

Studies in
Health Care Policy

FRASER
INSTITUTE

April 2013

Federal Delays
in Approving
New Medicines
2013

by Bacchus Barua
and Nadeem Esmail

Contents

| | | |
|-----------------------------------------------------|---|----|
| Executive summary | ❖ | 5 |
| Introduction | ❖ | 6 |
| Delays in Getting Access to New Medicines in Canada | ❖ | 7 |
| Drug Approval Times | ❖ | 9 |
| Discussion | ❖ | 13 |
| References | ❖ | 18 |
| About the authors | ❖ | 22 |
| Acknowledgments | ❖ | 23 |
| Publishing information | ❖ | 24 |
| About the Fraser Institute | ❖ | 27 |
| Editorial Advisory Board | ❖ | 28 |

Executive summary

This study measures delays in the approval of new medicines by Health Canada and provides patients with the information they need in order to determine whether the time they wait for access to new medicines in Canada is unnecessarily long.

Our findings reveal that Canadian approval delays are not insignificant. The most recent estimates calculated show that Health Canada took a median of 355 days to issue a notice of compliance for patented medicines in 2011—an improvement from the 448 days it took in 2010.

Between 2007 and 2011, Canadians could generally expect a delay of nearly a year or more for access to new medicines after submission for approval. That delay was longer than experienced in Europe for most years during that period. It was also longer than experienced under the US FDA for between two and four of the five years studied.

While the requirement for governmental approval for sale is not unique to Canada, the process can add further delays for Canadians seeking treatment from these new medicines. An important question that arises from this comparison is the value of duplicating the application of safety standards between jurisdictions. Given the similarity of international safety standards and the relatively small size of the population served by Health Canada's mandatory approval process, Canada's federal government could improve access to new medicines through international harmonization and mutual recognition agreements.

Introduction

Medicines are an important component of medical care and can provide significant benefits to patients. In addition to treating illness effectively (or more effectively than previous technologies or approaches, including surgery), they can provide more comfortable treatment regimes, reduce pain, and offer new treatment options for ill individuals where none previously existed. However, these benefits come with the potential for harm, which is one of the reasons why governments around the world regulate access to new medicines.

Before Canadians can receive a new medicine, it must have already successfully passed through extensive clinical trials in accordance with international scientific standards, after which its sale must be approved by Health Canada. Health Canada approves new pharmaceutical medicines through the Therapeutic Products Directorate and approves new biologic and radiopharmaceutical medicines through the Biologics and Genetic Therapies Directorate.¹ The regulation of medicines in Canada falls under the 1985 Food and Drugs Act.

The requirement for governmental approval for sale is not unique to Canada. For example, the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) perform a similar role. However, and critically, in addition to the time taken for development and testing of a new drug, this governmental approval can add further delays for Canadians seeking treatment from these new medicines.

This study² measures delays in the approval of new medicines by Health Canada. It gives patients the information they need to determine whether the time they wait for access to new medicines in Canada is unnecessarily long. We hope this report will encourage policy makers to consider sensible policy alternatives that give consumers greater choice and more rapid access to new medicines.

Our focus here is on governmental delays in approving *new* patented medicines. Generic drugs are not considered here because they are approved without substantial delay (observed or expected) since they are copies of drugs that have been previously approved.

-
- 1 “Biologics” are derived from living sources while pharmaceuticals are typically manufactured through chemical synthesis.
 - 2 Earlier versions of this study were released as part of *Access Delayed, Access Denied*.

Delays in Getting Access to New Medicines in Canada

Global factors affecting access to new medicines

It takes about 10 years to develop a new drug, from the time a drug discovery is patented to the time an application for FDA marketing approval is made (DiMasi, 2001; DiMasi et al., 1995, 2003; Adams and Brantner, 2006). The longest period³ within this drug-development phase involves clinically testing the new medicine on volunteer patients, the successful completion of which is an essential prerequisite to applying for market approval anywhere in the world.

The clinical testing process involves thousands of patients who are often located across international jurisdictions and monitored over many years. The trials are required to adhere to universal scientific standards of experimental research that determine, for example, the design and conduct of clinical drug testing in patient populations, the ethical standards with respect to the treatment and use of human and animal subjects, and the number of patients that must be enrolled in the testing of a new drug, etc.

While the international scientific standards for clinical trials established by the World Medical Association Declaration of Helsinki (World Medical Association, 1964) are generally interpreted as the minimum global standard, actual standards determining the number, length, and rigor of the required clinical trials are set by governments through domestic regulation.

