Health Canada Santé Canada

July 2, 2019

Notice

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Release of the Statistical Report 2018/2019 for the Patented Medicines (Notice of Compliance) Regulations, Data Protection and Certificates of Supplementary Protection.

Health Canada is pleased to announce the release of the Statistical Report 2018/2019 for the Patented Medicines (Notice of Compliance) Regulations, Data Protection and Certificates of Supplementary Protection. 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 under section C.08.004.1 of the Food and Drug Regulations, and related court activity. In addition, for the first time, information is included regarding Certificates of Supplementary Protection and applications under the Patent Act and the Certificate of Supplementary Protection Regulations.

The 2018/2019 report also marks the first use of a new reporting tool which has allowed patent listing data for all fiscal years to be reported directly from the Patent Register rather than from internal tracking systems. As patent listing data are recorded differently in the Patent Register, readers may note some differences in the current report as compared to previous reports, e.g. all patent lists added to the patent register are now being reported rather than only those added in respect of patents not previously listed.

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

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Canada

Health Canada Santé Canada

Statistical Report 2018 / 2019

Patented Medicines (Notice of Compliance) Regulations, Data Protection (C.08.004.1 of the Food and Drug Regulations) and Certificates of Supplementary Protection

Office of Patented Medicines and Liaison

Date: 2019/07/02

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 :
Rapport statistique 2018/2019 pour le Règlement sur les médicaments brevetés (avis de conformité), la protection des données (C.08.004.1 du Règlement sur les aliments et drogues) et les certificats de protection supplémentaire

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Table of Contents

Section I - Overview 4

Patented Medicines (Notice of Compliance) Regulations 4

Data Protection 4

Certificates of Supplementary Protection 5

Intellectual Property Hold 5

Section II - Statistics: Patented Medicines (Notice of Compliance) Regulations 6

Patent Lists Received 6

Additions to Patent Register 6

Rejections of Patent Lists 7

A Snapshot of the Patent Register as of March 31, 2019: Number of Patents per Drug Identification Number on the Patent Register 8

A Snapshot of the Patent Register as of March 31, 2019: Number of Patents per Drug on the Patent Register 9

Judicial Review Applications concerning Patent Eligibility under section 4 of the Patented Medicines (Notice of Compliance) Regulations 10

Form V: Declaration re: Patent List (Form V) 10

Judicial Review Applications concerning section 5 of the Patented Medicines (Notice of Compliance) Regulations 10

Prohibition Applications concerning section 6 of the pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations 11

Notices of Allegation 11

Prohibition Applications 11

Average Time to Resolution 12

Actions concerning section 6 of the post-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations 13

Notices of Allegation 13

Actions 13

Prohibition Applications, Actions and Judicial Review Applications concerning the Patented Medicines (Notice of Compliance) Regulations 14

Section III - Statistics: Data Protection (C.08.004.1 of the Food and Drug Regulations) 15

Register of Innovative Drugs 15

Human Drugs 15

Veterinary Drugs 16

Judicial Review Applications concerning Data Protection 17

Section IV - Statistics: Certificates of Supplementary Protection 18
Applications 18
Issuances and Refusals 18
Performance 18
Reasons for Refusal 19
Judicial Review Applications concerning Certificates of Supplementary Protection 20
Section V - Statistics: Intellectual Property Hold 21
Submissions Remaining on Intellectual Property Hold 21
Appendix A - Definitions 22

Section I - Overview

This document provides a statistical overview of the administration of the Patented Medicines (Notice of Compliance) Regulations, data protection under the Food and Drug Regulations, and Certificates of Supplementary Protection under the Patent Act and the Certificate of Supplementary Protection Regulations. These three regimes are administered by the Office of Patented Medicines and Liaison within the Office of Submissions and Intellectual Property, Resource Management and Operations Directorate, Health Products and Food Branch, Health Canada.

Patented Medicines (Notice of Compliance) Regulations

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 effective patent enforcement over patented drugs with the timely entry of lower priced 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 (generic or biosimilar) drug manufacturer to use a patented 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 subsequent-entry drug to the patent status of the drug that is being copied. As such, a drug manufacturer that makes a direct or indirect comparison with, or reference to, another 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 Office of Patented Medicines and Liaison maintains a Patent Register (http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp) 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 evaluated in order to determine its eligibility 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).

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.

Innovative drugs are listed on the Register of Innovative Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs/register.html) after the issuance of the Notice of Compliance.

Additional 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).

Certificates of Supplementary Protection

The Certificate of Supplementary Protection regime came into force on September 21, 2017 through amendments to the Patent Act and the introduction of the Certificate of Supplementary Protection Regulations. A Certificate of Supplementary Protection provides an additional period of protection for drugs containing a new medicinal ingredient, or a new combination of medicinal ingredients, protected by an eligible patent. This implements Canada's obligation under the Canada-European Union Comprehensive Economic and Trade Agreement to provide an additional period of protection for patent-protected pharmaceutical products.

Information regarding applications and Certificates of Supplementary Protection is maintained on the Register of Certificates of Supplementary Protection and Applications (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates.html#a1).

Additional information on the administration of Certificates of Supplementary Protection is available in the guidance document: Certificates of Supplementary Protection (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates/supplementary-protection-regulations-profile.html).

