Studies in
Pharmaceutical Policy

35 YEARS 1974-2009 FRASER INSTITUTE

August 2009

Access Delayed, Access Denied: Waiting for New Medicines in Canada

2009 Report

by Brett J. Skinner and Mark Rovere

Studies in
Pharmaceutical Policy

August 2009

Access Delayed, Access Denied: Waiting for New Medicines in Canada

2009 Report

by Brett J. Skinner and Mark Rovere

Contents

Executive summary

This is the Fraser Institute's third annual report on the amount of time patients must wait to access new medicines in Canada. [1] The 2009 edition of this study uses the most recent data available, covering the years 2004, 2005, 2006, and 2007. This edition replicates and adapts the method previously used by Skinner et al. (2007) and Skinner and Rovere (2008) to estimate the total amount of time patients must wait to access new patented prescription medicines in Canada. Previous editions included all types of new drug applications. This edition focuses more narrowly on the wait to access new drugs classified by Health Canada as new drug submissions (NDS) and excludes supplemental new drug submissions (SNDS).

The purpose of this report is (1) to draw attention to the impact that Canadian public policies and institutions have on lengthening the time it takes for patients to access newly invented, patented prescription drugs; and (2) to offer alternative policy options that could improve access to new drugs in Canada.

Access delayed

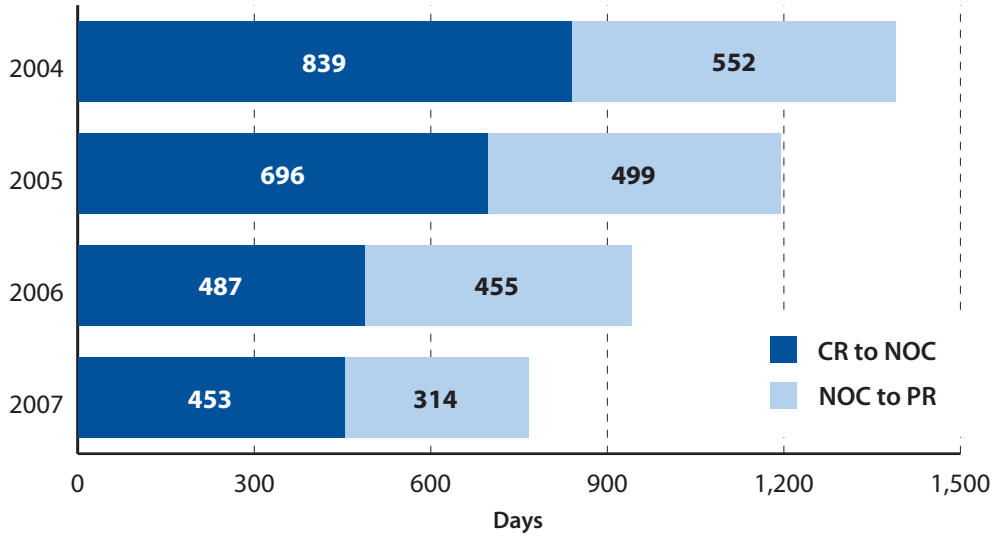
After a new drug is developed and ready for use by patients, various government policies are responsible for extending the time that patients must wait to access it. An estimate of the total additional time that Canadians must wait for access to new medicines because of government policies and institutional performance can be calculated by adding:

- The national delay—the time spent waiting for Health Canada to certify the safety and effectiveness of new drugs and approve them for use in Canada; and,
- The provincial delay—the time spent waiting for provincial drug insurance programs to approve the public reimbursement of new drugs.

Figure 1 shows the consolidated average wait time for access to new medicines in Canada, broken down by each of the two segments described above. This wait time is measured in days and is presented as a weighted average for

1 The first annual report that used this methodology was Skinner et al. (2007). However, John R. Graham (2005a) published an earlier Fraser Institute study on wait times for access to new medicines in Canada, using a slightly different method of analysis.

Figure 1: Weighted average total delay (days) for access to publicly insured new medicines in Canada, by wait segment, averaged across all provinces, 2004–2007



Abbreviations:

CR: the date the drug manufacturer's application for marketing approval is recorded or filed in Health Canada's Central Registry.

NOC: the date Health Canada issues an official Notice of Compliance, certifying that the new drug is safe and effective and is legally approved for sale in Canada.

PR: the date on which the first public reimbursement of the new drug is recorded in the formularies of each provincial drug program.

Sources: Health Canada, 2008a, 2008b; Brogan Inc., 2008; calculations by authors.

pharmaceutical and biological drugs [2], including all new drugs classified by Health Canada as new drug submissions (NDS) and excluding supplemental new drug submissions (SNDS). [3]

2 "Pharmaceutical" drugs are chemical-based products; "biological" drugs are biochemical-based products. According to the US Food and Drug Administration (2009), "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies."

3 There are three classes of new drug approval submissions: new active substance (NAS), new drug submission (NDS), and supplemental new drug submission (SNDS) (see Appendix).

National delay

Reading left to right in figure 1: the first segment of the bar represents the average time taken by Health Canada to certify that new drugs are safe and effective. In 2007, the average length of time taken by Health Canada to approve the use of new medicines was 453 days. Health Canada's new drug approval delays were shorter in 2007 than in the previous three years. In 2004, Health Canada took an average of 839 days to approve new medicines, compared to 696 days in 2005 and 487 days in 2006. These data suggest that Health Canada's approval times have steadily improved relative to the agency's performance in the previous three years. However, comparative data discussed later in this paper indicates that Health Canada's performance still lags behind that of its counterparts in Europe and the United States.

Provincial delay

The second segment of the bar represents the average wait time for insured access to new medicines for patients who are covered under provincial publicly funded drug programs. The delay between Health Canada's certification of and provincial reimbursement for new drugs was 314 days in 2007 (averaged across all provinces). Average wait times for provincial reimbursement have decreased since 2004. In 2004, patients relying on public drug programs waited approximately 552 days on average before new drugs were given approval for public reimbursement. In 2005, the average wait for reimbursement approval decreased to 499 days. The average wait for provincial reimbursement fell to 455 days in 2006. On average, the wait for provincial reimbursement approval of new medicines has improved over time.

Total delay

Adding together the wait times from the first and second segments discussed above, the total average wait for patients dependent on public drug programs for insured access to new medicines was 767 days (2.1 years) in 2007. The total average wait has decreased from an average of 1391 days (approximately 3.8 years) in 2004.

The reduction in approval delays in recent years is a positive development. Yet it could be argued that national and provincial governments are still creating lengthy and unnecessary waits for access to new medicines. One underappreciated consequence of this delay is that in the meantime, patients are not experiencing the potential health benefits that may result from earlier access to innovative new drug treatments.

Access denied

Despite improvements in the speed of decision making regarding national and provincial drug approvals, most of the drugs that are approved by Health Canada as safe and effective are not declared eligible for reimbursement under provincial drug plans.

Averaged across all provincial public drug programs, only 10.1% of all drugs that Health Canada approved as safe and effective in 2007 had actually been approved for reimbursement (fully or partially) by the provinces, as of December 31, 2008. On average, as of December 31, 2008, full or partial provincial reimbursement was approved for 25.6% of new drugs certified by Health Canada in 2006, 15.2% of new drugs certified in 2005, and 20.4% of new drugs certified in 2004.

Introduction

This annual report provides patients with some of the information they need to determine whether the time they wait for access to new medicines in Canada is unnecessarily long, and whether publicly funded and managed drug insurance programs provide adequate benefits and choice for patients. We hope that this report will encourage policy makers to consider policy alternatives that empower consumers with greater choice. One way to achieve this would be through the establishment of a properly regulated and competitive private sector insurance market in which access to insurance would be facilitated through subsidies for low-income people. Such a policy alternative could produce better outcomes for patients and taxpayers than current public drug insurance programs while achieving the same social goals.

This report focuses on new patented medicines because this class of drugs is uniquely affected by public policies that delay access for patients. Because government approval of generic drugs is based on the assumption that generics are copies of new drugs that have previously been approved, there is no substantive delay (observed or expected) before the public has access to generic products; consequently, this class of drugs is not studied in this report.

