Health Canada Santé Canada

October 11, 2013

Notice

Our file number: 13-115492-47

Release of the Therapeutic Products Directorate Statistical Report 2012/2013 for the *Patented Medicines (Notice of Compliance) Regulations* and Data Protection

Health Canada is pleased to announce the release of the Therapeutic Products Directorate Statistical Report 2012/2013 for the *Patented Medicines (Notice of Compliance) Regulations* and Data Protection. This report provides a statistical overview of Health Canada's administration of the *Patented Medicines (Notice of Compliance) Regulations*, and data protection under section C.08.004.1 of the *Food and Drug Regulations*.

As in previous reports, this report includes information regarding trends in the eligibility of patents for listing on the Patent Register, the eligibility of drugs for listing on the Register of Innovative Drugs, and related court activity, which has been presented using data in a fiscal year format (April 1st to March 31st).

Any concerns or questions regarding the contents of the report should be directed to:

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Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Health Canada
101 Tunney's Pasture Driveway
Postal Locator: 0201A1
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Canada

Therapeutic Products Directorate Statistical Report 2012 / 2013

Patented Medicines (Notice of Compliance) Regulations
And Data Protection
(C.08.004.1 of the *Food and Drug Regulations)*

Office of Patented Medicines and Liaison




2013-09-17

Canada

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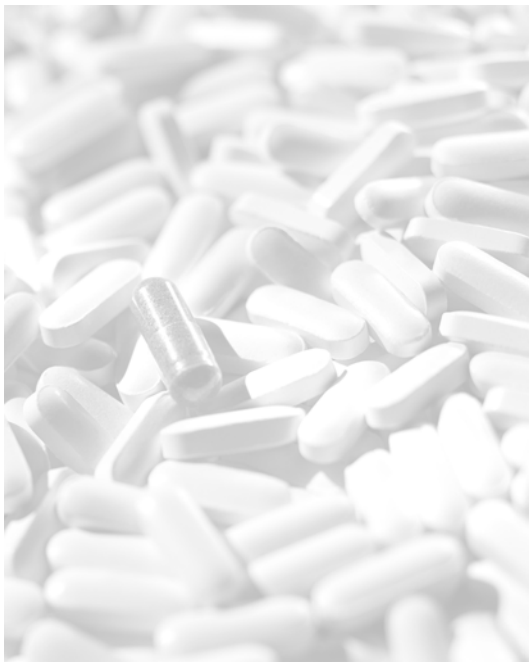


Section I
Overview

Overview

This document provides a statistical overview relating to the administration of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 as amended, and the data protection provisions of the *Food and Drug Regulations*, C.R.C., c.870 as amended by S.O.R./2006-241. The two sets of regulations are intended to act as a balanced set of measures, designed to work together to stabilize Canada's intellectual property protection for drugs by ensuring a minimum period of protection and maintaining a reasonable ceiling on the maximum protection available.

A. *Patented Medicines (Notice of Compliance) Regulations*

The *Patented Medicines (Notice of Compliance) Regulations* fall under the authority of the *Patent Act* which is within the mandate of Industry Canada. However, they are administered by the Office of Patented Medicines and Liaison (OPML), Office of Submissions and Intellectual Property (OSIP), Therapeutic Products Directorate, Health Products and Food Branch, Health Canada. The *Patented Medicines (Notice of Compliance) Regulations* came into force in March 1993 and were subsequently amended in 1998, 1999, 2006, 2008, 2010 and 2011.

According to the Regulatory Impact Analysis Statement published in Canada Gazette, Part II on October 18, 2006, the *Patented Medicines (Notice of Compliance) Regulations* help to balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors. On one end of the balance lies subsection 55.2(1) of the *Patent Act*, known as the "early-working" exception. Early-working allows a subsequent entry (typically generic) drug manufacturer to use a patented, innovative drug for the purpose of seeking regulatory approval to market a competing version of that drug. The *Patented Medicines (Notice of Compliance) Regulations* represent the other half of the balance by linking Health Canada's ability to approve a generic drug to the patent status of the equivalent innovative drug that the generic drug manufacturer seeks to copy. As such, a drug manufacturer that makes a direct or indirect comparison with, or reference to, an innovative drug in respect of which there are patents listed on the Patent Register, must either agree to await patent expiry before obtaining market authorization or make an allegation justifying immediate market entry that is either accepted by the innovator or upheld by the court.

Under the *Patented Medicines (Notice of Compliance) Regulations*, the OPML maintains a Patent Register that consists of patent lists submitted by drug manufacturers in respect of drugs for which market authorization has issued in the form of a Notice of Compliance. Each patent list is audited by the OPML in order to determine its eligibility under the *Patented Medicines (Notice of Compliance) Regulations*. As such, on behalf of the Minister of Health, the OPML may refuse to add or may delete any patent that does not meet the eligibility requirements. A web-accessible version of the Patent Register is found on the Health Canada website.

In addition, the OPML ensures that patents listed on the Patent Register are addressed under the *Patented Medicines (Notice of Compliance) Regulations*. Detailed information on the administration of the *Patented Medicines (Notice of Compliance) Regulations* can be found in the guidance document: *Patented Medicines (Notice of Compliance) Regulations*.

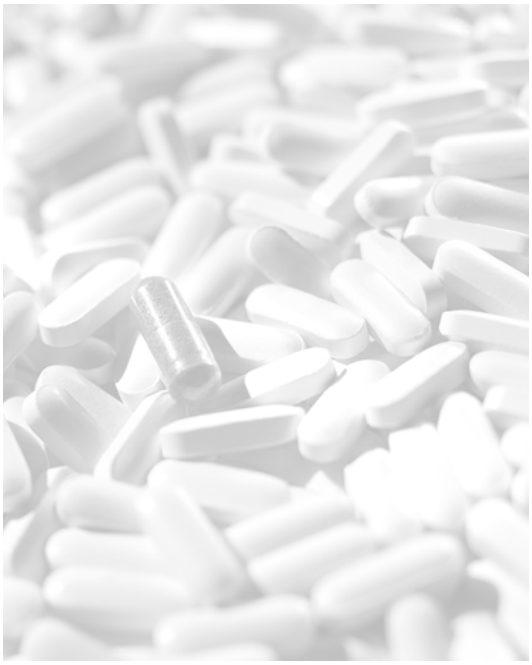
B. Data Protection

Amendments to the data protection provisions in section C.08.004.1 of the *Food and Drug Regulations* were brought into force on October 5, 2006 in order to clarify and effectively implement Canada's obligations under the *North American Free Trade Agreement* and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* with respect to the protection of undisclosed tests or other data necessary to determine the safety

and effectiveness of a pharmaceutical product which utilizes a new chemical entity. In keeping with those obligations, innovative drugs are provided with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. An additional six-month period is available for innovative drugs that have been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the use of the drug in pediatric populations.

