Health Canada Santé Canada

July 14, 2017

Notice

Our file number: 17-107303-579

Release of the Therapeutic Products Directorate Statistical Report 2016/2017 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 2016/2017 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.

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

Office of Patented Medicines and Liaison
Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Health Canada
101 Tunney's Pasture Driveway
Postal Locator: 0201A1
Ottawa, Ontario
K1A 0K9

E-mail: opml_bmbl@hc-sc.gc.ca

Canada

Therapeutic Products Directorate Statistical Report 2016 / 2017

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

Office of Submissions and Intellectual Property




2017/07/06

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Également disponible en français sous le titre :
Publication du rapport statistique 2016/2017 de la Direction des produits thérapeutiques sur le *Règlement sur les médicaments brevetés (avis de conformité*) et la protection des données

To obtain additional information, please contact:

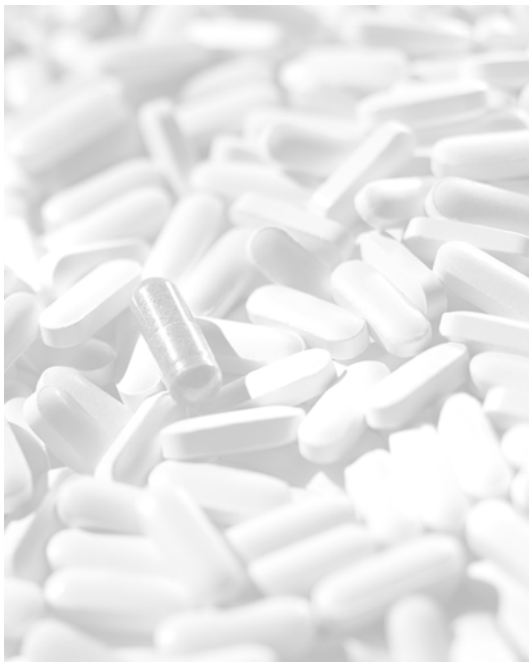
Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications@hc-sc.gc.ca

This publication can be made available in alternative formats upon request.

Publication date: July 2017

Cat.: H42-4/2E-PDF
ISSN: 2371-3259
Pub.: 170100

Table of Contents



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 amended in 1998, 1999, 2006, 2008, 2010, 2011 and 2015.

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 (http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp) 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* (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/patented-medicines/notice-compliance-regulations.html).

B. Data Protection

The data protection provisions in section C.08.004.1 of the *Food and Drug Regulations*

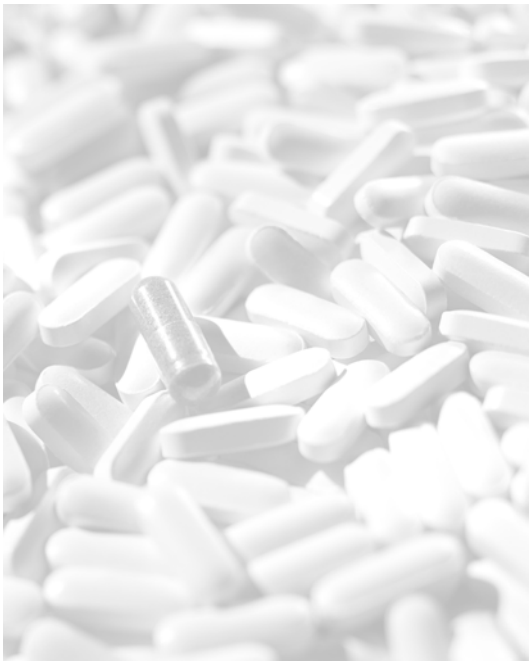
came into force in September 1995. They were amended in 2006, 2011 and 2014, in order to clarify and effectively implement Canada's obligations under the *North American Free Trade Agreement* and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* with respect to the protection of undisclosed tests or other data necessary to determine the safety and efficacy 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) (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs.html) 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* (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-document-data-protection-under-08-004-1-food-drug-regulations.html).

C. Intellectual Property (IP) Hold

Upon completion of the review of a submission, a final intellectual property 'check' is performed by the OPML. At this stage, Health Canada has completed the scientific assessment of the safety, efficacy and quality of the drug under the *Food and Drug Regulations*. If the Notice of Compliance would be issuable but for the operation of either the *Patented Medicines (Notice of Compliance) Regulations* or data protection, the drug manufacturer is so notified, and informed of the date on which the submission would have been eligible to receive a Notice of Compliance. The submission is then placed on an administrative hold called "Intellectual Property Hold" until all the relevant requirements regarding the *Patented Medicines (Notice of Compliance) Regulations* and data protection have been met.



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

This table shows the number of patent lists received in each fiscal year, where patent lists are counted by patent per submission.

