expenditures (including private and public spending) spent on prescription and nonprescription drugs would reach 15.2%, or $13 billion, in 1999.[1] This enlarging hole in the medicare net is a major weakness of Canadian medicare and threatens its comprehensiveness.[2,3]

The pharmaceutical industry in Canada is regulated by both the federal and provincial governments. The federal government has jurisdiction over intellectual property rights of manufacturers (i.e., patents) and the initial approval and labelling of prescription drugs and is responsible for ensuring overall market competitiveness. The provincial government has jurisdiction over, and is responsible for, the funding of all health care services. For pharmaceutical coverage each provincial drug plan sets specific price and other cost-containment guidelines (e.g., drug product substitution laws).[4,5] More recently, several provinces have mandated that a cost-effectiveness analysis of each new drug be done to help determine if the drug should be added to their formularies (i.e., extend coverage under the provincial drug plan). The impact of the various regulations at each level of government has

resulted in a uniquely Canadian landscape that is sometimes difficult to rationalize on efficiency grounds.

Interactions between the pharmaceutical industry, the federal and provincial governments and consumers have shaped the current landscape for prescription drugs in Canada. One key failing in the system is that the federal government is almost completely insulated from feeling the impact of its policies because, although it regulates drug prices, it does not buy any drugs. Conversely, provincial governments have no jurisdiction over market competitiveness or pricing, yet they end up paying for most of the drug expenditures incurred. The various regulations at each level of government that affect the pharmaceutical marketplace have both intended and unintended impacts.

Federal role: approval, price and patent regulation

Drug approval refers to a process that is under the jurisdiction of the Therapeutics Products Program, a division of Health Canada that reviews the safety and efficacy data for each new drug submission. If a new drug submission is found to be acceptable on the basis of clinical trial efficacy and toxicity data, the Therapeutics Products Program issues a notice of compliance and the associated product labelling. The drug is then approved and may be prescribed by physicians and dispensed by pharmacies in Canada. However, such approval does not mean that provincial drug plans or other third-party payers will pay for the approved drug. The decision regarding who pays is made by each province.

In addition to the initial approval of drugs, the Patented Medicines Prices Review Board of Canada, a federal agency with quasijudicial powers, regulates both the introductory price of new drugs and any price increases over time. The review board uses a set of pricing guidelines and relies on voluntary compliance by the pharmaceutical industry. The term "excessive price" is used to characterize either a high introductory price of a new medication or a substantial increase in the price of an existing medication. The essence of these regulations is based on the following categorization of new drugs:

- Category 1. Line extensions of existing medicines. Price is presumed excessive if it does not bear a reasonable relationship to the price of other medicines of the same strength sold by the patentee.
- Category 2. Breakthrough or substantial improvement. Price is presumed excessive if it exceeds the prices of all the medicines in the same therapeutic class or the median of the prices in 7 countries — France, Germany, Italy, Sweden, Switzerland, the UK and the US.
- Category 3. New chemical entities offering moderate, little or no therapeutic improvement. Price is presumed excessive if it exceeds the prices of all the medicines in the same therapeutic class.

The increase in the price of existing medications is considered excessive if it exceeds the increase in the general Consumer Price Index. When manufacturers are in violation of any of the guidelines the Patented Medicines Prices Review Board can impose fines equal to or double the amount of the excessive increase in price.

A study by the United States General Accounting Office reported that Canadian prescription drug prices were about 32% lower than those in the US.[6] This contrasts with the Patented Medicines Prices Review Board's findings that Canadian drug prices were often the highest (56% of all classes of patented drugs) in the world.[7] It is difficult to have much confidence in international price comparisons because the published prices in each country often do not reflect the actual transaction prices after adjusting for rebates (sometimes mandatory for certain US government programs), volume and other incentive discounts. Generally speaking though, both Canada and the US are regarded as high-price countries.

More recently, the efficacy of federal regulations in curbing drug prices has been questioned; although introductory prices for new drugs may be effectively controlled, the prices of existing drugs may not be as effectively constrained. Furthermore, the Patented Medicines Prices Review Board's pricing guidelines may actually have led to retaliatory measures in foreign countries (i.e., drug companies may strategically increase foreign prices so that prices can be increased in Canada as well).[8]

The mandate of the Patented Medicines Prices Review Board should be viewed in the context of a long history of regulations governing the Canadian pharmaceutical industry. The first of these regulations dates back to 1922 when the Commissioner of Patents allowed any Canadian manufacturer to imitate and produce a drug of another manufacturer, even if there was an existing patent. It was only in 1969, however, when Section 41(4) of the Canadian Patent Act was amended to allow import or manufacture, or both, of patented products under a scheme of compulsory licensing (4% of sales), that there was large-scale entry of generic drugs into Canada. So rapid was the growth of the generic industry that by 1970 (1 year later) there were already 52 generics, with such significant drugs as ampicillin and diazepam available generically.

The manufacturers of patented drugs strongly opposed the compulsory licensing provisions of the Canadian Patent Act, and the government relented in 1987 by introducing Bill C-22. Under Bill C-22, in exchange for an increase from 5% to 10% of sales for Canadian research and development, patent-holding firms were guaranteed a 10-year exclusivity period before a generic firm could be issued a compulsory license. Bill C-22 also led to the creation of the Patented Medicines Prices Review Board to regulate drug prices and ensure compliance with the 10% research and development spending rules. In 1993 further amendments were introduced through Bill C-91, and compulsory licensing was completely abolished. The period of exclusivity un-

der the new Canadian drug patent law was also extended to 20 years before generic competition was allowed.