The data protection provisions are administered by the OPML. Innovative drugs that are eligible for data protection are listed on the Register of Innovative Drugs (RID) after the issuance of the Notice of Compliance.

Detailed information on the administration of data protection is available in the guidance document: Data Protection under C.08.004.1 of the *Food and Drug Regulations*.



Section II
Statistics: Patent Register and *Patented Medicines (Notice of Compliance) Regulations*

Number of Patent Lists Submitted for Listing on the Patent Register

Number of Patent Lists Received

The information on this page is generated from the electronic Patent Register database. This table shows the total number of patent lists received in each fiscal year.

Table – Number of Patent Lists Received

Fiscal Year	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013
Number of patent lists received (during the fiscal year)	615	775	584	562	674

Number of Patent Lists Added to the Patent Register

This table shows the total number of patent lists added to the Patent Register in each fiscal year. Note that listings do not necessarily represent new patents being added to the Patent Register for the first time. Some listings represent patents already listed on the Patent Register - for previously approved drug submissions - which have been added again in relation to a different supplement to a new drug submission. Also, patent lists may have been received in one fiscal year but not added to the Patent Register until the following fiscal year.

Table – Number of Patent Lists Added to the Patent Register

Fiscal Year	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013
Number of patent lists added to the Patent Register (during the fiscal year)	516	412	394	360	400
Patents not previously listed (New Drug Submission)	69	82	101	118	104
Patents not previously listed (Supplemental New Drug Submission)	140	97	89	108	75

Number of Patent Lists Rejected for Listing on the Patent Register

This table shows the number of rejected patent lists which includes patents rejected for all submissions, and not only the number of distinct patents rejected.

Table - Number of Patent Lists Rejected for Listing on the Patent Register

Fiscal Year	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013
New Drug Submission (section 4(2))	30	47	25	25	25
Supplement to a New Drug Submission (section 4(3) and section 4.1(2))	90	78	34	72	39
Timing (sections 4(5) and 4(6))	7	39	44	11	8
Other	17	17	5	8	4
Total	**144**	**181**	**108**	**116**	**76**

A Snapshot of the Patent Register as of March 31, 2013: Number of Patents Per Drug Identification Number (DIN) on the Patent Register

This graph and table represent the number of patents that a second person is required to address when seeking a Notice of Compliance for a patented medicine. As of March 31, 2013 there were 1385 DINs listed on the Patent Register, representing 523 different drugs. The total number of patents listed on the Patent Register is 944 and they are distributed per DIN. For example, there are 694 DINs which only have one patent listed against them; on the other hand, there are eight DINs which have 20 patents listed against them. This data is product-specific, as each DIN is specific to a particular strength, route, and dosage form of a medicinal ingredient. Patents may apply to more than one DIN (for example, more than one strength, route, and dosage form of a medicinal ingredient). The numbers in the above graph do not include patents which have been removed from the Patent Register nor do they include patents which have expired prior to the generation of this report.

A Snapshot of the Patent Register as of March 31, 2013:
Number of Patents per Drug Identification Number (DIN) on the Patent Register

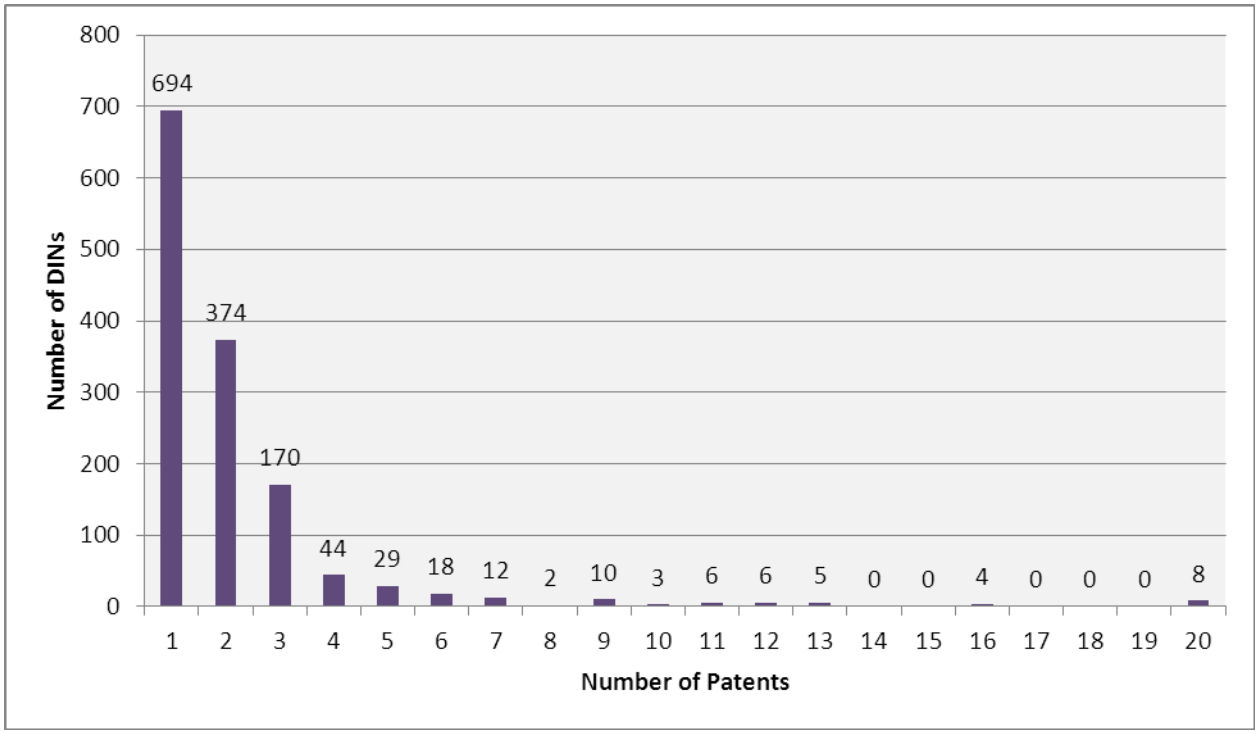


Table - Number of Patents per Drug Identification Number (DIN) on the Patent Register

Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Number of DINs	694	374	170	44	29	18	12	2	10	3	6	6	5	0	0	4	0	0	0	8

A Snapshot of the Patent Register as of March 31, 2013: Number of Patents Per Drug on the Patent Register

There are currently 523 different drugs listed on the Patent Register. The total number of different patents listed on the Patent Register is 944, and they are distributed per drug. For example, there are 242 drugs which only have one patent listed against them; on the other hand, there is one drug which has 20 patents listed against it. The numbers in the graph do not include patents which have been removed from the Patent Register nor do they include patents which have expired prior to the generation of this report.

The Patent Register is divided according to DIN in a product-specific manner. As this graph is produced by drug, some products have multiple strengths, routes, and dosage forms listed on the Patent Register while others do not.

A Snapshot of the Patent Register as of March 31, 2013:
Number of Patents per Drug on the Patent Register

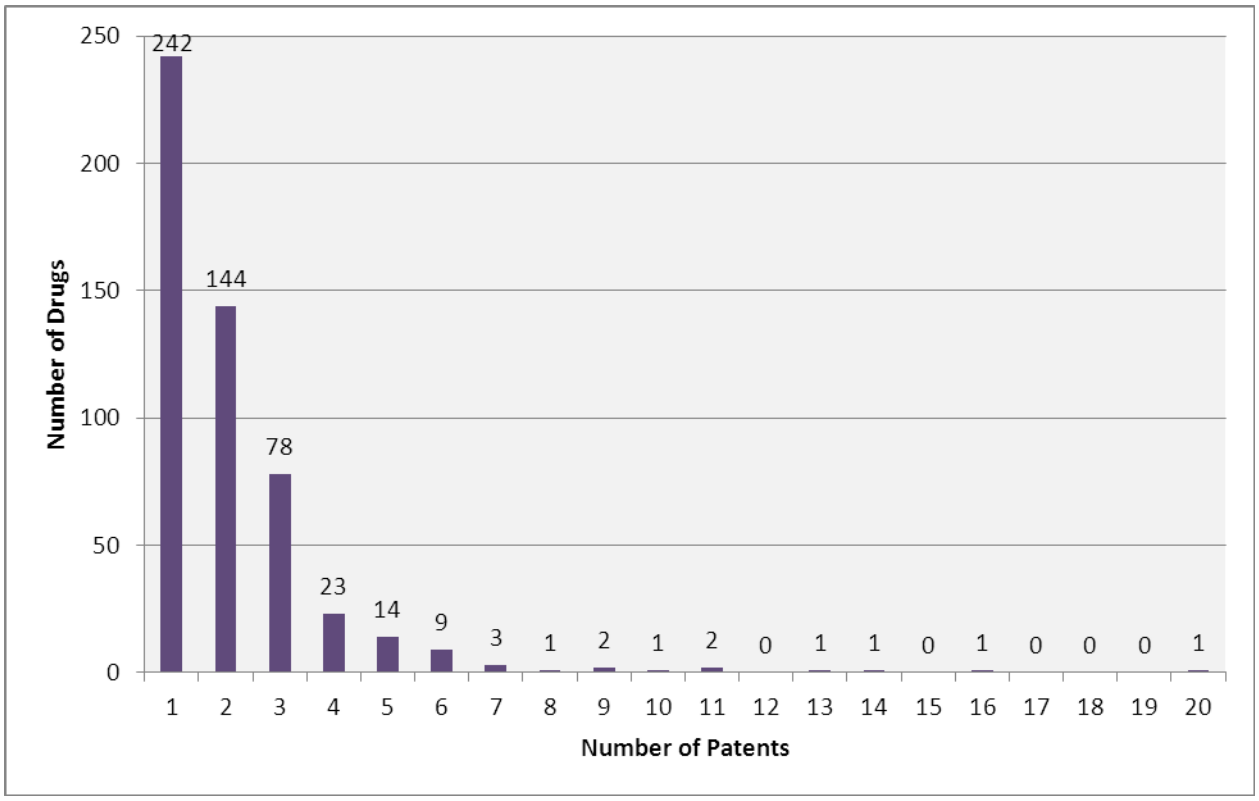


Table - Number of Patents Per Drug on the Patent Register

Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Number of Drugs	242	144	78	23	14	9	3	1	2	1	2	0	1	1	0	1	0	0	0	1

Judicial Review Applications Concerning Patent Eligibility: Sections 3 and 4 of the *Patented Medicines (Notice of Compliance) Regulations*

This table lists judicial review applications started between January 1, 2012 and March 31, 2013 and changes which took place to ongoing cases during that time period. The applications were filed pursuant to section 18.1 of the *Federal Courts Act* with respect to decisions concerning the eligibility of patents for listing on the Patent Register under sections 3 and 4 of the *Patented Medicines (Notice of Compliance) Regulations*. New cases and changes to open cases which occurred during this time period are presented in bold.

Table - Judicial Review Applications Concerning Patent Eligibility: Sections 3 and 4 of the *Patented Medicines (Notice of Compliance) Regulations*