Intellectual Property Hold

Upon completion of the review of a submission, a final intellectual property 'check' is performed. 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 the Patented Medicines (Notice of Compliance) Regulations and/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 of the Patented Medicines (Notice of Compliance) Regulations and/or data protection have been met.

Section II - Statistics: Patented Medicines (Notice of Compliance) Regulations

Patent Lists Received

Table 1 displays the number of patent lists received in each fiscal year. Data regarding the actual number of patent lists submitted are available only for the past two fiscal years. While a patent list is required for each Drug Identification Number in a drug submission, decisions with respect to a patent are typically the same for all associated Drug Identification Numbers. As such, the number of patent lists counted by patent per submission is also provided in order to reflect the number of requests for patent listing decisions received.

Table 1 - Patent Lists Received

Fiscal Year	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Patent Lists - Actual	-	-	-	2019	1495
Patent Lists - Patent per Submission	678	846	835	898	736

Additions to Patent Register

Table 2 displays the number of patent lists added to the Patent Register in each fiscal year under the applicable section of the Patented Medicines (Notice of Compliance) Regulations. While a patent list is required for each Drug Identification Number in a drug submission, decisions with respect to a patent are typically the same for all associated Drug Identification Numbers. As such, patent lists in this table are counted by patent per submission to reflect the number of decisions underlying the additions to the Patent Register. Note that 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	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
New Drug Submission, s. 4(2)	97	177	161	121	131
Supplement to a New Drug Submission, s. 4(3)	11	18	22	23	20
Supplement to a New Drug Submission, s. 4.1(2)	250	495	611	521	627
Total	358	690	794	665	778

Rejections of Patent Lists

Table 3 displays the number of rejections for listing in each fiscal year under the applicable section of the Patented Medicines (Notice of Compliance) Regulations. While a patent list is required for each Drug Identification Number in a drug submission, decisions with respect to a patent are typically the same for all associated Drug Identification Numbers. As such, patent lists in this table are counted by patent per submission to reflect the number of decisions underlying the rejections. Patent lists counted in the "Other" category include those received in respect of submissions that have been withdrawn or cancelled. Note that patent lists may have been received in one fiscal year but rejected the following fiscal year.

Table 3 - Rejections

Fiscal Year	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
New Drug Submission, s. 4(2)	43	15	15	46	32
Supplement to a New Drug Submission, ss. 4(3) and 4.1(2)	36	49	45	99	106
Timing, ss. 4(5) and 4(6)	8	20	9	7	3
Other	6	1	5	1	0
Total	93	85	74	153	141

A Snapshot of the Patent Register as of March 31, 2019: Number of Patents per Drug Identification Number on the Patent Register

Graph 1 and Table 4 represent the number of patents that a second person is required to address when seeking a Notice of Compliance for a subsequent-entry version of a patented drug with a particular Drug Identification Number. As of March 31, 2019 there were 1,285 Drug Identification Numbers listed on the Patent Register, representing 603 different drugs. Patents may apply to more than one Drug Identification Number (e.g. more than one strength, route of administration or dosage form of a medicinal ingredient). The numbers in the below graph do not include patents that were removed from the Patent Register nor do they include patents that expired.

