Health Canada Santé Canada

July 11, 2018

Notice

Our file number: 18-107850-551

Release of the Therapeutic Products Directorate Statistical Report 2017/2018 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 2017/2018 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:

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Canada

Health Canada Santé Canada

Therapeutic Products Directorate Statistical Report 2017 / 2018

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

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Publication du rapport statistique 2017/2018 de la Direction des produits thérapeutiques sur le Règlement sur les médicaments brevetés (avis de conformité) et la protection des données

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Table of Contents

Section I – 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 Innovation, Science and Economic Development Canada (ISED). 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, 2015 and 2017.

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, obtain consent from the patent owner or make an allegation in respect of the patent 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 and associated certificates of supplementary protection in respect of drugs for which market authorization has issued in the form of a Notice of Compliance. Each patent list is evaluated by the OPML in order to determine its eligibility under the Patented Medicines (Notice of Compliance) Regulations. 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 included 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 (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.php).

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 test 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) (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg_innov_dr-eng.php) 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 (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php).

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

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. While patent lists are submitted per Drug Identification Number (DIN), decisions with respect to the submission are typically the same for all associated DINs.

Table 1 - Number of Patent lists received

Fiscal Year	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Number of patent lists received	501	678	846	835	898

Additions

This table shows the number of patent lists added to the Patent Register in each fiscal year, where patent lists are counted by patent per submission. Note that the total added does 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 (carried forward) 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 2 - Additions

Fiscal Year	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Total added (during the fiscal year)	383	320	644	769	606
Not previously listed New Drug Submission (section 4(2))	117	73	145	167	119
Not previously listed Supplement to a New Drug Submission (section 4(3) and section 4.1(2))	79	21	123	263	335

Rejections

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

Table 3 - Rejections

Fiscal Year	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
New Drug Submission (section 4(2))	14	43	15	15	35
Supplement to a New Drug Submission (section 4(3) and section 4.1(2))	45	36	49	45	76
Timing (sections 4(5) and 4(6))	11	8	20	9	8
Other (withdrawn or cancelled)	8	6	1	5	1
Total	78	93	85	74	120

A Snapshot of the Patent Register as of March 31, 2018: 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, 2018 there were 1,575 DINs listed on the Patent Register, representing 591 different drugs. There are 755 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.

Graph 1: Snapshot of the Patent Register as of March 31, 2018: Number of patents per Drug Identification Number (DIN) on the Patent Register