Federal Court/ Federal Court of Appeal/Supreme Court of Canada	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-235-11 **(dismissed)** **A-44-12** **(dismissed)** **35123** **(dismissed)**	Gilead Sciences Canada, Inc. – and – The Minister of Health and The Attorney General of Canada	tenofovir disoproxil fumarate/ emtricitabine/ rilpivrine	2011-02-11 **2012-02-01** **2012-12-07**	**2012-01-03** **2012-10-09** **2013-03-21**	Listing eligibility of patent 2,512,475, entitled "Compositions and Methods for Combination Antiviral Therapy", under section 4(2)
T-1071-11 (on-going)	Eli Lilly Canada Inc. – and – Attorney General of Canada and Minister of Health	spinosad/ milbemycin oxime	2011-06-29		Listing eligibility of patent 2,379,329, entitled "Oral Treatment of Companion Animals with Ectoparasiticidal Spinosyns", under section 4(2)
T-1574-11 **(discontinued)**	Hoffmann-La Roche Limited – and – Attorney General of Canada and Minister of Health	tenecteplase	2011-09-23	**2012-02-22**	Listing eligibility of patent 1,341,609, entitled "Novel Human Tissue-Type Plasminogen Activator Variant", under section 4(2)
T-1679-11 **(dismissed)**	Novartis Pharmaceuticals Canada Inc. – and – Attorney General of Canada and Minister of Health	tobramycin	2011-10-14	**2012-06-29**	Listing eligibility of patent 2,304,819, entitled "Perforated Microparticles and Methods of Use", under section 4(2)
T-1854-11 **(discontinued)**	Novartis Pharmaceuticals Canada Inc. – and – Attorney General of Canada and Minister of Health	drug X	2011-11-14	**2012-02-21**	Listing eligibility of a patent under section 4(2)
T-920-12 **(discontinued)**	**Amgen Canada Inc. - and - The Minister of Health**	**cinacalcet hydrochloride**	**2012-05-10**	**2012-06-12**	**Listing eligibility of patent 2,536,487, entitled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound", under section 4(3)**

Judicial Review Applications Concerning Section 5 of the *Patented Medicines (Notice of Compliance) Regulations*

This table lists judicial review applications started between January 1, 2012 and March 31, 2013 and changes which took place to ongoing cases during that time period. The applications were filed pursuant to section 18.1 of the *Federal Courts Act* with respect to decisions concerning section 5 of the *Patented Medicines (Notice of Compliance) Regulations*. New cases and changes to open cases which occurred during this time period are presented in bold.

Table - Judicial Review Applications Concerning Section 5 of the *Patented Medicines (Notice of Compliance) Regulations*

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-818-12 (discontinued)	**Actelion Pharmaceuticals Canada Inc. –and- Pharmascience Inc., Attorney General of Canada and The Minister of Health**	**bosentan monohydrate**	**2012-04-23**	**2012-05-30**	**Ability of second persons to amend Form Vs**
T-1332-12 (ongoing)	**Actelion Pharmaceuticals Canada Inc. –and- The Attorney General of Canada and The Minister of Health**	**bosentan monohydrate**	**2012-07-04**		**Challenge to guidance document "*Patented Medicines (Notice of Compliance) Regulations*" regarding administrative cross-referenced submission"**

Judicial Review Applications Concerning the *Patented Medicines (Notice of Compliance) Regulations* – Other

This table lists judicial review applications started between January 1, 2012 and March 31, 2013 and changes which took place to ongoing cases during that time period. The applications were filed pursuant to section 18.1 of the *Federal Courts Act* with respect to decisions concerning procedure and other matters under the *Patented Medicines (Notice of Compliance) Regulations*. New cases and changes to open cases which occurred during this time period are presented in bold.

Table - Judicial Review Applications Concerning the *Patented Medicines (Notice of Compliance) Regulations* - Other

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-1372-10 (dismissed) A-452-11 **(dismissed)**	Apotex Inc. -and- The Minister of Health and The Attorney General of Canada	omeprazole magnesium	2010-08-26 2011-11-28	2011-11-23 **2012-12-07**	Rights in respect of submissions on patent hold
T-2042-12 (discontinued)	**Apotex Inc. –and- Minister of Health and Attorney General of Canada**	**sildenafil**	**2012-11-09**	**2012-11-21**	**Refusal to issue a Notice of Compliance**

Prohibition Applications concerning section 6 of the *Patented Medicines (Notice of Compliance) Regulations* – Summary as of March 31, 2013

The first table shows the number of submissions received with Form Vs during a specific fiscal year and the number of Notices of Allegation received as of March 31, 2013.

The second table summarizes the outcome of applications for orders of prohibition filed in the Federal Court pursuant to Section 6 of the *Patented Medicines (Notice of Compliance) Regulations* (commonly referred to as prohibition applications), beginning with the number of court applications commenced by first persons. The break-down of subsequent appeals for each possible application conclusion - granted, dismissed, partially granted - is also included. The court applications commenced are the result of the Notices of Allegation made by second persons in respect of first persons' patents. The start date of the application determines the year in which the outcome is reported.

Table - Prohibition Applications concerning section 6 of the *Patented Medicines (Notice of Compliance) Regulations* - Summary as of March 31, 2011

Fiscal Year	2008/2009	2009/2010	2010/2011	2011/2012	2012/2013
Submissions received with Form V	157	168	159	165	164
Notices of Allegation received	153	221	197	141	109

Table - Prohibition Applications concerning section 6 of the *Patented Medicines (Notice of Compliance) Regulations* - Summary as of March 31, 2011

Fiscal Year			2008/2009	2009/2010	2010/2011	2011/2012	2012/2013
Prohibition applications commenced			61	67	60	57	82
Prohibition applications discontinued			41	52	43	24	19
Prohibition applications granted			10	9	6	10	1
	Appeals Filed		2	4	3	2	
		Discontinued	1	2			
		Granted	1				
		Dismissed		2	1		
		Pending			2	2	
Prohibition applications dismissed			10	4	7	2	0
	Appeals Filed		4	0	2	0	
		Discontinued	3				
		Granted					
		Dismissed	1		2		
		Pending					
Prohibition applications partially granted			0	2	3	4	0
	Appeals Filed		0	0	1	2	
		Discontinued					
		Granted					
		Dismissed					
		Pending			1	2	
Prohibition applications pending resolution			0	0	1	17	62

Average Time to Resolution of Prohibition Applications under the *Patented Medicines (Notice of Compliance) Regulations*

This table represents information regarding court cases filed pursuant to Section 6 of the *Patented Medicines (Notice of Compliance) Regulations*. The start date of the application determines the year in which it will be included. Average time to resolution is calculated from the start date to the close date of the application in the Federal Court (appeals not included). The 24-month period is prescribed by paragraph 7(1)(e) of the *Patented Medicines (Notice of Compliance) Regulations.* Pursuant to subsection 7(5), the court may make an order to vary the length of the 24-month stay.

