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Access Delayed, Access Denied 2008

Waiting for New Medicines in Canada

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Executive summary

This is the Fraser Institute's second annual report on the amount of time patients must wait to access new medicines in Canada.[1] 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; (2) to compare consumer access to new drugs under government drug insurance programs with access under private sector drug insurance in Canada; and (3) 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.

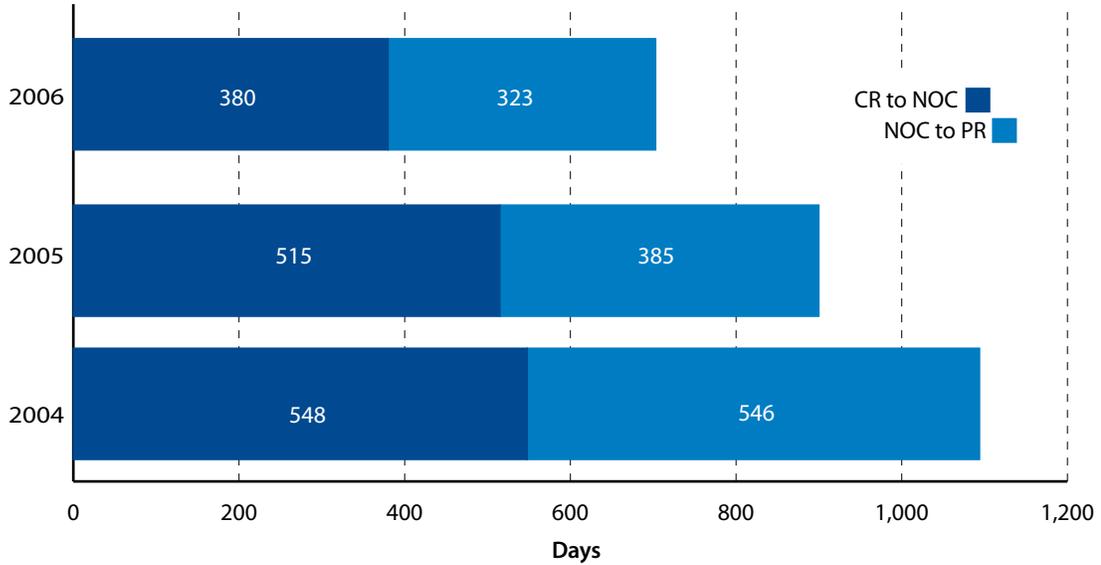
Figure 1 shows the consolidated average wait time for access to new medicines in Canada, broken down by each of the two segments described above. This wait time is measured in days and is presented as an average of wait times for pharmaceutical and biological drugs[2] from all classes of drug approval submissions.[3]

[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 regarding wait times for access to new medicines in Canada, using a slightly different method of analysis.

[2] “Pharmaceutical” drugs are chemical based products; “biological” drugs are biochemical based products.

[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).

Figure 1: Total time (days) spent waiting after a new drug has been developed before patients dependent on public drug programs have access to new medicines in Canada, by wait segment, averaged across all provinces and all new drug submission classes, 2004-2006



Abbreviations:

CR: the date the drug manufacturer’s application for approval is recorded or filed in the Central Registry.
 NOC: the date Health Canada issues an official Notice of Compliance, certifying that the new drug is safe and effective.

PR: the date at which the first public reimbursement of the new drug is recorded in the formularies of each federal, provincial, and territorial drug program.

Sources: Health Canada (2007); Brogan Inc. (2007); calculations by authors.

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 2006, the average length of time taken by Health Canada to approve the use of new medicines was 380 days. Health Canada’s new drug approval delays were shorter in 2006 than in the previous two years. In 2004, Health Canada took an average of 548 days to approve new medicines, compared to 515 days in 2005. This data suggests that Health Canada’s approval times have improved compared to previous years.

