Health Canada Santé Canada

June 23, 2023

Notice

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Release of the Statistical Report 2022/2023 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 2022/2023 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*, Certificates of Supplementary Protection and applications under the *Patent Act* and the *Certificate of Supplementary Protection Regulations*, and related court activity.

The 2022/2023 report marks a change to the reporting of statistics for Intellectual Property Hold. Prior information on drug submissions remaining on hold has been replaced with updates to show the number of drug submissions that were placed on hold in each fiscal year, and the reason (i.e., patents, data protection, or both).

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 2022 / 2023

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: 2023/06/23

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 2022/2023 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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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* 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 adjudicated in the Federal Court.

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* implement Canada's trade obligations 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. 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.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 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 trade obligations 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. 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 provided in order to reflect the number of requests for patent listing decisions received.

Table 1 - Patent Lists Received

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Patent Lists - Patent per Submission	736	762	934	854	1147

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	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
New Drug Submission, s. 4(2)	131	112	121	126	113
Supplement to a New Drug Submission, s. 4(3)	20	10	16	10	9
Supplement to a New Drug Submission, s. 4.1(2)	627	434	605	682	662
Total	778	556	742	818	784

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. Note that patent lists may have been received in one fiscal year but rejected the following fiscal year.

Patent lists counted in the "Other" category include those received in respect of submissions that have been withdrawn or cancelled.

Table 3 - Rejections

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
New Drug Submission, s. 4(2)	32	29	19	28	46
Supplement to a New Drug Submission, ss. 4(3) and 4.1(2)	106	54	53	106	110
Timing, ss. 4(5) and 4(6)	3	4	32	8	16
Other	0	1	0	2	17
Total	141	88	104	144	189

A Snapshot of the Patent Register as of March 31, 2023: Number of Patents per Drug 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. There are currently 631 different drugs listed on the Patent Register. Some drugs have multiple Drug Identification Numbers (e.g., 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 1 - Patents per Drug on the Patent Register