Table - Average Time to Resolution of Prohibition Applications under the *Patented Medicines (Notice of Compliance) Regulations*

Fiscal Year	Number of cases per fiscal year	Number of cases closed[1]	Average resolution time[1] (months)	Range[1] (months)
2008/2009	61	20	17.3	5.1 – 31.8
2009/2010	67	15	15.1	0.9 - 26
2010/2011	60	16	14.4	3.2 – 27.1
2011/2012	57	16	12.7	4.6 - 22
2012/2013	82	1	7.1	7.1

1 These numbers do not include cases which have been discontinued by the Applicant.

Prohibition Applications Exceeding a 24-Month Resolution Timeframe

This graph and table represent the number of closed applications per year which were resolved within 24 months and the number of closed applications which exceeded 24 months to resolve. The numbers do not include cases which were discontinued.

Closed Prohibition Applications

Table – Closed Prohibition Applications

Fiscal Year	2008/2009	2009/2010	2010/2011	2011/2012	2012/2013
Closed within 24 months	15	14	15	16	1
Closed applications which exceeded 24 months to resolve (out of time)	5	1	1	0	0
Total number of applications closed	20	15	16	16	1

Prohibition and Judicial Review Applications Initiated Per Fiscal Year

This graph and table compare the number of applications for judicial review of the Minister's decisions concerning sections 3, 4, and 5 with the number of applications for orders of prohibition with respect to section 6 of the *Patented Medicines (Notice of Compliance) Regulations.*

Prohibition and Judicial Review Applications Initiated Per Fiscal Year

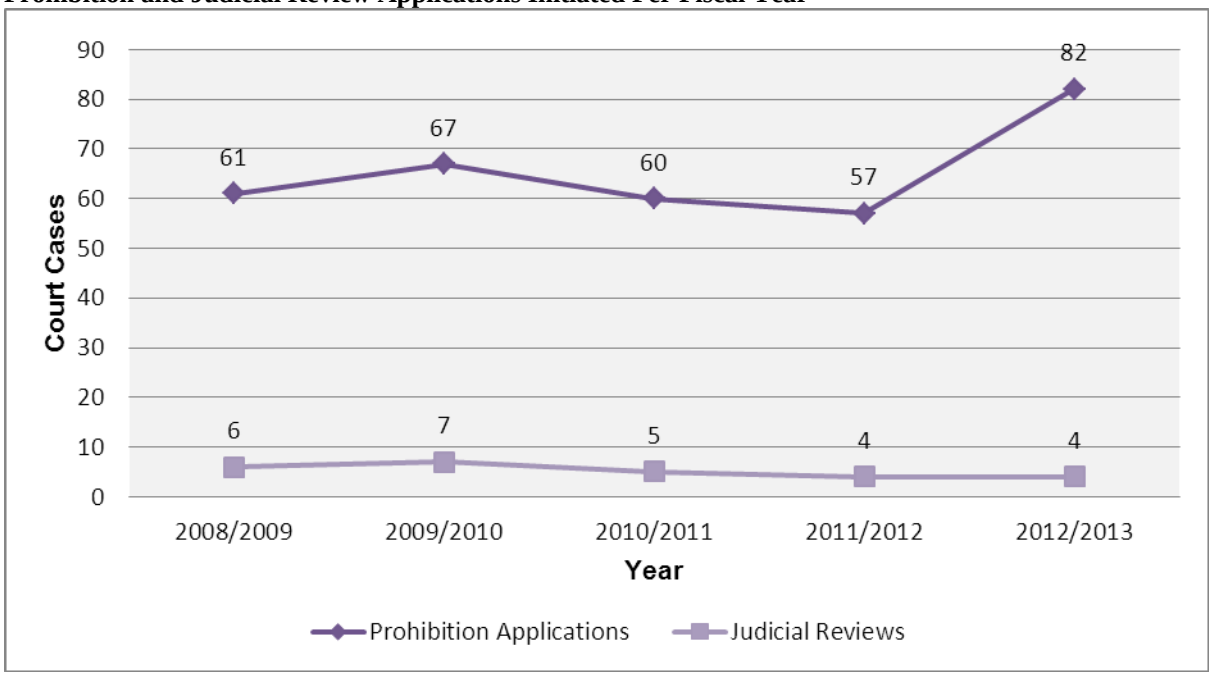


Table - Prohibition and Judicial Review Applications Initiated Per Year

Fiscal Year	2008/2009	2009/2010	2010/2011	2011/2012	2012/2013
Prohibition Applications	61	67	60	57	82
Judicial Reviews	6	7	5	4	4

Submissions on Intellectual Property (IP) Hold

The first graph and table show the number of submissions that previously had been on IP hold and are now cleared by the year in which they received their Notice of Compliance. The second graph and table show the average time, in days, that these submissions spent on IP hold.

Number of Submissions Previously on IP Hold by Notice of Compliance Date

Table – Number of Submissions Previously on IP Hold by Notice of Compliance Date

Fiscal Year	2008/2009	2009/2010	2010/2011	2011/2012	2012/2013
Number of Submissions	89	149	150	188	132

Average Number of Days on IP Hold by Fiscal Year in which Notice of Compliance was issued

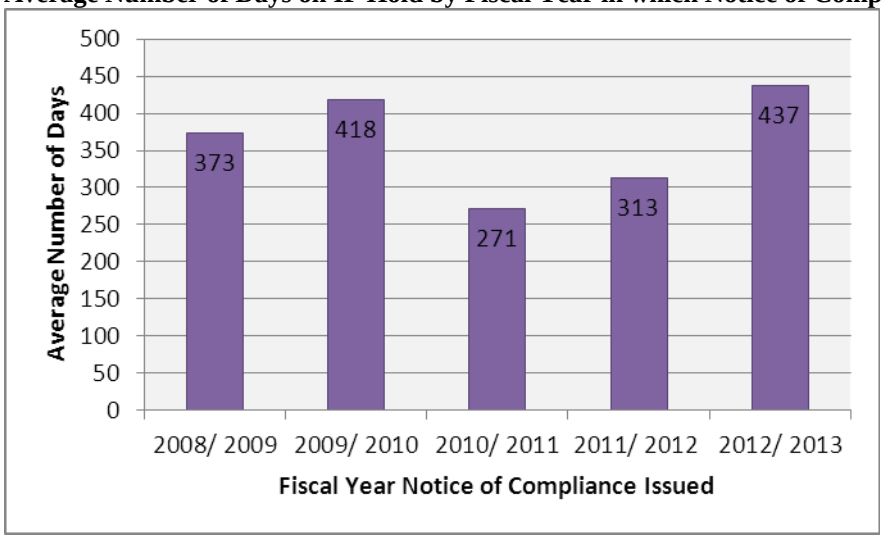


Table - Average Number of Days on IP Hold by Fiscal Year in which Notice of Compliance was issued

Fiscal Year	2008/2009	2009/2010	2010/2011	2011/2012	2012/2013
Number of Days	373	418	271	313	437

Submissions Still on IP Hold

This graph and table show the number of submissions by year filed which were still on IP hold as of March 31, 2013.