Global factors affecting access to new medicines

It takes a long time to develop a new drug. The development period for new drugs is measured from the patented discovery of a new drug molecule to the first time an application is submitted for marketing approval anywhere in the world. Governments around the world regulate drugs to ensure the safety of the product. For example, Health Canada has a national mandate to ensure the safety of all drugs sold in Canada and thus it regulates which products are allowed to be sold and under what conditions. Health Canada approves new pharmaceutical medicines through the Therapeutic Products Directorate (TPD) and approves new biological medicines through the Biologics and Genetic Therapies Directorate (BGTD). Canadian regulations fall under the 1985 Food and Drugs Act.

In order to obtain marketing approval for a drug, manufacturers must provide Health Canada with evidence of its successful clinical testing. The longest period within the drug development phase involves clinical testing of a new medicine on volunteer patients. Clinical testing of new drugs involves thousands of patients who are often located across international jurisdictions and monitored over many years. No drug is submitted for marketing approval anywhere in the developed world without having first completed successful clinical tests.

The cost of and time spent in the development of new drugs is affected by universal scientific standards of experimental research. These standards determine, for example, how many patients must be enrolled in the testing of a new drug in order for researchers to have confidence in the statistical results and conclusions. There are also scientific standards for the design and conduct of clinical drug testing in patient populations, as well as ethical standards with respect to the treatment and use of human and animal subjects. These standards have international acceptance and affect the absolute minimum period of time it takes to complete clinical testing of the safety and effectiveness of any new medicine. International scientific standards for clinical trials are established by the World Medical Association Declaration of Helsinki (World Medical Association, 1964). These are generally interpreted as the minimum global standard. In practice, actual standards for demonstrating the safety of drug products are set by national governments through domestic regulation. These standards determine the number, length, and rigor of the required clinical trials. For instance, Health Canada's regulations require minimum compliance with international standards for clinical research on

new medicines, but do not exclude stricter regulations as deemed necessary by the government of Canada (Health Canada, 2006a). Nevertheless, because of the importance of the American and European markets throughout the world, the actual minimum time spent during drug development is determined by the clinical testing time necessary to satisfy the requirements of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA).

The most recent research indicates that, on a global basis, the process of developing a new drug takes, on average, approximately 10 years (DiMasi, 2001; DiMasi et al., 1995, 2003; Adams and Brantner, 2006). The length of this process is measured from the time a drug discovery is patented to the time an application for FDA marketing approval is made (table 1). Moreover, this lengthy development process comes with a steep price. The cost of developing a new patented prescription drug ranges from $521 million to $2,119 million, depending on the company and the drug. The average cost is $868 million (above figures adjusted to 2000 US dollars) (DiMasi, 2001; DiMasi et al., 1995, 2003; Adams and Brantner, 2003, 2006).

For the purposes of this report, the global development time for new medicines is assumed to be a function of factors outside of Canada's control; therefore, the time associated with this segment is presented for completeness but is not the focus of the main policy discussion in this paper, nor is it part of the overall wait time for access to new medicines measured here. This paper is primarily concerned with government policies that contribute to an unnecessary delay in access to new medicines after the lengthy period of time it takes to develop them in the first place.

Table 1: Estimated time (in months) from issuance of a new drug patent to application for US FDA regulatory/marketing approval, drugs approved between 1985 and 2000

Patented discovery to start of human clinical trials	52.0 months
Start of human clinical trials to new drug application for US FDA marketing approval	72.1 months
Total	**124.1 months (10.3 years)**

Sources: DiMasi et al., 1995, 2003.

Delays caused by the federal government

After the development phase is over, the first segment of the wait for new medicines that is affected by public policies and institutional performance in Canada is the wait for the federal government to approve the safety and effectiveness of new drugs. Before any new drug is legally allowed to be sold in Canada, it must first receive official approval from Health Canada. Health Canada reviews published clinical research conducted on new drugs before it certifies that a drug is safe for sale in Canada and that the drug's effectiveness has been scientifically demonstrated. [4] Because marketing approval for new drugs occurs at the national level, any delay caused by Health Canada's drug review process affects the wait time for access to new medicines for all Canadians.

In Canada, the time patients spend waiting for the federal government's approval of a new drug is measured from the date the drug manufacturer's application for approval is recorded or filed in the Central Registry (CR) of Health Canada's Therapeutic Products Directorate (TPD) or Biologics and Genetics Therapies Directorate (BGTD) following the completion of clinical testing. This approval period ends when Health Canada issues an official Notice of Compliance (NOC), certifying that the new drug is safe and effective.

Drug approval systems in Europe and the United States measure the same period but use different terminology for describing the start and end dates. As of 1999, responsibility for approving both pharmaceutical and biological medicines was centralized for all European Union countries in the European Medicines Agency (EMEA). Since 2004, the equivalent authority to approve pharmaceutical and biological medicines in the United States has fallen under the Department of Health and Human Services (HHS) with the Center for Drug Evaluation and Research (CDER), a part of the Food and Drugs Administration (FDA). Prior to 2004, the Center for Biologics Evaluation and Research (CBER) was the approving authority for biological medicines.

4 For general information about Canada's review process, please see Health Canada (2001).

Drug approval times in Canada, 2004–2007

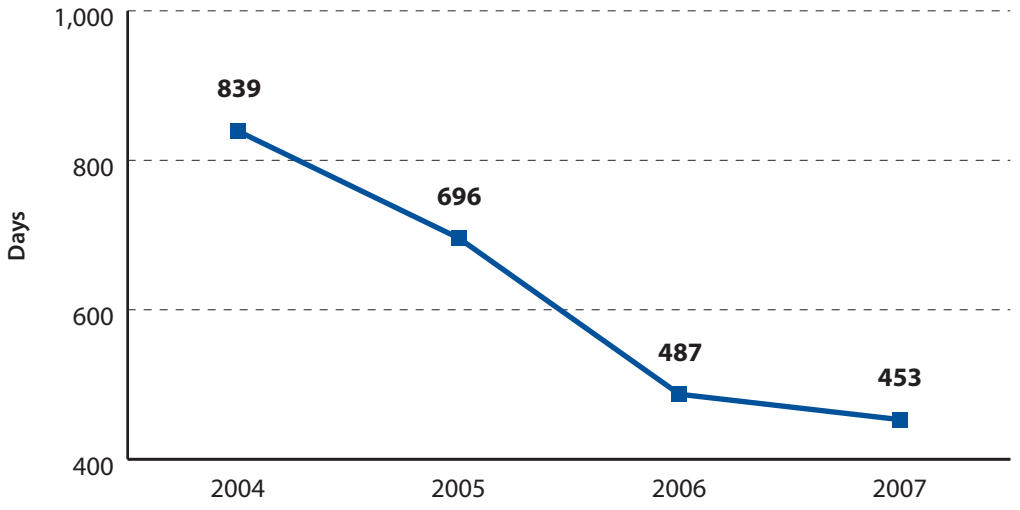
In 2004, Health Canada took 839 days (on average) to issue a notice of compliance (NOC) (figure 2). In comparison, Health Canada took 696 days to grant market authorization for new medicines in 2005, 487 days in 2006, and 453 days in 2007. This data suggests that Health Canada's approval times have improved significantly over the study period (2004 to 2007).

Drug approval times in Canada and the European Union, 2006–2007

The Canadian data presented here are different from the Canadian data shown in the previous section because the data in the previous section are weighted by biologic and pharmaceutical drug type. Unfortunately, the EMEA data available for this study were not detailed enough to permit the calculation of an average that is weighted by drug type. To make the Canadian and European data comparable, the data for Health Canada and the EMEA are shown as non-weighted, consolidated averages across biologic and pharmaceutical drug types.