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 reimburse-

ment for new drugs averaged 323 days in 2006 (averaged across all provinces and drug submissions). Similar to the first segment of the bar, average wait times for provincial reimbursement have decreased since 2004. In 2004, patients relying on public drug programs waited approximately 546 days (averaged across all provinces and all drugs submissions) before new drugs were given approval for public reimbursement. In 2005, the wait for reimbursement approval decreased to an average of 385 days. 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 benefits for insured access to new medicines was 703 days (1.9 years) in 2006. The total average wait has decreased from an average of 1094 days (approximately 3.0 years) in 2004, and 900 days (approximately 2.5 years) in 2005.

Even though there has been a reduction in approval delays in recent years, national and provincial governments are still creating lengthy and unnecessary waits for accessing new medicines. 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.

Provincial denials

Averaged across all provincial public drug programs, only 39% of all drugs that Health Canada approved as safe and effective in 2006 had actually been reimbursed (fully or partially) by the provinces as of October 20, 2007. This represents reduced coverage from previous years. On average, full or partial provincial reimbursement was approved for 44% of new drugs in 2004 and 41% of drugs in 2005 (as of October 20, 2007).

Access under private sector drug insurance

By contrast, 100% of all new drugs are usually eligible for private insurance reimbursement as soon as Health Canada has certified that the drugs are safe and effective. Instead of resorting to centrally planned restrictions on the scope of drug benefits, private insurers tend to use partial price incentives to encourage consumers to adjust

their own demand for drugs. For instance, private sector insurers often apply co-payments to reimbursements of prescription drugs. By creating a price at the point of consumption, co-payments encourage patients to make cost-efficient utilization and substitution choices between treatment alternatives. Sometimes private sector insurers also employ deductibles that appropriately restrict insurance coverage to the range of expenses considered individually unaffordable for consumers. Rarely, some private sector insurers have imposed annual coverage limits that might expose patients to significant cash costs in rare cases involving very expensive drugs.

Introduction

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

This report focuses on newly 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.

The findings presented here may differ from those of other studies due to differences in methodology. For instance, some studies separate the wait time for access to “new active substances” (NAS)—i.e., a drug molecule that has never been invented before—from other types of new drug submission classes (i.e., modifications of previously approved molecules). By comparison, this paper looks only at an aggregate average of the time spent waiting for access to medicines across all new drug submission classes. This is done so that the data can be compared to other international jurisdictions where data for individual drug submission classes that are equivalent to Canada’s is not available (from centralized sources). In addition, this study consolidates new pharmaceutical and biological medicines in order to measure the wait time for all types of new drugs.[4]

[4] This is a change from previous methodology used in Skinner et al. (2007).

The global wait for new drug development

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; consequently, 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* [Canada, DOJ, 1985].

In order to obtain marketing approval for a drug, manufacturers must provide Health Canada with evidence of its successful clinical testing in patients. 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. Actual standards for demonstrating the safety of drug products are set by national governments through domestic regulation. These standards determine the number, length, and rigour of clinical trials that will be required. 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 length of clinical testing time it takes to satisfy the requirements

of the US Food and Drug Administration (US FDA) and the European Medicines Agency (EMA). 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 is made for marketing approval with the US FDA (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 spent (in months) from issuance of new drug patent to application for US FDA marketing approval, for drugs approved between 1985 and 2000

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

Sources: DiMasi et al. (1995; 2003).

Delays caused by the federal government

The first segment of the wait for new medicines which 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 to Canadians and that the drug's effectiveness has been proven to acceptable scientific standards for health treatments.^[5] Marketing approval for new drugs occurs at the national level; therefore, any delay caused by Health Canada's drug review process affects the wait time for access to new medicines for the entire Canadian population.

In Canada, the time patients spend waiting for government 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 (EMA). 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.

The following subsections present the findings on Health Canada's performance with respect to approving new drugs. The first subsection examines changes in national drug approval times within Health Canada from 2002 to 2006. The second and third subsections compare Health Canada's performance with that of the EMA and the FDA from 2002 to 2006.