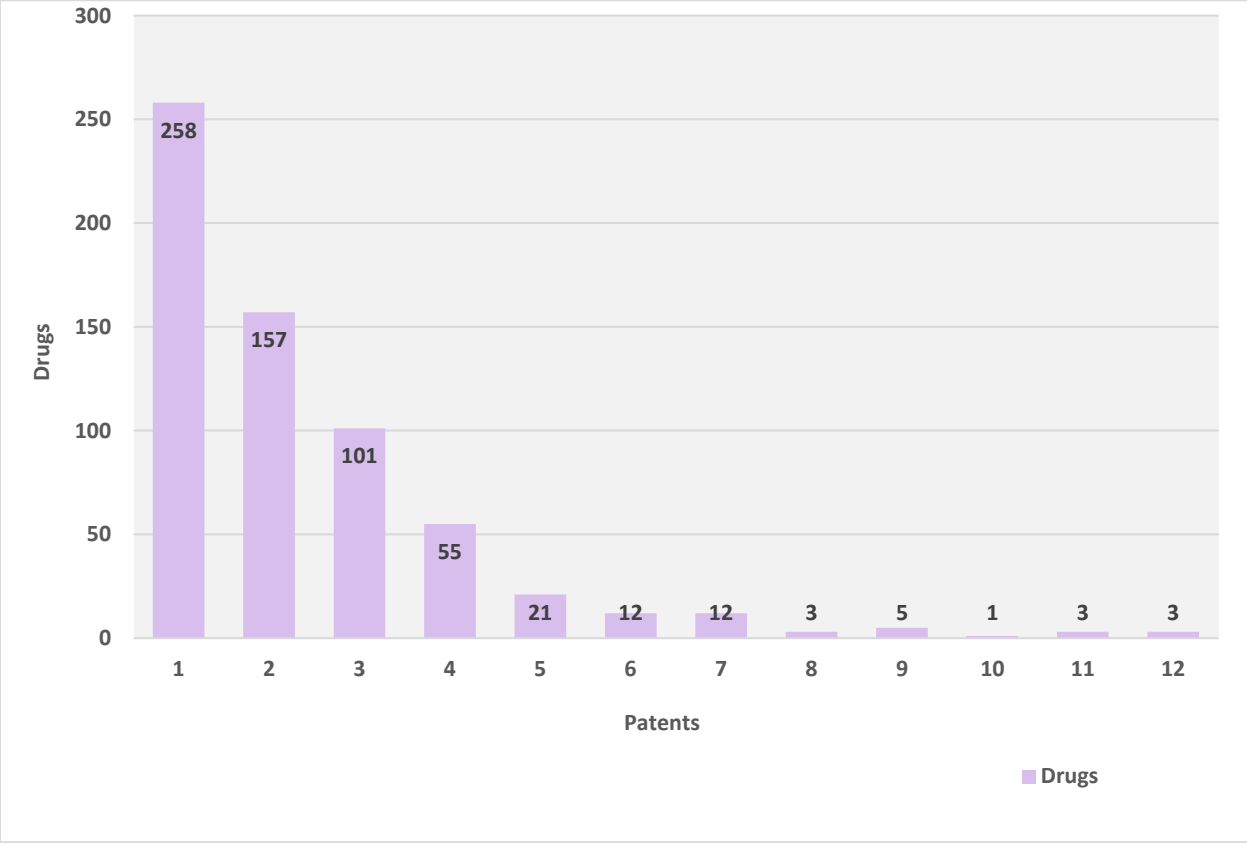

Table 4 - Patents per Drug on the Patent Register

Patents	1	2	3	4	5	6	7	8	9	10	11	12
Drugs	258	157	101	55	21	12	12	3	5	1	3	3

A Snapshot of the Patent Register as of March 31, 2023: Drug Identification Number 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 with a particular Drug Identification Number. As of March 31, 2023, there were 1,097 Drug Identification Numbers listed on the Patent Register, representing 631 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 2 - Patents per Drug Identification Number on the Patent Register

