

# Approving New Medicines in Canada: Health Canada Needs a Dose of Competition

by John R. Graham

One of the areas in which Canada lags the world is in the speed with which it allows its citizens to use new medicines. The Canadian government forbids patients from using prescription drugs that American, European, and Australian patients have already used months earlier.

When any new drug is invented and ready for distribution in Canada, Health Canada responds by enforcing an automatic moratorium on the right of patients to use it. This general ban is only lifted after the manufacturer has paid a fee and waited for Health Canada to undertake a lengthy review to certify the safety and efficacy of the medicine.

In a recent Fraser Institute Publication, *A Lethal Guardian*, I explain that this ban is harmful to Canadians' health and

is implicated in the deaths of hundreds of patients annually. Although other developed countries have similar regulations, they take much less time to lift their bans on new medicines. In 2003, the Canadian government took more than three months longer than the United States to lift its prohibitions: 20.3 months versus 16.9 months, and Health Canada also approved fewer new medicines than did the US Food and Drug Administration (FDA). Furthermore, during the three years from 1999 through 2001, the US lifted its bans 9 months earlier than Canada; other developed countries were also faster (see table 1).

Although many people accept as normal regulatory delays in their access to new medicines, such government imposed waits are in fact only a relatively recent development. Prior to the 1960s the government did not prevent patients from getting the medicines that they wanted by automatically banning new

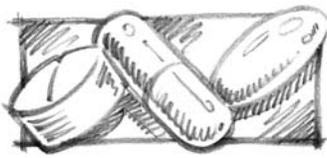
therapeutic drugs. Although previous laws have increasingly interfered with patients' rights to exercise their own judgment in taking medicines, it was the 1963 amendments to the Food and Drug Act that greatly increased government power and created today's regulatory environment.

Most importantly, these amendments required manufacturers to demonstrate the effectiveness, as well as the safety, of a new drug to the government before it would allow them to distribute their new medicines. This greatly increased both costs and the manufacturers' burden of communication with the government, because it takes a lot more data from clinical trials to demonstrate effectiveness than safety. These amendments also increased the federal government's control over research and development, manufacturing, and distribution. In summary, the changed regulatory environment treated all new drugs as guilty until proven innocent.

Over the years, this burden eventually caused the approval process for new medicines to slow down. In order to recover the bureaucratic costs associated with drug approvals, and to create incentives and resources for regulators to speed up approvals, Health Canada introduced user fees in 1995. Health Canada levies the fees upon manufacturers when they submit new medicines for approval. Unfortunately, this initiative has also proved unsuccessful at increasing the speed of drug approvals, especially in comparison to international standards. In response, the 2002 Throne Speech committed the government to speeding up the process, and increased Health Canada's regulatory budget. However, the addition of more public money is unlikely to be effective, because Canada already uses more resources to approve new medicines than other countries, and still takes sig-



*John R. Graham is Director of Health Policy Research at the Pacific Research Institute (PRI) in San Francisco, California and former adjunct scholar at The Fraser Institute.*



**Table 1: Time to Approval for New Drugs in Five Countries, 1999-2001**

	Number of New Drugs Approved over 3 Years	Median Time to Approval (days)	Faster than Canada (months)
Canada	78	645	N/A
Australia	89	551	3.1
Sweden	89	431	7.0
United Kingdom	71	479	5.5
United States	85	371	9.0

Source: Graham, 2005, p. 16 (table 2) and sources.

**Table 2: Productivity of New Drug Approvals for Five Countries, 1999-2001**

	Full Time Equivalent Staff per Application	Median Time to Approval (days)	Productivity Index
Canada	6	645	38
Australia	3	551	77
Sweden	2	431	100
United Kingdom	3	479	68
United States	57	371	2

Source: Graham, 2005, p. 17 (table 4) and sources. NB: Detailed calculation of index in Graham, 2005.

nificantly longer to approve them than do Australia, Sweden, or the United Kingdom (table 2). Canada is simply unproductive in this area of regulation.

