Patented Medicines Regulations.

SOR/94-688, as amended by SOR/2019-298, SOR/2020-126, and SOR/2020-298.

PATENT ACT

Registration 1994-11-07

1 [Repealed]

INTERPRETATION.

2 The definitions in this section apply in these Regulations.

Act means the *Patent Act*. (*Loi*)

notice of compliance means a notice issued under section C.08.004 or C.08.004.01 of the *Food and Drug Regulations*. (*avis de conformité*)

NON-APPLICATION OF CERTAIN PROVISIONS.

2.1 Sections 4.1 to 4.4 do not apply to any medicine for which a drug identification number has been assigned under the *Food and Drug Regulations* before August 21, 2019.

INFORMATION RESPECTING THE IDENTITY AND PRICE OF MEDICINES.

3 (1) For the purposes of paragraphs 80(1)(a) and (2)(a) of the Act, information identifying the medicine shall be accompanied by the product monograph for the medicine or, if a notice of compliance has not been issued in respect of the medicine, by information similar to that contained in a product monograph, and shall indicate

(a) the name and address of the patentee or former patentee and the address for correspondence in Canada;

(b) whether the reporting patentee referred to in paragraph (a) is the patent holder, a person holding a licence other than a licence continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, or any other person referred to in the definition ***patentee*** in subsection 79(1) of the Act;

(c) the generic name and brand name of the medicine;

(d) whether the medicine is for human or veterinary use;

(e) the therapeutic use of the medicine approved by the Minister of Health;

(f) the date on which the first notice of compliance was issued to the patentee or former patentee in respect of the medicine;

(g) the drug identification number assigned to each strength and dosage form of the medicine under the *Food and Drug Regulations*;

(h) the patent number of each invention of the patentee or former patentee pertaining to the medicine, the date on which each patent was granted and the date on which each patent will expire.

(2) The information required under subsection (1) shall be provided if

(a) a notice of compliance has been issued in respect of the medicine; or

(b) the medicine is being offered for sale in Canada.

(3) The information referred to in subsection (1) shall be provided no later than the earlier of

(a) seven days after the day on which the first notice of compliance is issued in respect of the medicine; and

(b) seven days after the day on which the medicine is first offered for sale in Canada.

(3.1) Despite subsection (3), in each of the following cases, the information referred to in subsection (1) shall be provided within 30 days after the day on which the Board sends a request for the patentee to provide that information:

(a) the medicine is not a *prescription drug* as defined in section A.01.010 of the *Food and Drug Regulations* and is not a drug described in Schedule D to the *Food and Drugs Act*;

(b) the medicine contains a *controlled substance* as defined in subsection 2(1) of the *Controlled Drugs and Substances Act*, the sale or provision of which does not require a prescription under that Act;

(c) a notice of compliance has been issued in respect of the medicine on the basis of information and material contained in a submission filed under section C.08.002.1 of the *Food and Drug Regulations*;

(d) the medicine is for veterinary use.

(4) The information referred to in subsection (1) shall be up to date and any modification of that information shall be reported within 30 days after the modification.

4 (1) For the purposes of paragraphs 80(1)(b) and (2)(b) of the Act, information identifying the medicine and concerning the price of the medicine shall indicate

(a) the identity of the patentee or former patentee;

(b) the generic name and brand name of the medicine;

(c) the date on which the medicine is first sold in Canada;

(d) the day or period, referred to in subsection (2) or (3), to which the information pertains;

(e) the drug identification number assigned under the *Food and Drug Regulations* in respect of the medicine or, if no drug identification number has been assigned, any other identification number assigned in respect of each dosage form and strength of the medicine of the patentee or former patentee; and

(f) in respect of the day or period referred to in paragraph (d),

(i) the quantity of the medicine sold in final dosage form and either the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory,

(ii) the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory, and

(iii) if the medicine is being sold in one or more of the countries set out in the schedule, the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each of those countries.

(g) [Repealed]

~~**(2)** In the case of a medicine for human use that contains a controlled substance as defined in the *Controlled Drugs and Substances Act* or a substance listed or described in Schedule C or D to the *Food and Drugs Act* or that is a prescription drug as defined in section A.01.010 of the *Food and Drug Regulations*, the information referred to in subsection (1) shall be provided~~

(2) The information referred to in subsection (1) shall be provided to the Board

(a) for the day on which the medicine is first sold in Canada, within 30 days after that day; and

(b) for each six-month period beginning on January 1 and July 1 in a year, within 30 days after the end of the period.