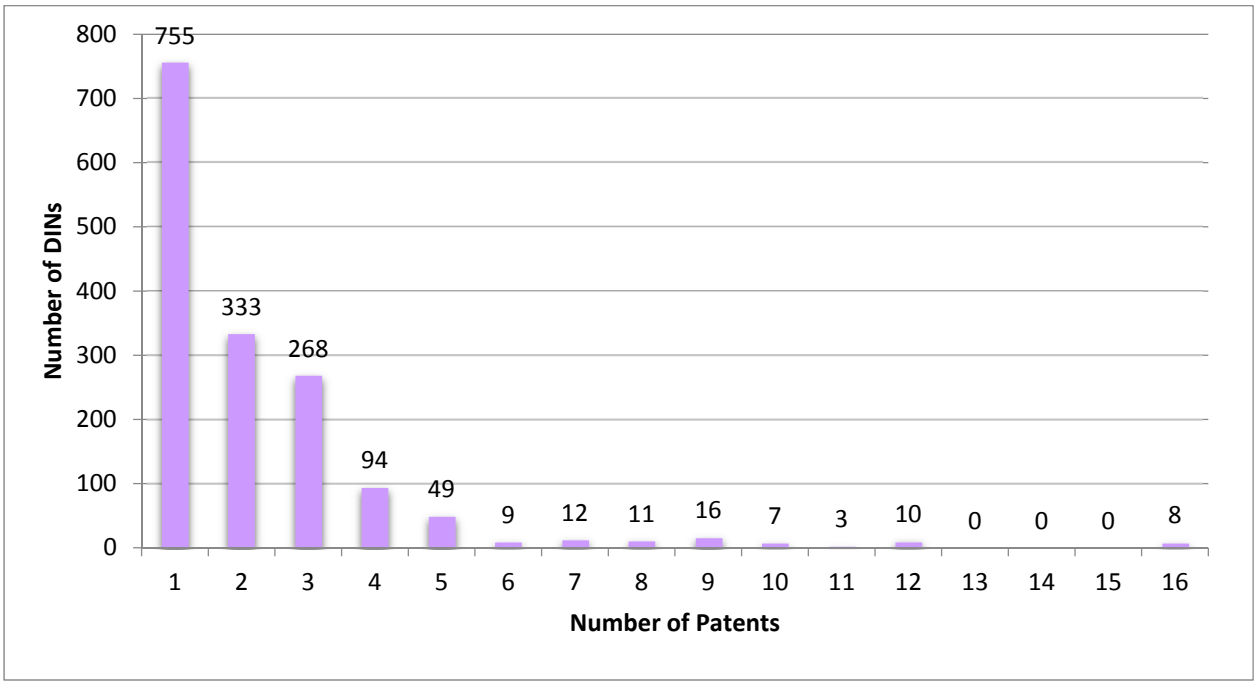

Table 4 - Number of patents per Drug Identification Number (DIN) on the Patent Register

Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Number of DINs	755	333	268	94	49	9	12	11	16	7	3	10	0	0	0	8

A Snapshot of the Patent Register as of March 31, 2018: Number of patents per drug on the Patent Register

There are currently 591 different drugs listed on the Patent Register and 272 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.

Graph 2: Snapshot of the Patent Register as of March 31, 2018: Number of patents per drug on the Patent Register

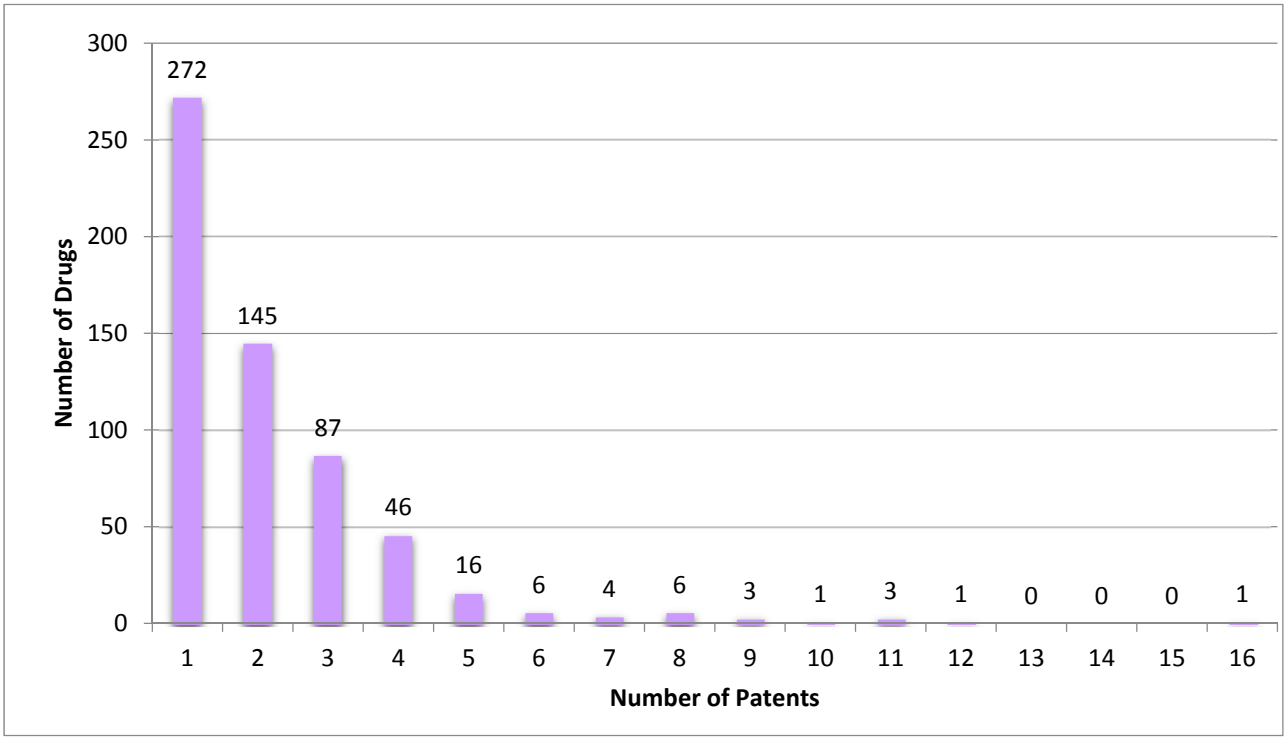

Table 5 - Number of patents per drug on the Patent Register

Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Number of Drugs	272	145	87	46	16	6	4	6	3	1	3	1	0	0	0	1