Table - Number of Patent Lists Received

Fiscal Year	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Number of patent lists received (during the fiscal year)	674	501	678	846	835

Number of Patent Lists Added to the Patent Register

This table shows the number of patent lists counted by patent per submission 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. Patents may be already listed on the Patent Register - for previously approved drug submissions - and are 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	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Total added (during the fiscal year)	407	383	320	644	769
Patents not previously listed (New Drug Submission)	104	117	73	145	167
Patents not previously listed (Supplemental New Drug Submission)	78	79	21	123	263

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	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
New Drug Submission (section 4(2))	24	14	43	15	15
Supplement to a New Drug Submission (section 4(3) and section 4.1(2))	40	45	36	49	45
Timing (sections 4(5) and 4(6))	8	11	8	20	9
Other	4	8	6	1	5
Total	**76**	**78**	**93**	**85**	**74**

A Snapshot of the Patent Register as of March 31, 2017: 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, 2017 there were 1,451 DINs listed on the Patent Register, representing 583 different drugs. The total number of patents listed on the Patent Register is 1,070 and they are distributed per DIN. For example, there are 716 DINs which only have one patent listed against them; on the other hand, there are 8 DINs which have 16 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, 2017:
Number of Patents per Drug Identification Number (DIN) on the Patent Register

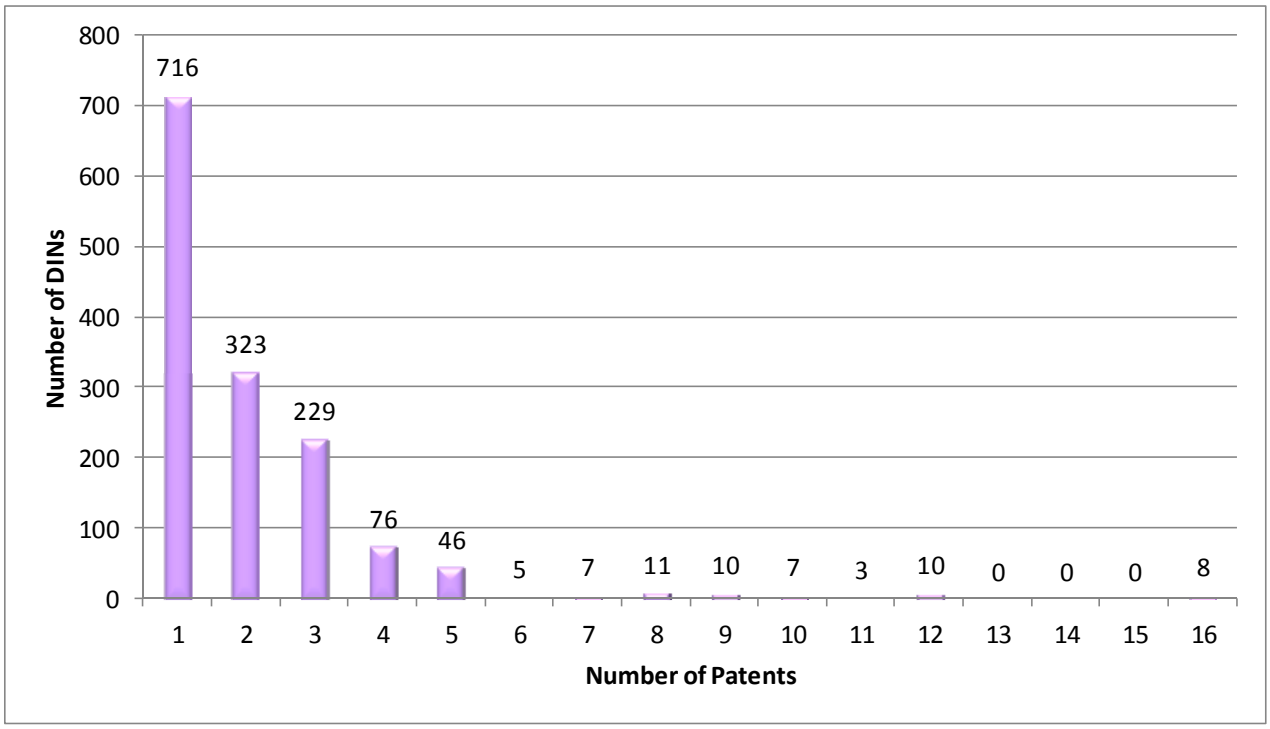


Table - Number of Patents per Drug Identification Number (DIN) on the Patent Register

Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Number of DINs	716	323	229	76	46	5	7	11	10	7	3	10	0	0	0	8

A Snapshot of the Patent Register as of March 31, 2017: Number of Patents Per Drug on the Patent Register

There are currently 583 different drugs listed on the Patent Register. The total number of different patents listed on the Patent Register is 1,070 and they are distributed per drug. For example, there are 267 drugs which only have one patent listed against them; on the other hand, there is one drug which has 16 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, 2017:
Number of Patents per Drug on the Patent Register