~~**(3)** In the case of a medicine for human use that does not contain a controlled substance as defined in the *Controlled Drugs and Substances Act* or a substance listed or described in Schedule C or D to the *Food and Drugs Act* or that is not a prescription drug as defined in section A.01.010 of the *Food and Drug Regulations* or in the case of a medicine for veterinary use, the information referred to in subsection (1), for each six-month period beginning on January 1 and July 1 of each year, shall be provided to the Board within 30 days after the day on which the Board sends a request in response to a complaint respecting the price of the medicine and, during the two years following the request, within 30 days after the end of each six-month period.~~

(3) Despite subsection (2), in each of the following cases, the information referred to in subsection (1), for each six-month period beginning on January 1 and July 1 of each year, shall be provided within 30 days after the day on which the Board sends a request for the patentee to provide that information and, during the two years following the request, within 30 days after the end of each six-month period:

(a) the medicine is not *a prescription drug* as defined in section A.01.010 of the *Food and Drug Regulations* and is not a drug described in Schedule D to the *Food and Drugs Act*;

(b) the medicine contains a *controlled substance* as defined in subsection 2(1) of the *Controlled Drugs and Substances Act*, the sale or provision of which does not require a prescription under that Act;

(c) a notice of compliance has been issued in respect of the medicine on the basis of information and material contained in a submission filed under section C.08.002.1 of the *Food and Drug Regulations*;

(d) the medicine is for veterinary use.

(4) For the purposes of subparagraph (1)(f)(i),

~~(a) in calculating the average price per package of medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of the federal sales tax shall be used; and~~

~~(b) in calculating the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of federal sales taxes shall be used.~~

(a) in calculating the average price per package of a medicine, the actual price obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature; and

(b) in calculating the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature.

(5) Subject to subsection (6), this section does not apply to medicine sold by a patentee or former patentee to a person with whom they do not deal at arm's length or to another patentee or former patentee.

(6) If the patentee or former patentee sells the medicine to a person with whom they do not deal at arm's length and who is not required to provide information under paragraphs 80(1)(a) or (2)(a) of the Act, the patentee or former patentee shall provide the information required under paragraph (1)(f) in respect of any resale of the medicine by the person.

(7) For the purposes of subparagraph (1)(f)(iii), the price at which a medicine was sold in a country other than Canada shall be expressed in the currency of that country.

(8) For the purposes of this section, the *Income Tax Act*, as that Act read on December 1, 1987, applies, with any modifications that the circumstances require, in determining whether a patentee or former patentee is dealing at arm's length with another person.

(9) For the purposes of this section, ***publicly available ex-factory price*** includes any price of a patented medicine that is agreed on by the patentee or former patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee.

(10) [Repealed]

4.1 (1) For the purposes of paragraphs 80(1)(d) and 2(d) of the Act, in respect of the factor referred to in paragraph 4.4(a), the patentee shall provide to the Board every cost-utility analysis prepared by a publicly funded Canadian organization, if published

and communicated to the patentee, for which the outcomes are expressed as the cost per quality-adjusted life year for each indication that is the subject of the analysis.

(2) The patentee shall provide to the Board any information about the medicine that was redacted from a published analysis.

(3) An analysis shall be provided

(a) if the analysis is published before the day on which the medicine is first offered for sale in Canada, within 30 days after that day; or

(b) if the analysis is not published before the day on which the medicine is first offered for sale in Canada, within 30 days after the day on which it is published.

(4) Despite subsection (3), in the case of a medicine that is offered for sale in Canada before July 1, 2021, an analysis shall be provided

(a) if the analysis is published before July 1, 2021, by July 30, 2021; or

(b) if the analysis is not published before July 1, 2021, within 30 days after the day on which it is published.

(5) An analysis shall be provided to the Board only if any cost for the medicine as identified in the analysis is or would be, when that cost is pro-rated to account for that medicine's use over a 12-month period, greater than or equal to 50 per cent of the gross domestic product per capita in Canada at the time of publication of the analysis.

4.2 (1) For the purposes of paragraphs 80(1)(d) and (2)(d) of the Act, in respect of the factor referred to in paragraph 4.4(b), the patentee shall provide to the Board the estimated maximum use of the medicine in Canada, as measured by the total quantity of the medicine in final dosage form expected to be sold.

(2) The patentee shall provide to the Board the period of time used for the estimate of the maximum use of the medicine.

(3) The patentee shall provide to the Board the estimated maximum use of the medicine within 30 days after the day on which the medicine is first offered for sale in Canada.

(4) Despite subsection (3), in the case of a medicine that is offered for sale in Canada before July 1, 2021, the most recent version of the estimated maximum use of the medicine shall be provided

(a) if the medicine is first offered for sale in Canada during the period beginning on July 1, 2018 and ending on June 30, 2021, by July 30, 2021; or

(b) if the medicine is first offered for sale in Canada before July 1, 2018, but the Minister of Health assigns a drug identification number under the *Food and Drug Regulations*

(i) during the period beginning on August 21, 2019 and ending on June 30, 2021, by July 30, 2021, or

(ii) after June 30, 2021, within 30 days after the day on which the drug identification number is assigned.