Graph 1 - Patents per Drug Identification Number on the Patent Register

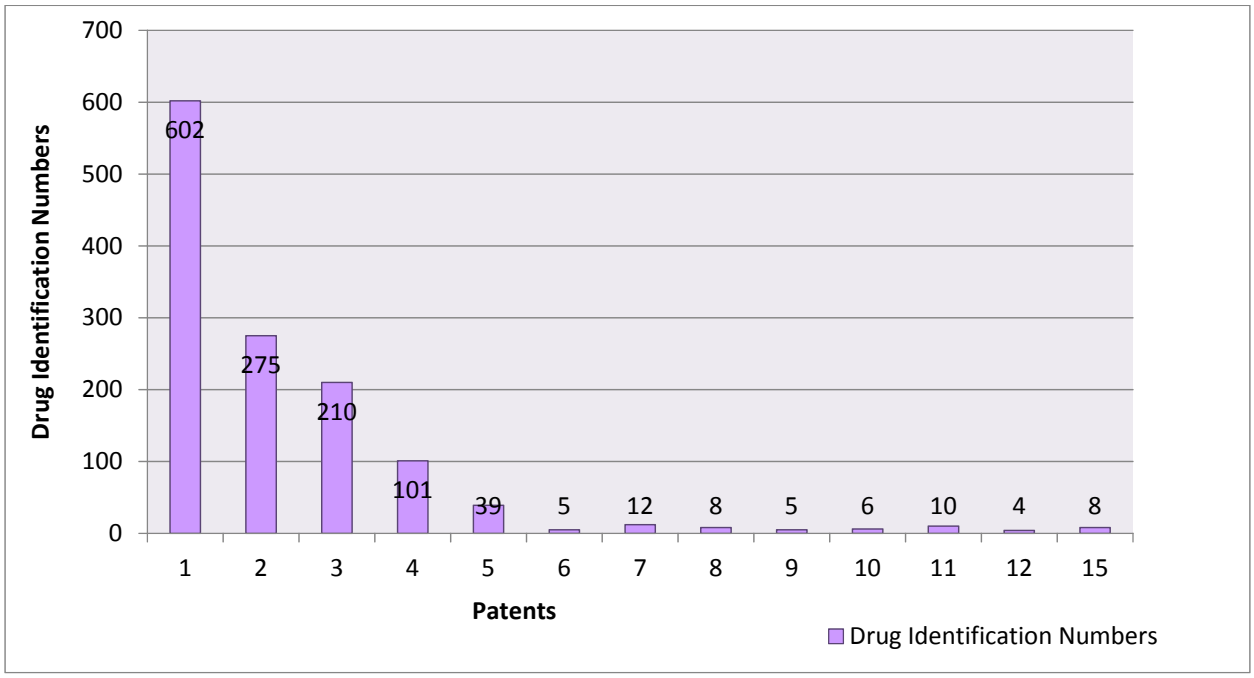

Table 4 - Patents per Drug Identification Number on the Patent Register

Patents	1	2	3	4	5	6	7	8	9	10	11	12	15
Drug Identification Numbers	602	275	210	101	39	5	12	8	5	6	10	4	8

A Snapshot of the Patent Register as of March 31, 2019: Number of Patents per Drug on the Patent Register

Graph 2 and Table 5 represent the number of patents that a second person is required to address when seeking a Notice of Compliance for a subsequent-entry version of a patented drug. There are currently 603 different drugs listed on the Patent Register. Some drugs have multiple strengths, routes of administration or dosage forms listed on the Patent Register while others do not. The numbers in the graph do not include patents that were removed from the Patent Register nor do they include patents that expired.

Graph 2 - Patents per Drug on the Patent Register

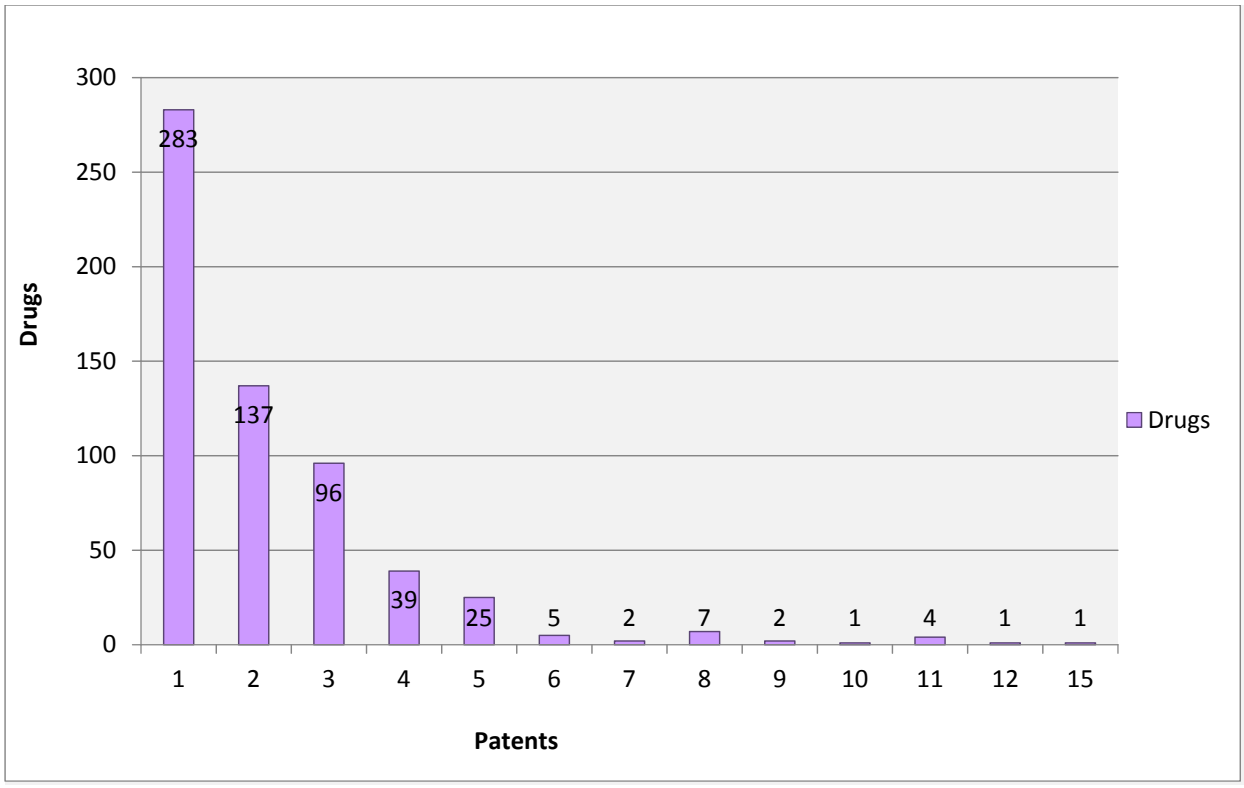

Table 5 - Patents per Drug on the Patent Register

Patents	1	2	3	4	5	6	7	8	9	10	11	12	15
Drugs	283	137	96	39	25	5	2	7	2	1	4	1	1

Judicial Review Applications concerning Patent Eligibility under section 4 of the Patented Medicines (Notice of Compliance) Regulations

Table 6 summarizes judicial review applications 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 that were active over the past fiscal year. New cases and changes that took place to ongoing cases during the fiscal year are presented in bold.