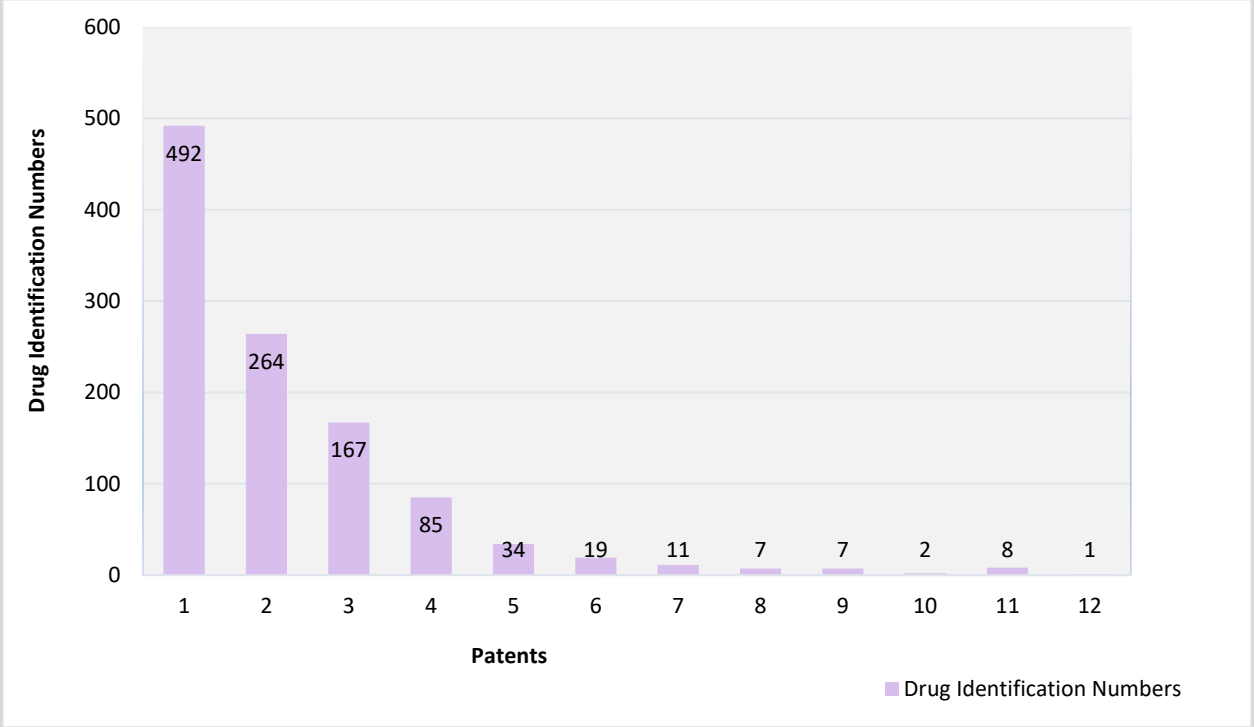

Table 5- Patents per Drug Identification Number on the Patent Register

Patents	1	2	3	4	5	6	7	8	9	10	11	12
Drug Identification Numbers	492	264	167	85	34	19	11	7	7	2	8	1

Judicial Review Applications concerning patent eligibility: 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 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 6 - Judicial review applications concerning patent eligibility: Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*

Federal Court / Federal Court of Appeal / Supreme Court of Canada	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-1476-20 (Dismissed) A-143-21 (Dismissed) 40043 **(Leave Dismissed)**	*Merck Canada Inc v the Minister of Health*	pembrolizumab	2020-12-04 2021-05-13 2022-02-14	2021-04-20 2021-11-22 **2022-05-12**	Rejection on the basis that patent lists did not meet timing requirements
T-2627-22 (Ongoing)	***Janssen Inc v the Minister of Health and Attorney General of Canada***	**ustekinumab**	**2022-12-14**		**Refusal on the basis that patent lists did not meet the requirements of subsection 4(3)**

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 under section 5 of the *Patented Medicines (Notice of Compliance) Regulations*. A drug manufacturer that makes a direct or indirect comparison with, or reference to, a marketed 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	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Submissions	96	153	110	142	113

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

Table 8 summarizes judicial review applications with respect to decisions concerning the administration of section 5 of the *Patented Medicines (Notice of Compliance) Regulations* 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 8 - Judicial review applications concerning the administration of 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-10-22/ T-130-22 **(Dismissed)** **A-203-22 (Ongoing)**	*AbbVie Corporation and AbbVie Biotechnology Ltd v The Minister of Health and JAMP Pharma Corporation*	adalimumab	2022-01-04 **2022-10-03**	**2022-08-17**	Decision on the basis that section 5 did not apply

Actions concerning section 6 of the *Patented Medicines (Notice of Compliance) Regulations*

The September 21, 2017, amendments to the *Patented Medicines (Notice of Compliance) Regulations* permit full actions resulting in final determinations of patent infringement and validity. These may arise following the service of a Notice of Allegation.

Notices of Allegation

Table 9 displays the number of Notices of Allegation served on or after September 21, 2017, reported in the fiscal year received by the Office of Patented Medicines and Liaison.

Table 9 - Notices of Allegation

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Notices of Allegation	65	78	85	46	59

Actions

Table 10 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 subsequent appeals for each 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 10 – Actions

Fiscal Year	September 21, 2017, to March 31, 2018	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Actions Filed	10	46	55	60	23	53
Actions Discontinued	9	31	47	51	14	10
Actions Granted	1	6	1	4	1	0
Appeals Filed	1	5	1	4	1	0
Discontinued	0	2	0	0	0	0
Granted	0	0	0	0	0	0
Dismissed	1	3	0	0	0	0
Partial	0	0	0	0	0	0
Pending	0	0	0	4	1	0
Actions Dismissed	0	9*	7	1[#]	0	0
Appeals Filed	0	6	7	0	0	0
Discontinued	0	1	4	0	0	0
Granted	0	0	0	0	0	0
Dismissed	0	5	3^	0	0	0
Partial	0	0	0	0	0	0
Pending	0	0	0	0	0	0
Actions Partially Granted	0	0	0	0	0	0
Appeals Filed	0	0	0	0	0	0
Discontinued	0	0	0	0	0	0
Granted	0	0	0	0	0	0
Dismissed	0	0	0	0	0	0
Partial	0	0	0	0	0	0
Pending	0	0	0	0	0	0
Actions Pending Resolution	0	0	0	4	8	43