(5) The patentee shall update the estimated maximum use of the medicine within 30 days after the day on which the Minister of Health issues a notice of compliance approving a new or modified therapeutic use of the medicine.

4.3 (1) Despite subsections 4.1(3) and (4) and 4.2(3) and (4), in each of the following cases, the information referred to in subsections 4.1(1) and (2) and 4.2(1) and (2) shall be provided within 30 days after the day on which the Board sends a request for the patentee to provide that information:

(a) the medicine is not *a prescription drug* as defined in section A.01.010 of the *Food and Drug Regulations* and is not a drug described in Schedule D to the *Food and Drugs Act*;

(b) the medicine contains a *controlled substance* as defined in subsection 2(1) of the *Controlled Drugs and Substances Act*, the sale or provision of which does not require a prescription under that Act;

(c) a notice of compliance has been issued in respect of the medicine on the basis of information and material contained in a submission filed under section C.08.002.1 of the *Food and Drug Regulations*;

(d) the medicine is for veterinary use.

(2) The requirements of subsection 4.2(5) apply in respect of the information provided under subsection (1).

OTHER FACTORS TO BE CONSIDERED — EXCESSIVE PRICES.

4.4 For the purposes of paragraph 85(1)(e) of the Act, the other factors that the Board shall take into consideration to determine whether a medicine that is sold in any market in Canada after June 30, 2021 is being or has been sold at an excessive price are the following:

(a) the medicine's pharmacoeconomic value in Canada;

(b) the size of the market for the medicine in Canada; and

(c) the gross domestic product in Canada and the gross domestic product per capita in Canada.

REVENUES AND RESEARCH AND DEVELOPMENT EXPENDITURES.

5 (1) For the purposes of subsection 88(1) of the Act, information concerning the identity of any licensee in Canada of the patentee and the revenues and research and development expenditures of the patentee shall indicate

(a) the name and address of the patentee and the address for correspondence in Canada;

(b) the name and address of all licensees in Canada of the patentee;

(c) the total gross revenues from all sales in Canada during the year by the patentee of medicine for human and veterinary use and the total revenues received from all licensees from the sale in Canada of medicine for human and veterinary use; and

(d) a summary of all expenditures made during the year by the patentee towards the cost of research and development relating to medicine for human or veterinary use carried out in Canada by or on behalf of the patentee, including

(i) a description of the type of research and development and the name of the person or entity that carried out the research and development,

(ii) the expenditures of the patentee or the person or entity that carried out the research and development, in respect of each type of research and development, and

(iii) the name of the province in which the research and development was carried out and the expenditures in that province by the patentee or the person or entity.

(2) The information referred to in subsection (1) shall be provided for each calendar year and shall be submitted within 60 days after the end of each calendar year.

(3) The total gross revenues referred to in paragraph (1)(c) shall comprise revenues from sales of medicine

(a) for which a drug identification number has been issued under the *Food and Drug Regulations* or which has been approved for sale to qualified investigators under those Regulations;

(b) that is used in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptoms thereof or in the modification of organic functions in humans or animals; and

(c) the sale of which is promoted by any means to physicians, dentists, veterinarians, hospitals, drug retailers or wholesalers or manufacturers of ethical pharmaceutical products.

(4) For the purposes of paragraph (1)(d), the patentee shall specify

(a) the total capital expenditures on buildings and the annual depreciation of the buildings which depreciation shall be calculated at an annual rate of four per cent for a maximum of 25 years;

(b) the total capital expenditures on equipment; and

(c) the source and amount of the funds for expenditures made by the patentee towards the cost of research and development.

6 For the purposes of subsection 88(1) of the Act, the expression ***research and development*** means those activities for which expenditures qualify, or would qualify if the expenditures were made by a taxpayer in Canada, for an investment tax credit in respect of scientific research and experimental development under the *Income Tax Act* as that Act read on December 1, 1987.

GENERAL.

7 (1) Every person required by these Regulations to provide information to the Board shall do so by using the appropriate electronic document made available on the Board's website and by sending the completed electronic document, in its original format and file type, to the email address specified by the Board on its website.

(2) The electronic document shall bear the electronic signature of an authorized individual, certifying that the information set out in the document is true and complete.

SCHEDULE.

(Subparagraph 4(1)(f)(iii))

Item	Country
	Australia
	Belgium
1	France
2	Germany
3	Italy
	Japan
	Netherlands
	Norway
	Spain
4	Sweden
5	~~Switzerland~~
6	United Kingdom
7	~~United States~~