Judicial review applications concerning patent eligibility: Section 4 of the Patented Medicines (Notice of Compliance) Regulations

This table lists judicial review applications started between April 1, 2017 and March 31, 2018 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 section 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 6 - Judicial review applications concerning patent eligibility: Section 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, 2017 and March 31, 2018 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 7 - 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-485-17 **(Withdrawn)**	**Tillotts Pharma AG - and- The Attorney General of Canada, The Minister of Health and Allergan Inc.**	**mesalamine**	2017-03-31	**2018-03-16**	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 pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations – summary as of March 31, 2018

The Patented Medicines (Notice of Compliance) Regulations were amended on September 21, 2017. Under the pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations, innovative drug companies could commence legal proceedings (commonly referred to as prohibition applications) for an order prohibiting the Minister of Health from granting a notice of compliance for a generic version of a patented medicine. The September 21, 2017 amendments to the Patented Medicines (Notice of Compliance) Regulations replaced prohibition applications with full actions resulting in final determinations of patent infringement and validity. The pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations will continue to apply in respect of any matter that relates to a notice of allegation served on a first person before September 21, 2017.

The table 8 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, 2018.

The table 9 summarizes the outcome of prohibition applications filed in the Federal Court pursuant to Section 6 of the Patented Medicines (Notice of Compliance) Regulations, beginning with the number of applications commenced by first persons. The break-down of subsequent appeals for each possible application conclusion - granted, dismissed, partially granted - is also included. The applications commenced are the result of Notices of Allegation served on first persons before September 21, 2017. The start date of the application determines the year in which the outcome is reported.

Table 8 - Number of submissions with Form Vs and Notices of Allegation received as of March 31, 2018

Fiscal Year	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018
Submissions with Form V	187	138	200	126	126
Notices of Allegation received	146	118	176	105	82

Table 9 - Prohibition applications - summary as of March 31, 2018

Fiscal Year	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018
Prohibition applications commenced	44	53	18	32	41
Prohibition applications discontinued	26	38	10	22	19
Prohibition applications granted	12	7	5	2	0
Appeals Filed	3	1	2	0	0
Discontinued	0	1	0	0	0
Granted	0	0	0	0	0
Dismissed	3	0	0	0	0
Partial	0	0	0	0	0
Pending	0	0	0	0	0

Table 9, Cont'd - Prohibition applications - summary as of March 31, 2018

Prohibition applications dismissed	6	5	3	3	0
Appeals Filed	1	1	2	0	0
Discontinued	1	0	0	0	0
Granted	0	0	0	0	0
Dismissed	0	1	0	0	0
Partial	0	0	0	0	0
Pending	0	0	0	0	0
Prohibition applications partially granted	0	3	0	1	0
Appeals Filed	0	0	0	0	0
Discontinued	0	1	0	0	0
Granted	0	0	0	0	0
Dismissed	0	1	0	0	0
Partial	0	0	0	0	0
Pending	0	0	0	0	0
Prohibition applications pending resolution	0	0	0	4	22

Actions concerning section 6 of the post-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations

The following table shows the number of actions for declarations of infringement filed in the Federal Court pursuant to Section 6 of the Patented Medicines (Notice of Compliance) Regulations, from September 21, 2017 to March 31, 2018. The break-down of possible action conclusion - granted, dismissed, partially granted - is also included. The actions commenced are the result of Notices of Allegation served on first persons on or after September 21, 2017.

Table 10 - Actions - summary as of March 31, 2018

Fiscal Year	**2017/2018 September 21, 2017 to March 31, 2018**
Actions commenced	12
Actions discontinued	0
Declaration of Infringement granted	0
Actions dismissed	0
Declaration of Infringement partially granted	0
Actions pending resolution	12

Average time to resolution of prohibition applications under the pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations

This table represents information regarding prohibition applications filed pursuant to Section 6 of the Patented Medicines (Notice of Compliance) Regulations in respect of Notices of Allegation served on a first person before September 21, 2017. 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 11 - Average time to resolution of prohibition applications

Fiscal Year	Number of cases per fiscal year	Number of cases closed[1]	Average resolution time[1] (months)	Range[1] (months)
2013/2014	44	18	18.5	4.1-24
2014/2015	53	15	18.8	5.5-24
2015/2016	18	8	16	8.3-24
2016/2017	32	6	9.8	1-18.3
2017/2018	41	0	0	0

1 The numbers do not include discontinued cases

Prohibition applications under the pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations 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.