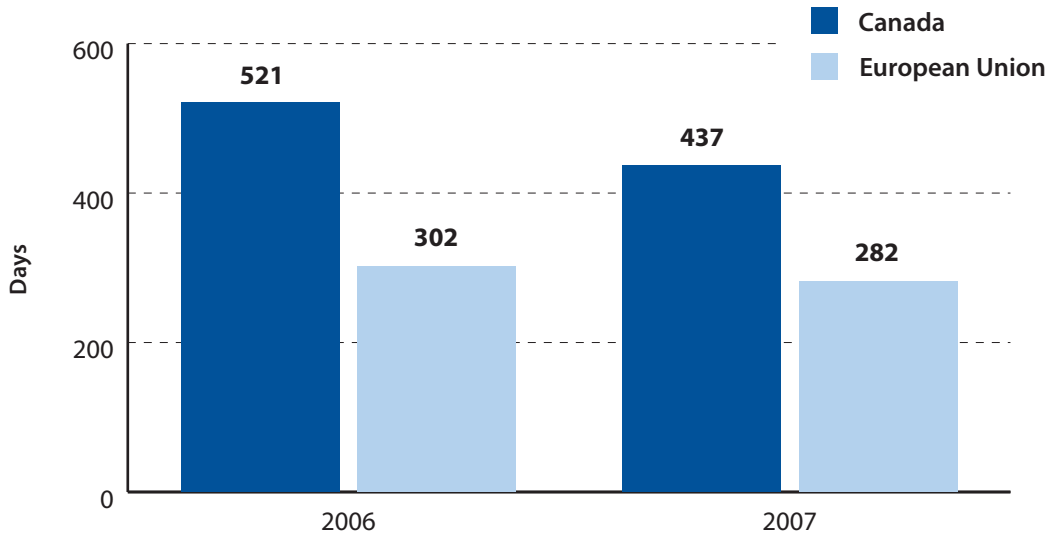
Figure 3 displays the average number of days spent waiting for the approval of new medicines in the European Union and Canada in 2006 and 2007, the only years for which comparable data are available (due to changes

Figure 2: Weighted average delay (days) for Health Canada to grant new drugs (NDS) regulatory/marketing approval, 2004–2007



Source: Health Canada, 2008a; calculations by authors.

Figure 3: Non-weighted consolidated average delay (days) for regulatory/marketing approval of new drugs, Canada and the European Union, 2006–2007



Sources: Health Canada, 2008a; EMEA, 2008; calculations by authors.

in data reporting by the European Medicines Agency). The data indicate that in both 2006 and 2007, Health Canada took longer (on average) than the European Medicines Agency (EMEA), its European equivalent, to grant market approval for new drugs. In 2006, Health Canada took 521 days (on average) to approve new medicines, while the EMEA took 302 days. Likewise, Health Canada took 437 days (on average) to grant market authorization for new medicines in 2007, while the EMEA took 282 days.

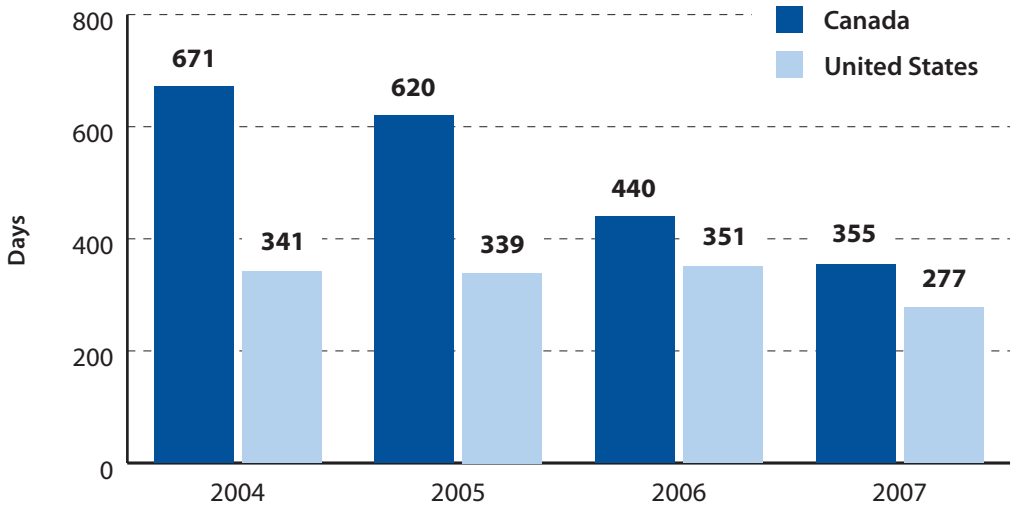
Drug approval times in Canada and the United States, 2004–2007

The Canadian data presented here are different from the previous sections because they are based on a different method of aggregating the statistics. In the previous sections, the statistics were aggregated on the basis of averages. However, the United States (FDA) only publishes median figures for drug approval times. Fortunately, Health Canada publishes both average and median figures, making comparisons to the US data possible. The data for both Canada and the United States are detailed enough to permit a calculation of a weighted average of the medians according to drug submission

category (priority or non-priority). However, the US data does not allow weighting by drug type (biologic or pharmaceutical).

Figure 4 displays the differences between median approval times (weighted average medians) in Canada and the United States for new drug applications between 2004 and 2007. The data indicate that, in all four years studied, Health Canada took longer (on average) than the FDA to grant marketing approval for new drugs. In 2004, Health Canada took approximately 671 days to approve new drugs, while the FDA took 341 days. In 2005, Health Canada's median approval time to grant market authorization for new drugs was 620 days, while the FDA's median approval time was 339 days. In 2006, Health Canada took 440 days to approve new drugs, while the FDA took 351 days. In 2007, Health Canada's median approval time to grant market authorization for new drugs was 355 days, while the FDA's median approval time was 277 days.

Figure 4: Weighted average median delay (days) for regulatory/marketing approval of new drugs, Canada and the United States, 2004–2007



Sources: Health Canada, 2008a; FDA, 2008; calculations by authors.

Delays caused by provincial governments

The second segment of the wait for new medicines that is affected by government policies and institutional performance is the time spent by the federal, [5] provincial, and territorial (FPT) governments to decide whether to reimburse a new drug under their respective publicly funded drug insurance programs. Each jurisdiction determines reimbursement eligibility through its own government agency; consequently, the wait time for access to new medicines differs by jurisdiction. This wait is measured from the date on which Health Canada issues a NOC for a new drug to the date on which the first public reimbursement (PR) of the same drug is recorded in the formularies of each federal, provincial, and territorial drug program.

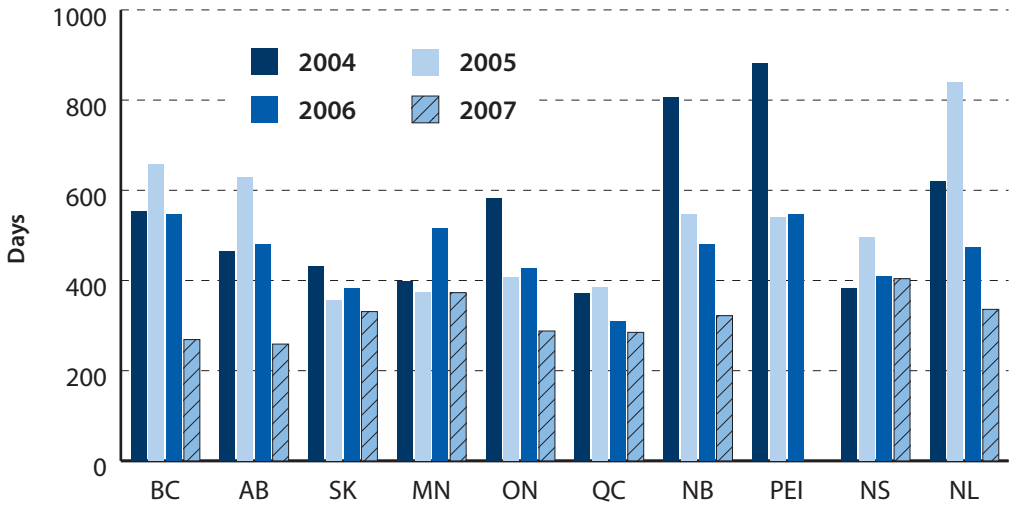
Provincial reimbursement delays, 2004–2007

FPT authorities have three options when determining reimbursement eligibility under public drug plans. First, they can declare a drug ineligible for public reimbursement. Second, they can declare a drug eligible for full reimbursement without conditions. Third, FPT authorities can declare a new medicine eligible for reimbursement with restrictions. The analysis presented here considers any type of approval (full or restricted) to be an approval for the purpose of measuring and comparing performance between jurisdictions. The analysis does not present data on reimbursement delays for federal or territorial government drug programs. This analysis is focused only on the performance of provincial drug plans.