Submissions Still on IP Hold by Fiscal Year Filed

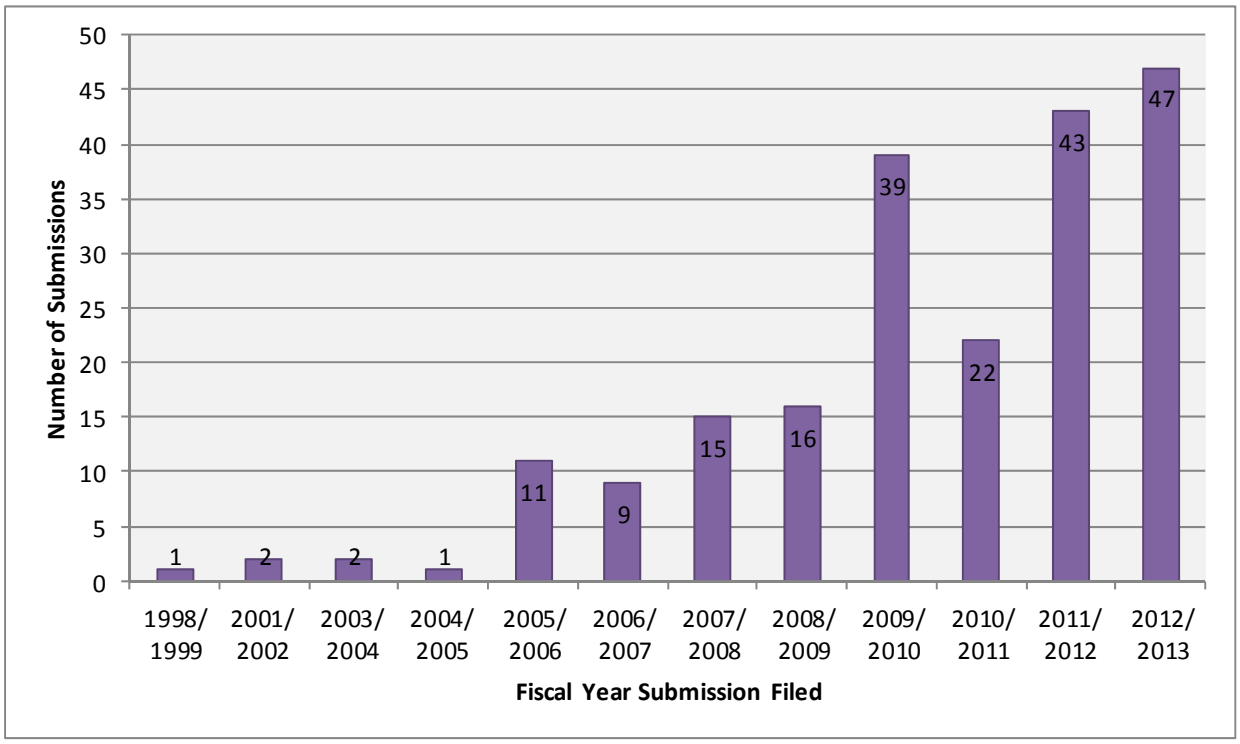
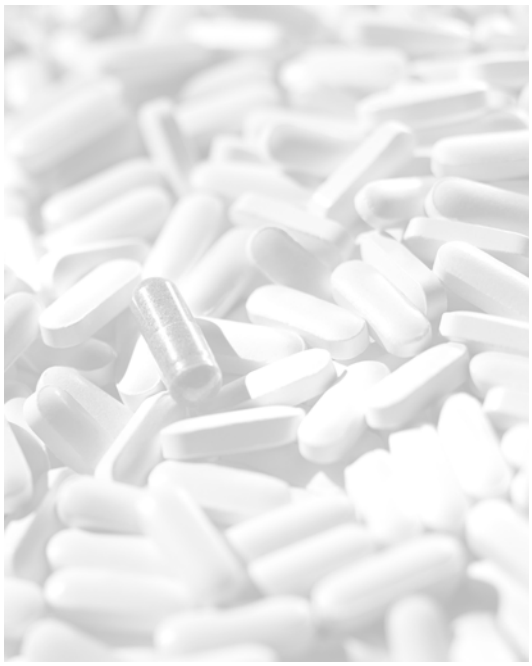


Table - Submissions Still on IP hold by Fiscal Year Filed

Fiscal Year	1998/ 1999	2001/ 2002	2003/ 2004	2004/ 2005	2005/ 2006	2006/ 2007	2007/ 2008	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013
Number of Submissions Still on IP Hold	1	2	2	1	11	9	15	16	39	22	43	47



Section III
Statistics: Data Protection (C.08.004.1 of the *Food and Drug Regulations)*

Register of Innovative Drugs - Human Drugs

This graph and table display the number of human drugs that were added to the Register of Innovative Drugs by Notice of Compliance date. Note that pediatric extensions for previously listed drugs may be added at a later date.