For example, Health Canada, which has a national mandate to ensure the safety of all drugs sold in the country, requires minimum compliance with international standards for clinical research on new medicines but does not exclude stricter regulations as deemed necessary by the government of Canada (Health Canada, 2006). Further, because of the importance of the American and European markets throughout the world, the actual minimum time spent in drug development is determined by the clinical testing time necessary to satisfy the requirements of the FDA and the EMA.

3 It takes about an estimated 52.0 months between patented discovery to the start of human clinical trials and 72.1 months between the start of human clinical trials to new drug application for US FDA marketing approval (DiMasi et al., 2003).

Governmental delays affecting access to new medicines in Canada

It is clear that the development period for a new drug molecule, measured from its patented discovery to the first time an application is submitted for marketing approval anywhere in the world, is long and rigorous. From the Canadian perspective, this is not a delay that is likely to be affected meaningfully by Canadian governmental approval requirements, public policies, and institutional performance. Thus, the analysis of delays in access to new medicines below considers only the time between submission of a new medicine for approval and the granting of that approval in Canada, the United States, and Europe.

It is important to recognize that marketing approval for new medicines in Canada occurs at the national level and applies to all drugs sold in Canada. Thus, any delay caused by Health Canada's drug review process affects the wait time for access to new medicines for all Canadians, regardless of whether they are publicly insured, privately insured, or uninsured.

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 of Health Canada's Therapeutic Products Directorate or Biologics and Genetics Therapies Directorate following the completion of clinical testing. This approval period ends when Health Canada issues an official Notice of Compliance certifying that the new drug is considered by the government agency to be safe and effective. While the terminology for describing start and end dates varies, regulatory bodies in both Europe (EMA) and the United States (FDA) measure the same period of time for approval.

The discussion of approval times below examines publicly available data on delays for medicines approved in a given year. Differences in submission (new medicines are not necessarily submitted to the FDA, EMA, and Health Canada for approval at the same time or even in the same year⁴) are not considered here and are left for future research. Differences in the number and type of drugs approved in a given year are also not considered here.

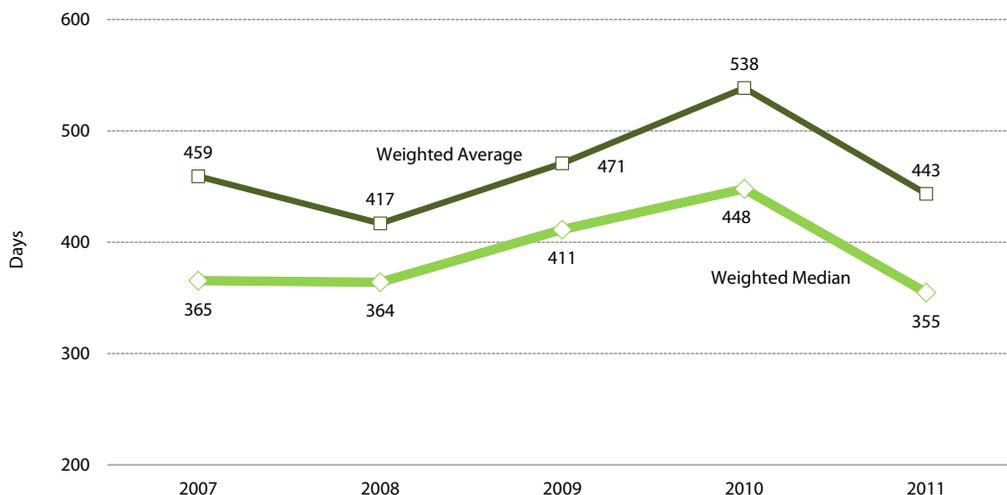
4 For example, if a medicine was submitted to the FDA or EMA before submission to Health Canada for approval, the true relative delay for access to that drug in Canada would be longer than suggested by the annual measures of delay discussed here. The reverse is true if submission to Health Canada took place before submission to the FDA or EMA.

Drug Approval Times

Drug approval times in Canada (2007-2011)

The most recent estimates calculated show that Health Canada took an average of 443 days to issue a notice of compliance for patented medicines in 2011 (figure 1). This is an improvement from the 538 days it took in 2010. Previous studies also indicate that this is a significant improvement over the 839-day wait for approval in 2004 (Rovere and Skinner, 2012).

Figure 1: Average and median delays (days) for Health Canada to grant regulatory and marketing approval for new drugs, 2007-2011



Source: Health Canada 2012; calculations by authors.