Table 6 - Judicial Review Applications concerning Patent Eligibility

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Filing Date	Close Date	Summary of Issue
T-1978-16 **(Dismissed)**	Elanco, a division of Eli Lilly Canada Inc. -and- The Attorney General of Canada and The Minister of Health	pegbovigrastim	2016-11-16	**2019-01-02**	**Refusal on the basis that the patent did not comply with the timing requirements of subsection 4(6)**

Form V: Declaration re: Patent List (Form V)

Table 7 displays the number of submissions containing at least one Form V received during each fiscal year. A drug manufacturer that makes a direct or indirect comparison with, or reference to, a drug in respect of which there are patents listed on the Patent Register, must file a Form V, agreeing to await patent expiry before obtaining market authorization, indicating that consent has been obtained from the patent owner, or making an allegation in respect of the patent.

Table 7 - Submissions containing Form Vs

Fiscal Year	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019
Submissions	138	200	126	126	96

Judicial Review Applications concerning section 5 of the Patented Medicines (Notice of Compliance) Regulations

There were no judicial review applications concerning section 5 of the Patented Medicines (Notice of Compliance) Regulations filed or ongoing between April 1, 2018 and March 31, 2019.

Prohibition Applications concerning section 6 of the pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations

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, first persons could commence legal proceedings, commonly referred to as prohibition application for an order prohibiting Health Canada from granting a Notice of Compliance for a subsequent-entry version of a patented drug.

Notices of Allegation

The pre-September 21, 2017 version of the Patented Medicines (Notice of Compliance) Regulations continues to apply in respect of any matter that relates to a Notice of Allegation served on a first person before September 21, 2017. Table 8 displays the number of such Notices of Allegation reported in the fiscal year received by the Office of Patented Medicines and Liaison.

Table 8 - Notices of Allegation

Fiscal Year	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019
Notices of Allegation	118	176	105	51	3

Prohibition Applications

Table 9 summarizes the outcome of prohibition applications filed as a result of Notices of Allegation served on first persons before September 21, 2017. The break-down of subsequent appeals for each possible application conclusion - granted, dismissed, partially granted - is also included. The filing date of the application determines the year in which the outcome is reported.

Table 9 - Prohibition Applications

Fiscal Year	2014/2015	2015/2016	2016/2017	2017/2018
Applications Filed	53	18	32	41
Applications Discontinued	38	10	23	35
Applications Granted	7	5	3	2
Appeals Filed	1	2	1	0
Discontinued	1	0	0	0
Granted	0	0	0	0
Dismissed	0	2	0	0
Partial	0	0	0	0
Pending	0	0	1	0

Table 9 - Continued - Prohibition Applications

Fiscal Year	2014/2015	2015/2016	2016/2017	2017/2018
Applications Dismissed	5	3	5	0
Appeals Filed	1	2	0	0
Discontinued	0	1	0	0
Granted	0	0	0	0
Dismissed	1	0	0	0
Partial	0	1	0	0
Pending	0	0	0	0
Applications Partially Granted	3	0	1	0
Appeals Filed	2	0	0	0
Discontinued	1	0	0	0
Granted	0	0	0	0
Dismissed	1	0	0	0
Partial	0	0	0	0
Pending	0	0	0	0
Applications Pending Resolution	0	0	0	4

Average Time to Resolution

Table 10 displays the average resolution times of closed prohibition applications. The filing date of the application determines the fiscal year in which it will be reported. The average time to resolution is calculated from the filing date to the close date of the application in the Federal Court. Appeals and discontinued cases are not included. The 24-month period is prescribed by the Patented Medicines (Notice of Compliance) Regulations and may be varied by the Federal Court.

Table 10 - Average Time to Resolution

Fiscal Year	Applications Filed	Applications Closed	Average Resolution Time (months)	Range (months)
2014/2015	53	15	18.7	5.5 - 24
2015/2016	18	8	15.9	8.3 - 23.9
2016/2017	32	9	13.7	1 - 23.9
2017/2018	41	2	15.3	9.9 - 20.7

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

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.

Notices of Allegation

Table 11 displays the number Notices of Allegation served on or after September 21, 2017 reported by in the fiscal year received by the Office of Patented Medicines and Liaison.

Table 11 - Notices of Allegation

Fiscal Year	2017/2018	2018/2019
Notices of Allegation	31	65

Actions

Table 12 summarizes the outcome of actions for declarations of infringement filed as a result of Notices of Allegation served on the first person on or after September 21, 2017. The break-down of possible action conclusion - granted, dismissed, partially granted - is also included. The filing date of the action determines the year in which the outcome is reported.

Table 12 - Actions

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019
Actions Filed	10	46
Actions Discontinued	7	12
Declaration of Infringement (granted)	0	0
Actions Dismissed	0	1[1]
Declaration of Infringement (partially granted)	0	0
Actions Pending Resolution	3	33
[1] Action dismissed on consent		

Prohibition Applications, Actions and Judicial Review Applications concerning the Patented Medicines (Notice of Compliance) Regulations

Graph 3 and Table 13 compare the number of applications for judicial review of final decisions under the Patented Medicines (Notice of Compliance) Regulations with the number of prohibition applications and actions under section 6 of the Patented Medicines (Notice of Compliance) Regulations. Each court proceeding is recorded in the fiscal year in which it was filed.