Human Drugs Added to the Register of Innovative Drugs

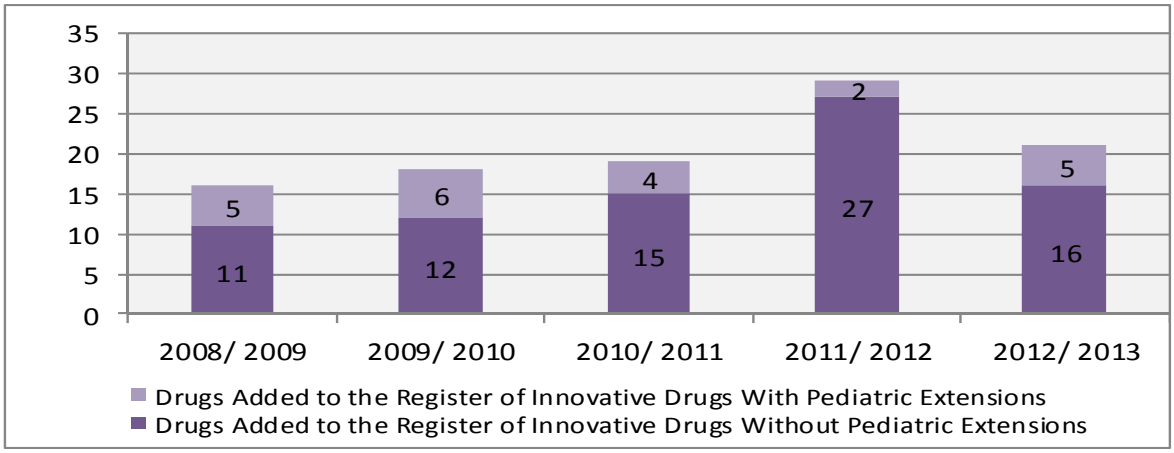


Table - Human Drugs Added to the Register of Innovative Drugs

Fiscal Year	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013
Human Innovative Drugs with Pediatric Extensions	5	6	4	2	5
Human Innovative Drugs without Pediatric Extensions	11	12	15	27	16
Total Human Drugs	**16**	**18**	**19**	**29**	**21**

This graph and table display the number of human drugs added to the Register of Innovative Drugs by product type.

Human Innovative Drugs by Product Type

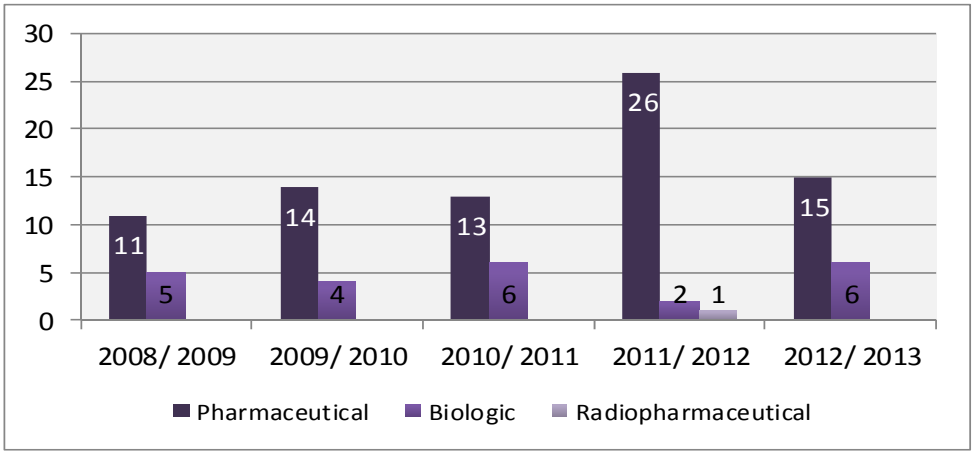


Table - Human Innovative Drugs by Product Type

Fiscal Year	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013
Biologic	5	4	6	2	6
Pharmaceutical	11	14	13	26	15
Radiopharmaceutical	0	0	0	1	0

Register of Innovative Drugs – Veterinary Drugs

This graph and table display the number of veterinary drugs that were added to the Register of Innovative Drugs by Notice of Compliance date.

Veterinary Drugs Added to the Register of Innovative Drugs

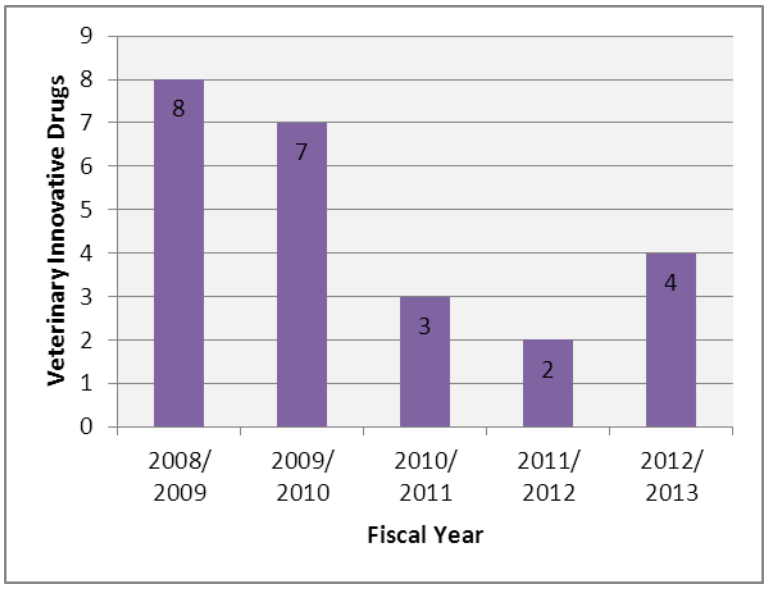


Table - Veterinary Drugs Added to the Register of Innovative Drugs

Fiscal Year	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013
Veterinary Innovative Drugs	8	7	3	2	4

Court Cases Concerning Data Protection Provisions (C.08.004.1) of the *Food and Drug Regulations*

This table lists judicial review applications started between January 1, 2012 and March 31, 2013 and changes which took place to ongoing cases during that time. The applications were filed pursuant to section 18.1 of the *Federal Courts Act* with respect to decisions concerning the data protection provisions (C.08.004.1) of the *Food and Drug Regulations.* New cases and changes to open cases which occurred during the fiscal year are presented in bold.