* 2 of the 9 actions were dismissed on consent
^ 1 of the 3 appeals was dismissed on consent
[#]The action was dismissed on consent

Average Time to Resolution

Table 11 displays the average resolution times of closed actions. The filing date of the action determines the fiscal year in which it is reported. The average time to resolution is calculated from the filing date to the close date of the action in the Federal Court. Appeals and cases that were discontinued or dismissed on consent are not included.

The Federal Court has varied the 24-month period prescribed by the *Patented Medicines (Notice of Compliance) Regulations* in some circumstances.

Table 11 - Average Time to Resolution

Fiscal Year	Actions Filed	Actions Closed	Average Resolution Time (months)	Range (months)
2018/2019	46	13	24.3	15.4 - 42.6
2019/2020	55	8	21.5	13.5 - 24.1
2020/2021	60	4	20.3	12.4 – 24.0
2021/2022	23	1	5.3	5.3
2022/2023	53	0	-	-

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

Graph 3 and Table 12 compare the number of applications for judicial review of final decisions under the *Patented Medicines (Notice of Compliance) Regulations* with the number of actions under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*. The filing date of the application or action determines the fiscal year in which the proceeding is reported.

Graph 3 - Actions and Judicial Review Applications

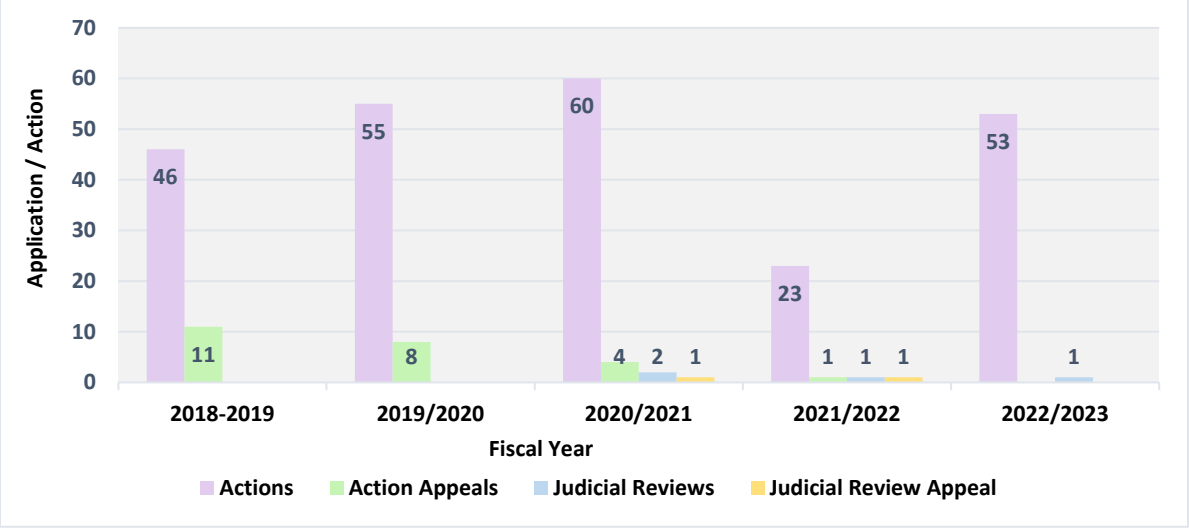

Table 12 - Actions and Judicial Review Applications

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Actions	46	55	60	23	53
Action Appeals	11	8	4	1	0
Judicial Reviews	0	0	2	1	1
Judicial Review Appeals	0	0	1	1	0

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

Human Drugs

Graph 4 and Table 13 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 14 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