Note: These data are presented by fiscal year, and both the overall average delay and median delay are a weighted construct of biologic and pharmaceutical drug approval delays.

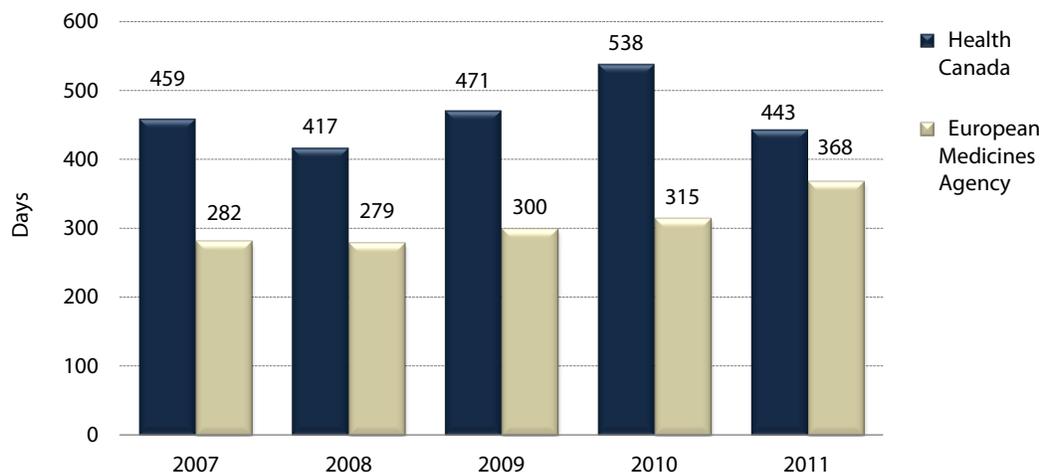
Drug approval times in Canada and the European Union from 2007 to 2011

As of 1999, responsibility for approving both pharmaceutical and biological medicines was centralized for all European Union countries in the European Medicines Agency (EMA).

Figure 2 indicates that on average, in all five years observed, Health Canada took longer to approve drugs than the EMA. In 2011, Health Canada took an average of 443 days to approve new drugs compared to the 368 days it took the EMA. The difference between the two approval times is, however, smaller than the previous year compared (2010) when Health Canada took an average 538 days to approve new drugs compared to the EMA which took 315 days.

When comparing weighted medians, figure 3 indicates that, in four of the five years compared, Health Canada took longer to approve drugs than the European Medicines Agency.

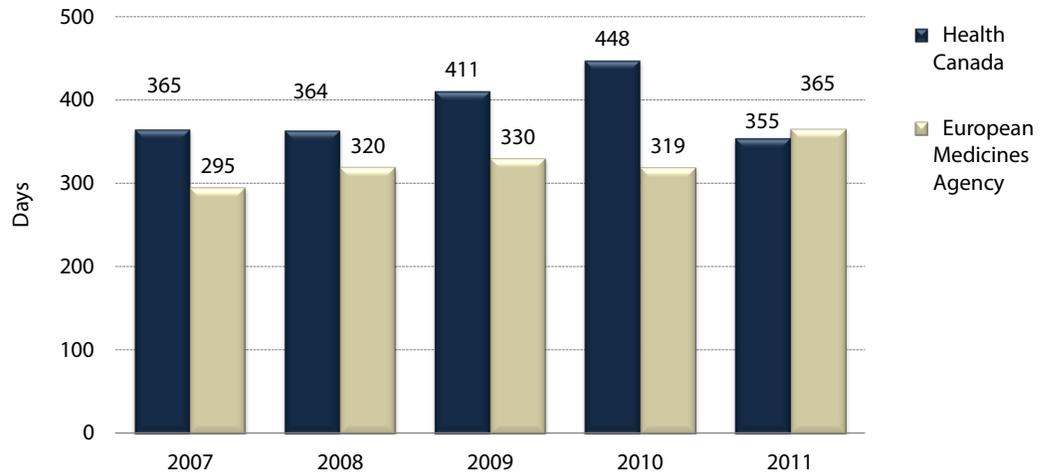
Figure 2: Average delay (in days) for regulatory and marketing approval for new drugs, Canada and the European Union, 2007-2011



Sources: Health Canada 2012; EMA 2008, 2009, 2010, 2011, 2012; calculations by authors.

Notes: EMA presents data by calendar year. EMA averages and medians were calculated directly by the authors using data for approval times for individual drugs. Health Canada data is presented by fiscal year, and both the overall average delay and median delay are a weighted construct of biological and pharmaceutical drug approval delays.