Drug approval times in Canada, 2002-2006

In this section, aggregate delays in the approval of drugs are presented across all types of new drug submissions, including new active substances (NAS), new drugs submis-

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

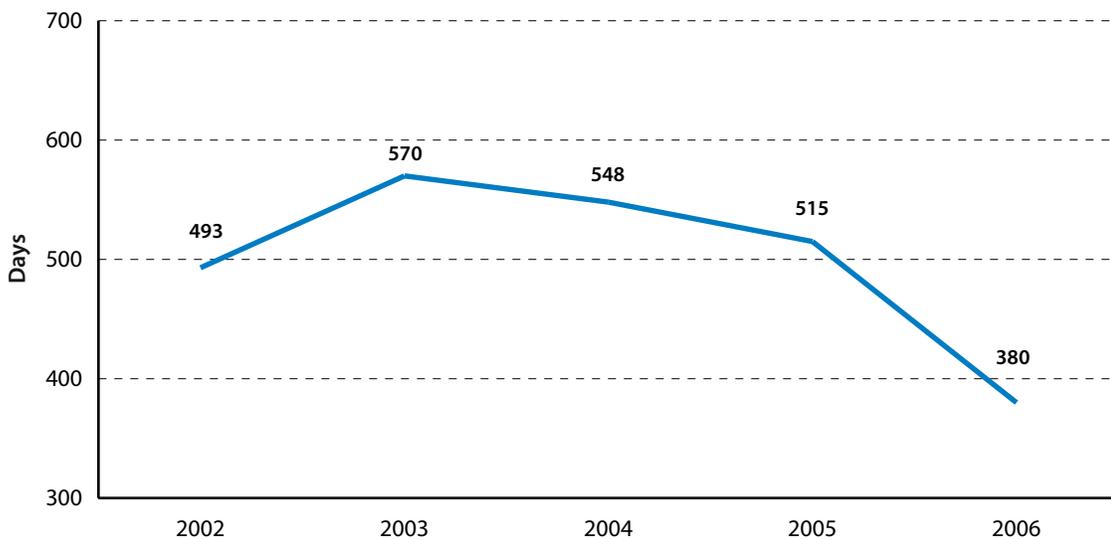
sions (NDS), and supplemental new drug submissions (SNDS). The data presented will be used to measure the average time taken by Health Canada to issue an approval of any drug from all new non-generic drug submission classes. The data combines both pharmaceutical and biological medicines in order to measure the approval times of all new drug submissions.

Our analysis shows that approval times for new medicines have fluctuated between 2002 and 2006 (figure 2). Average approval times slightly increased from 493 days in 2002 to 570 days in 2003, the year in which average approval times were longest during the period studied. However, average approval times for new medicines have decreased in Canada since 2003. In 2006, Health Canada spent 380 days on average to approve new medicines, 190 days less than the average approval time in 2003.

Drug approval times in Canada and Europe, 2002-2006

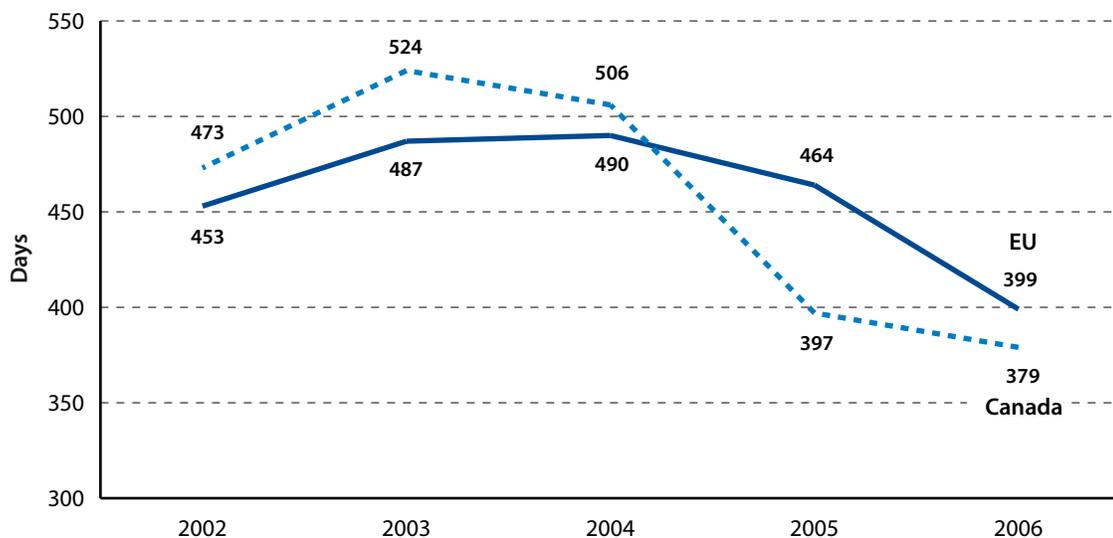
Figure 3 displays the average number of days spent waiting for approval of new medicines in Europe and Canada between 2002 and 2006. The data presented are different from the previous section because it is based on a more limited sample of drugs. The data only show the time spent in both jurisdictions for the approval of new pharmaceutical medicines. Separate comparable data for biological medicines was not available.