Figure 5 shows the time spent by the provinces to grant reimbursement eligibility for new drugs. The average time taken by the provinces to grant reimbursement eligibility for new drugs that were approved by Health Canada in 2004 was 552 days; the average for new drugs that received market approval in 2005 was 499 days; the average for new drugs approved in 2006 was 455 days; and the average for new medicines approved in 2007 was 314 days.

5 The government of Canada, through various programs, provides prescription drug coverage for about one million Canadians who are members of eligible groups. These groups include First Nations and Inuit, members of the military, veterans, members of the RCMP, and inmates in federal penitentiaries.

Figure 5: Weighted average time (days) between Health Canada regulatory/marketing approval and provincial public reimbursement approval for new medicines, by province, 2004–2007



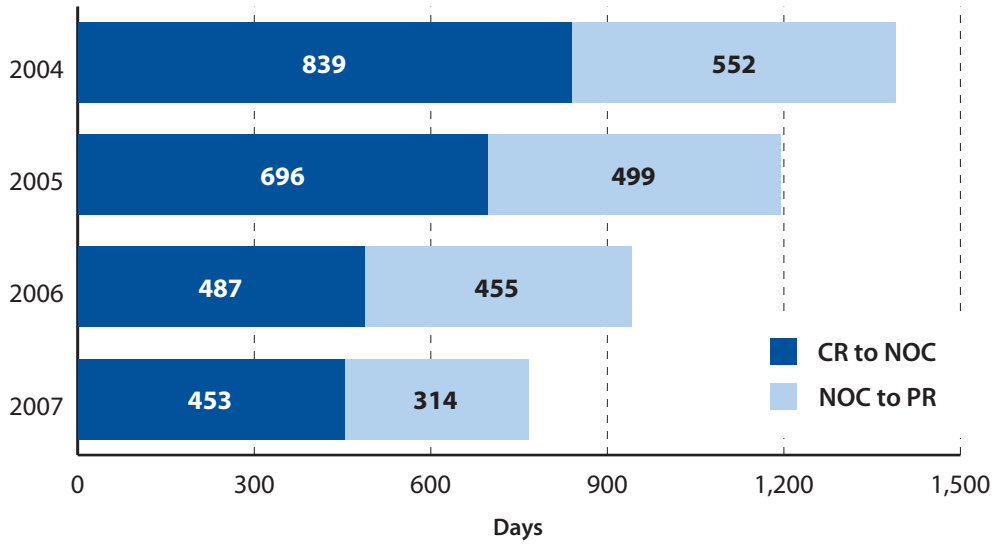
Note: The missing bar for PEI indicates that none of the new drugs that were approved by Health Canada in 2007 had been declared eligible for reimbursement in that province as of December 31, 2008.

Sources: Health Canada, 2008b; Brogan Inc., 2008; calculations by authors.

Total delay for access to new medicines

An estimate of the total time spent waiting for access to new medicines after they have been developed can be calculated by adding the time taken by Health Canada to issue a safety approval (CR to NOC) and the provincial reimbursement delay (NOC to PR). Figure 6 shows the consolidated average wait for access to new medicines, measured in days, for the years 2004, 2005, 2006, and 2007. Reading left to right: the first segment of the bar represents the time needed for Health Canada to certify that new drugs are safe and effective before allowing patients to use them. This segment of the wait for

Figure 6: Weighted average total delay (days) for access to publicly insured new medicines in Canada, by wait segment, averaged across all provinces, 2004–2007



Abbreviations:

CR: the date the drug manufacturer's application for marketing approval is recorded or filed in Health Canada's Central Registry.

NOC: the date Health Canada issues an official Notice of Compliance, certifying that the new drug is safe and effective and is legally approved for sale in Canada.

PR: the date on which the first public reimbursement of the new drug is recorded in the formularies of each provincial drug program.

Sources: Health Canada, 2008a, 2008b; Brogan Inc., 2008; calculations by authors.

access to new medicines affects all patients in Canada equally, whether they pay for their drugs through private insurance, out-of-pocket expenditure, or public drug programs. Only improving the efficiency and capacity of Health Canada to conduct new drug reviews can reduce the time spent in approval. The length of time taken by Health Canada to grant marketing approval for new medicines has decreased over the last four years (figure 6).

The second segment of the bar represents the period of waiting for those who are dependent on public drug programs. As figure 6 shows, the time spent by the provinces to grant eligibility for the public reimbursement of new drugs decreased over the four-year period. The total average wait for publicly insured access to new medicines approved by Health Canada in 2007 was 767 days (2.1 years). This total average delay has decreased from 942 days (approximately 2.6 years) for drugs that received a NOC in 2006, 1195 days (approximately 3.3 years) for drugs that were granted market authorization in 2005, and 1391 days (3.8 years) for drugs approved for sale in 2004. Nevertheless, wait times for these drugs remain significant.

Denials by provincial governments

It is important to examine provincial reimbursements, not just in terms of delays, but also in terms of denials of access. Although most provinces have reduced the number of days that patients must wait to have new drugs publicly reimbursed, this does not necessarily mean that the overall percentage of drugs that eventually become eligible for reimbursement has remained the same. Provincial agencies could be taking less time to review and grant reimbursement approval for new drugs because fewer drugs are ultimately being accepted for reimbursement.

Reimbursement approval rates are estimated by calculating the number of full or partial reimbursement approvals recorded in each province (as of December 31, 2008) as a percentage of the total number of drugs already approved as safe and effective (i.e., drugs issued a NOC) by Health Canada in each year.

The analysis shows that most of the drugs that are approved by Health Canada as safe and effective are not declared eligible for reimbursement under provincial drug plans. Averaged across all provincial public drug programs, as of December 31, 2008, only 10.1% of all drugs approved by Health Canada as safe and effective in 2007 had actually been approved for reimbursement (fully or partially) by the provinces (table 2). On average, as of December 31, 2008, full or partial provincial reimbursement was approved for 20.4% of new drugs that were approved by Health Canada in 2004, 15.2% of new drugs approved in 2005, and 25.6% of new drugs approved in 2006.

Table 2: Public reimbursement approvals, as a percentage of NDS-class drugs approved by Health Canada, by province, 2004–2007, as of December 31, 2008

	2004		2005		2006		2007	
	Number of drugs approved	Drugs approved as a % of NOCs	Number of drugs approved	Drugs approved as a % of NOCs	Number of drugs approved	Drugs approved as a % of NOCs	Number of drugs approved	Drugs approved as a % of NOCs
AB	8	17.4%	2	4.8%	9	20.9%	1	2.3%
BC	7	15.2%	2	4.8%	5	11.6%	2	4.7%
MB	8	17.4%	4	9.5%	7	16.3%	3	7.0%
NB	10	21.7%	9	21.4%	16	37.2%	1	2.3%
NL	9	19.6%	9	21.4%	13	30.2%	3	7.0%
NS	8	17.4%	7	16.7%	14	32.6%	5	11.6%
ON	7	15.2%	4	9.5%	7	16.3%	3	7.0%
PEI	8	17.4%	7	16.7%	9	20.9%	0	N/A
QC	17	37.0%	13	31.0%	18	41.9%	19	44.2%
SK	12	26.1%	7	16.7%	12	27.9%	2	4.7%
Provincial average		**20.4 %**		**15.2%**		**25.6%**		**10.1%**
Total NDS NOCs	**46**		**42**		**43**		**43**	

Note: Provinces often take more than a year to decide whether or not to make a new drug eligible for public reimbursement. Therefore, more new drugs that were approved by Health Canada in 2006 and 2007 could eventually be granted eligibility for public reimbursement in the future. The delay will be captured in future reports and will be reflected in the percentages shown above.

Source: Brogan Inc., 2008; calculations by authors.

Conclusions

- In total, Canadians wait more than two years (on average) for access to publicly insured drugs.
- Health Canada's approval times have improved since 2004, relative to the agency's own performance.
- Health Canada's performance was worse than that of the European EMEA in both years studied (2006 and 2007).
- Health Canada's performance was worse than that of the American FDA in all four years studied (2004 to 2007).
- Previous research (Skinner and Rovere, 2008) indicates that when all application classes for new drug approvals are studied together, Health Canada's performance was better than that of the EMEA and the FDA in some years. The difference between the estimate provided in Skinner and Rovere (2008) and this current analysis suggests that Health Canada is more efficient at processing the least novel drug applications (e.g., SNDS classes) and less efficient at processing the more innovative types of new drug applications (e.g., NAS and NDS classes), relative to the EMEA and the FDA.
- Only a small percentage of the new drugs that Health Canada certifies as safe and effective are finally declared eligible for reimbursement under provincial public drug programs.
- The provincial governments take a significant amount of time to approve the few drugs that they declare eligible for public reimbursement.