Figure 3: Median delay (in days) for regulatory and marketing approval for new drugs, Canada and the European Union, 2007-2011



Sources: Health Canada 2012; EMA 2008, 2009, 2010, 2011, 2012; calculations by authors.

Notes: EMA presents data by calendar year. EMA averages and medians were calculated directly by the authors using data for approval times for individual drugs. Health Canada data is presented by fiscal year, and both the overall average delay and median delay are a weighted construct of biological and pharmaceutical drug approval delays.

Drug approval times in Canada and the United States from 2007 to 2012

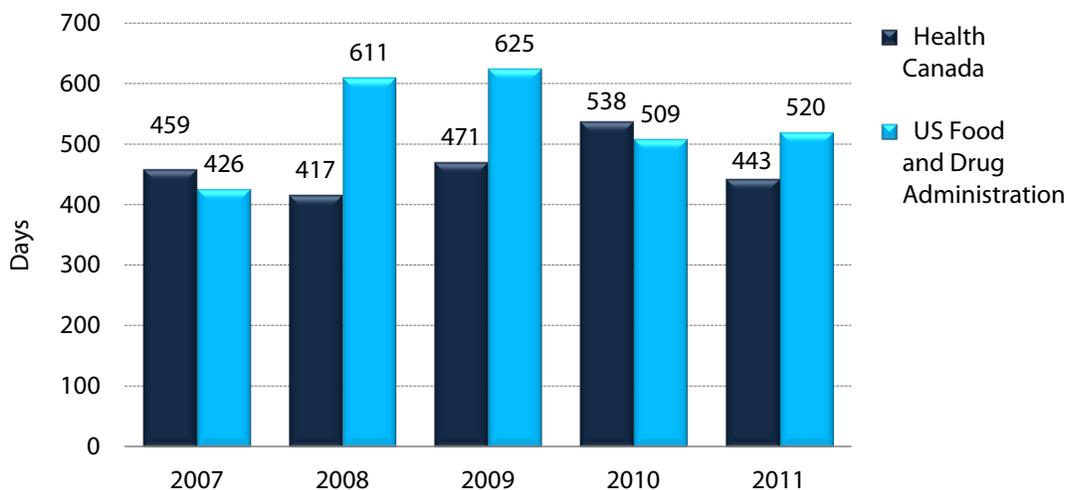
Since 2004, the authority equivalent to Health Canada to approve pharmaceutical and biological medicines in the United States has been the Center for Drug Evaluation and Research, which is part of the Food and Drug Administration (FDA).

Figure 4 shows that on average, Health Canada took longer than the FDA to approve drugs in two of the five years compared. In 2011, Health Canada took an average of 443 days to approve new drugs compared to the 520 days for FDA approval. This contrasts with 2010 when Health Canada took an average of 538 days to approve new drugs compared to 509 days for FDA approval.

When comparing median delays, however, a different story emerges. Figure 5 shows that Health Canada took longer to approve drugs than the FDA in four of the five years compared.

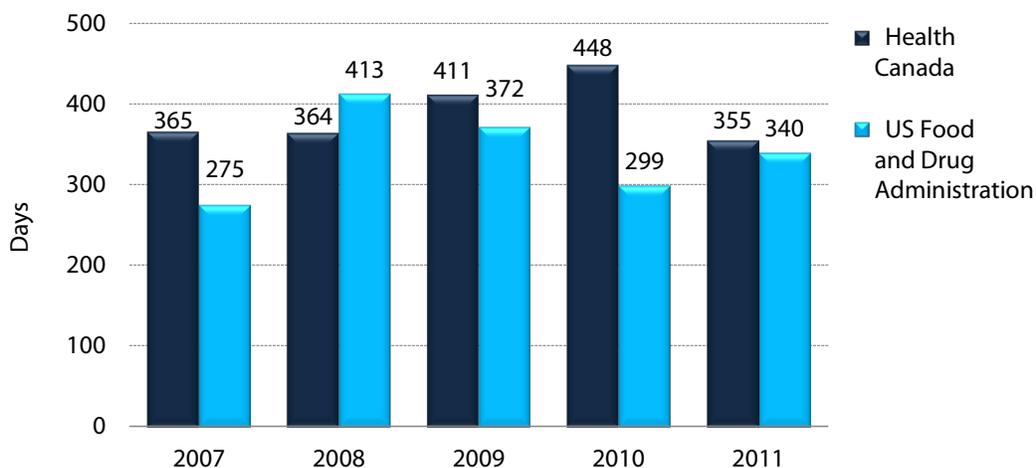
It is possible that this difference might be due to the fact that the FDA may be taking a very long time to approve a small number of drugs (increasing the average approval time), but approves the vast majority more expediently than Health Canada (suggested by a lower weighted median approval time). Unfortunately, the publicly available data used for this report is not detailed enough to confirm that hypothesis.