Graph 3 - Prohibition Applications, Actions and Judicial Review Applications

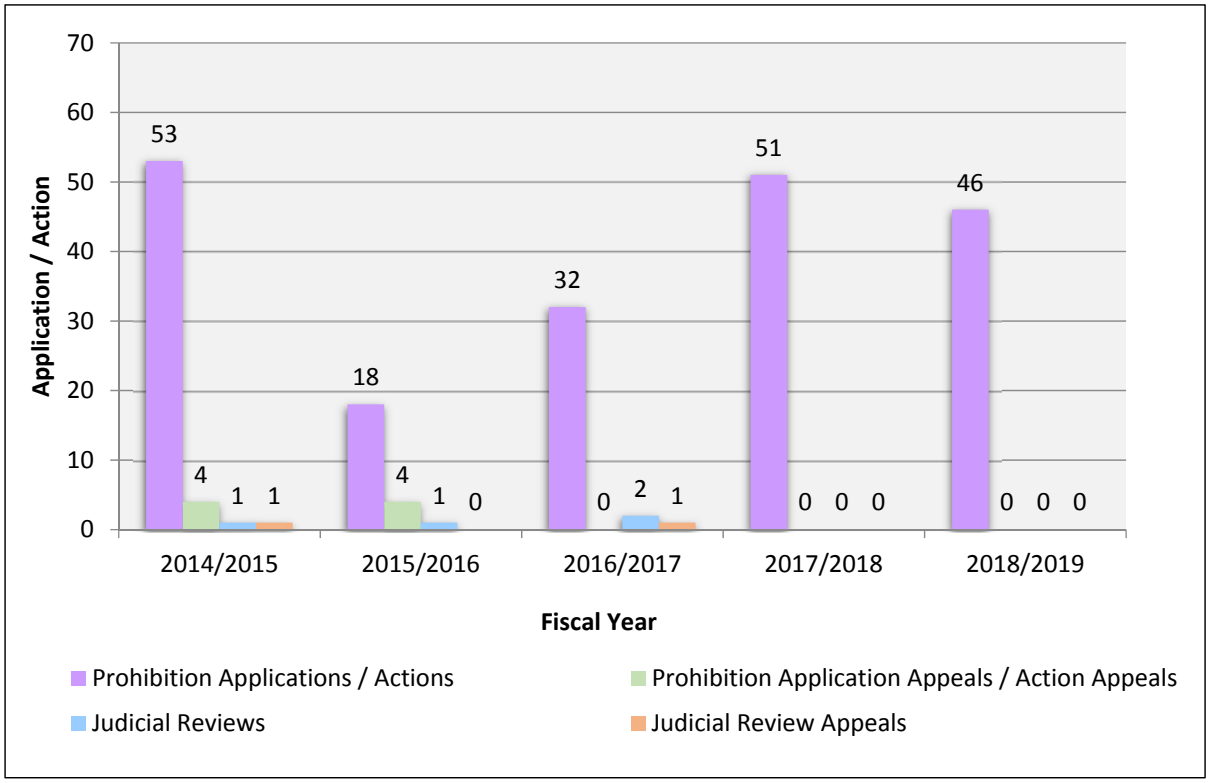

Table 13 - Prohibition Applications, Actions and Judicial Review Applications

Fiscal Year	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019
Prohibition Applications / Actions	53	18	32	51	46
Prohibition Application Appeals / Action Appeals	4	4	0	0	0
Judicial Reviews	1	1	2	0	0
Judicial Review Appeals	1	0	1	0	0

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

Register of Innovative Drugs

Human Drugs

Graph 4 and Table 14 display the number of human drugs that were added to the Register of Innovative Drugs by fiscal year in which the product received a Notice of Compliance. Pediatric extensions for previously listed drugs may be added up to 6 years after the issuance of the Notice of Compliance. Graph 5 and Table 15 display the number of human drugs added to the Register of Innovative Drugs by product type.