Policy options: improving access to new drugs

Harmonization: cooperation with other jurisdictions

Health Canada essentially duplicates the new drug approval process of the FDA in the United States. Canada could speed up its regulatory process by taking advantage of the regulatory knowledge and capacity of other jurisdictions, rather than attempting to duplicate the American process. A consolidation of resources through the sharing of data, workload, and processes would be of great benefit to all participating countries. For example, if Canada entered into agreements of "mutual recognition" with other countries, new medications already approved in those countries could be introduced into the Canadian market far more rapidly and vice versa. In an effort to reduce the time taken to review new medications, Canada's recent Smart Regulation strategy proposed a form of mutual recognition to reduce persistent delays in the drug approval process (EACSR, 2004).

User fees

There are other measures that could be taken to improve Canada's regulatory productivity. For instance, Health Canada collects fees from drug companies that wish to have their products reviewed. If this user fees program were combined with strictly enforced and appropriate targets that Health Canada must meet before receiving the user fees, this might succeed in reducing delays even further, as has been the case in the United States. Research suggests that the existing system of user fees has failed to improve Health Canada's performance, relative to most comparable countries that also have user fees, because the fees are not linked to performance (Graham, 2005b). By contrast, in return for levying user fees, the FDA is required to meet a number of performance goals intended to speed up drug approvals. The establishment of user fees in the United States has resulted in the vast majority of review targets established under the Food and Drug Modernization Act of 1997 being met (Berndt et al., 2005). Research has shown that the establishment of user fees in the United States reduced drug approval times from a median of 22 months in 1992 to a median of less than 12 months in 1999, because the fees enabled the FDA to increase its review staff and achieve much faster review times (Philipson et al., 2005).

Replace government drug programs with subsidized access to private insurance

Policy makers should consider the merits of introducing means-tested, publicly subsidized access to private insurance as a better mechanism for achieving universal access to prescription drug coverage and containing costs, without restricting consumer choice through central planning. Research suggests that private-payment health systems (a combination of private insurance and out-of-pocket spending) are better structured to encourage the efficient demand for and supply of health technology (cf. Danzon, 1993; Newhouse and the Insurance Experiment Group, 1993). Most private plans have various kinds of co-payments. By creating a price at the point of consumption, co-payments encourage patients to make cost-efficient utilization and substitution choices regarding treatment alternatives. Consumer sensitivity to prices in turn creates incentives for health care providers to supply and utilize resources efficiently. This creates incentives for drug manufacturers to invest efficiently in the development of new drugs. It is also common for private sector insurers to employ deductibles that appropriately restrict insurance coverage to a range of expenses considered individually unaffordable for consumers. Private sector insurers sometimes impose annual coverage limits that might expose patients to significant cash costs in unusual cases involving very expensive drugs. Yet, in a competitive private sector insurance market where individuals buy insurance directly, patients who prefer higher insurance coverage limits can opt to pay higher premiums to cover the risk of such extraordinary expenses. Under a system with subsidies for low-income people, maximum coverage limits for subsidized populations would have to be determined through public decision-making processes.

Appendix: Classes, data sources, and comparability

Data sources and comparability issues

There are four main sources of data cited in this report. The first source is Health Canada, which is the only source of data on drug safety approval times in Canada that comprehensively includes all drugs. [6] Health Canada publishes data on pharmaceutical medicines through the Therapeutic Products Directorate (TPD) and on biologic medicines through the Biologics and Genetic Therapies Directorate (BGTD). Data published in annual reports on drug approvals by the TPD and the BGTD are stated in aggregates and are not broken down in detail. Health Canada publishes this data separately by drug submission class, priority (or "fast track") review status, and therapeutic category. Health Canada's published approval times include the entire period between the original filing of the new drug submission application (CR) and the issuance of the Notice of Compliance (NOC), inclusive of all company time spent to address any deficiencies in the manufacturer's application. It is unclear whether Health Canada records the filing of a new drug submission application on the actual date it was delivered to the TPD or the date on which a reviewer first saw the file (Health Canada, 2001, 2003, 2004a, b, 2005a, b, c, 2006a, b, c, 2007, 2008a).

The two sources of international comparative data on drug safety approval times cited are the United States Department of Health and Human Services, Food and Drug Administration (FDA, 1996, 2002, 2008) and the European Medicines Agency (EMEA, 2005, 2006, 2007, 2008). The FDA and the EMEA publish separate data for the time spent by companies to correct the deficiencies in their applications. Health Canada does not do so; instead, it publishes an entire approval delay that includes what they call "company" time. In order to make the data comparable among countries, "company" time was included in the total approval delay for the FDA and the EMEA.

6 Another public source of aggregated Canadian and international data on drug approval times is the industry association, Rx&D, which represents the makers of new drugs otherwise known as brand-name pharmaceutical companies. Rx&D conducts an annual survey of its member companies (representing most but not all of the industry) to collect data on their actual experience with government approval times for a defined basket of specific drug products (i.e., new drug submissions, supplemental drug submissions, and clinical trial applications) (Canada's Research-Based Pharmaceutical Companies, 2005).

Health Canada publishes both average and median figures for drug approval wait times. The FDA only publishes median figures. The EMEA only publishes average figures. As a result, Canadian and European data were compared using averages, while Canadian and American data were compared using medians.

Unlike Health Canada and the FDA, the EMEA does not publish approval wait time data that separates priority and non-priority new drug submissions.

In the US data, drug types (pharmaceutical and biological medicines) are aggregated, but the data is separated by submission status type (priority or non-priority review). The Canadian figures published by Health Canada are separated according to submission status type (priority or non-priority review); however, unlike the American data, the Canadian figures are reported separately by drug type. In order to make the two sets of data more comparable, it was necessary to aggregate the separately reported medians by calculating a weighted median proportional to the number of drugs approved in each subset as a percentage of the total number of drugs approved overall. The Health Canada data is weighted by drug type (biological and pharmaceutical drugs) and by submission status type (priority and non-priority). As drug types are already consolidated by the FDA, the US data is only weighted by submission status type.

The fourth main source of data cited in this paper is Brogan Inc. (Brogan Inc., 2008). Brogan Inc. is a private consulting and data firm that collects information that permits the measurement of public reimbursement delays and the rate of positive reimbursement approvals in each of the provinces. Brogan Inc.'s database contains the date on which Health Canada issued a NOC for each new drug and the first date on which public reimbursement of a drug was approved in each of the provinces, as well as a classification of whether reimbursement was full, restricted, or declined.

Canadian and international definitions of classes for new drug submissions

In Canada, new drugs fall under different classifications defined by Health Canada's Therapeutic Products Directorate (TPD) and the Biologics and Genetic Therapies Directorate (BGTD). In Canada, non-generic new drug approvals involve new active substances (NAS), new drug submissions (NDS), and supplemental new drug submissions (SNDS). Similar classifications are used by the European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA) but under different terminology. The Canadian and international classifications are briefly described in the following tables.

Table 3: Classes of new drug submissions used by Health Canada's Therapeutic Products Directorate (TPD) and the Biologics and Genetic Therapies Directorate (BGTD)

New Active Substance (NAS)

A New Active Substance is a therapeutic substance that has never before been approved for marketing in any form; a chemical or biological substance not previously approved for sale in Canada as a drug; an isomer, derivative, or salt of a chemical substance previously approved for sale as a drug in Canada but differing in properties with regard to safety and efficacy; and a biological substance previously approved for sale in Canada as a drug but differing in molecular structure, nature of the source material, or manufacturing process.

New Drug Submission (NDS)

New Drug Submission includes all NASs, as well as combinations of previously approved NASs, and any drug that has not been sold in Canada for sufficient time and in sufficient quantity to establish its safety and effectiveness under use or its recommended conditions for use.

Supplemental NDS (SNDS)

A Supplemental NDS (SNDS) must be filed by the manufacturer if certain changes are made to products that have already been authorized. Such changes might include the dosage form or strength of the drug product, the formulation, method of manufacture, labelling, or recommended route of administration. An SNDS must also be submitted if a manufacturer wants to expand the indications (claims or conditions of use) for the drug product.

