Health Canada Santé Canada

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Notice

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Release of the Statistical Report 2023/2024 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 2023/2024 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.

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

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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 2023/2024 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, Marketed Health Products 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 been 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 tests 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	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Patent Lists - Patent per Submission	762	934	854	1147	988

Additions to the 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	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
New Drug Submission, s. 4(2)	112	121	126	113	107
Supplement to a New Drug Submission, s. 4(3)	10	16	10	9	14
Supplement to a New Drug Submission, s. 4.1(2)	434	605	682	662	757
Total	556	742	818	784	878

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	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
New Drug Submission, s. 4(2)	29	19	28	46	17
Supplement to a New Drug Submission, ss. 4(3) and 4.1(2)	54	53	106	110	129
Timing, ss. 4(5) and 4(6)	4	32	8	16	4
Other	1	0	2	17	0
Total	88	104	144	189	150

A Snapshot of the Patent Register as of March 31, 2024: 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, 2024, there were 1,205 Drug Identification Numbers listed on the Patent Register, representing 547 different medicinal ingredients. 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
Drug Identification Numbers	514	307	163	111	34	31	9	14	5	8	8	1

Judicial Review Applications concerning Patent Eligibility: Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*

Table 5 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 ongoing cases that occurred during the fiscal year are presented in **bold**.

Table 5 - 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 Decision
T-2627-22 **(Dismissed)**	*Janssen Inc v the Minister of Health and Attorney General of Canada*	ustekinumab	2022-12-14	**2023-06-21**	Refusal on the basis that patent lists did not meet the requirements of subsection 4(3)
A-192-23 (Dismissed)			**2023-07-26**	**2023-11-21**	
T-873-23 (Discontinued)	***Janssen Inc v The Minister of Health and Attorney General of Canada***	**ustekinumab**	**2023-04-26**	**2024-02-26**	**Refusal to add a new patent in respect of a New Drug Submission for a new brand name**
T-1369-23 (Ongoing)	***EMD Serono, a Division of EMD Inc, Canada and Merck Serono SA v the Minister of Health and Apotex Inc***	**cladribine**	**2023-07-04**		**Decision that the date for the addition of a patent to the register is the date of the eligibility decision**
T-2728-23 (Ongoing)	***Bayer Inc v Amgen Canada Inc and the Minister of Health***	**aflibercept**	**2023-12-22**		**Decision that the date for the addition of a patent to the register is the date of the eligibility decision and a second person is not required to comply with section 5 in respect of a patent added to the register on or after the date of filing of its submission**

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

Table 6 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 6 - Submissions containing Form Vs

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Submissions	153	110	142	113	107

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

Table 7 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 ongoing cases that occurred during the fiscal year are presented in **bold**.

Table 7 - 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 Decision
T-10-22/ T-130-22 (Dismissed)	*AbbVie Corporation and AbbVie Biotechnology Ltd v The Minister of Health and JAMP Pharma Corporation*	adalimumab	2022-01-04	2022-08-17	Decision on the basis that section 5 did not apply
A-203-22 (Ongoing)			2022-10-03		
T-1178-23 (Dismissed)	***Bayer Inc and Regeneron Pharmaceuticals, Inc v BGP Pharma ULC d.b.a. Viatris Canada and Biosimilar Collaborations Ireland Limited***	**aflibercept**	**2023-06-06**	**2023-10-03**	**Decision that a successor manufacturer adopts the steps taken by its predecessor under section 5**
A-283-23 (Dismissed)			**2023-10-19**	**2024-02-13**	

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

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 8 displays the number of Notices of Allegation received by the Office of Patented Medicines and Liaison in each fiscal year.

Table 8 - Notices of Allegation

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Notices of Allegation	78	85	46	59	46

Actions

Table 9 summarizes the outcome of actions for declarations of infringement. The breakdown of subsequent appeals for each possible action conclusion - granted, dismissed (including on consent), partially granted - is also included. Table 9 also includes outcomes resulting from a successful appeal from a dismissal of a motion for summary judgment. The filing date of the action determines the year in which the outcome is reported.