Figure 4: Average delay (in days) for regulatory and marketing approval for new drugs, Canada and the United States, 2007-2011



Sources: Health Canada 2012; FDA 2009, 2010, 2011, 2012a, 2013; calculations by authors
 Notes: FDA data are presented by fiscal year. Both the overall average delay and median delay are a weighted construct of priority and non-priority (standard) drug-submission status approval delays. Health Canada data are also presented by fiscal year, and both the overall average delay and median delay are a weighted construct of biological and pharmaceutical drug approval delays.

Figure 5: Median delay (in days) for regulatory and marketing approval for new drugs, Canada and the United States, 2007-2011



Sources: Health Canada 2012; FDA 2009, 2010, 2011, 2012a, 2013; calculations by authors.
 Notes: FDA data are presented by fiscal year. Both the overall average delay and median delay are a weighted construct of priority and non-priority (standard) drug-submission status approval delays. Health Canada data are also presented by fiscal year, and both the overall average delay and median delay are a weighted construct of biological and pharmaceutical drug approval delays.

Discussion

Clearly, Canadian approval delays are not insignificant. Between 2007 and 2011, Canadians could expect a delay of nearly a year or more for access to new medicines after submission for governmental approval. That delay was longer than experienced in Europe for most years during that period. It was also longer than experienced under the US FDA for between two and four of the five years studied.

An important question that arises from this comparison is the value of duplicating the application of safety standards between jurisdictions. Given the similarity of international safety standards and the relatively small size of the population served by Health Canada's mandatory approval process, Canada's federal government could improve access to new medicines through harmonization and mutual recognition. Specifically, FDA or EMA approval decisions could be accepted as equivalent to Health Canada decisions, thus reducing the cost of drug approvals in Canada (both for taxpayers and for drug manufacturers) while simultaneously reducing approval delays.

While this may seem controversial, it is a concept that has been explored in both Canadian and international discussions of drug approval. In an effort to reduce the time taken to review new medications, Canada's Smart Regulation strategy proposed a form of mutual recognition to reduce persistent delays in the drug-approval process (External Advisory Committee on Smart Regulation, 2004). Similar thinking was reflected in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).⁵ The intention of the conference was to establish international technical requirements and guidelines for increasing the efficiency of drug development by reducing unnecessary duplication (thus reducing costs), while also accelerating market approval so that new drug products were made available to patients as soon as possible (ICH, 2009).

Data sources and comparability issues

Three main data sources are cited in this report. Health Canada publishes data on pharmaceutical medicines through the Therapeutic Products Directorate (TPD) and on biologic and radiopharmaceutical 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.

5 Health Canada is an official observer to and active participant in the International Conference on Harmonisation (ICH). It is also currently in the process of moving to "adopt ICH guidances once routine administrative steps have been completed" (Health Canada, 2011).

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 and the issuing of the Notice of Compliance, inclusive of all company time spent to address any deficiencies in the manufacturer’s application.⁶

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, 2009, 2010, 2011, 2012a, 2013) and the European Medicines Agency (EMA, 2008, 2009, 2010, 2011, 2012). Health Canada and the FDA publish an entire approval delay that includes what they call “company” time, i.e., the time companies spend to correct the deficiencies in their applications. While the EMA does publish “company time” data separately, the authors included it in their estimations of total approval delay in order to make the data comparable.

The different ways in which these agencies publish data requires the use of different methods in order to calculate aggregated medians and averages.

For Health Canada, both the overall average delay and median delay are a weighted construct of biological and pharmaceutical drug approval delays. The following equation was used for this calculation:

$$\begin{aligned} \text{Weighted Average Delay} = & \\ & ((\text{Total NDS Count})_{\text{BGTD}} * (\text{Total NDS Average Delay})_{\text{BGTD}} + \\ & (\text{Total NDS Count})_{\text{TPD}} * (\text{Total NDS Average Delay})_{\text{TPD}}) / \\ & ((\text{Total NDS Count})_{\text{BGTD}} + (\text{Total NDS Count})_{\text{TPD}}) \end{aligned}$$

A similar formula was used to calculate the weighted median delay.