Figure 2: Average time (days) spent waiting for Health Canada to approve new drugs, averaged across all new drug-submission classes, 2002-2006



Source: Health Canada (2007); calculations by authors.

Figure 3: Average time (days) spent waiting for government approval of new drugs (pharmaceutical medicines only) averaged across all new drug submission classes, Canada and Europe, 2002-2006



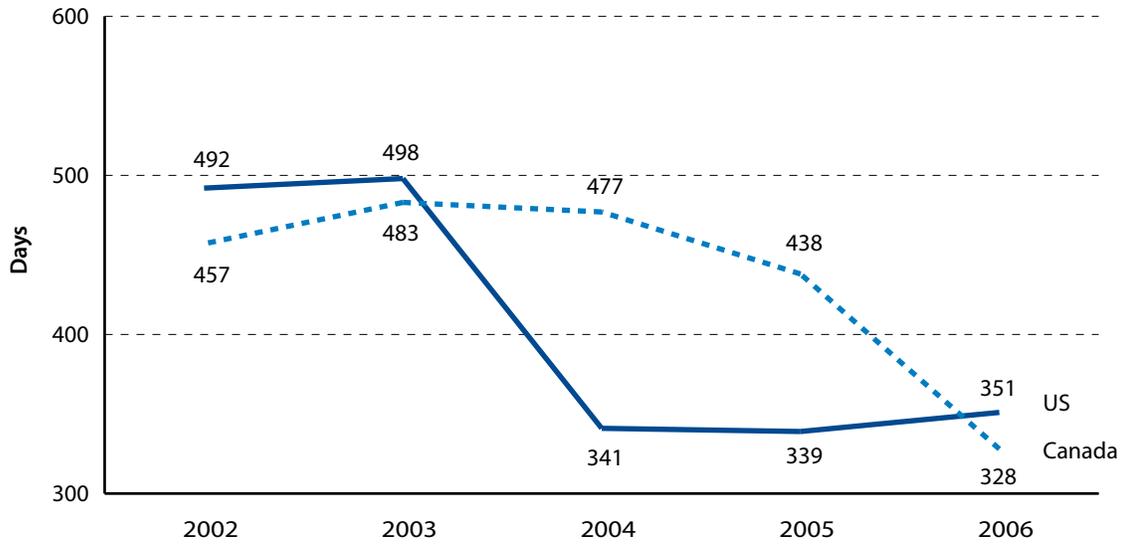
Sources: Health Canada (2007); EMEA (2007); calculations by authors.

The data indicate that from 2002 to 2004, Health Canada took longer on average to approve new pharmaceuticals compared to the European Medicines Agency (EMA), its European equivalent. In 2005, Health Canada’s performance improved significantly relative to its European counterpart, approving new pharmaceuticals 67 days sooner than the EMA (on average). Similarly, Health Canada took 379 days on average to approve new pharmaceutical medicines in 2006, compared to 399 days (on average) for the EMA.

