Patented Medicines Regulations

(SOR/94-688)

(as amended up to March 6, 2008)

Registration November 7, 1994

Patented Medicines Regulations

P.C. 1994-1819 November 1, 1994

His Excellency the Governor General in Council, on the recommendation of the Minister of National Health and Welfare, pursuant to section 101* of the *Patent Act*, is pleased hereby to revoke the *Patented Medicines Regulations*, made by Order in Council P.C. 1988-2013 of September 15, 1988**, and to make the annexed *Regulations specifying the information to be provided relating to patented medicines and patentees' revenues and research and development expenditures*, in substitution therefor.

* S.C. 1993, c. 2, s. 7

** SOR/88-474, 1988 *Canada Gazette* Part II, p. 3921

PATENTED MEDICINES REGULATIONS

1. [Repealed, SOR/2008-70, s. 2]

INTERPRETATION
[SOR/98-105, s. 1(F)]

2. The definitions in this section apply in these Regulations.

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

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

SOR/98-105, s. 1.

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.
(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.
SOR/98-105, s. 2(E); SOR/2008-70, s. 3.
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, SOR/2008-70, s. 4]
(2) If the medicine is for human use and 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 Schedule F to the *Food and Drug Regulations*, the information referred to in subsection (1) shall be provided
(*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) If the medicine is for human use and does not contain a controlled substance as defined in the *Controlled Drugs and Substances Act* or does not contain a substance listed or described in Schedule C or D to the *Food and Drugs Act* or in Schedule F to the *Food and Drug Regulations* or is 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 date 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 each six-month period.
(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.
(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, SOR/2008-70, s. 4]
SOR/98-105, s. 3; SOR/2008-70, s. 4.

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.
SOR/95-172, s. 4.

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.
SOR/2008-70, s. 5.

SCHEDULE

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

Item	Country
1.	France
2.	Germany
3.	Italy
4.	Sweden
5.	Switzerland
6.	United Kingdom
7.	United States

SOR/2008-70, s. 6.