Abbreviated NDS (ANDS)

An Abbreviated NDS (ANDS) must be filed by a manufacturer wishing approval of a substance that is not a new drug but a generic "copy" of a drug that has been previously approved for sale in Canada

Priority or Non-Priority review status

Priority review status is a "fast-track" status granted to eligible new drug submissions for human use, following review and approval of a request submitted by the manufacturer of the drug. Priority review status assigns eligible submissions a shortened review target of 180 days, in comparison to 300 days for submissions classed as non-priority. Health Canada believes it is in the best interest of Canadians to review potentially lifesaving drugs as early as possible. Priority review status may be granted to drug submissions intended for the treatment, prevention, or diagnosis of serious, life-threatening, or severely debilitating illnesses or conditions where (a) there is no existing drug on the Canadian market with the same profile, or (b) the new product has a benefit/risk profile that is a significant improvement over the profile of existing products.

Source: Health Canada, 2006a.

Table 4: Classifications of new drug applications (NDA) used by the FDA's Center for Drug Evaluation and Research (CDER)

New Molecular Entity (NME)

A New Molecular Entity is an active ingredient that has never before been marketed in the United States in any form.

New Drug Application (NDA)

When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDA's are assigned an NDA number.

Supplement

A supplement is an application to allow a company to make changes in a product that already has an approved new drug application (NDA). CDER must approve all important NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still met.

Abbreviated New Drug Application (ANDA) Number

This six-digit number is assigned by FDA staff to each application for approval to market a generic drug in the United States.

Biologic License Application (BLA)

Biological products are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm who manufactures a biologic for sale in interstate commerce to hold a license for the product. A biologics license application is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical affects of the biologic product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the firm to market the product.

Review Priority Classification

The Review Priority Classification is a determination that is made based on an estimate of the therapeutic preventive or diagnostic value of the drug submitted. The designations "Priority" (P) and "Standard" (S) are mutually exclusive. Both original NDAs and effectiveness supplements receive a review priority classification but manufacturing supplements do not.

Priority review (P)

Priority review is granted when a drug product, if approved, would be a significant improvement over marketed products in the treatment, diagnosis, or prevention of a disease. Improvement can be demonstrated by, for example, (1) evidence of increased effectiveness in treatment, prevention, or diagnosis of disease; (2) elimination or substantial reduction of a treatment-limiting drug reaction; (3) documented enhancement of patient compliance; or (4) evidence of safety and effectiveness in a new subpopulation.

Standard review (S)

All non-priority applications will be considered standard applications.

The Center for Biologics Evaluation and Research's definition of priority review

The Center for Biologics Evaluation and Research (CBER) definition of a priority review is stricter than the definition that CDER uses. The biological drug, if approved, must offer a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease.

Sources: FDA, 1996, 2009.

Table 5: Classifications of new drug market authorization applications by the European Medicines Agency (EMEA)

New Active Substance (NAS)

A new chemical, biological, or radiopharmaceutical active substance includes:

- a chemical, biological, or radiopharmaceutical substance not previously authorized as a medicinal product in the European Union;
- an isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously authorized as a medicinal product in the European Union but differing in properties with regard to safety and efficacy from that chemical substance previously authorized;
- a biological substance previously authorized as a medicinal product in the European Union, but differing in molecular structure, nature of the source material, or manufacturing process;
- a radiopharmaceutical substance, which is a radionuclide, or a ligand, not previously authorized as a medicinal product in the European Union, or the coupling mechanism to link the molecule and the radionuclide has not been authorized previously in the European Union.

Extensions

An extension of a new drug is defined according to the following:

- different salt/ester complex/derivative (with the same therapeutic moiety): Evidence that there is no change in the pharmacokinetics of the moiety, pharmacodynamics, and/or in toxicity which could change the safety/efficacy profile (otherwise, to be considered as a new active substance);
- different route/pharmaceutical form (for parenteral administration, it is necessary to distinguish between intraarterial, intravenous, intramuscular, subcutaneous, and other routes): (i) new route of administration; (ii) new pharmaceutical form (same route);
- different strength, same route/pharmaceutical form and posology: Bioavailability (cf. guideline);
- suprabioavailable products: (i) same dosage intervals but reduced doses intended to achieve same plasma/blood concentrations as a function of time; bioavailability studies may suffice (see paragraph 5 of Bioequivalence guideline);
- active substances associated in a different proportion/different posology or if one or more is intended for modified release.

Source: European Medicines Agency, 2005.

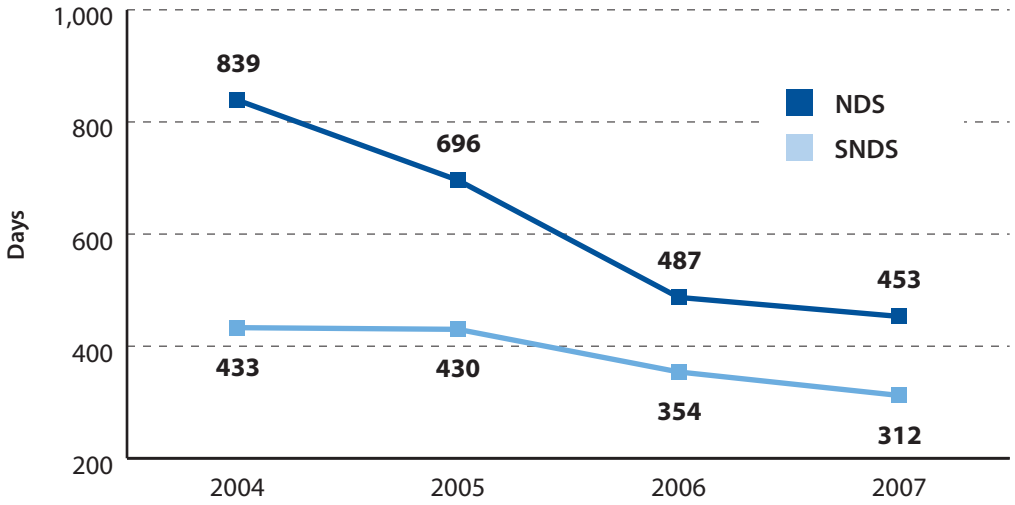
Drug approval times in Canada: comparing NDS and SNDS applications

In contrast to previous editions of this report, this analysis only includes new drugs that have never been granted market authorization in their respective jurisdictions (new drug submissions (NDS) in Canada and the equivalent in Europe and the United States).

As table 3 notes, a new drug submission (NDS) is "any drug that has not been sold in Canada for sufficient time and in sufficient quantity to establish its safety and effectiveness under use or its recommended conditions for use" (Health Canada, 2006: 27). A supplemental new drug submission (SNDS) is filed if minor changes are made to a drug product that has already been authorized for sale in Canada (Health Canada, 2006). Minor drug changes might include the "dosage form or strength of the drug product, the formulation, method of manufacture, labeling, or recommended route of administration" (Health Canada, 2006: 8). An SNDS is also filed if a drug manufacturer wants to modify the indications (claims or conditions of use) of a medicine (Health Canada, 2006).

In theory, a drug combination that has already been approved as safe and effective by Health Canada but has had minor changes to its indication or formulation (e.g., SNDS) should not take as long to approve as a new chemical compound that has never received market authorization (e.g., NDS). Indeed, between 2004 and 2007, Health Canada took much longer (on average) to issue a notice of compliance for NDS applications than for SNDS applications (figure 7). Furthermore, during that period, Health Canada issued significantly fewer Notices of Compliance for NDS applications than for SNDS applications (table 6).

Figure 7: Weighted average time (days) for Health Canada to grant regulatory/marketing approval for NDS and SNDS applications, 2004–2007



Source: Health Canada, 2008a; calculations by authors.

Table 6: Total number of Notices of Compliance (NOCs) issued by Health Canada for NDS and SNDS applications, 2004–2007

	NDS applications	SNDS applications
2004	52	158
2005	48	159
2006	55	224
2007	51	235

Source: Health Canada, 2008a; calculations by authors.