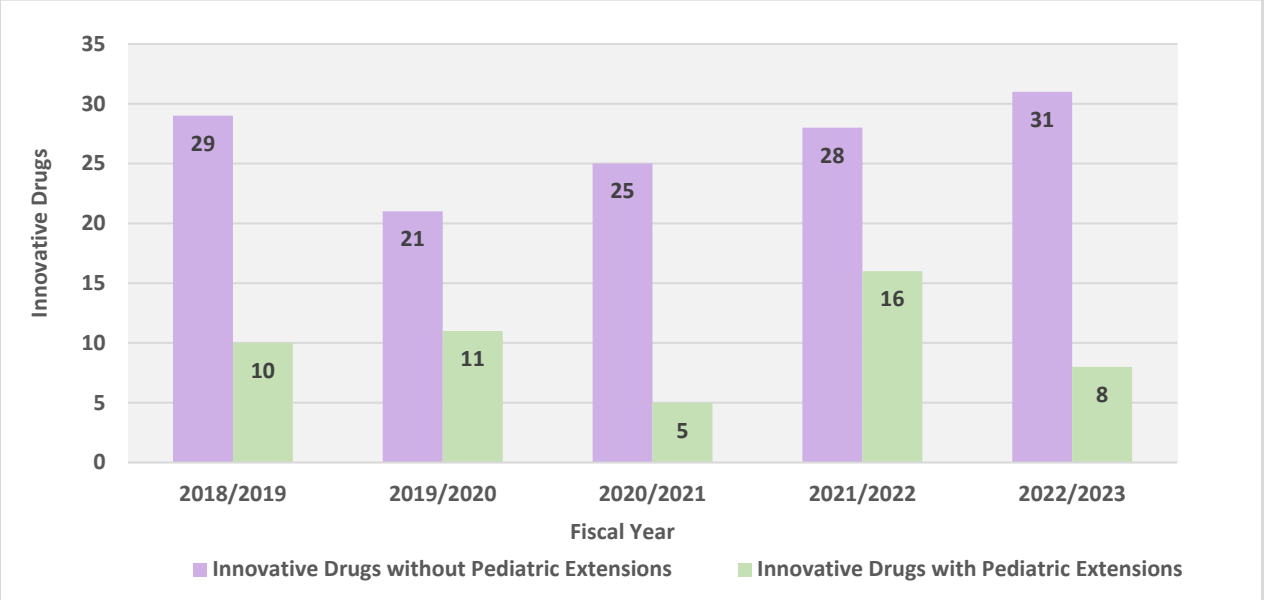

Table 13 - Human Drugs added to the Register of Innovative Drugs

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Innovative Drugs with Pediatric Extensions	10	11	5	16	8
Innovative Drugs without Pediatric Extensions	29	21	25	28	31
Total	39	32	30	44	39