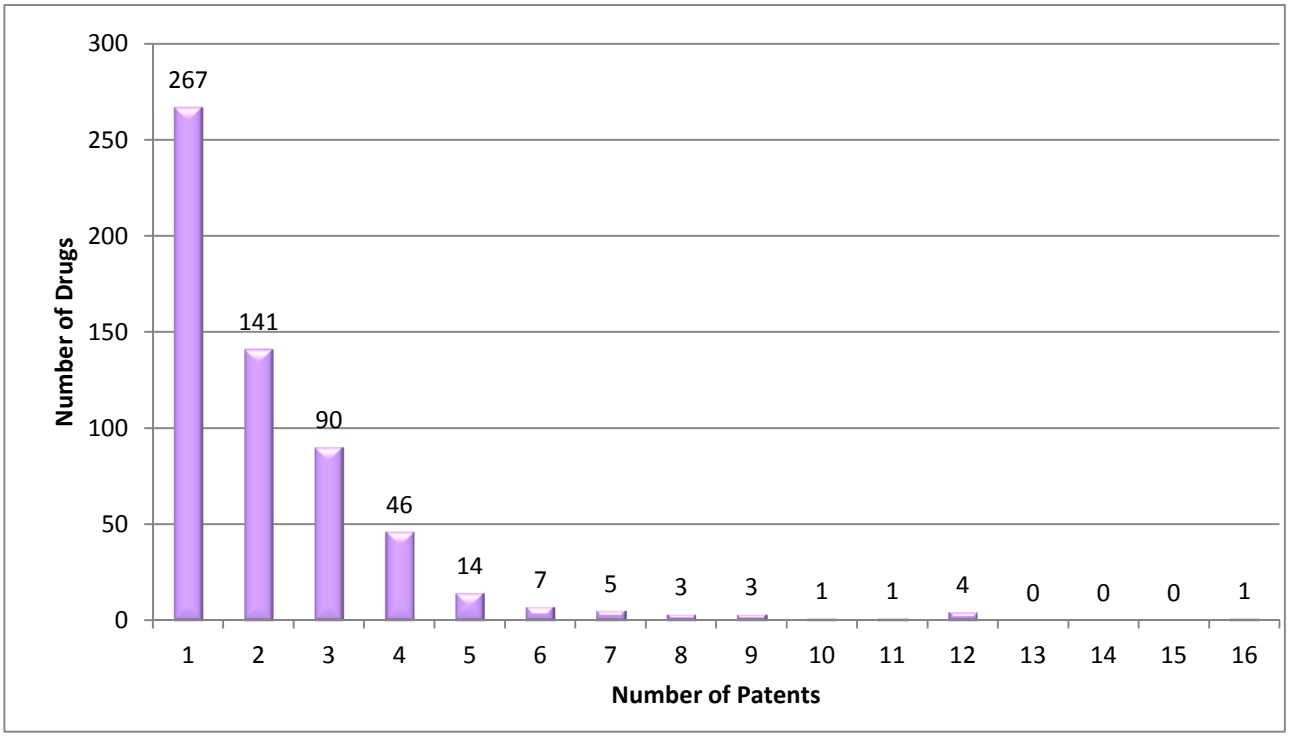


Table - Number of Patents Per Drug on the Patent Register

Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Number of Drugs	267	141	90	46	14	7	5	3	3	1	1	4	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 April 1, 2016 and March 31, 2017 and changes which took place to ongoing cases during the fiscal year. 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	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-1978-16 (Ongoing)	**Elanco, a division of Eli Lilly Canada Inc. -and- The Attorney General of Canada and The Minister of Health**	**pegbovigrastim**	**2016-11-16**		**Listing eligibility of patent no. 2,812,704, entitled "Formulations for Bovine Granulocyte Colony Stimulating Factor and Variants Thereof"**

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

This table lists judicial review applications started between April 1, 2016 and March 31, 2017 and changes which took place to ongoing cases during the fiscal year. 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-1703-13 A-27-15/ A-28-15 **(Granted)**	Pfizer Canada Inc. -and- The Minister of Health and Teva Canada Limited	exemestane	2013-10-16 2015-01-16/ 2015-01-16	2014-12-19 **2016-10-12**	Challenge to the Minister's decision made in accordance with the guidance document "*Patented Medicines (Notice of Compliance) Regulations"* regarding administrative cross-referenced submissions
T-742-14 **(Withdrawn)**	Actavis Pharma Company -and- The Minister of Health and The Attorney General of Canada	oxycodone hydrochloride	2014-03-27	**2017-02-23**	Challenge to the Minister's decision that the applicant's submission triggered subsection 5(2) of the *Patented Medicines (Notice of Compliance) Regulations*
T-1516-14 A-143-15/ A-172-15 **(Granted)** **37342** **(Ongoing)**	Janssen Inc. and The Kennedy Trust For Rheumatology Research -and- The Attorney of Canada, The Minister of Health and Hospira Healthcare Corporation	infliximab	2014-07-02 2015-03-16/ 2015-03-27 **2016-12-09**	2015-03-09 **2016-10-12**	Challenge to the Minister's decision made in accordance with the guidance document "*Patented Medicines (Notice of Compliance) Regulations"* regarding administrative cross-referenced submissions

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

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-157-16 **(Withdrawn)**	Paladin Labs Inc. -and- The Minister of Health, The Attorney General of Canada and Taro Pharmaceuticals Inc.	tramadol	2016-01-25	**2016-06-30**	Challenge to the Minister's decision to issue a Notice of Compliance to the second person
T-485-17	**Innovator Company -and- The Attorney General of Canada and The Minister of Health**	**Dosage Strength B**	**2017-03-31**		**Challenge to the Minister's decision that the applicant's submission triggered subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations***

Prohibition Applications concerning section 6 of the *Patented Medicines (Notice of Compliance) Regulations* – Summary as of March 31, 2017

The first table shows the number of submissions with Form Vs received during a specific fiscal year and the number of Notices of Allegation received as of March 31, 2017.