References

Adams, Christopher P., and Van V. Brantner (2003). *New Drug Development: Estimating Entry from Human Clinical Trials*. FTC Working Paper No. 262. Federal Trade Commission.

Adams, Christopher P., and Van V. Brantner (2006). Estimating the Cost of New Drug Development: Is It Really $802 Million? *Health Affairs* 25, 2: 420–28.

Berndt, Ernst R., Adrian H. B. Gottschalk, Tomas J. Philipson, and Matthew W. Strobeck (2005). Industry Funding of the FDA: Effects of PDUFA on Approval Times and Withdrawal Rates. *Nature Reviews* 4 (July): 545–54.

Brogan Inc. (2008). Special data request.

Canada's Research-Based Pharmaceutical Companies (2005). *Rx&D 2005 NOC Survey: Results and Key Messages*. Canada's Research-Based Pharmaceutical Companies. <http://canadapharma.org/Pubs/NOC_Survey/2005-NOC-Survey-Binder.pdf>.

Clever, Linda Hawes, et al. (1997). Additional Statements from the International Committee of Medical Journal Editors. *Canadian Medical Association Journal* 156, 4: 571–74.

Danzon, P.M. (1993). Health Care. *Concise Encyclopedia of Economics: The Library of Economics and Liberty*. <http://www.econlib.org/library/enc/HealthCareIndustry.html>.

Davidoff, Frank, et al. (2001). Sponsorship, Authorship and Accountability. *Canadian Medical Association Journal* 165, 6: 786–87.

DiMasi, J.A. (2001). Risks in New Drug Development: Approval Success Rates for Investigational Drugs. *Clinical Pharmacology and Therapeutics* 69, 5 (May): 297–307.

DiMasi, J.A., R.W. Hansen, and H.G. Grabowski (2003). The Price of Innovation: New Estimates of Drug Development Costs. *Journal of Health Economics* 22, 2: 151–85.

DiMasi, J.A., R.W. Hansen, H.G. Grabowski, and L. Lasagna (1995). Research and Development Costs for New Drugs by Therapeutic Category: A Study of the US Pharmaceutical Industry. *PharmacoEconomics* 7, 2: 152–69.

European Medicines Agency [EMEA] (2005). *The Rules Governing Medicinal Products in the European Community: Volume 2a, Procedures for Marketing Authorization*, Chapter 1 Marketing Authorisation (November). European Commission Enterprise Directorate-General, Consumer Goods, Pharmaceuticals.

European Medicines Agency [EMEA] (2006). *Annual Report of the European Medicines Agency 2005*. <http://www.emea.europa.eu/pdfs/general/direct/emeaar/AnnualReport2005.pdf>.

European Medicines Agency [EMEA] (2007). *Annual Report of the European Medicines Agency 2006*. EMEA. <http://www.emea.europa.eu/pdfs/general/direct/emeaar/EMEA_Annual_Report_2006_full.pdf>.

European Medicines Agency [EMEA] (2008). *Annual Report of the European Medicines Agency 2007*. EMEA. <http://www.emea.europa.eu/pdfs/general/direct/emeaar/AnnualReport2007.pdf>.

External Advisory Committee on Smart Regulation [EACSR] (2004). *Smart Regulation: A Regulatory Strategy for Canada*. Report to the Government of Canada (September). <http://www.regulatoryreform.com/pdfs/Canada%20Smart%20Regulation%20Report%20Sept%202004.pdf>.

Food and Drugs Act, R.S.C. 1985, c. F-27. <http://laws.justice.gc.ca/en/F-27/index.html>.

Graham, John R. (2005a). *A Lethal Guardian: The Canadian Government's Ban on Prescription Drugs*. Fraser Institute Digital Publication. Fraser Institute.

Graham, John R. (2005b). Approving New Medicines in Canada: Health Canada Needs a Dose of Competition. *Fraser Forum* (June): 9–11.

Graham, John R., and T. Tabler (2005). *Canadian Pharmacare: Performance, Incentives, and Insurance*. Fraser Institute Digital Publication. Fraser Institute.

Health Canada (2001). *How Drugs Are Reviewed in Canada*. Health Products and Food Branch, Therapeutic Products Directorate. <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd_e.html>.

Health Canada (2003). *Therapeutic Products Directorate (TPD) - 2003 Annual Submission Performance Report - Part I.* <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/docs/perform-rendement/ar-ra/tpd_dpt_annual_annuel_03_e.html>. Last updated April 28, 2004.

Health Canada (2004a). *Biologics and Genetic Therapeutics Directorate - 2004 Annual Submission Performance Report - Part II.* <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/docs/perform-rendement/ar-ra/bgtd_dpbtg_annual_annuel_04_e.html>. Last updated May 24, 2005.

Health Canada (2004b). *Therapeutic Products Directorate - 2004 Annual Submission Performance Report - Part I.* <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/docs/perform-rendement/ar-ra/tpd_dpt_annual_annuel_04_e.html>. Last updated May 24, 2005.

Health Canada (2005a). *Biologics and Genetic Therapeutics Directorate - 2005 Annual Submission Performance Report - Part II.* <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/docs/perform-rendement/ar-ra/bgtd_dpbtg_annual_annuel_05_e.html>. Last updated March 14, 2006.

Health Canada (2005b). *Therapeutic Products Directorate (TPD) - 2005 Annual Submission Performance Report - Part I.* <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/docs/perform-rendement/ar-ra/tpd_dpt_annual_annuel_05_e.html>. Last updated March 14, 2006.

Health Canada (2005c). *Regulatory Review of Pharmaceuticals, Biologics and Medical Devices: 2005 Annual Summary of Performance.* <http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/performance_rendement_2005_e.html>. Last updated July 25, 2006.

Health Canada (2006a). *Access to Therapeutic Products: The Regulatory Process in Canada*. Health Canada, Health Products and Food Branch. <http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique_e.html#2.1>. Last updated June 28, 2006.

Health Canada (2006b). *2005 Annual Drug Submission Performance Report: Part I Therapeutic Products Directorate (TPD); Part II Biologics and Genetic Therapies Directorate (BGTD)*. Health Canada, Health Products and Food Branch.

Health Canada (2006c). *Priority Review of Drug Submissions*. Health Canada, Health Products and Food Branch: Therapeutic Products

Directorate. <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/prds_tppd_pol_2006_e.html>. Last updated January 10, 2006.

Health Canada (2007). *2006 Annual Drug Submission Performance Report: Part I Therapeutic Products Directorate (TPD); Part II Biologics and Genetic Therapies Directorate (BGTD)*. Health Canada, Health Products and Food Branch.

Health Canada (2008a). *2007 Annual Drug Submission Performance Report: Part I Therapeutic Products Directorate (TPD); Part II Biologics and Genetic Therapies Directorate (BGTD)*. Health Canada, Health Products and Food Branch.

Health Canada (2008b). Special Data Request. Detailed drug product data matching the Brogan Inc. (2008) dataset, which was used to measure provincial reimbursement delays and rates.

Newhouse, J.P., and the Insurance Experiment Group (1993). *Free For All? Lessons From The RAND Health Insurance Experiment*. RAND. Harvard University Press.

Patented Medicine Prices Review Board [PMPRB] (2008). *PMPRB 2007 Annual Report*. Government of Canada. <http://www.pmprb-cepmb.gc.ca>.

Philipson, Tomas J., Ernst R. Berndt, Adrian H. B. Gottschalk, and Matthew W. Strobeck (2005). *Assessing the Safety and Efficacy of the FDA: The Case of the Prescription Drug User Fee Acts*. NBER Working Paper No. 11724. National Bureau of Economic Research.

Skinner, Brett J. (2006, June 21). Sure, It's Cheap to Make Drugs. But the Cost of Discovering and Developing Them Is Enormous. *Globe and Mail*.

Skinner, Brett J., and Mark Rovere (2008). *Access Delayed, Access Denied 2008: Waiting for New Medicines in Canada*. Fraser Institute.

Skinner, Brett J., Mark Rovere, and Courtney Glen (2007). *Access Delayed, Access Denied: Waiting for Medicines in Canada*. Fraser Institute.

US Food and Drug Administration [FDA] (1996). *Manual of Policies and Procedures*. MAPP 6020.3. Center for Drug Evaluation and Research.

US Food and Drug Administration [FDA] (2002). *The FDA and the Drug Development Process: How the FDA Insures that Drugs Are Safe and Effective*. FDA Fact Sheet. FDA.