Drug approval times in Canada and the United States, 2002-2006

The data presented here is different from the previous sections because it is based on a different method of aggregating the statistics. The United States only publishes median figures for drug approval times. Figures for pharmaceutical and biological medicines are published in separate tables in some years (2001-2003) and aggregated in other years (2004-2005). Canada also publishes median drug approval times. The Canadian data are aggregated by Health Canada according to the priority or non-priority review status of the drugs, and reported separately by drug submission class. In order to make the two sets of data comparable, it was necessary to aggregate the separately

Figure 4: Median time (days) spent waiting for government approval of new drugs, across all new drug submission classes, average weighted by submission class, Canada and United States, 2002-2006



Sources: Health Canada (2007); US FDA (2007); calculations by authors.

reported medians by calculating a weighted median proportional to the number of drugs approved in each sub-set as a percentage of the total number of drugs approved overall.[6]

Figure 4 displays the difference between median approval times in Canada and the United States for all new drug applications between 2002 and 2006. The delays are presented as consolidated figures across all classes of new drug applications and are an aggregate that includes both pharmaceutical and biological medicines. The data show that the wait times for new drug approvals in Canada were shorter than those in the United States in three of the five years studied. In 2006, Health Canada’s median approval time significantly decreased from the previous year and was below the US FDA’s median approval time. The FDA’s median approval time in 2006 was 351 days, while Health Canada’s median approval time was 328 days. Health Canada took a shorter time than the FDA to approve new drugs in 2002 and 2003, but a longer time in 2004 and 2005.

The data from 2002 to 2006 suggest that Health Canada’s approval times have improved since 2003, relative to its own performance. Health Canada’s performance

[6] The methodology of calculating average weighted medians was based on the approach used by Esmail and Walker (2006).

was worse than the performance of the EMEA in three of the five years studied, but was better than the EMEA's performance in the most recent two years. Health Canada's performance was also better than the FDA in three of the five years studied, and the most recent year suggests a reversal in the previous two-year trend in which Health Canada performed worse than the FDA. These analyses suggest that Health Canada has been improving the performance of its drug approval process. Nevertheless, delays in accessing new medicines caused by Health Canada's approval process currently average more than a year (380 days in 2006 when measured against its own performance; figure 2).

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, provincial, and territorial (FPT) governments to decide whether to reimburse a new drug under their respective publicly funded drug insurance programs.^[7] Once certified to be safe for sale by Health Canada, new drugs must receive additional approvals from federal,^[8] provincial, and territorial (FPT) government agencies before they become eligible for public reimbursement under FPT health and drug insurance programs. Each jurisdiction determines reimbursement eligibility through their own government agency; consequently, the wait time for access to new medicines differs by jurisdiction. The delay in this segment is measured from the date at which Health Canada issues a NOC for a new drug to the date at which the first public reimbursement (PR) of the same drug is recorded in the formularies of each federal, provincial, and territorial drug program.