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 - Number of Submissions with Form Vs and Notices of Allegation received as of March 31, 2017

Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017
Submissions with Form V	239	187	138	200	126
Notices of Allegation received	163	146	118	176	105

Table - Prohibition Applications concerning section 6 of the *Patented Medicines (Notice of Compliance) Regulations* - Summary as of March 31, 2017

Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017
Prohibition applications commenced	84	44	53	18	32
Prohibition applications discontinued	58	26	38	10	15
Prohibition applications granted	9	12	7	2	-
Appeals Filed	4	3	1	-	-
Discontinued	1	-	1	-	-
Granted	-	-	-	-	-
Dismissed	3	3	-	-	-
Pending	-	-	-	-	-
Prohibition applications dismissed	11	6	5	3	3
Appeals Filed	4	1	1	2	-
Discontinued	1	1	-	1	-
Granted	-	-	-	-	-
Dismissed	3	-	1	-	-
Pending	-	-	-	1	-
Prohibition applications partially granted	4	-	3	-	-
Appeals Filed	3	-	2	-	-
Discontinued	1	-	-	-	-
Granted	-	-	-	-	-
Dismissed	2	-	-	-	-
Pending	-	-	2	-	-
Prohibition applications pending resolution	2	-	-	3	14

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)
2012/2013	84	24	21.3	7.1-36
2013/2014	44	18	18.5	4.1-24
2014/2015	53	15	18.8	5.5-24
2015/2016	18	5	12.5	8.3-20
2016/2017	32	3	2.8	1-5.8

1 The numbers do not include discontinued cases

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 applications which exceeded 24 months to resolve. The numbers do not include discontinued cases.

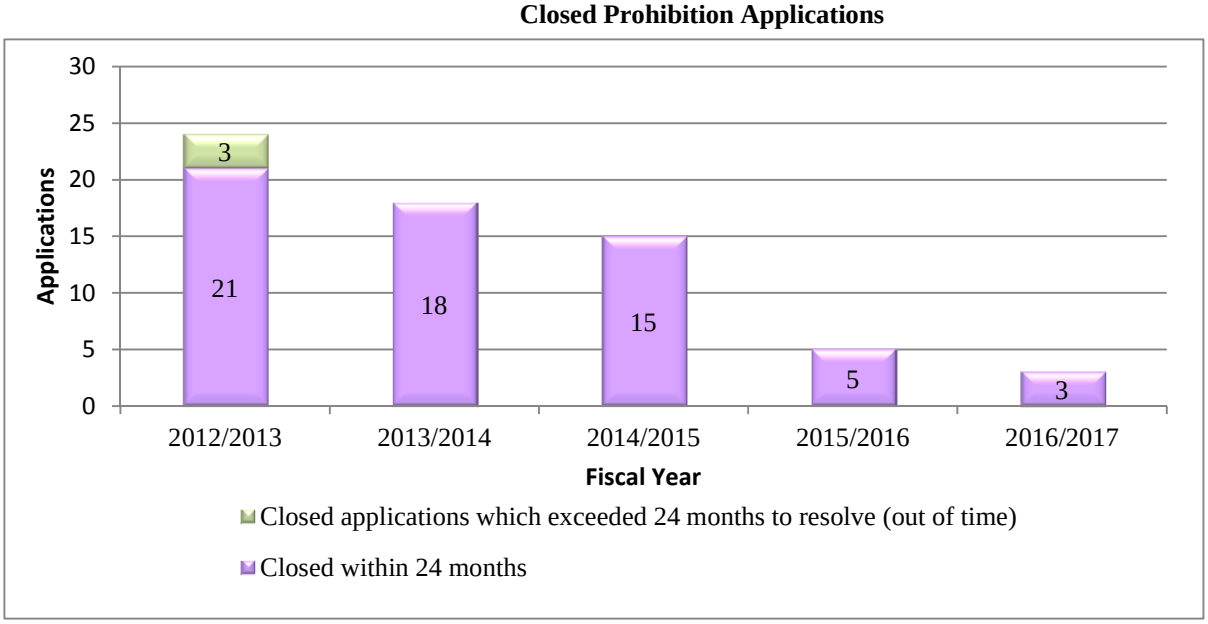


Table - Closed Prohibition Applications

Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017
Closed within 24 months	21	18	15	5	3
Closed applications which exceeded 24 months to resolve (out of time)	3	0	0	0	0
Total number of applications closed	24	18	15	5	3