US Food and Drug Administration [FDA] (2008). *New Drug Application (NDAs) & Biologic License Applications (BLAs)*. Center for Drug Evaluation and Research. <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM123957.pdf>.

US Food and Drug Administration [FDA] (2009). *Drugs@FDA Glossary of Terms*. US Department of Health and Human Services. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>. Last updated June 18, 2009.

World Medical Association [WMA] (1964). *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. <http://www.wma.net/e/policy/b3.htm>.

About the authors

Brett J. Skinner

Brett J. Skinner is the Director of Bio-Pharma and Health Policy research and of Insurance Policy research at the Fraser Institute. He is also the Manager of the Institute's Ontario regional office. He is a Ph.D. candidate in Public Policy and Political Science, specializing in public policy, at the University of Western Ontario in London, Ontario, where he has lectured in both the Faculty of Health Sciences and the Political Science department. He earned a B.A. through the University of Windsor in Windsor, Ontario, and an M.A. through joint studies between the University of Windsor and Wayne State University in Detroit, Michigan. He also spent a year working as a research consultant with the Insurance Bureau of Canada in Toronto. Mr. Skinner's research has been published in many major papers, articles, and opinion editorials through the Fraser Institute in Vancouver and Toronto, as well as the Atlantic Institute for Market Studies in Halifax, Nova Scotia. He appears frequently as an expert in the North American media, and his research and opinions have been cited in media from around the world. Mr. Skinner has presented his research at government, academic, and industry conferences around the world, and has twice testified about his research before the Canadian House of Commons Standing Committee on Health.

Mark Rovere

Mark Rovere is a Senior Policy Analyst, Bio-Pharma and Health Policy, at the Fraser Institute. He holds an Honours B.A. and an M.A. in Political Science from the University of Windsor. Mr. Rovere has contributed research to, authored, and co-authored numerous studies and articles on a range of health and pharmaceutical policy issues including Canadian pharmaceutical pricing, access to new medicines, government drug expenditures, Canadian and American prescription drug spending, and the sustainability of public health care in Canada. His recent co-publications include *Paying More, Getting Less* (2008); *The Cost Burden of Prescription Drug Spending in Canada and the United States* (2008); *The Misguided War against Medicines* (2008); and *Canada's Drug Price Paradox* (2008).

Disclosure

Because the authors' employer receives charitable donations from research-based pharmaceutical manufacturers, the authors have chosen to disclose financial relationships in accordance with the policies of the International Committee of Medical Journal Editors (Clever et al., 1997; Davidoff et al., 2001). The authors acknowledge with sincere gratitude those who financially support the Fraser Institute and this research including research-based pharmaceutical companies (whose contributions make up less than 5% of the Fraser Institute's budget), as well as the general membership and other supporters of the Institute. With respect to this manuscript, no drug-maker or other donor had any input into the collection, analysis, or interpretation of the research, nor in the manuscript's writing. Nor did any drug-maker or other donor preview this manuscript before publication. The Fraser Institute accepts no government funding and no private contracts for research. The donations we receive are unrestricted and come only from private foundations, organizations, or individuals.

Publishing information

Periodically, the Fraser Institute publishes timely and comprehensive studies of current issues in economics and public policy. This study is one such example belonging to a series of related publications.

Distribution

These publications are available from <http://www.fraserinstitute.org> in Portable Document Format (PDF) and can be read with Adobe Acrobat® 7 or later or with Adobe Reader® 7 or later. Adobe Reader® 9, the most recent version, is available free of charge from Adobe Systems Inc. and may be downloaded from: <http://get.adobe.com/reader/>. We encourage you to install the most recent version.

Ordering publications

For information about ordering the printed publications of the Fraser Institute, please contact the publications coordinator

- e-mail: sales@fraserinstitute.org
- telephone: 604.688.0221 ext. 580 or, toll free, 1.800.665.3558 ext. 580
- fax: 604.688.8539.

Media

For media inquiries, please contact our Communications Department

- 604.714.4582
- e-mail: communications@fraserinstitute.org.

Disclaimer

The author of this publication has worked independently and opinions expressed by her are, therefore, her own, and do not necessarily reflect the opinions of the supporters, trustees, or other staff of the Fraser Institute. This publication in no way implies that the Fraser Institute, its trustees, or staff are in favor of, or oppose the passage of, any bill; or that they support or oppose any particular political party or candidate.

Copyright

Copyright© 2009 by the Fraser Institute. All rights reserved. No part of this publication may be reproduced in any manner whatsoever without written permission except in the case of brief passages quoted in critical articles and reviews.

ISSN
ISSN 1920-4094 Studies in Pharmaceutical Policy (online version)

Date of issue
August 2009

Editing and production
Kristin Fryer

Design
Lindsey Thomas Martin.

Cover design
Bill Ray

Images for cover
Pills © Andrzej Tokarski, Fotolia

Pills © Andrzej Tokarski, Fotolia

Pharmaceuticals detail © icholakov, Fotolia

Pills © zagorskid, Fotolia

Lots of yellow pills and one red © Nadezhda Bolotina, Fotolia

Blue pills © Marcelo Wain, iStockphoto

Supporting the Fraser Institute

To learn how to support the Fraser Institute, please contact

- Development Department, Fraser Institute
  Fourth Floor, 1770 Burrard Street
  Vancouver, British Columbia, V6J 3G7 Canada
- telephone, toll-free: 1.800.665.3558 ext. 586
- e-mail: development@fraserinstitute.org.

About the Fraser Institute

Our vision is a free and prosperous world where individuals benefit from greater choice, competitive markets, and personal responsibility. Our mission is to measure, study, and communicate the impact of competitive markets and government interventions on the welfare of individuals.

Founded in 1974, we are an independent research and educational organization with locations throughout North America and international partners in over 70 countries. Our work is financed by tax-deductible contributions from thousands of individuals, organizations, and foundations. In order to protect its independence, the Institute does not accept grants from government or contracts for research.

菲沙研究所的願景乃一自由而昌盛的世界，當中每個人得以從更豐富的選擇、具競爭性的市場及自我承擔責任而獲益。我們的使命在於量度、研究並使人知悉競爭市場及政府干預對個人福祉的影響。

Nous envisageons un monde libre et prospère, où chaque personne bénéficie d'un plus grand choix, de marchés concurrentiels et de responsabilités individuelles. Notre mission consiste à mesurer, à étudier et à communiquer l'effet des marchés concurrentiels et des interventions gouvernementales sur le bien-être des individus.

تتمثل رؤيتنا في وجود عالم حر ومزدهر يستفيد فيه الأفراد من القدرة على الاختيار بشكل أكبر، والأسواق التنافسية، والمسؤولية الشخصية. أما رسالتنا فهي قياس، ودراسة، وتوصيل تأثير الأسواق التنافسية والتدخلات الحكومية المتعلقة بالرفاه الاجتماعي للأفراد.

Nuestra visión es un mundo libre y próspero donde los individuos se beneficien de una mayor oferta, la competencia en los mercados y la responsabilidad individual. Nuestra misión es medir, estudiar y comunicar el impacto de la competencia en los mercados y la intervención gubernamental en el bienestar de los individuos.

Editorial Advisory Board

Prof. Armen Alchian

Prof. Terry Anderson

Prof. Robert Barro

Prof. Michael Bliss

Prof. James M. Buchanan†

Prof. Jean-Pierre Centi

Prof. Thomas J. Courchene**

Prof. John Chant

Prof. Bev Dahlby

Prof. Erwin Diewert

Prof. Stephen Easton

Prof. J.C. Herbert Emery

Prof. Jack L. Granatstein

Prof. Herbert G. Grubel

Prof. Friedrich A. Hayek* †

Prof. James Gwartney

Prof. H.G. Johnson*

Prof. Ronald W. Jones

Dr. Jerry Jordan

Prof. David Laidler**

Prof. Richard G. Lipsey**

Prof. Ross McKitrick

Prof. Michael Parkin

Prof. F.G. Pennance*

Prof. Friedrich Schneider

Prof. L.B. Smith

Prof. George Stigler* †

Mr. Vito Tanzi

Sir Alan Walters

Prof. Edwin G. West*

* deceased; ** withdrawn; † Nobel Laureate