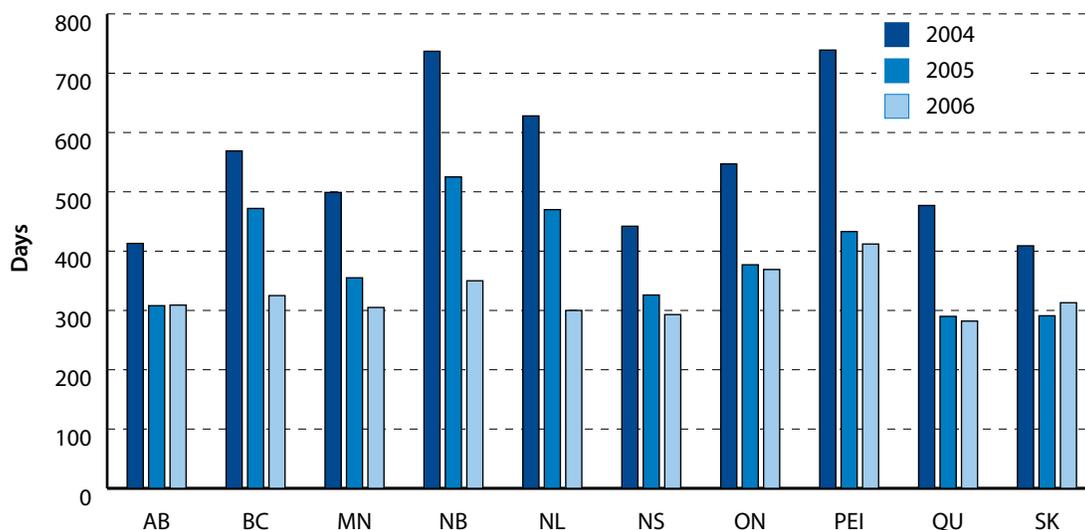
-
- [7] The wait for public reimbursement most heavily affects recipients of public drug plans, but it also affects those who are privately insured for drugs. In Canada, provincially funded and managed health insurance plans generally cover the cost of health care delivered in hospitals and physicians' clinics for the entire population. Private payment for these services is effectively prohibited. Therefore, drugs administered to patients in hospitals or clinics are paid for through publicly funded health insurance programs. However, public reimbursement of drug expenses for out-patients (patients who do not require hospitalization) is not available on a universal basis; only particular sub-populations (e.g., seniors, welfare recipients, military, and aboriginals) are eligible. The bulk of the Canadian population pays for drugs administered on an outpatient basis through private insurance or cash expenditure. However, private insurance does not generally cover any drugs administered on an in-patient basis (i.e., in a hospital). Private insurers in Canada generally grant automatic reimbursement to out-patients for any drug that has been approved by Health Canada. This means that access to drugs for out-patients with private insurance or those with the ability to pay cash is not affected by delays in provincial reimbursement approval. But for drugs administered on an in-patient basis, all those who lack the means to pay cash, whether they have public or private insurance, are equally affected by government reimbursement delays or denials. Further, it is possible that, when drug makers know that their product must be delivered on an in-patient basis, they will not bring a product to market at all in the absence of public reimbursement, because there will not be enough cash-paying patients to make it economical [Skinner, 2006]. In this case, everyone is affected by delays in provincial reimbursement approval.
- [8] 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.
-

Provincial reimbursement delays: 2004, 2005, and 2006

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 compares the average time (in days) that each province took to approve the public reimbursement of new drugs (excluding drugs that were declared ineligible for reimbursement).

The average number of days between Health Canada’s issuance of a NOC and the first recorded decision to publicly reimburse new drugs has decreased in every province since 2004. For instance, in 2004, New Brunswick residents relying on public drug programs waited 737 days on average for the public reimbursement of new drugs. This was down to 350 days by 2006. Thus, patients relying on New Brunswick’s public drug programs waited 389 days less in 2006 for access to new drugs (those that were finally approved) than they did in 2004.

Figure 5: Comparison of the average time (days) spent waiting in Canadian provinces between Health Canada safety approval and provincial reimbursement approval for new medicines, by province, 2004-2006

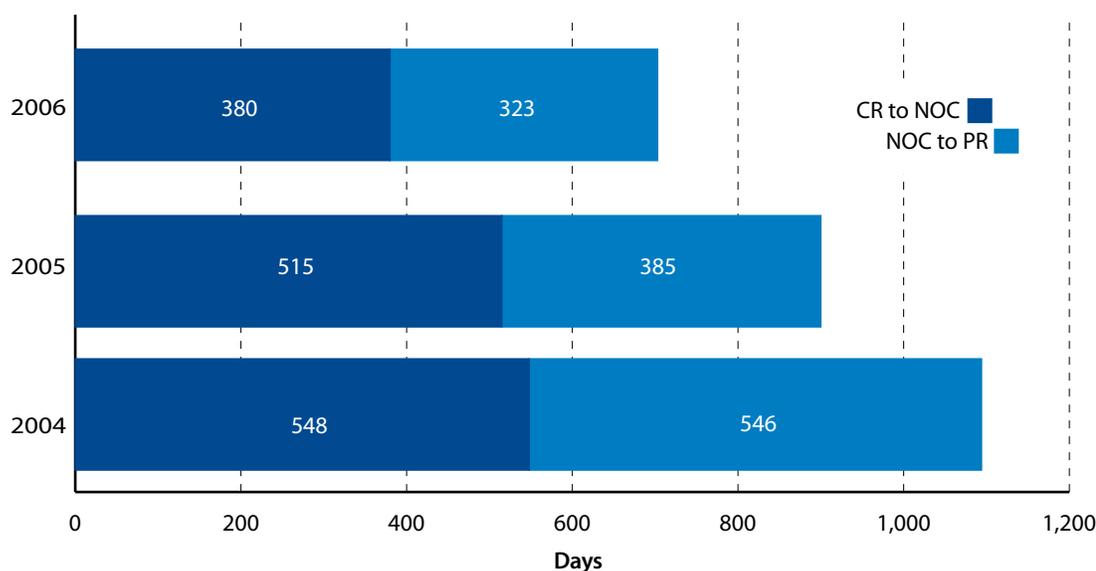


Source: Brogan Inc. (2007); calculations by authors.