For the EMA, averages and medians were calculated directly using data for approval times for individual drugs (both biological and therapeutic) from the EMA.

For the FDA, the overall average delay and median delay are a weighted construct of priority and non-priority (standard) drug-submission status approval delays, as the FDA does not publish separate data for biological and therapeutic drug delays. The following equation was used for this calculation:

$$\begin{aligned} \text{Weighted Average Delay} = & \\ & ((\text{NDA and BLA Approvals})_{\text{Priority}} * (\text{NDA and BLA Average Delay})_{\text{Priority}} + \\ & (\text{NDA and BLA Approvals})_{\text{Standard}} * (\text{NDA and BLA Average Delay})_{\text{Standard}}) / \\ & ((\text{NDA and BLA Approvals})_{\text{Priority}} + (\text{NDA and BLA Approvals})_{\text{Standard}}) \end{aligned}$$

6 In a previous Fraser Institute publication, Rovere and Skinner (2012) note that it is unclear whether Health Canada records the filing of a new drug submission application on the actual date it was delivered or the date on which a reviewer first saw the file.

A similar formula was used to calculate the weighted median delay.

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 and the Biologics and Genetic Therapies Directorate. In Canada, non-generic new drug approvals involve new active substances, new drug submissions, and supplemental new drug submissions. The European Medicines Agency and the US Food and Drug Administration use similar classifications, but under different terminology. Tables 1, 2, and 3 briefly describe the Canadian and international classifications.

Table 1: Classes of New Drug Submissions used by Health Canada's Therapeutic Products Directorate and the Biologics and Genetic Therapies Directorate

New Active Substance

A New Active Substance (NAS) is a therapeutic substance that has never before been approved for marketing in any form. Specifically, this refers to submissions in support of a drug, excluding a disinfectant, that contain a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved ingredient such as a salt, ester, enantiomer, solvate or polymorph.

New Drug Submission

New Drug Submission (NDS) refers to any drug (including all NASs), 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

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, labeling, 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

An Abbreviated NDS is used for a generic product. The submission must meet the same quality standards as an NDS and the generic product must be shown to be as safe and efficacious as the (previously approved) brand-name product.

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, rather than the 300 days assigned to submissions classed as non-priority. 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) no product is currently marketed in Canada, or (b) the new product represents a significant increase in efficacy and/or significant decrease in risk such that the overall risk-benefit profile is better than that of existing therapies.

Source: Health Canada (2006).

Table 2: Classifications of New Drug Applications Used by the US FDA's Center for Drug Evaluation and Research

New Molecular Entity

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

New Drug Application

When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet the FDA's requirements for marketing approval, the sponsor submits to the 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. The US FDA's Center for Drug Evaluation and Research 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)

An Abbreviated New Drug Application contains data that provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug).

Biologic License Application

Biological products are approved for marketing under the provisions of the Public Health Service Act. The Act requires a firm that manufactures a biologic for sale in interstate commerce to hold a license for the product. A biologic 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.

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, has the potential to provide, in the treatment, prevention, or diagnosis of a disease, one of the following: (1) safe and effective therapy where no satisfactory alternative therapy exists; or (2) a significant improvement compared to marketed products, including nondrug products or therapies. 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.

Source: US FDA, 2012b, 2012c.

Table 3: Classifications of New Applications for Drug-market Authorization by the European Medicines Agency

New Active Substance

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 that 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 that 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 (c.f. 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.

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 (United States).

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.

Canada's Research-Based Pharmaceutical Companies (2005). *Rx&D 2005 NOC Survey: Results and Key Messages*. Canada's Research-Based Pharmaceutical Companies.

Danzon, P.M. (1993). Health Care Industry. *Concise Encyclopedia of Economics*, 1st ed. The Library of Economics and Liberty. <<http://www.econlib.org/library/Enc1/HealthCareIndustry.html>>, as of April 17, 2013.

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 [EMA] (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 [EMA] (2008). *Annual Report of the European Medicines Agency 2007*. European Medicines Agency. <http://www.emea.europa.eu/docs/en_GB/document_library/Annual_report/2009/12/WC500016591.pdf>, as of April 18, 2013.

European Medicines Agency [EMA] (2009). *Annual Report of the European Medicines Agency 2008*. European Medicines Agency (July 3).

<http://www.emea.europa.eu/docs/en_GB/document_library/Annual_report/2009/12/WC500016589.pdf>, as of April 17, 2013.