Prohibition and Judicial Review Applications

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

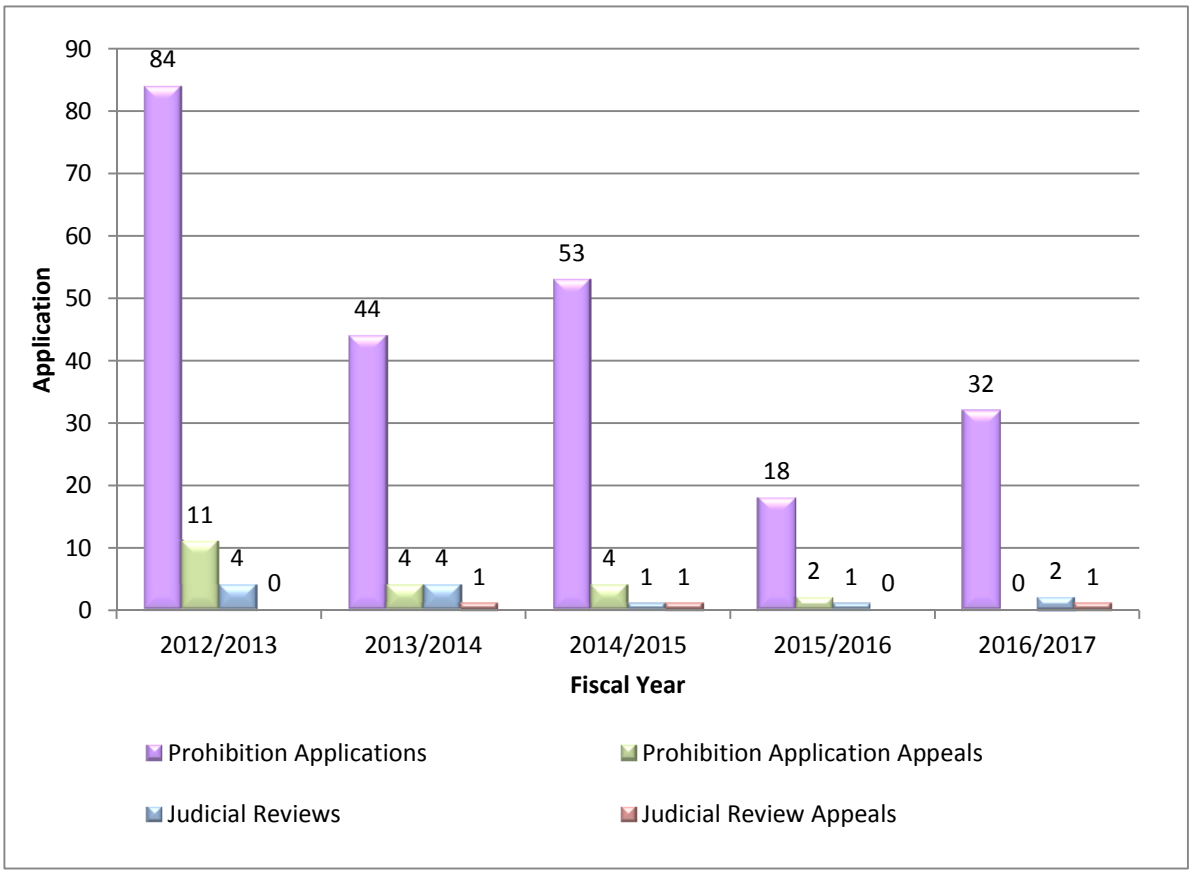
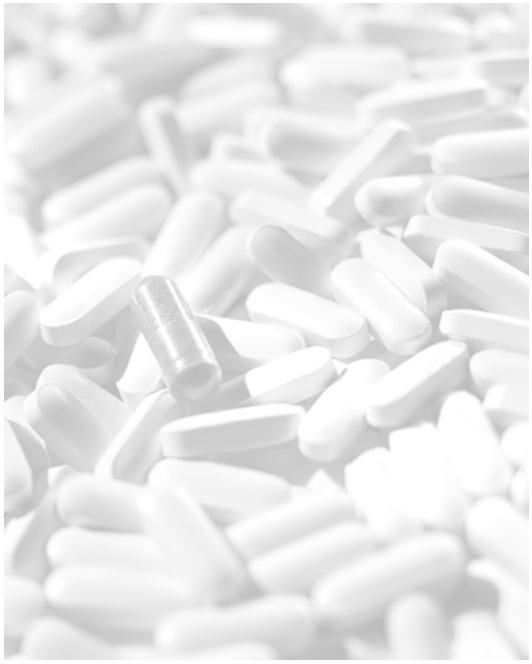


Table - Prohibition and Judicial Review Applications Initiated Per Fiscal Year

Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017
Prohibition Applications	84	44	53	18	32
Prohibition Application Appeals	11	4	4	2	0
Judicial Reviews	4	4	1	1	2
Judicial Review Appeals	0	1	1	0	1



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

Register of Innovative Drugs - Human Drugs

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

Human Drugs Added to the Register of Innovative Drugs

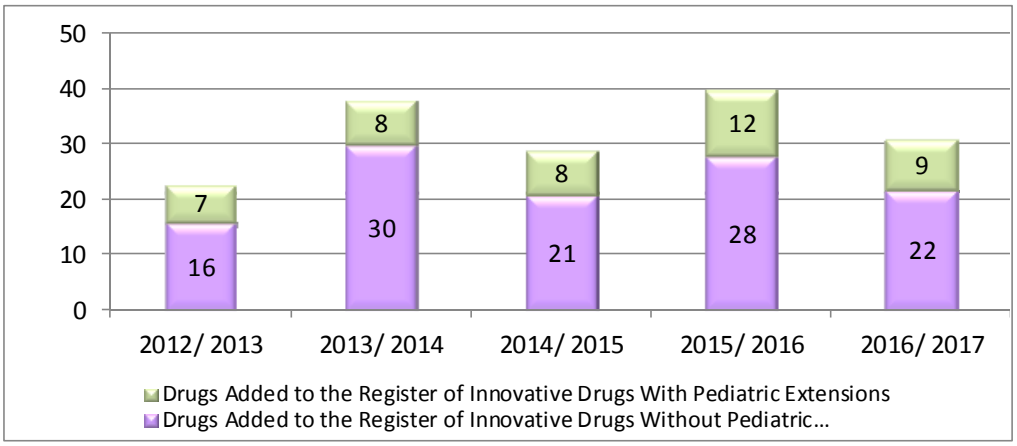


Table - Human Drugs Added to the Register of Innovative Drugs

Fiscal Year	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Human Innovative Drugs with Pediatric Extensions	7	8	8	12	9
Human Innovative Drugs without Pediatric Extensions	16	30	21	28	22
Total Human Drugs	**23**	**38**	**29**	**40**	**31**