Graph 4 - Human Drugs added to the Register of Innovative Drugs

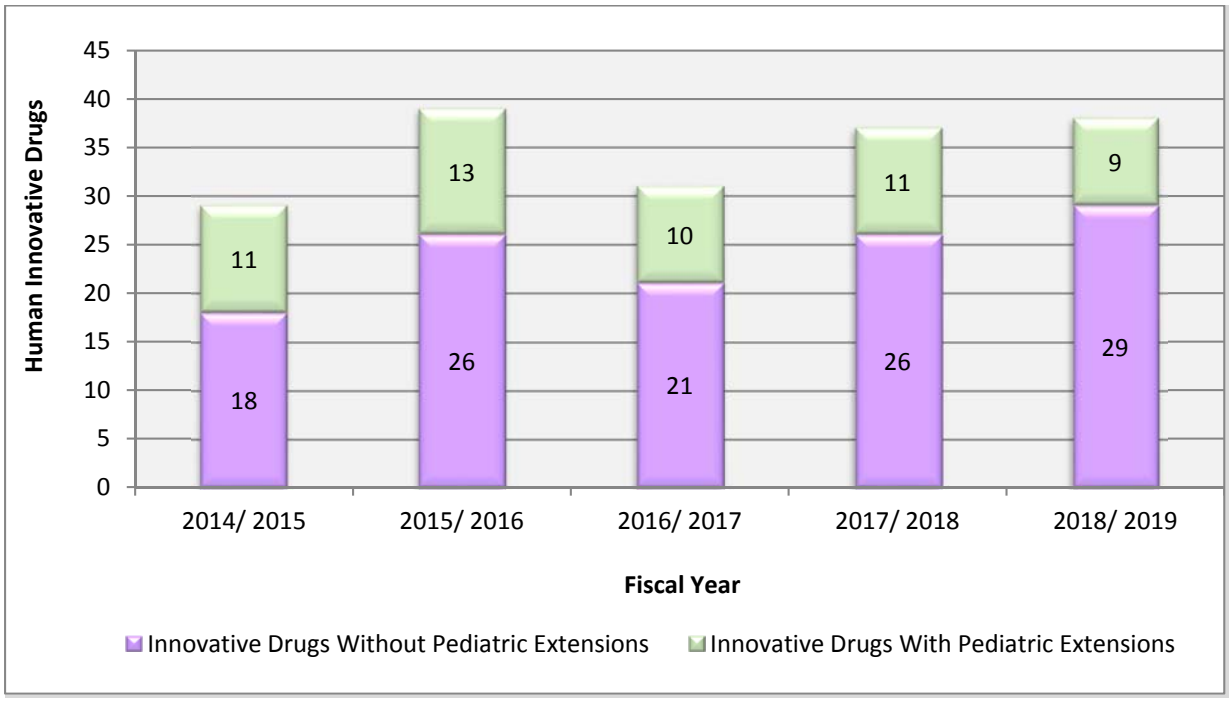

Table 14 - Human Drugs added to the Register of Innovative Drugs

Fiscal Year	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Innovative Drugs with Pediatric Extensions	11	13	10	11	9
Innovative Drugs without Pediatric Extensions	18	26	21	26	29
Total	29	39	31	37	38

Graph 5 - Human Innovative Drugs by Product Type

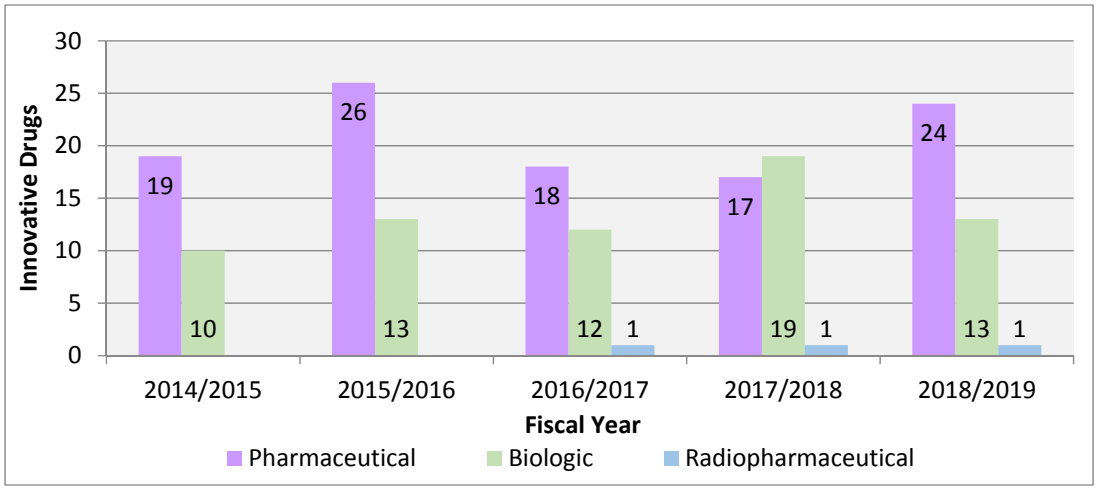

Table 15 - Human Innovative Drugs by Product Type

Fiscal Year	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Pharmaceutical	19	26	18	17	24
Biologic	10	13	12	19	13
Radiopharmaceutical	0	0	1	1	1

Veterinary Drugs

Graph 6 and Table 16 display the number of veterinary drugs that were added to the Register of Innovative Drugs by fiscal year in which the product received a Notice of Compliance.

Graph 6 - Veterinary Drugs added to the Register of Innovative Drugs

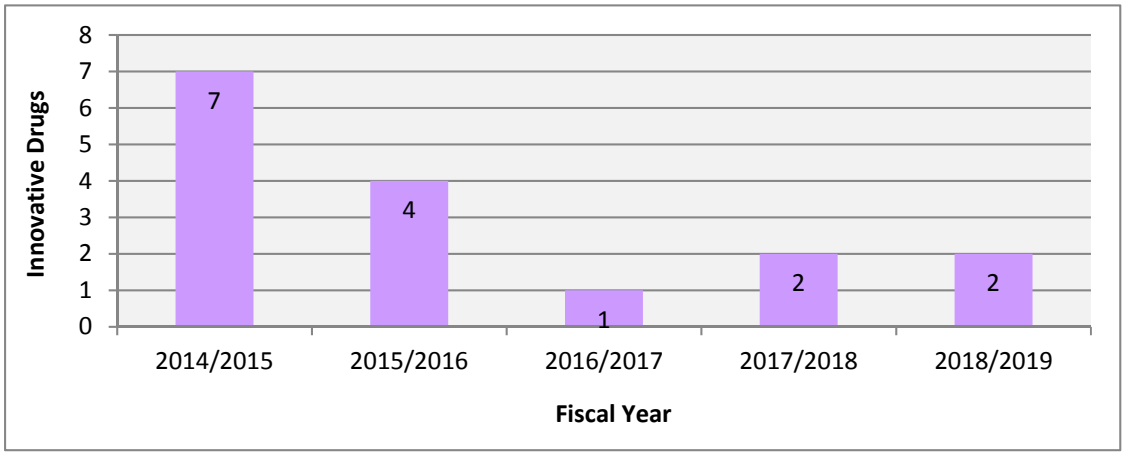

Table 16 - Veterinary Drugs added to the Register of Innovative Drugs

Fiscal Year	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Innovative Drugs	7	4	1	2	2

Judicial Review Applications concerning Data Protection

Table 17 displays the number of judicial review applications and appeals that have been filed over the past five years. Each case is recorded in the fiscal year it was filed.