Provincial role: substitution laws and cost-effectiveness

Provincial regulations of prescription drugs fall into 2 broad categories — those aimed at promoting substitution of cheaper drugs for expensive drugs, either by generic substitution or therapeutic substitution (reference-based pricing), and those focusing on cost-effectiveness or pharmacoeconomic evidence to determine if a new drug should be included in the provincial formulary.

Drug substitution regulations have been in place in most provinces for over 3 decades. With the exception of the Reference Drug Program in BC, these regulations have exclusively focused on promoting the substitution of generic drugs for brand-name drugs. Substitution toward the cheaper generics is typically achieved by implementing product- and price-selection rules. Product selection involves switching from a branded to a generic drug, whereas price selection involves choosing the least-costly generic available. Together, these rules direct the physician to prescribe generics and the pharmacist to dispense the cheapest generic available for all prescriptions. To facilitate this most provinces also instituted laws that exempted physicians and pharmacists from any legal liability associated with switching to generic prescriptions. I have shown elsewhere that, with the exception of formularies, most of the substitution rules led to greater use of generics and, therefore, cost containment.[4] However, because each provincial drug plan has a unique set of policies, the degree of cost containment achieved varies by province.

A reference drug program, which is essentially a program of therapeutic substitution, was implemented in BC in late 1995 for a select number of therapeutic classifications; for example, it was recommended that cimetidine (the reference drug for histamine-2 receptor antagonists) be substituted for ranitidine.[9] The evidence on the impact of reference drug pricing is yet to be published. However, recent publications have argued that such therapeutic substitution may lead to greater nondrug health care costs in the future.[9,10] Until the results of ongoing evaluations of BC data become available, this initiative will remain controversial.

The costs for drugs have been increasing steadily over the last decade. They are now one of the fastest growing components of total health care expenditures in Canada, and in 1993, for the first time, drug costs exceeded payments to physicians. Given these cost pressures most provinces now conduct a second review of each new drug before it is included in the provincial drug plan as a reimbursable benefit. In this second review the new drug is typically compared with other similar drugs (in contrast with the Federal Therapeutics Products Program, which typically compares new drugs with placebo) and, more importantly, the economic data and cost-effectiveness of the new drug are also considered. This approach, based on assessing new health technologies for their cost-effectiveness, has also recently been implemented in several countries worldwide, especially those with publicly funded health care systems.[11] Australia and Canada were among the first countries to require drug firms to submit cost-effectiveness data (also referred to as pharmacoeconomic data) for all new drugs.[12,13]

Canada initially entertained several alternatives for conducting pharmacoeconomic assessments; the appropriate infrastructure was established so that assessments could be routinely conducted and the results could be widely disseminated,[14] and in 1993 national guidelines for the conduct of pharmacoeconomic assessments were published.[15,16] At present, pharmacoeconomic analyses and compliance with published guidelines are not mandatory under federal regulations. However, pharmacoeconomic evaluations are used in several provinces to evaluate new drug products seeking reimbursement eligibility from provincial drug plans, and pharmacoeconomic assessments must accompany all new drug submissions seeking provincial formulary approval in BC and Ontario.

An expert committee (or committees) in each province, whose members typically have varying backgrounds in pharmacy, pharmacology, medicine, economics, statistics or epidemiology, is responsible for making the final recommendation regarding reimbursement eligibility. The exact size and composition of the expert committee and the procedures used may differ across provinces, but the intended goals are similar — each committee attempts to assess the therapeutic significance and affordability of each new drug.

A recent study evaluating the uniformity of coverage for prescription drugs among the Canadian provinces[17] found that the overall level of agreement for funding decisions made in all of the provinces was very low, and furthermore, pair-wise agreement between any 2 provinces was also low and below levels of significant concordance. Thus, the existing pattern of access to prescription drugs is quite variable across the country and may be related to the haphazard manner in which the provinces have adapted inconsistent policies to respond to rising drug costs. The study does not necessarily imply that patients are getting less than optimal therapy in one province relative to the other; it may simply signify that different provinces may have chosen to fund different brands of drugs within the same therapeutic category.

Conclusion

Most readers do not need to be convinced that the pharmaceutical marketplace in Canada is extremely regulated. What may not be apparent, however, is that there has been a change in the manner in which regulations at the federal and provincial levels mesh with each other. From the late 1960s until the introduction of Bill C-22, federal and provincial policies seemed to be working in the same direc-

tion; the federal policy of compulsory licensing made cheaper generics available earlier, and the provincial substitution laws directed physicians and pharmacists to switch prescribing toward generic brands. The end result was to lower expenditures on drugs. With the introduction of Bill C-22 and then Bill C-91, which led to the abolition of compulsory licensing, federal and provincial policies have moved in opposite directions. Federal regulations allow longer patent terms, higher prices and less generic competition. At the same time provincial policies, such as requiring a cost-effectiveness justification prior to formulary listing and reference pricing, seem to be attempting to contain higher and higher drug-acquisition costs.

It would appear that one of the unfortunate realities facing the Canadian pharmaceutical marketplace is that although Ottawa regulates drug prices and patent terms, it does not face any of consequences of its policies — the provinces and the general public must pay for drug costs and suffer the consequences of federal policies.

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