Graph 5 - Human Innovative Drugs by Product Type

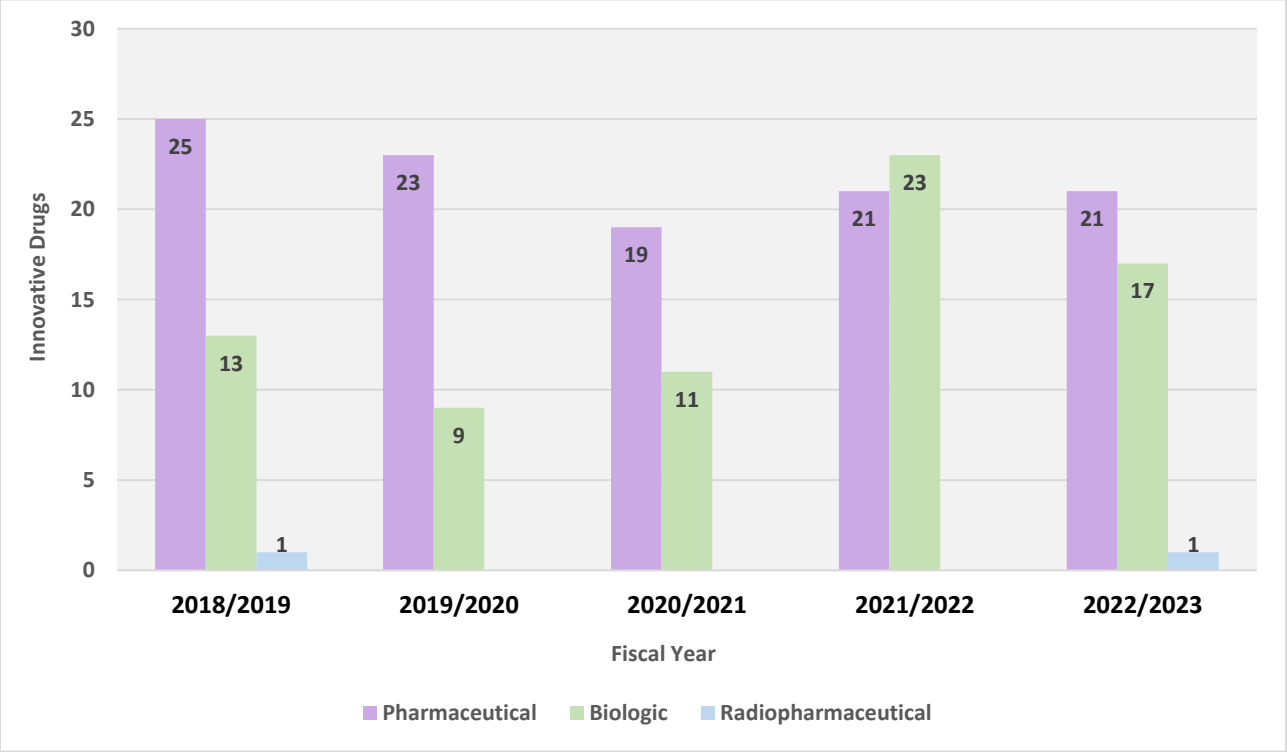

Table 14 - Human Innovative Drugs by Product Type

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Pharmaceutical	25	23	19	21	21
Biologic	13	9	11	23	17
Radiopharmaceutical	1	0	0	0	1

Veterinary Drugs

Graph 6 and Table 15 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. Pediatric extensions are not available for veterinary drugs.