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 it takes 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, and 2006. 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 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

Figure 6: Total time (days) spent waiting after a new drug has been developed before patients have access to new medicines in Canada, by wait segment, averaged across all provinces and all new drug submission classes, 2004-2006



Abbreviations:

CR: the date the drug manufacturer’s application for approval is recorded or filed in the Central Registry.
 NOC: the date Health Canada issues an official Notice of Compliance, certifying that the new drug is safe and effective.

PR: the date at which the first public reimbursement of the new drug is recorded in the formularies of each federal, provincial, and territorial drug program.

Sources: Health Canada (2007); Brogan Inc. (2007); calculations by authors.

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 three years (figure 6). In 2004, Health Canada averaged 548 days to issue a notice of compliance, compared to 515 days in 2005, and 380 days in 2006.

The second segment of the bar represents a single period of waiting for those who are dependent on public drug programs, or for anyone who needs drugs that are only administered on an in-patient basis and cannot afford to pay cash. As figure 6 shows, the time spent by the provinces to grant eligibility for the public reimbursement of new drugs decreased over the three year period. The average wait for reimbursement approval of was 546 days in 2004, 385 days in 2005, and 323 days in 2006.^[9] Nevertheless, wait times for these drugs remain significant. Patients who are dependent on public drug benefits or who need drugs that are delivered only through in-patient settings must wait almost a year after Health Canada has certified a new drug as safe and effective before they finally have access to it.

The total average wait for patients dependent on public drug benefits in Canada for access to new medicines was 1094 days in 2004 (approximately 3 years). The average wait was 900 days (approximately 2.5 years) in 2005. Using the most recent available data, patients waited approximately 703 days (1.9 years) in 2006.

[9] Some new medicines take over a year to be reimbursed by the provinces and thus are not included in this number. This could create a lag effect in the data. Future reports will remedy this with more mature data.

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 every province has 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 eligibility 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 the most recently available date) 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. Table 2 shows that, averaged across all provinces and public drug plans, only 39% of new drugs that obtained a NOC from Health Canada in 2006 were declared eligible for public reimbursement under provincial drug insurance programs as of October 20, 2007. The approval rates in the previous two years (as of October 20, 2007) were 44% in 2004 and

Table 2: Public reimbursement approval for new drugs, as a percentage of new drugs approved safe and effective by Health Canada, by province, 2004-2006

	2004		2005		2006	
	Drugs Approved for Public Reimbursement	Approved Drugs as a % of total NOCs	Drugs Approved for Public Reimbursement	Approved Drugs as a % of total NOCs	Drugs Approved for Public Reimbursement	Approved Drugs as a % of total NOCs
AB	35	42.2%	17	31.5%	4	20.0%
BC	32	38.6%	14	25.9%	2	10.0%
MB	32	38.6%	22	40.7%	2	10.0%
NB	39	47.0%	29	53.7%	13	65.0%
NL	28	33.7%	11	20.4%	10	50.0%
NS	40	48.2%	24	44.4%	10	50.0%
ON	25	30.1%	25	46.3%	4	20.0%
PEI	14	16.9%	9	16.7%	5	25.0%
QC	81	97.6%	42	77.8%	16	80.0%
SK	41	49.4%	29	53.7%	11	55.0%
Provincial Average		44.0%		41.0%		39.0%
Total NOCs	83		54		20	

Source: Brogan Inc. (2007); calculations by authors.

41 % in 2005. However, it is unclear whether fewer drugs are being reimbursed. Long delays (longer than one year) in reimbursement approval decisions by provincial governments may explain why the final reimbursement approval rate is slightly lower in the most recent year of data. Future updates to this analysis will capture any lag effect by using more mature data.