Table 17 - Judicial Review Applications and Appeals

Fiscal Year	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019
Judicial Reviews	1	1	0	0	1
Judicial Review Appeals	0	0	0	0	0

Table 18 summarizes judicial review applications with respect to data protection that were active over the past fiscal year. New cases and changes to ongoing cases that occurred during the fiscal year are presented in bold.

Table 18 - Judicial Review Applications concerning Data Protection

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Filing Date	Close Date	Summary of Issue
T-700-18 **(Discontinued)**	Acerus Pharmaceuticals Corporation – and- The Minister of Health and The Attorney General of Canada	Estriol / Lactobacillus acidophilus	**2018-04-12**	**2019-03-05**	**Ineligibility on the basis that the medicinal ingredients were previously approved in a drug by the Minister**

Section IV - Statistics: Certificates of Supplementary Protection

Applications

Table 19 displays information regarding the applications for Certificates of Supplementary Protection that were filed since the coming into force of the regime on September 21, 2017. Applications may be filed before the end of a 120-day period that begins on either the day on which the patent at issue was granted, or the day on which the Notice of Compliance for the underlying submission was issued, as applicable.

Table 19 - Applications

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019
Total Applications	12	26
Median Days to File	46	85
Range of Days to File	1-118	3-119

Issuances and Refusals

Table 20 summarizes the outcomes of the Certificate of Supplementary Protection applications. A Certificate of Supplementary Protection may be issued or refused in a different fiscal year from that in which the application was filed. The refusals counted in this table represent final decisions.

Table 20 - Issuances and Refusals

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019
Issuances (total)	0	26
Issuances (less than 2-year term)	0	2
Refusals	1	6
Total Decisions	1	32

Performance

Health Canada's performance in meeting the service standard is displayed in Table 21. The service standard is 60 calendar days (average) for the first eligibility decision beginning on the day there are no conflicting applications of the highest priority and the time for filing an application having the same or higher priority has ended. According to this standard, Health Canada will inform the applicant either that the Certificate of Supplementary Protection has issued or that the application has been preliminarily refused with an opportunity to provide representations, within an average of 60 calendar days. If the Certificate of Supplementary Protection is issued, this represents a first and final decision regarding eligibility. If the application is refused, this represents a first decision regarding eligibility.

Table 21 - Performance

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019
Average Days for First Decision	44	40

Reasons for Refusal

Table 22 provides a summary of the reasons for refusal of applications up to March 31, 2019.

Table 22 - Reasons for Refusal

Application Number	Drug (Medicinal Ingredient(s))	Patent Number	Reasons for Refusal
900001	MAVIRET (glecaprevir / pibrentasvir)	2807847	The timing requirement of paragraph 106(1)(c) of the Patent Act was not met because the authorization for sale issued before September 21, 2017. In addition, the patent did not meet the requirements of paragraph 106(1)(c) of the Patent Act and subsection 3(2) of the Certificate of Supplementary Protection Regulations because it did not pertain to the combination of medicinal ingredients.
900006	SHINGRIX (varicella-zoster virus) (glycoprotein E)	2600905	The patent did not meet the requirements of paragraph 106(1)(c) of the Patent Act and subsection 3(2) of the Certificate of Supplementary Protection Regulations because it did not pertain to the medicinal ingredient.
900011	REBINYN (coagulation factor IX (recombinant), pegylated)	2462930	The application did not meet the requirements of paragraph 106(1)(d) of the Patent Act because the authorization for sale was not the first authorization for sale that had been issued with respect to the medicinal ingredient. The medicinal ingredient differed from the coagulation factor IX in previously authorized drugs only with respect to prescribed variations and was considered to be the same medicinal ingredient in accordance with subsection 105(3) of the Patent Act.
900014	BEVESPI AEROSPHERE (glycopyrronium (as bromide) / formoterol fumarate dehydrate)	2763936	The patent did not meet the requirements of paragraph 106(1)(c) of the Patent Act and subsection 3(2) of the Certificate of Supplementary Protection Regulations because it did not pertain to the combination of medicinal ingredients.
900021	JULUCA (dolutegravir sodium / rilpivirine hydrochloride)	2606282	The patent did not meet the requirements of paragraph 106(1)(c) of the Patent Act and subsection 3(2) of the Certificate of Supplementary Protection Regulations because it did not pertain to the combination of medicinal ingredients.

Table 22 - Continued - Reasons for Refusal

Application Number	Drug (Medicinal Ingredient(s))	Patent Number	Reasons for Refusal
900022	OXERVATE (cenegermin)	2346257	There was no authorization for sale as required by paragraphs 106(1)(c) and (d) of the Patent Act, amongst other provisions.
900028	BIKTARVY (bictegravir sodium/ emtricitabine/ tenofovir alafenamide hemifumarate)	2416757	The patent did not meet the requirements of paragraph 106(1)(c) of the Patent Act and subsection 3(2) of the Certificate of Supplementary Protection Regulations because it did not pertain to the combination of medicinal ingredients.