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

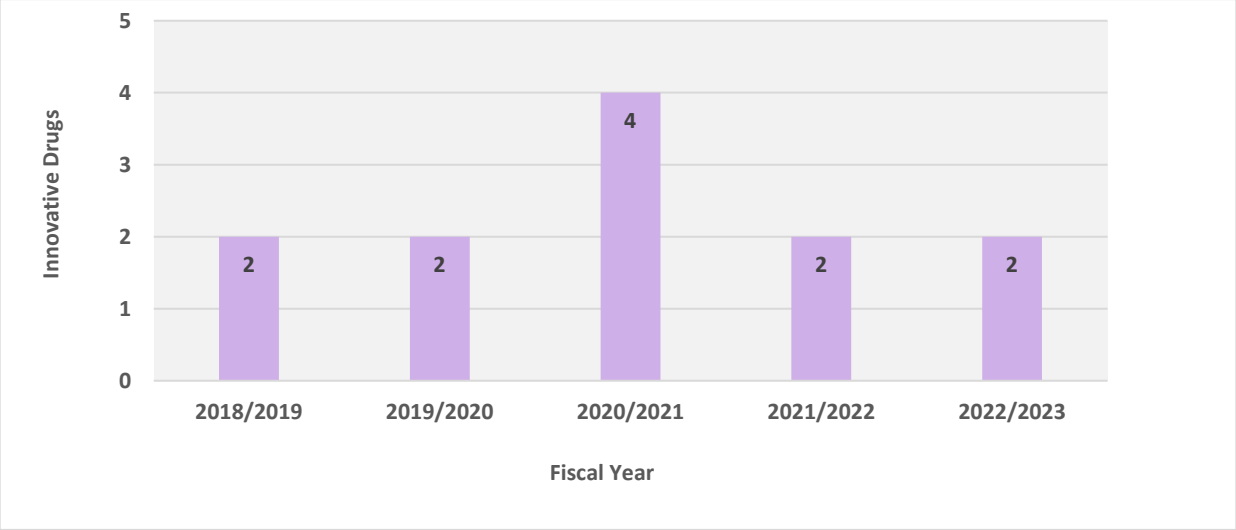

Table 15 - Veterinary Drugs added to the Register of Innovative Drugs

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Innovative Drugs	2	2	4	2	2

Judicial Review Applications concerning Data Protection

Table 16 displays the number of judicial review applications and appeals that have been filed over the past five years. The filing date of the application determines the fiscal year in which the proceeding is reported.

Table 16 - Judicial Review Applications and Appeals

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Judicial Reviews	1	2	1	2	0
Judicial Review Appeals	0	1	0	2	0

Table 17 summarizes judicial review applications with respect to decisions concerning 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 17 - 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-1047-21 (Granted) **A-78-22 (Appeal allowed, Cross-appeal dismissed)**	*Catalyst Pharmaceuticals, Inc., Kye Pharmaceuticals Inc. v Attorney General of Canada and Médunik Canada*	amifampridine	2021-07-05 **2022-04-11**	2022-03-10 **2023-01-09**	Issuance of a Notice of Compliance on the basis that there was no direct or indirect comparison with an innovative drug
T-1867-21 **(Dismissed)** **A-21-23 (Ongoing)**	*Janssen Inc. v Attorney General of Canada and the Minister of Health*	esketamine hydrochloride	2021-12-08 **2023-02-02**	**2023-01-05**	Ineligibility on basis that the medicinal ingredient is a variation of a previously approved medicinal ingredient.

Section IV - Statistics: Certificates of Supplementary Protection

Applications

Table 18 displays information regarding the applications for Certificates of Supplementary Protection in each fiscal year. 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 18 - Applications

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Total Applications	26	15	23	17	18
Median Days to File	85	63	42	64	76
Range of Days to File	3-119	17-114	4-116	13-121	15-116

Outcomes

Table 19 summarizes the outcomes of the applications for Certificates of Supplementary Protection. 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 19 - Outcomes

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Issued (2-year term)	24	12	21	7	16
Issued (less than 2-year term)	2	1	0	6	1
Refused	6	1	1	4	1
Total Decisions	32	14	23	17	18

Performance

Health Canada's performance in meeting the service standard is displayed in Table 20. 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 been issued or 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 Certificate of Supplementary Protection is refused, this represents a first decision regarding eligibility.

Table 20 – Performance

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Average Days for First Decision	40	22	20	36	26

Reasons for Refusal

Table 21 provides a summary of the reasons for refusal of applications between April 1, 2022, and March 31, 2023.

Table 21 - Reasons for Refusal

Application Number	Drug (Medicinal Ingredient(s))	Patent Number	Reasons for Refusal
900090	TRUSELTIQ (infigratinib phosphate)	2,781,431	The application did not meet the timing requirements under subsection 106(3) of the *Patent Act* and subsection 6(2) of the *Certificate of Supplementary Protection Regulations* to apply for a certificate of supplementary protection.

Judicial Review Applications concerning Certificates of Supplementary Protection

There were no judicial review applications with respect to decisions concerning the eligibility of applications for Certificate of Supplementary Protection that were active over the past fiscal year.

Section V - Statistics: Intellectual Property Hold

A Snapshot of Drug Submissions Placed on Intellectual Property Hold as of March 31, 2023

Graph 7 and Table 22 display the number of drug submissions that were placed on Intellectual Property Hold as of March 31, 2023, and the reason.