Table 9 – Actions

Fiscal Year	**2019/ 2020**	**2020/ 2021**	**2021/ 2022**	**2022/ 2023**	**2023/ 2024**
Actions Filed	55	56	23	53	39
Actions Discontinued	47	51	20	31	4
Actions Granted	1	4	2	4	0
Appeals Filed	1	4	2	0	0
Discontinued	1	0	0	0	0
Granted	0	0	0	0	0
Dismissed	0	4	1	0	0
Partial	0	0	0	0	0
Pending	0	0	1	0	0
Actions Dismissed	7	1	1	0	0
Appeals Filed	7	0	0	0	0
Discontinued	4	0	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
Actions Partially Granted	0	0	0	0	0
Appeals Filed	0	0	0	0	0
Discontinued	0	0	0	0	0
Granted	0	0	0	0	0
Dismissed	0	0	0	0	0
Partial	0	0	0	0	0
Pending	0	0	0	0	0
Actions Pending Resolution	0	0	0	18	35

Average Time to Resolution

Table 10 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 10 - Average Time to Resolution

Fiscal Year	Actions Filed	Actions Closed	Average Resolution Time (months)	Range (months)
2019/2020	55	8	21.5	13.5 - 24.1
2020/2021	56	4	20.3	12.4 – 24.0
2021/2022	23	3	17.5	5.3 – 23.9
2022/2023	53	4	18.4	18.2 – 18.7
2023/2024	39	0	–	–

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

Graph 2 and Table 11 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 2 - Actions and Judicial Review Applications

Table 11 - Actions and Judicial Review Applications

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Actions	55	56	23	53	39
Action Appeals	8	4	2	0	0
Judicial Reviews	0	2	1	1	4
Judicial Review Appeals	0	1	1	1	1

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

Human Drugs

Graph 3 and Table 12 display the number of human drugs added to the Register of Innovative Drugs by fiscal year in which the product received a Notice of Compliance. Pediatric extensions for previously added drugs may be reported up to 6 years after the issuance of the Notice of Compliance. Graph 4 and Table 13 display the number of human drugs added to the Register of Innovative Drugs by product type.

Graph 3 - Human Drugs Added to the Register of Innovative Drugs

Table 12 - Human Drugs Added to the Register of Innovative Drugs

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Innovative Drugs with Pediatric Extensions	11	6	17	10	15
Innovative Drugs without Pediatric Extensions	21	24	27	29	24
Total	32	30	44	39	39

Graph 4 - Human Innovative Drugs by Product Type

Table 13 - Human Innovative Drugs by Product Type

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Pharmaceutical	23	19	21	21	16
Biologic	9	11	23	17	23
Radiopharmaceutical	0	0	0	1	0

Veterinary Drugs

Graph 5 and Table 14 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 5 - Veterinary Drugs added to the Register of Innovative Drugs

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

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Innovative Drugs	2	4	2	2	4

Judicial Review Applications Concerning Data Protection

Table 15 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 15 - Judicial Review Applications and Appeals

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Judicial Reviews	2	1	2	0	0
Judicial Review Appeals	1	0	2	0	0

Table 16 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 16 - Judicial Review Applications Concerning Data Protection

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Filing Date	Close Date	Summary of Decision
T-1867-21 (Dismissed)	*Janssen Inc v Attorney General of Canada and the Minister of Health*	esketamine hydrochloride	2021-12-08	2023-01-05	Ineligibility on the basis that the medicinal ingredient is a variation of a previously approved medicinal ingredient
A-21-23 (Ongoing)			2023-02-02		

Section IV - Statistics: Certificates of Supplementary Protection

Applications

Table 17 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 17 - Applications

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Total Applications	15	23	17	18	18
Median Days to File	63	42	64	76	62
Range of Days to File	17-114	4-116	13-121	15-116	13-119

Outcomes

Table 18 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 18 - Outcomes

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Issued (2-year term)	12	21	7	16	13
Issued (less than 2-year term)	1	0	6	1	2
Refused	1	1	4	1	0
Total Decisions	14	23	17	18	15

Performance

Health Canada's performance in meeting the service standard is displayed in Table 19. 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 the first and final decision regarding eligibility. If the Certificate of Supplementary Protection is refused, this represents a first decision regarding eligibility.

Table 19 - Performance

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Average Days for First Decision	22	20	36	26	23

Reasons for Refusal

No applications for Certificate of Supplementary Protection were refused between April 1, 2023, and March 31, 2024.

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

Drug Submissions Placed on Intellectual Property Hold

Graph 6 and Table 20 display the number of drug submissions that were placed on Intellectual Property Hold in each fiscal year, and the reason.

Graph 6 - Drug Submissions Placed on Intellectual Property Hold by Fiscal Year

Table 20 - Drug Submissions placed on Intellectual Property Hold by fiscal year

Fiscal Year	2019/ 2020	2020/ 2021	2021/ 2022	2022/ 2023	2023/ 2024
Patent	55	73	60	83	77
Data Protection	13	21	28	13	9
Patent and Data Protection	3	16	23	27	5
Total	71	110	111	123	91

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.

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

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

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.