Graph 3: Closed prohibition applications

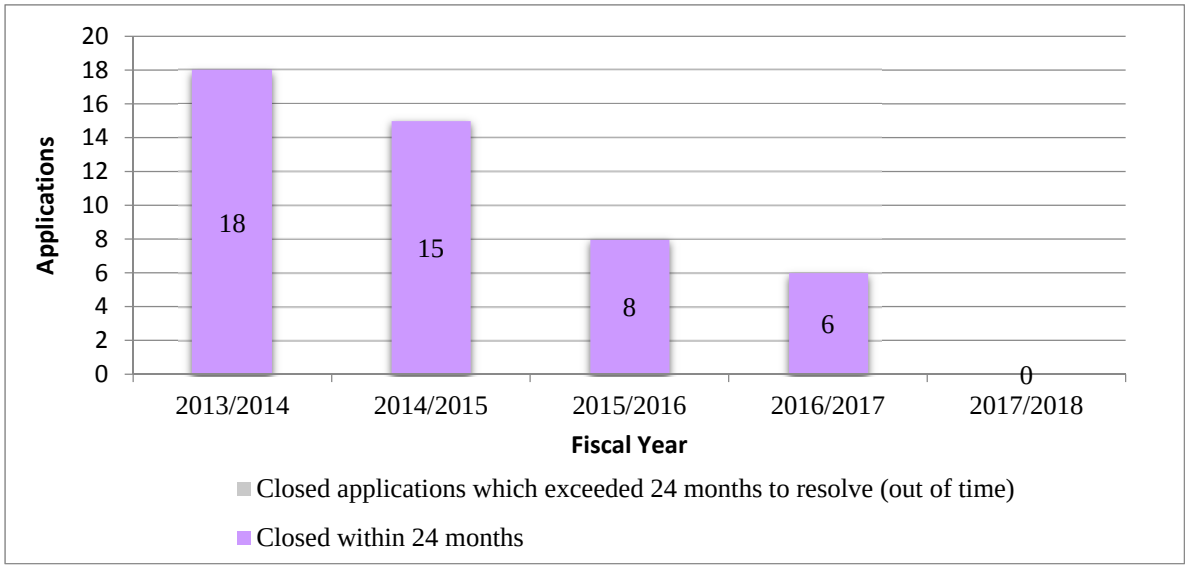

Table 12 - Closed prohibition applications

Fiscal Year	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018
Closed within 24 months	18	15	8	6	0
Closed prohibition applications which exceeded 24 months to resolve (out of time)	0	0	0	0	0
Total number of prohibition applications closed	18	15	8	6	0

Prohibition and judicial review applications

This graph and table compare the number of applications for judicial review of the Minister's decisions with the number of prohibition applications with respect to section 6 of the pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations.