Graph 7 - Drug Submissions Placed on Intellectual Property Hold by fiscal year

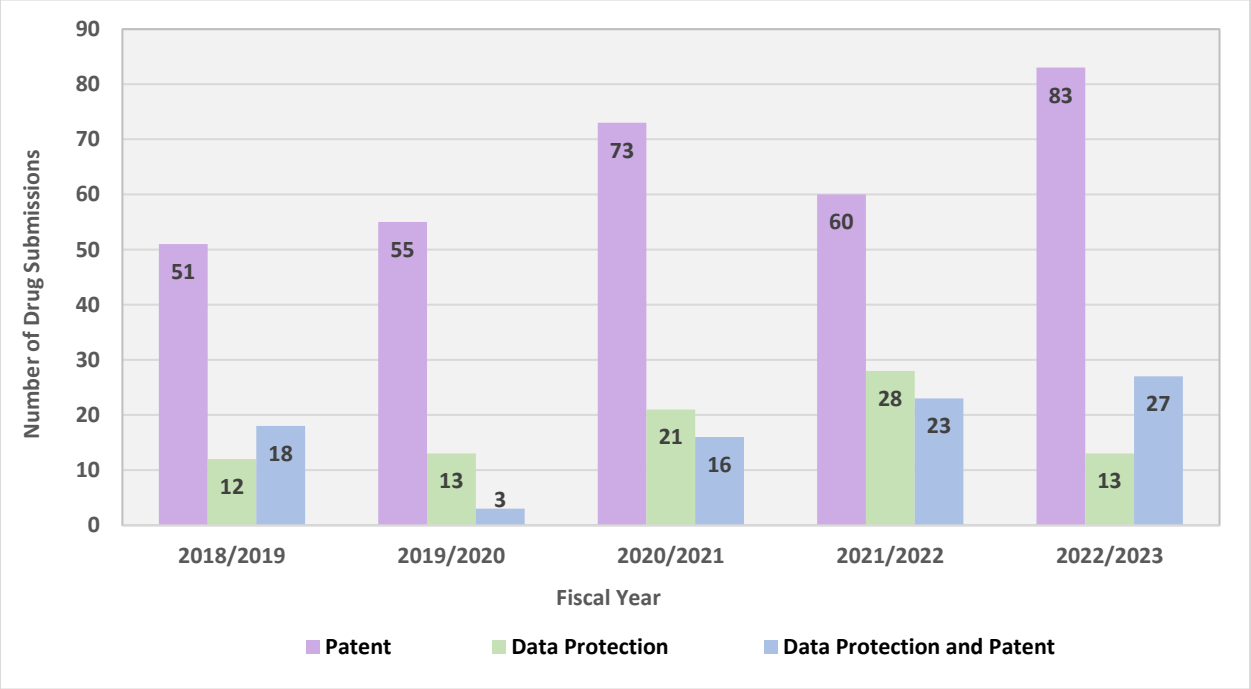

Table 22 - Drug Submissions placed on Intellectual Property Hold by fiscal year

Fiscal Year	2018/ 2019	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023
Patent	51	55	73	60	83
Data Protection	12	13	21	28	13
Data Protection and Patent	18	3	16	23	27
Total	81	71	110	111	123

Appendix A - Definitions

Action Granted:
The Federal Court granted a declaration that the making, constructing, using or selling of a drug would infringe all patents and certificates of supplementary protection at issue in an action brought under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*.

Action Partially Granted:
The Federal Court granted a declaration that the making, constructing, using or selling of a drug would infringe one or more, but not all, patents and certificates of supplementary protection at issue in an action brought under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*.

Drug Identification Number:
A computer-generated 8-digit number assigned by Health Canada to a drug upon market authorization under subsection C.01.014.2 (1) of the Food and Drug Regulations.

It identifies each drug under the Food and Drug Regulations, sold in a dosage form in Canada, and is located on the package label of prescription and non-prescription drugs 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.

Notice of Allegation:
A notice served under section 5 of the *Patented Medicines (Notice of Compliance) Regulations*. Such a notice sets out the nature of the second person's challenge to a patent or certificate of supplementary protection listed on the Patent Register or on the Register of Certificates of Supplementary Protection and Applications.

Notice of Compliance:
Market authorization issued under section C.08.004.01 or C.08.004 of the *Food and Drug Regulations*.

Pending:
A court case awaiting judgment.

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