Judicial Review Applications concerning Certificates of Supplementary Protection

Table 23 summarizes judicial review applications with respect to decisions concerning the eligibility of Certificate of Supplementary Protection applications that were active over the past fiscal year. New cases and changes to open cases that occurred during the fiscal year are presented in bold.

Table 23 - Judicial Review Applications concerning Certificates of Supplementary Protection

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Filing Date	Close Date	Summary of Issue
T-1603-18	GlaxoSmithKline Biologicals SA - and - The Minister of Health	varicella zoster virus glycoprotein E	**2018-08-31**		**Refusal on the basis that the patent does not pertain to the medicinal ingredient**
T-353-19	Viiv Healthcare ULC – and - The Minister of Health	dolutegravir sodium / rilpivirine hydrochloride	**2019-02-22**		**Refusal on the basis that the patent does not pertain to the combination of medicinal ingredients**

Section V - Statistics: Intellectual Property Hold

Submissions Remaining on Intellectual Property Hold

Graph 7 and Table 24 display the number of submissions filed by fiscal year that were still on IP Hold as of March 31, 2019. Data are shown beginning with the 2010/2011 fiscal year.

Graph 7 - Submissions Remaining on Intellectual Property Hold

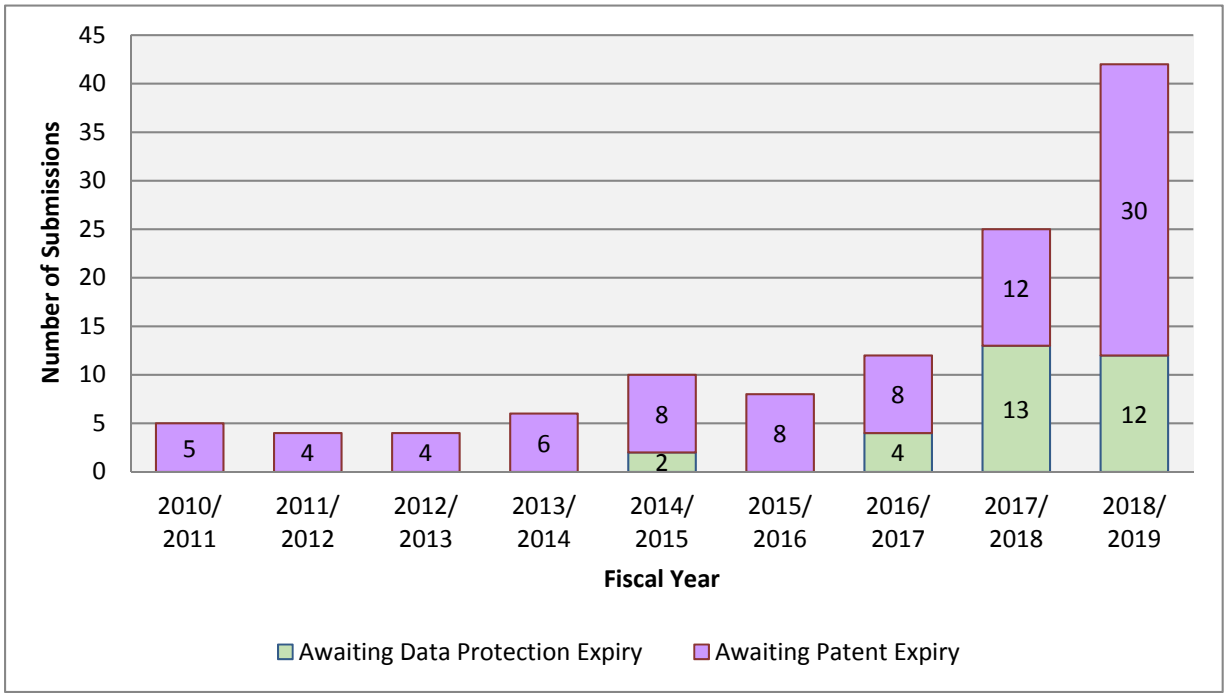

Table 24 - Submissions remaining on Intellectual Property Hold

Fiscal Year	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019
Awaiting Data Protection Expiry	0	0	0	0	2	0	4	13	12
Awaiting Patent Expiry	5	4	4	6	8	8	8	12	30
Total	5	4	4	6	10	8	12	25	42

Appendix A - Definitions

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

Declaration of Infringement Granted:
A declaration by the Federal Court that the making, constructing, using or selling of a drug in accordance with a submission or supplement would infringe all patents and certificates of supplementary protection at issue in an action brought under subsection 6(1) of the Patented Medicines (Notice of Compliance) Regulations.

Declaration of Infringement Partially Granted:
A declaration by the Federal Court that the making, constructing, using or selling of a drug in accordance with a submission or supplement would infringe one or more, but not all, patents and certificates of supplementary protection at issue in an action brought under subsection 6(1) of the Patented Medicines (Notice of Compliance) Regulations.

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.

Drug Identification Number:
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.

Fiscal Year:
The period of time beginning on April 1 and ending on March 31 of the following calendar year.

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 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 served 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.08.004.01 or 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, an abbreviated new drug submission, an extraordinary use new drug submission and supplements to those submissions