Table - Court Cases Concerning Data Protection Provisions (C.08.004.1) of the *Food and Drug Regulations*

Federal Court/ Federal Court of Appeal/ Supreme Court of Canada	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-1172-10 (dismissed) **A-215-11 (dismissed)**	Teva Canada Limited - and - The Minister of Health and sanofi-aventis Canada Inc.	oxaliplatin	2010-07-21 2011-06-11	2011-05-02 **2012-04-10**	Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)
T-2044-10 (dismissed) **A-9-12 (dismissed)** **35276 (denied)**	Takeda Canada Inc. - and - The Minister of Health, Attorney General of Canada	dexlansoprazole	2010-12-08 **2012-01-06** **2013-03-19**	2011-12-09 **2013-01-18** **2013-06-13**	Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)
T-148-11 **(granted)** **A-75-12 (dismissed)**	Celgene Inc.- and - The Minister of Health	thalidomide	2011-02-03 **2012-03-01**	**2012-02-06** **2013-02-15**	Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)
T-1488-12 (on-going)	**Bayer Inc.- and - The Minister of Health and The Attorney General of Canada**	**ethinyl estradiol/ drospirenone / levomefolate calcium**	**2012-08-03**		**Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)**

Data Protection Court Cases Initiated Per Year

This graph and table represent the number of court proceedings with respect to data protection under (C.08.004.1) of the *Food and Drug Regulations.*

Data Protection Cases

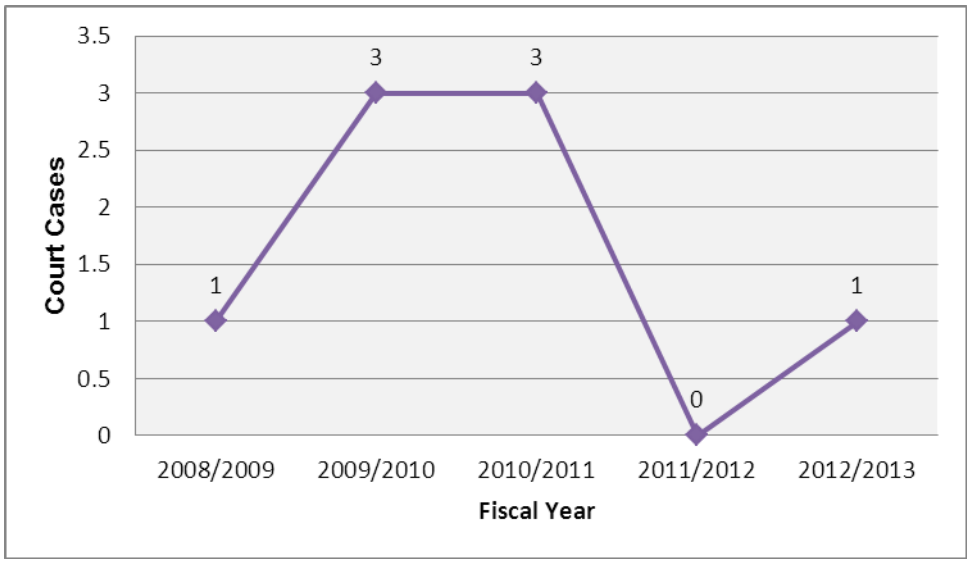
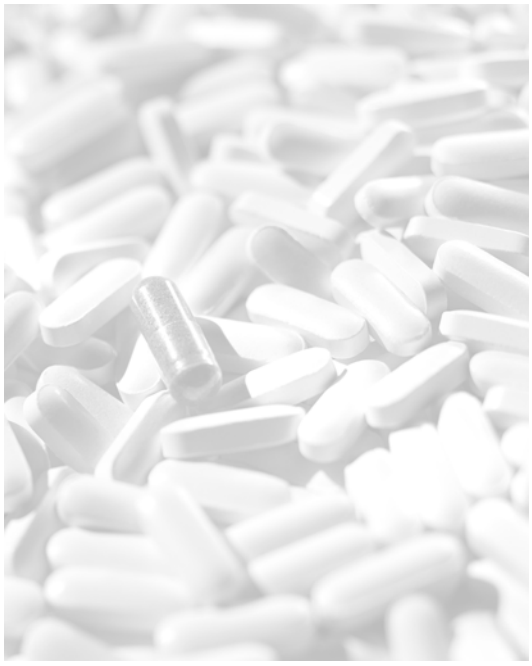


Table - Data Protection Cases

Fiscal Year	2008/2009	2009/2010	2010/2011	2011/2012	2012/2013
Court Cases	1	3	3	0	1



Appendix A Definitions

Definitions

Court:
The Federal Court of Canada or any other superior court of competent jurisdiction.

Discontinued:
The cessation of court proceedings where the applicant voluntarily puts an end to the case, with or without leave of the court.

Dismissed:
The removal of a case from court, the termination of a case before trial or before a complete trial. In the case of the *Patented Medicines (Notice of Compliance) Regulations*, however, the dismissal indicates a decision at any point in the matter, either summary, as a result of a motion, or at the end of the proceeding following arguments (hearing).

Drug Identification Number (DIN):
A Drug Identification Number is a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada.

First Person:
The person referred to in subsection 4(1) of the *Patented Medicines (Notice of Compliance) Regulations*, typically a brand name drug manufacturer.

Innovative Drug:
A drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.
(C.08.004.1 (1), *Food and Drug Regulations*)

IP (Intellectual Property) Hold:
The period of time when, upon completion of the review of a submission, a Notice of Compliance would be issuable but for the provisions of the *Patented Medicines (Notice of Compliance) Regulations* and/or data protection provisions under section C.08.004.1 of the *Food and Drug Regulations*.

Notice of Allegation:
A notice issued under section 5 of the *Patented Medicines (Notice of Compliance) Regulations*. Such notices set out the nature of the generic manufacturer's challenge to a patent listed on the Patent Register.

Notice of Compliance:
Market authorization issued under section C.08.004 of the *Food and Drug Regulations*.

Patent List:
Form IVs submitted by the first person pursuant to section 4 of the *Patented Medicines (Notice of Compliance) Regulations*.

Patent Register:
The register of patents and other information maintained by the Minister in accordance with subsection 3(2) of the *Patented Medicines (Notice of Compliance) Regulations*.

Pending:
A court case awaiting judgment.

Prohibition Granted:
An order of prohibition which prevents the Minister from issuing a Notice of Compliance.

Prohibition Partially Granted:
An order of prohibition applying to one or more but not to all patents that are the subject of a case under section 6 of the *Patented Medicines (Notice of Compliance) Regulations* where more than one patent is at issue.

Register of Innovative Drugs
The register maintained by the Minister in accordance with section C.08.004.1(9) of the *Food and Drug Regulations.*

Second Person:
The person referred to in section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, typically a generic drug manufacturer.

Submission:
Any or all of: a new drug submission (NDS); an abbreviated new drug submission (ANDS); a supplement to a new drug submission (SNDS); a supplement to an abbreviated new drug submission (SANDS); and an extraordinary use new drug (EUNDS).