Human Innovative Drugs by Product Type

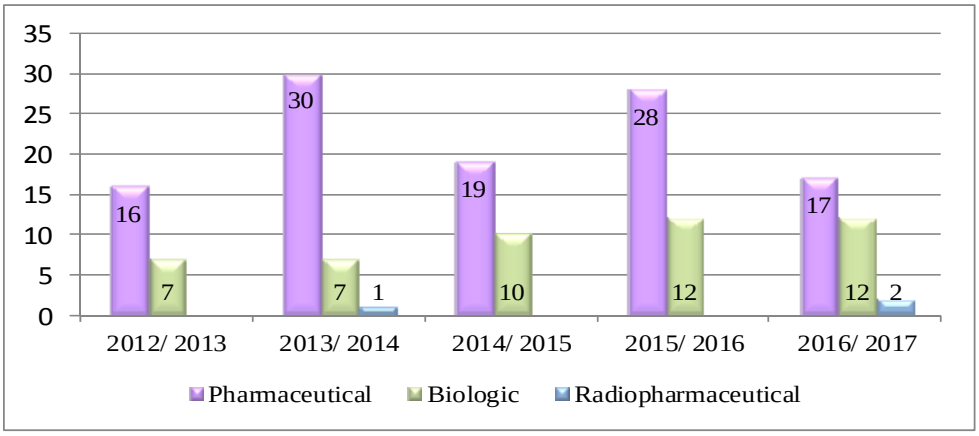


Table - Human Innovative Drugs by Product Type

Fiscal Year	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Biologic	7	7	10	12	12
Pharmaceutical	16	30	19	28	17
Radiopharmaceutical	0	1	0	0	2

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

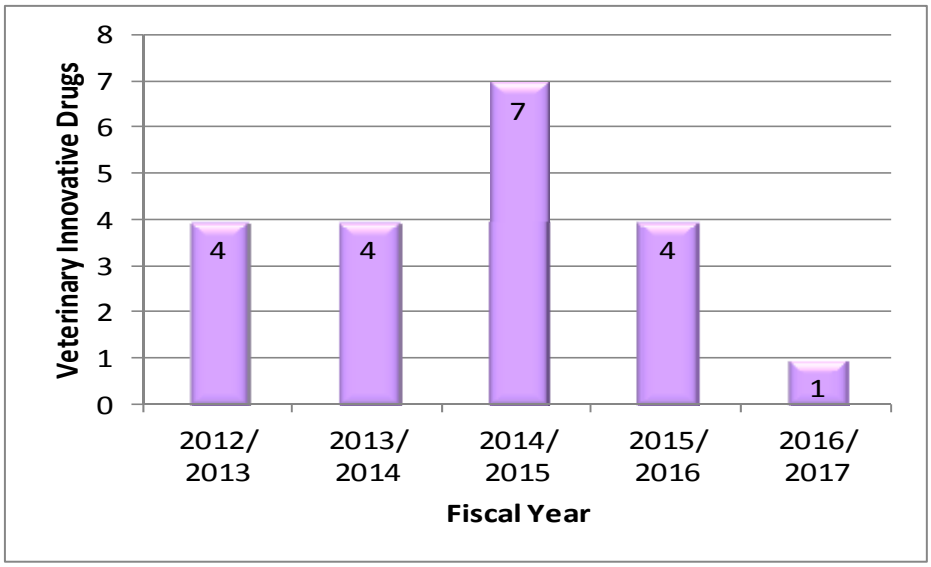


Table - Veterinary Drugs Added to the Register of Innovative Drugs

Fiscal Year	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Veterinary Innovative Drugs	4	4	7	4	1

Judicial Reviews Applications Concerning the Data Protection Provisions (C.08.004.1) of the *Food and Drug Regulations*

There we no judicial review applications started between April 1, 2016 and March 31, 2017 or changes which took place to ongoing cases during the fiscal year.