Graph 4: Prohibition and judicial review applications initiated per fiscal year

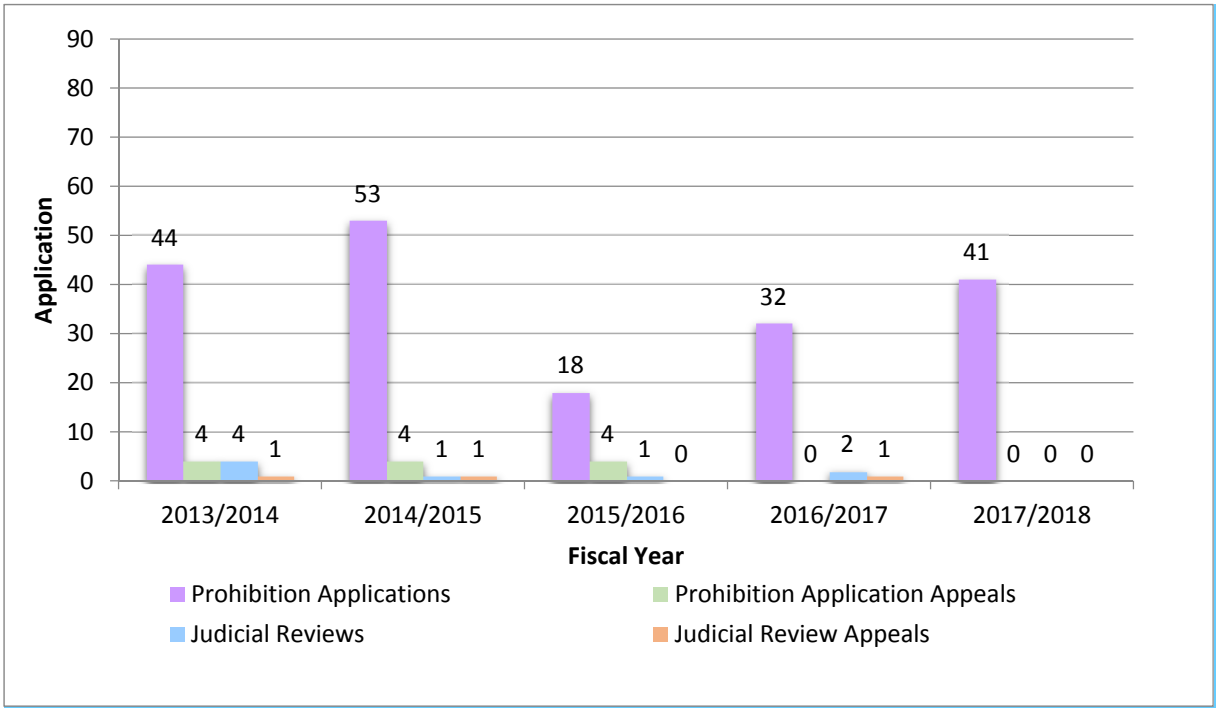

Table 13 - Prohibition and judicial review applications initiated per fiscal year

Fiscal Year	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018
Prohibition Applications	44	53	18	32	41
Prohibition Application Appeals	4	4	4	0	0
Judicial Reviews	4	1	1	2	0
Judicial Review Appeals	1	1	0	1	0

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

Register of Innovative Drugs - human drugs

Graph 5 and table 14 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. Graph 6 and table 15 display the number of human drugs added to the Register of Innovative Drugs by product type.