Readers may think that approving new drugs too quickly could be harmful. We sometimes read of newly approved drugs being withdrawn because they are riskier than previously believed. Vioxx™ (rofecoxib) is a recent example. However, even if we believe that governments should prevent patients themselves from deciding how much risk they prefer to take with their medicines, it is still clear that the benefits of speedier approval of new drugs is, on balance, positive.

Some of the evidence for this comes from the US, where the implementation of user fees drastically improved approval times after 1992. In one recent analysis, the Office of the Inspector General of the US Department of Health and Human Services reported the rates of subsequent withdrawal of new medicines according to the years in which manufacturers applied to the FDA for approval (Rehnquist, 2003). Of drugs submitted from 1988 through 1992 (before user fees), 2.6 percent were subsequently withdrawn. After the

implementation of user fees (which sped up approvals), the rate increased slightly from 1993 through 1997 to 3.1 percent. However, it dropped back to 2.3 percent for 1998 through 2002. Importantly, neither of these changes was statistically significant.

Comparing the US to Canada, Professors Nigel S.B. Rawson and Kenneth I. Kaitin examined drugs that manufacturers withdrew from the market for safety concerns during the 10 years from 1992 through 2001 (Rawson and Kaitin, 2003). They reported that 2.0 percent of news drugs approved in Canada are subsequently withdrawn, whereas the figure for the US was 3.6 percent. This makes it appear as though Canada does more thorough reviews than the US does. However, such a conclusion confuses the average rate of withdrawals with withdrawals at the margin. Primarily because of the drug approval lag the FDA had approved 337 drugs during the 10-year period while Health Canada approved only 268 of those drugs. This means that at the end of 2001, Canadians were waiting for 69 drugs (337 minus 268) that had already been approved by the FDA. Therefore, Health Canada “saved” Canadians from 3.6 percent of the 69 drugs that were

“unsafe”: fractionally less than 3 drugs. On the other hand, Health Canada deprived us of fractionally more than 66 of the drugs that were “safe”: a ratio of about 27-to-1. (Even this is too generous to Health Canada, because it approves 2.0 percent of “unsafe” drugs anyway, so the difference from the FDA is only 1.6 percent, or about one drug of the 69.) Such a result is unacceptable to great number of patients who would have benefited from earlier access to the medicines they needed, but couldn’t get because of government regulations.

In contrast to Canada, the European Union has implemented a policy of regulatory competition. The process works by requiring central regulators and the national regulators of EU member states to compete for the user fees charged to manufacturers to cover the costs of regulatory approval for new drugs. When any one regulator approves a new medicine for sale, regulators in all other participating countries must generally reciprocate by lifting their bans on the marketing of the product. The first country to approve the new drug wins the right to collect the user fee. This model creates competition for user fees and introduces incentives for countries to be more efficient at approving new drugs. The evidence

shows that such regulatory competition has improved the productivity of drug approvals in the European Union. (Notable exceptions include the approval of biotech products, because manufacturers must submit such products to a central regulatory agency for approval. Also, in 2002 and 2003, the EU decided to require medicines for cancer, AIDS, diabetes, and neuro-degenerative diseases to be approved centrally and approvals for these drugs have been slow.)

The first step in addressing the unacceptable over-regulation of Canadians' ability to use new medicines is to do what the European Union has done: open Health Canada to competition by allowing Canadians to use new drugs once they

are approved by the US, European, or Australian agencies. Health Canada should retain the right to compel manufacturers to label their medicines with the warning that Health Canada has not approved the safety or efficacy of the medicine. This would give consumers the information they need to make rational choices about drug consumption. Such a process will also allow Canadian patients to decide individually how much they value Health Canada's regulatory limits on their freedom to use new medicines, and how much risk they are willing to take in using medicines. Finally, regulatory reform of this sort will improve waiting times for access to medicines that patients in other countries enjoy much earlier than do Canadians.

## References

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