Judicial Review Applications

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.*

Judicial Review Applications Initiated Per Fiscal Year

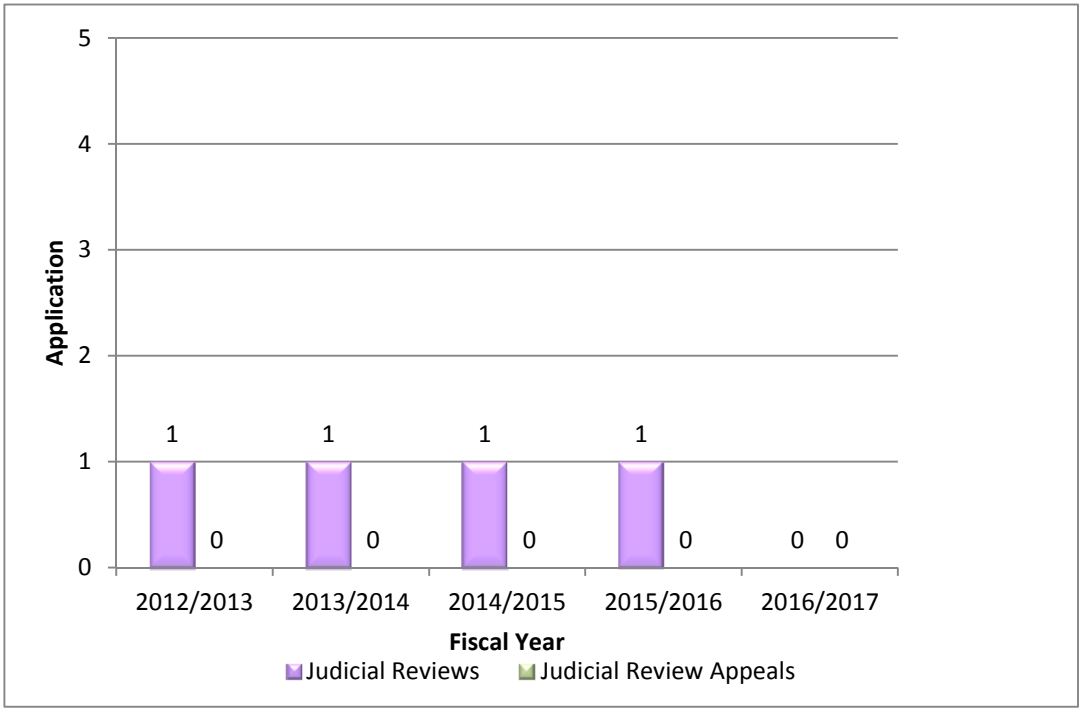
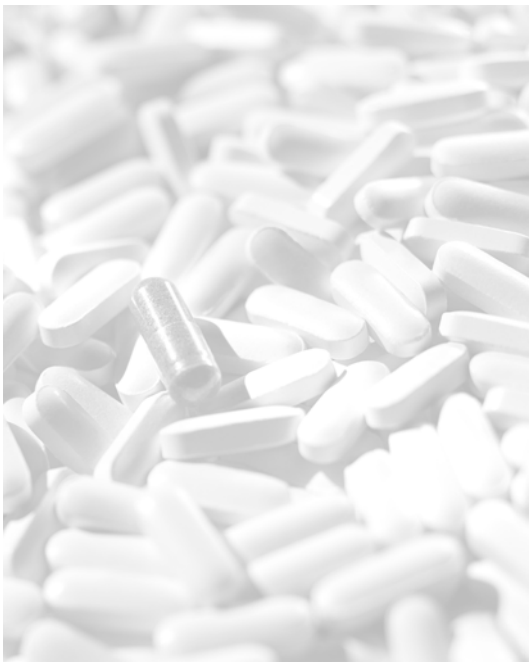


Table - Judicial Review Applications Initiated Per Fiscal Year

Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017
Judicial Reviews	1	1	1	1	0
Judicial Review Appeals	0	0	0	0	0



Section IV
Statistics: Intellectual Property (IP) Hold

Submissions Previously 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 fiscal 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

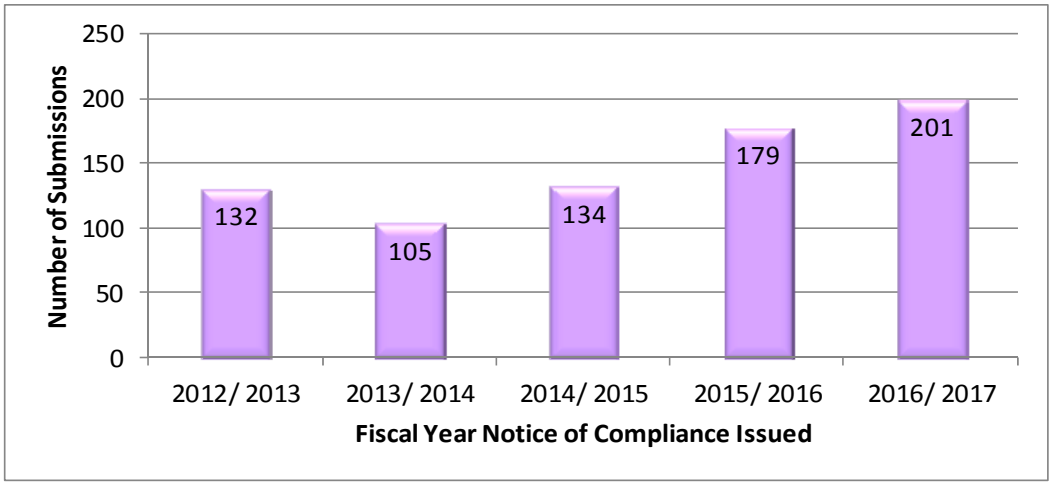


Table - Number of Submissions Previously on IP Hold by Notice of Compliance Date

Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017
Number of Submissions	132	105	134	179	201