European Medicines Agency [EMA] (2010). *European Medicines Agency Annual Report 2009: Annexes*. European Medicines Agency. <http://www.emea.europa.eu/docs/en_GB/document_library/Annual_report/2010/05/WC500090710.pdf>, as of April 17, 2013.

European Medicines Agency [EMA] (2011). *European Medicines Agency Annual Report 2010: Annexes*. European Medicines Agency. <http://www.emea.europa.eu/docs/en_GB/document_library/Annual_report/2011/06/WC500108076.pdf>, as of April 17, 2013.

European Medicines Agency [EMA] (2012). *European Medicines Agency Annual Report 2011: Annexes*. European Medicines Agency. <http://www.emea.europa.eu/docs/en_GB/document_library/Annual_report/2012/06/WC500128161.pdf>, as of April 17, 2013.

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>>, as of April 17, 2013.

Government of Canada. *Food and Drugs Act (R.S.C. 1985, c. F-27)*. Minister of Justice, Government of Canada. last updated October 25, 2012. <<http://laws-lois.justice.gc.ca/eng/acts/F-27/>>, as of April 18, 2013.

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 (2006). *Access to Therapeutic Products: The Regulatory Process in Canada*. Government of Canada. <http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique-eng.php>, as of April 17, 2013.

Health Canada (2011). *Drugs and Health Products: ICH*. Web page. Government of Canada. <<http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/guide-ld/ich/index-eng.php>>, as of April 17, 2013.

Health Canada, Health Products and Food Branch (2012). *2011 Annual Drug Submission Performance Report: Part I Therapeutic Products Directorate (TPD); Part II Biologics and Genetic Therapies Directorate (BGTD)*. Government of Canada.

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use [ICH] (2009). *History and Future of ICH*.

Rovere, Mark and Brett J. Skinner (2012). *Access Delayed, Access Denied: Waiting for New Medicines in Canada, 2011 Report*. Fraser Institute.

US Food and Drug Administration [FDA] (2009). *Justification of Estimates for Appropriations Committees. Fiscal Year 2009. Narratives by Activity. Human Drugs*. US Department of Health and Human Services.

US Food and Drug Administration [FDA] (2010). *Justification of Estimates for Appropriations Committees. Fiscal Year 2010. Narratives by Activity. Human Drugs*. Department of Health and Human Services. US Department of Health and Human Services.

US Food and Drug Administration [FDA] (2011). *Justification of Estimates for Appropriations Committees. Fiscal Year 2011. Narratives by Activity. Human Drugs*. Department of Health and Human Services. US Department of Health and Human Services.

US Food and Drug Administration [FDA] (2012a). *Justification of Estimates for Appropriations Committees. Fiscal Year 2012. Narratives by Activity. Human Drugs*. Department of Health and Human Services. US Department of Health and Human Services.

US Food and Drug Administration [FDA] (2012b). *Manual of Policies and Procedures: Center for Drug Evaluation and Research*. US Department of Health and Human Services. <<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/ucm082000.pdf>>, as of April 17, 2013.

US Food and Drug Administration [FDA] (2012c). *Drugs@FDA Glossary of Terms*. US Department of Health and Human Services. <<http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>>, as of April 17, 2013.

US Food and Drug Administration [FDA] (2013). Justification of Estimates for Appropriations Committees. Fiscal Year 2013. Narratives by Activity. Human Drugs. Department of Health and Human Services. US Department of Health and Human Services.

World Medical Association [WMA] (1964). *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. World Medical Association.

About the authors

Bacchus Barua is a Senior Economist in the Fraser Institute's Centre for Health Policy Studies. He completed his BA (Honours) in Economics at the University of Delhi (Ramjas College) and received an MA in Economics from Simon Fraser University. Bacchus is the author of the *Provincial Healthcare Index* (2013) and *Why We Wait: Physician Opinions on Factors Affecting Health Care Wait Times*; as well as the lead author of *Hospital Report Card: British Columbia* (2011) and *Waiting Your Turn: Wait Times for Healthcare in Canada* (2010–2012).

Nadeem Esmail is Director of Health Policy Studies at the Fraser Institute. He completed his BA (Honours) in Economics at the University of Calgary and received an MA in Economics from the University of British Columbia. Nadeem has authored or co-authored more than 30 comprehensive studies and more than 150 articles on a wide range of health care topics including waiting lists, international comparisons of health care systems, hospital report cards, medical technology, and the physician shortage. His articles have appeared in newspapers across North America including the *National Post*, *Globe and Mail*, *National Review Online*, and *Wall Street Journal*. He has also spoken nationally and internationally on health care policy and reform.

