Are drugs too expensive in Canada?

YES

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Are drugs too expensive? The answer to that simple question depends on who is being asked. Those who pay for them, such as individuals, private insurance companies, and provincial drug plans, are likely to answer yes. Pharmaceutical companies would probably answer no. Without a frame of reference, it is impossible to decide who is correct. My objective is to examine the question from the perspective of the pharmaceutical industry and see whether its rationale for current prices stands up to critical analysis.

Canada's Research-Based Pharmaceutical Companies, the organization representing the brand-name industry, argues that prices in Canada need to be raised in order to recognize the requirements for producing new innovative medications, a theme that is echoed in a recent report from the United States Department of Commerce.[1] The main message in that report is that controls in countries like Canada keep prices artificially low and impede research and development, thereby limiting the supply of new medications.

Before dealing with these claims, it is important to agree that prices for individual drugs in Canada are substantially lower than prices in the United States—by almost 45% according to the latest report from the Patented Medicine Prices Review Board (PMPRB), the federal body charged with setting limits on the prices of patented medications. (Compared with prices in most other developed countries, Canadian prices are about at the median.) Since the early 1990s, prices for patented medications have remained virtually flat because of PMPRB regulations that restrict price rises to no more than the rate of inflation.[2] Where Canadian prices stand relative to those in other countries and how quickly they are going up are irrelevant to the question of whether the prices charged for drugs are justifiable.

Cost of producing drugs

Companies maintain that high prices are needed to generate the capital that goes into developing the next generation of medicines. According to the pharmaceutical industry, it now costs more than $802 million (US) to bring a new drug to market.[3] But this figure is subject to serious debate.[4] To begin with, it does not apply to all new drugs, just new chemical entities (NCEs), drug molecules that have never been marketed before. Only 36% (467/1284) of new drugs approved in the United States between 1990 and 2004 were NCEs; all the others

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Rather than being too expensive, we believe that brand-name prescription medicines and vaccines offer tremendous value for money to patients, physicians, and the entire health care system. That value can be seen and realized in physicians' practices on a daily basis. Evidence-based pharmaceutical therapy is one of the most cost-effective treatments available and can provide physicians with new and innovative tools to help patients live longer, healthier, and more productive lives.

Pharmaceutical therapy can also free up health care resources for use in other parts of the system. Every dollar invested in new medicines helps relieve the health care system of expenses *seven times greater* in other medical areas. Two thirds of these savings are in lower hospital costs, and the remaining third is in reduced costs for home care and physicians.[1]

Prescription patented medicines purchased from manufacturers account for about 7 cents of each health care dollar invested in Canada (not including hospital purchases).[2] Manufacturers' prices for patented medicines in Canada have declined or showed near-negligible increases over the past decade and were 9% below the international price median in 2004.[3]

Patient outcomes

Costs, however, should not be the only focus in the health care debate. Improved patient outcomes and quality of life are of paramount importance to physicians and their patients. Over the past 2 decades, we have seen many advances in medicine that provide physicians with the means to offer their patients hope. For example, physicians can tell their HIV and AIDS patients that death rates dropped by 76% in Canada between 1993 and 2003.[4]

Between 1980 and 2003, death rates in Canada also decreased dramatically for a number of diseases or conditions, such as heart attacks, chronic respiratory ailments, and chronic liver disease.[4] Advances in medicinal therapies over this period are believed to have contributed to the drop in death rates. In aggregate, expenditures on medicines show a strong statistical relationship with improvements in health outcomes, such as infant mortality and life expectancy.[5]

Rates of hospitalization for many diseases treated with pharmaceuticals have dropped appreciably. For patients with ulcers, the rate fell by 68%; for patients with diabetes, it dropped by 43% between 1983 and

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were new formulations of, or combinations of, existing drugs.[5]

The author of the study that reported the $802 million figure invited 24 companies out of 33 members of the Pharmaceutical Research and Manufacturers of America to submit data on drug-development costs. Only 12 accepted, and data from 2 of these were unusable. The data the companies supplied could not be independently audited, so there was no way of knowing exactly what was counted as a research cost.

Only drugs developed in-house were included; products based partly on work done by the National Institutes of Health, charities, or other institutions were not considered. This restriction would have excluded as much as 33% of the drugs made by the sample firms.[6] Finally, DiMasi et al did not deduct the tax credits companies received for doing research from the overall total, arguing strenuously that an after-tax figure is "inadequate for our purposes and potentially misleading."[3] Elsewhere, however, this is precisely what DiMasi and others did, ie, use an after-tax figure for research and development costs. If this figure is used, the pretax estimate is reduced by 30%.[7]

Even if every new drug actually does cost $802 million, there is still the question of whether we are getting value for money spent. The PMPRB classifies new active substances, equivalent to NCEs, into 1 of 2 categories: moderate, little, or no therapeutic advance; or major therapeutic gains or breakthroughs. Between 1999 and 2004, 122 new active substances were introduced into Canada. Only 10% were put into the second category as major therapeutic advances or breakthrough products. The rest were considered to offer moderate, little, or no therapeutic gain compared with existing drugs.[2]

The drug companies dispute the validity of the PMPRB numbers, claiming that they are generated for pricing purposes. These numbers, however, are remarkably similar to results published in the independent French drug bulletin *Prescrire International*. Since 1981, *Prescrire* has been evaluating new drugs and new indications for older drugs. By 2003, it had done almost 2900 such assessments and found that only 11% of medications were rated as substantial advances.[8]

Promotion costs

We also need to remember that rolled into the price of medicines is the cost of promotion. While there are no current figures for promotion costs as a percentage of sales in Canada, in the United States the figure is about 15%. With Canadian sales by brand-name companies at $13.9 billion in 2004,[2] that works out to $2.1 billion or about $30 000 in promotion costs per physician. The drug companies claim that promotion provides doctors with information about the existence of

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2002.[4] While medications are instrumental to this change, further research in disease management is needed to develop approaches to close the gap between optimal and usual care and to address key factors, such as diagnosis, prescription, and patient compliance.