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

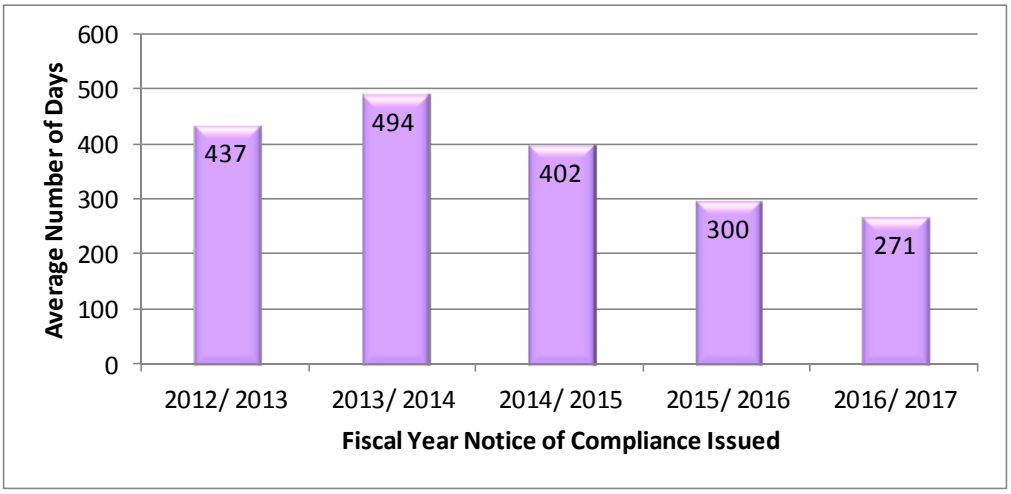


Table - Average Number of Days on IP Hold by Fiscal Year in which Notice of Compliance was Issued

Fiscal Year	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017
Number of Days	437	494	402	300	271

Submissions Remaining on IP Hold

This graph and table show the number of submissions by fiscal year filed which were still on IP Hold as of March 31, 2017.

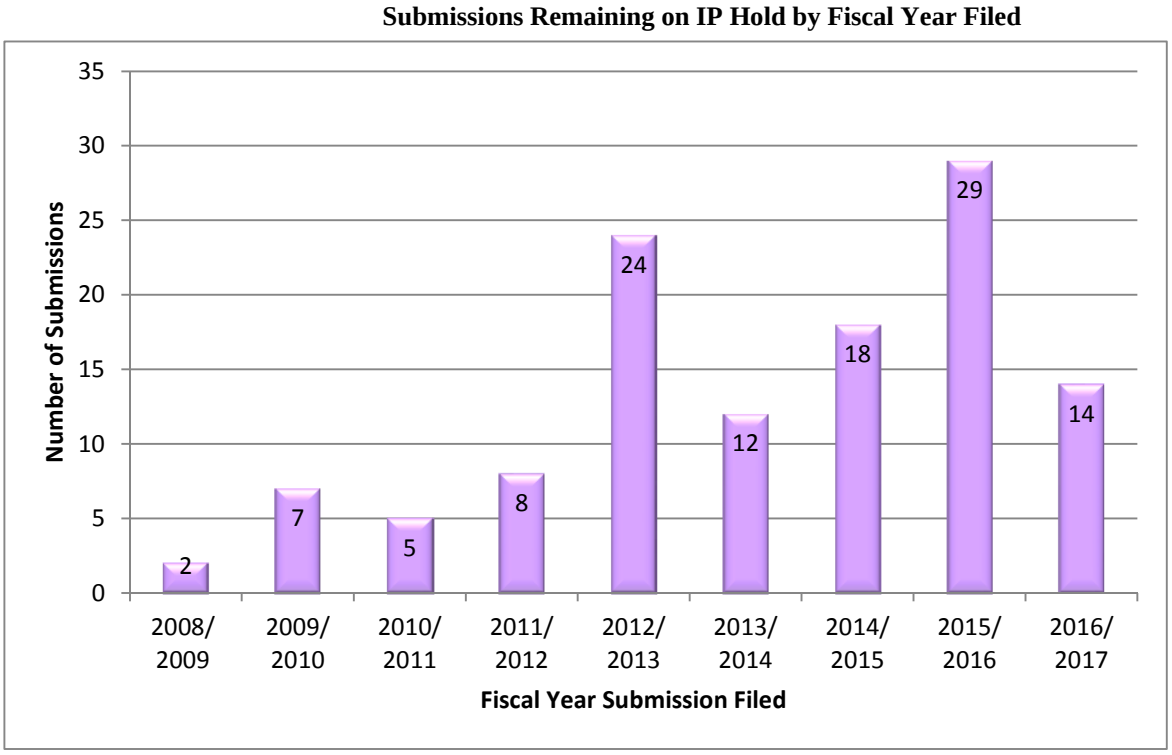
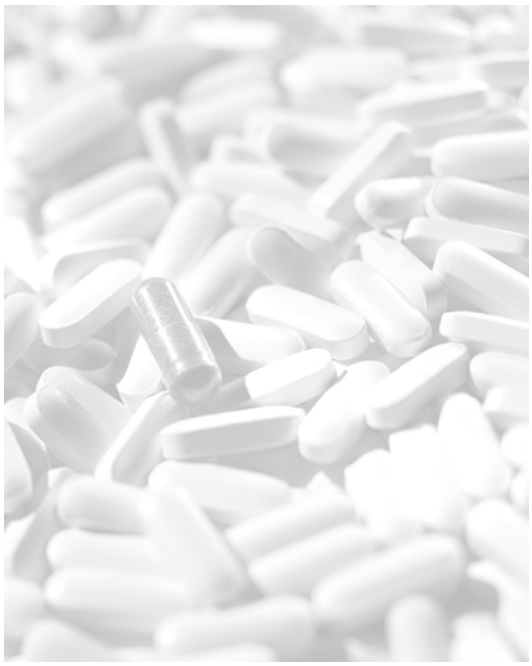


Table - Submissions Remaining on IP Hold by Fiscal Year Filed

Fiscal Year	2008/ 2009	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017
Number of Submissions Remaining on IP Hold	2	7	5	8	24	12	18	29	14



Appendix A Definitions

Defnitions

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*)

Intellectual Property (IP) 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).