Graph 5: Human drugs added to the Register of Innovative Drugs

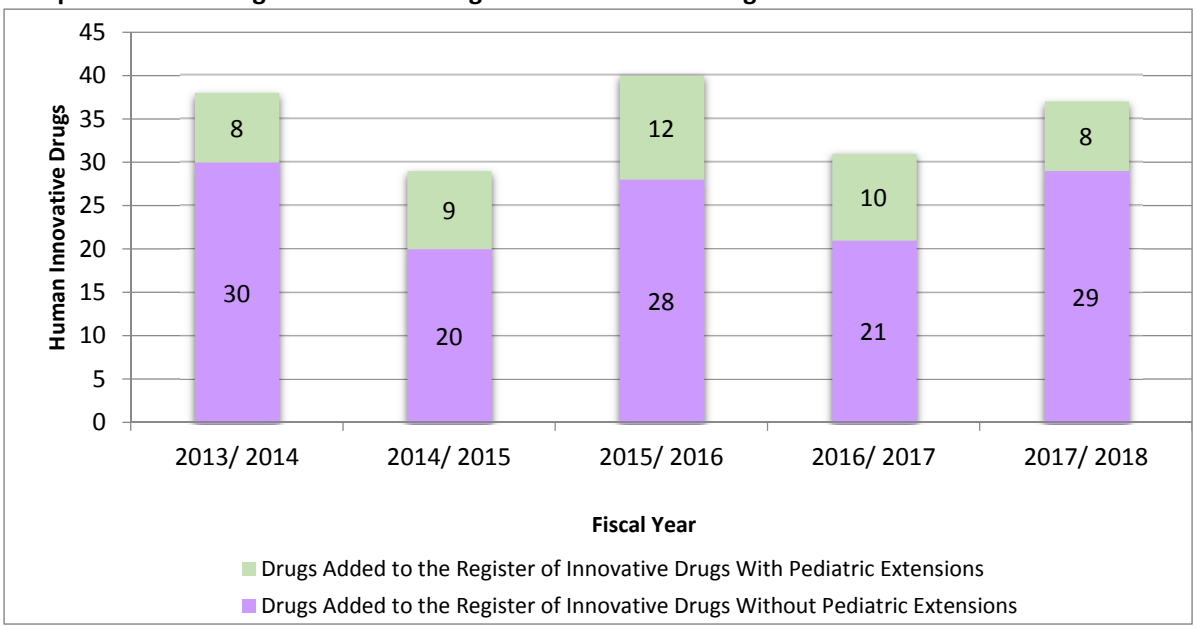

Table 14 - Human drugs added to the Register of Innovative Drugs

Fiscal Year	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Human Innovative Drugs with Pediatric Extensions	8	9	12	10	8
Human Innovative Drugs without Pediatric Extensions	30	20	28	21	29
Total Human Drugs	38	29	40	31	37

Graph 6: Human innovative drugs by product type

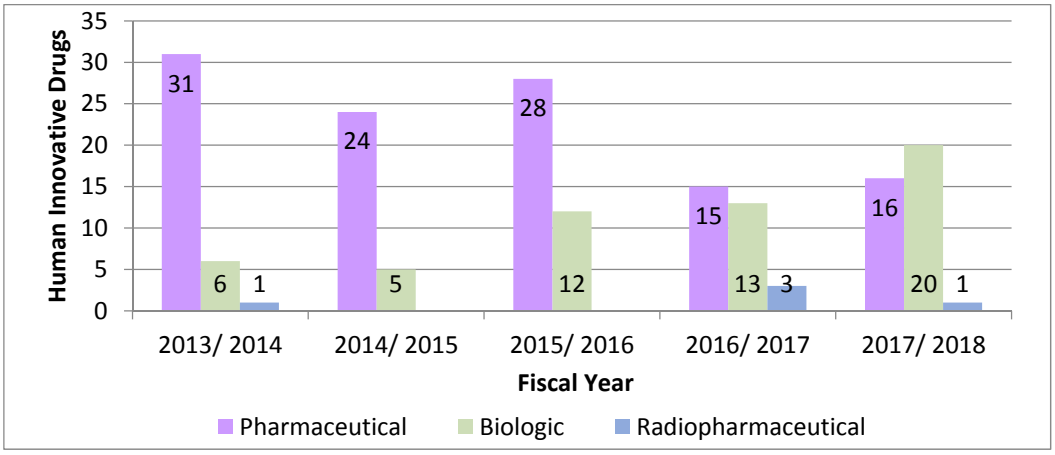

Table 15 - Human innovative drugs by product type

Fiscal Year	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Biologic	6	5	12	13	20
Pharmaceutical	31	24	28	15	16
Radiopharmaceutical	1	0	0	3	1

Register of Innovative Drugs – veterinary drugs

This graph 7 and table 15 display the number of veterinary drugs that were added to the Register of Innovative Drugs by Notice of Compliance date.