Acknowledgments

This study draws extensively on the Fraser Institute's *Access Delayed, Access Denied* series of publications, and the authors would like to acknowledge the important contributions of Fraser Institute researchers Brett Skinner and Mark Rovere in constructing the methodological framework upon which this report is based.

We would also like to thank all those involved in the production and release of this edition of the report. The authors, of course, take full and complete responsibility for any remaining errors or omissions. As they have worked independently, the views expressed in this study do not necessarily represent the views of the trustees, supporters, or other staff of the Fraser Institute.

Publishing information

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® X, 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 Fraser Institute's printed publications, 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

Media

For media inquiries, please contact our Communications Department:

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

Copyright

Copyright © 2013 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.

Disclaimer

The authors of this publication have worked independently and opinions expressed by them are, therefore, their 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.

Date of issue

April 2013

Citation

Barua, Bacchus, and Nadeem Esmail (2013). *Federal Delays in Approving New Medicines, 2013*. Studies in Health Policy. Fraser Institute.

ISSN

I1918-2082 (print version); 1918-2090 (online version) Studies in Health Policy

Editing and production

Kristin McCahon

Design

Lindsey Thomas Martin

Cover design

Bill Ray

Cover images

Test Tubes in Science Research Lab © Olivier, Bigstock

Supporting the Fraser Institute

To learn how to support the Fraser Institute, please contact

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

Lifetime Patrons

For their long-standing and valuable support contributing to the success of the Fraser Institute, the following people have been recognized and inducted as Lifetime Patrons of the Fraser Institute.

Sonja Bata

Charles Barlow

Ev Berg

Art Grunder

Jim Chaplin

Serge Darkazanli

John Dobson

Raymond Heung

Bill Korol

Bill Mackness

Fred Mannix

Jack Pirie

Con Riley

Catherine Windels

Purpose, funding, and independence

The Fraser Institute provides a useful public service. We report objective information about the economic and social effects of current public policies, and we offer evidence-based research and education about policy options that can improve the quality of life.

The Institute is a non-profit organization. Our activities are funded by charitable donations, unrestricted grants, ticket sales and sponsorships from events, the licensing of products for public distribution, and the sale of publications.

All research is subject to rigorous review by external experts, and is conducted and published separately from the Institute's Board of Trustees and its donors.

The opinions expressed by staff or author(s) are those of the individuals themselves, and should not be interpreted to reflect those of the Institute, its Board of Trustees, or its donors and supporters.

As a healthy part of public discussion among fellow citizens who desire to improve the lives of people through better public policy, the Institute welcomes evidence-focused scrutiny of the research we publish, including verification of data sources, replication of analytical methods, and intelligent debate about the practical effects of policy recommendations.

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 Canadian research and educational organization with locations throughout North America and international partners in over 85 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.

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.

Peer review

Validating the accuracy of our research

The Fraser Institute maintains a rigorous peer review process for its research. New research, major research projects, and substantively modified research conducted by the Fraser Institute are reviewed by experts with a recognized expertise in the topic area being addressed. Whenever possible, external review is a blind process. Updates to previously reviewed research or new editions of previously reviewed research are not reviewed unless the update includes substantive or material changes in the methodology.

The review process is overseen by the directors of the Institute's research departments who are responsible for ensuring all research published by the Institute passes through the appropriate peer review. If a dispute about the recommendations of the reviewers should arise during the Institute's peer review process, the Institute has an Editorial Advisory Board, a panel of scholars from Canada, the United States, and Europe to whom it can turn for help in resolving the dispute.

Editorial Advisory Board

Professor Terry L. Anderson

Professor Robert Barro

Professor Michael Bliss

Professor Jean-Pierre Centi

Professor John Chant

Professor Bev Dahlby

Professor Erwin Diewert

Professor Stephen Easton

Professor J.C. Herbert Emery

Professor Jack L. Granatstein

Professor Herbert G. Grubel

Professor James Gwartney

Professor Ronald W. Jones

Dr. Jerry Jordan

Professor Ross McKittrick

Professor Michael Parkin

Professor Friedrich Schneider

Professor Lawrence B. Smith

Dr. Vito Tanzi

Past members

Professor Armen Alchian*

Professor James M. Buchanan*†

Professor Friedrich A. Hayek*†

Professor H.G. Johnson*

Professor F.G. Pennance*

Professor George Stigler*†

Professor Edwin G. West*

Sir Alan Walters*

* Deceased

† Nobel Laureate