Research and development costs

To provide patients and their physicians with the means to improve quality of life, research and development must keep pace with new technologies and new insights and discoveries in genetics, genomics, biochemistry, and physiology, among others. Pursuing research and development (R&D) programs in new areas of science requires adequate funding. Indeed, over the past 25 years, expenditures on R&D have increased dramatically with no guarantees of success.

From the 1970s to 2000, average inflation-adjusted R&D costs to discover and develop an approved new drug increased by 480% to more than $1 billion.[6] This estimate does not include postapproval R&D costs. A body of scientific knowledge rapidly increasing in complexity and growing requirements for evidence of safety and efficacy are likely to be important factors affecting the cost of drug development.

Consider for a moment that only 1 in thousands of compounds assessed in the laboratory will make it to the pharmacy shelf as a new medicine after about 12 years of sustained effort.[7] Only 1 in 10 investigational drugs that enter clinical development will receive regulatory approval.[8] And only 3 of 10 new prescription medicines that enter the market will recoup their R&D investment costs.[9]

New medications of similar classes must undergo the same development and regulatory process whether they lead to markedly improved therapies or provide incremental benefits. Although there is concern that new entrants in a therapeutic class influence drug costs, they can improve outcomes for specific diseases using one medication over another. For one third of new compounds, "best in class" does not correspond to first in class.[10] In addition, incremental drugs provide physicians with the means to better target therapy based on patients' medical histories and genetics and to develop evidence-based guidelines.

Whether a medication is first in its class, a markedly improved therapy, or an incremental innovation, it serves to advance patient care. It is essential that patients and their physicians have choices.

The pharmaceutical community is collaborating with regulatory authorities and researchers in various jurisdictions to advance drug-development science to ensure better predictability of efficacy and safety, as well as better risk assessment at product launch.[11,12] Such initiatives have the potential to lower R&D costs

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new medications and their therapeutic value. A more objective assessment shows that there is a strong and consistent negative association between reliance on promotional material and the quality of doctors' prescribing practices.[9]

Finally, there is no evidence to show that Canadian prices are causing economic hardship for the multinational subsidiaries operating here. In the mid-1990s, the industry had a 16% rate of return on capital compared with about 14% for makers of computer equipment, 10% for makers of other types of electronic equipment, and 9% for telecommunications carriers.[10]

Conclusion

Drug prices reflect research and development costs, but the exact nature of these costs is subject to considerable dispute and could be considerably lower than the figure claimed by the pharmaceutical industry. The vast majority of new drugs add little to our therapeutic armamentarium, and a major component of their price—the $2 billion spent on promotion—leads to poorer prescribing. The prices that Canadians are paying for their drugs are not justified by these costs.

KEY POINTS

- The claim that it costs more than $800 million (US) to bring a new drug to market is highly debatable.
- Most new drugs do not represent any substantial therapeutic advance over existing products.
- The prices companies charge include the $2.1 billion they spend promoting their medications.

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as well as to provide patients with more effective and safer medicines.

Medications can be effective in improving health and lowering overall costs, and it is in the interest of physicians and patients to have access to new medicines as soon as they become available. Canadians agree: the eighth annual Health Care in Canada survey of public and health care professionals (including physicians) conducted recently found that 92% of Canadians think government drug plans should cover any medications that patients and their doctors agree is the most effective treatment. The same survey also found that more than 75% believe the prices for drugs must be competitive with prices in the rest of the world to attract R&D to Canada.

That is good for patients and good for physicians. I believe that Canada must enact policies that encourage innovation, provide effective data protection, and improve access to new medicines and vaccines for physicians and patients.

The pharmaceutical industry in Canada makes the overwhelming majority of expenditures in health R&D in the business sector, the largest single source of funding for medical research in the country.[13] The R&D community itself employs 22 000 Canadians throughout the country. When employment in other sectors is factored in, the pharmaceutical industry generates close to 100 000 jobs in Canada.

The pharmaceutical industry also invests more than $1.5 billion annually in basic preclinical and clinical research and capital in Canada. This research is designed to discover new medicines and vaccines that physicians can use to ensure their patients live longer and healthier lives.

KEY POINTS

- New medicines are effective treatment. Family physicians know the therapeutic value of new medicines in helping patients live longer and healthier lives. Medicines are important contributors to reducing mortality and hospitalization due to heart attacks and many other life-threatening diseases.
- New medicines are cost-effective. Prescription patented medicines account for less than 7 cents of each health care dollar invested in Canada and reduce costs in other parts of the health care system.
- The pharmaceutical community is a partner of the health care system. It works in partnership with physicians and other health care professionals to deliver effective and innovative treatments to patients.

YES

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Conclusion

The pharmaceutical community will continue to partner with Canada's health care professionals, governments, stakeholders, and academic institutions to maximize the benefits of life sciences innovation and improve health outcomes for patients. Together we can tackle a key threat to society and our health care system: the burden and hidden cost of disease.

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