Graph 7: Veterinary drugs added to the Register of Innovative Drugs

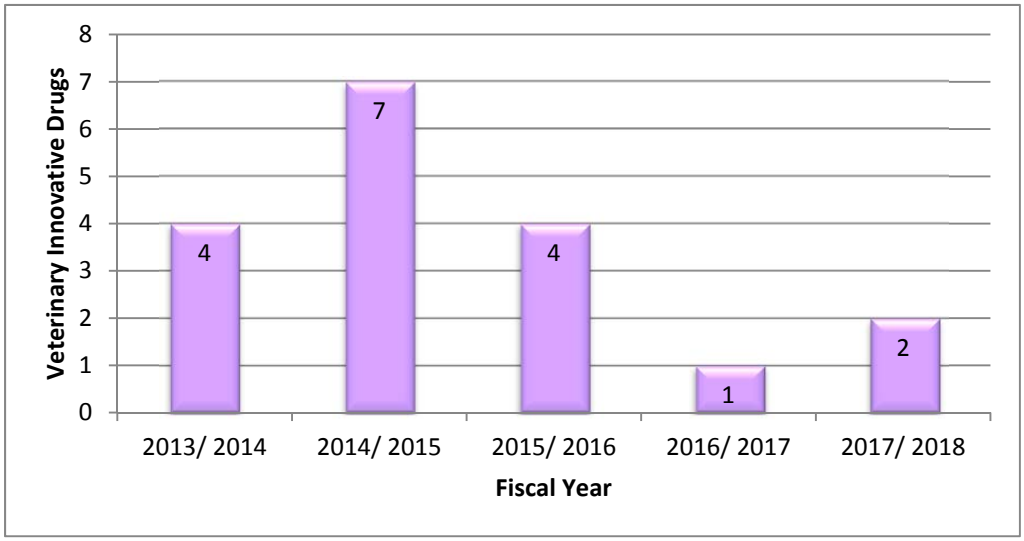

Table 16 - Veterinary drugs added to the Register of Innovative Drugs

Fiscal Year	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Veterinary Innovative Drugs	4	7	4	1	2

Judicial review 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, 2017 and March 31, 2018 or changes which took place to ongoing cases during the fiscal year.

This table 17 represents the number of court proceedings with respect to data protection under (C.08.004.1) of the Food and Drug Regulations over the past five years.

Table 17 - Judicial review applications initiated per fiscal year

Fiscal Year	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018
Judicial Reviews	1	1	1	0	0
Judicial Review Appeals	0	0	0	0	0

Section IV - Statistics: Intellectual Property (IP) hold

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, 2018.

Graph 8: Submissions remaining on IP hold by fiscal year filed

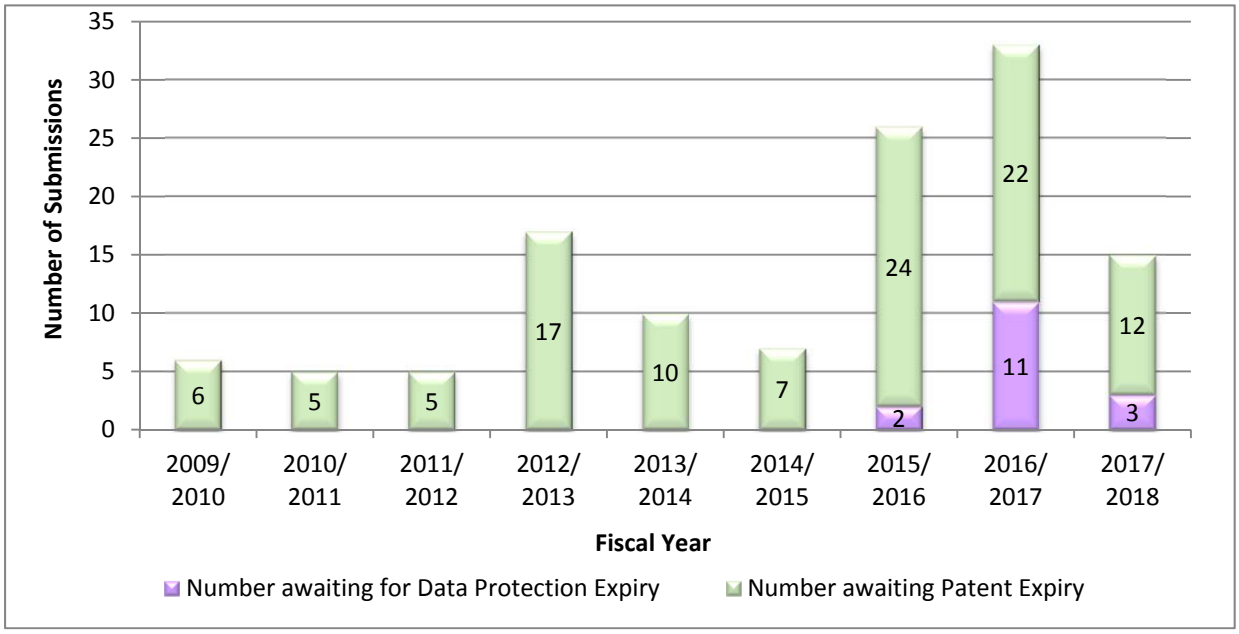

Table 18 - Submissions remaining on IP hold by fiscal year filed

Fiscal Year	2009/ 2010	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018
Number of Submissions Remaining on IP Hold	6	5	5	17	10	7	26	33	15
Number awaiting for Data Protection Expiry	0	0	0	0	0	0	2	11	3
Number awaiting Patent Expiry	6	5	5	17	10	7	24	22	12

Appendix A - 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)

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).