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 can 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, as has been the case in the United States. A decade of user fees intended to increase the budget available to Health Canada has failed to improve its 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 US 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, without restricting consumer choice through central planning.

Research conducted for this study indicates that new drugs are generally eligible for private insurance reimbursement as soon as Health Canada has certified the drugs as safe and effective for use by Canadians. Some private plans have made certain broad categories of drugs, such as the so-called “lifestyle” drugs, ineligible for coverage. However, in almost all private plans, outside of such broad exclusions, every drug that receives a NOC from Health Canada is eligible for reimbursement immediately. Private insurers cover close to 100% of new “medically necessary” drugs for which NOCs have been issued, and the delay to approval of reimbursement is practically non-existent [cf. Graham and Tabler, 2005].

Research also 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 in turn 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 the range of expenses considered individually unaffordable for consumers. Rarely, some private sector insurers have imposed annual coverage limits that could expose some patients to significant cash costs in rare cases involving very expensive drugs.

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. [10] Health Canada publishes data on pharmaceutical medicines through the TPD, and on biologic medicines through the BGTD. Data published in annual reports on drug approvals by the TPD and the BGTD is stated in aggregates and is 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 data on drug approval delays excludes administrative SNDS applications, which apply to drug products that have already been marketed and have previously received Health Canada’s approval, but are now being duplicated by a new manufacturer. This usually results from the buyout or merger of patent-holding drug companies and so there are very few such applications and they do not occur on a regular basis. Because these approvals are merely administrative in nature, they are completed more quickly than standard new drug applications. Finally, Health Canada’s published approval times include the entire period between original filing of the new drug submission application (CR) to 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].

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 [US FDA, 1996; 2002; 2007] and the European Medicines Agency [EMA, 2005; 2006; 2007]. The FDA and the EMA publish data on approval delays that is inclusive of all new drug submission classes, even administrative applications. This has the effect of reducing the average wait time when calculated across all new drug submissions, but probably not that significantly because of the infrequency with which this type of application is submitted. Therefore, a direct comparison of approval delays

[10] 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) [Rx&D, 2005].

between Health Canada's data and data from the FDA or the EMEA can produce minor inaccuracies if not treated carefully. Nevertheless, it is the only fully comprehensive data publicly available for this research and reasonable comparisons can be made if conclusions are drawn cautiously from the results. The FDA and the EMEA also publish separate data for the time spent by companies to correct the deficiencies in their applications. Health Canada does not do so, but instead publishes an entire approval delay that includes what they call "company" time. This makes it difficult to accurately compare the direct institutional performance of Health Canada and its international counterparts because it is impossible to determine what part of Health Canada's approval delay is attributable to its own performance and what part to deficient company applications. The EMEA publishes average figures on drug approval delays but does not include median figures. Unlike Health Canada and the FDA, the EMEA does not publish data that separates priority and non-priority new drug submissions. Also, like the FDA, the EMEA includes administrative new drug applications in its published figures on drug approval delays and separately publishes both institutional time spent and time spent for companies to correct deficiencies in their applications.

The fourth main source of data cited in this paper is Brogan Inc. [Brogan Inc., 2007]. 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 that Health Canada issued a NOC for each new drug and the first date that 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 (EMA) and the US Food and Drug Administration (FDA), but under different terminology, and the classes of new drug applications in each of the three jurisdictions do not match perfectly. The Canadian and international classifications are briefly described below.

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 the 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 US FDA's Center for Drug Evaluation and Research (CDER)

New Molecular Entity (NME)

New salt of previously approved drug (not an NME)

New Formulation of previously approved drug (not a new salt or NME)

New combination of two or more drugs

Already marketed drug product—duplication by new manufacturer

New indication for already marketed drug

Already marketed drug not previously approved by NDA

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.

Source: US FDA (1996).

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

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.

Orphan

A medicinal product shall be designated as an orphan drug where it can be established that:

- it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10, 000 persons in the Community at the time when the application is made, or it is intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating, or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment; and,
- there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

Source: European Medicines Agency (2005).

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