Patented Medicine Prices Review Board

NOVEMBER 2008 UPDATE

Patentee's Guide to Reporting

Form 1, 2 and 3 pursuant to the *Patented Medicines Regulations*

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Canada

Since 1987
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Introduction

Background and Authority

The 1987 amendments to the Patent Act established the *Patented Medicine Prices Review Board* (hereafter referred to as the PMPRB). *The Patented Medicines Regulations* (hereafter referred to as the *Regulations*), as provided for by the Patent Act, establish the data reporting requirements to which this Guide is addressed.

This reporting Guide has been prepared under the authority of the PMPRB, which is responsible for ensuring compliance with the Patent Act and the Regulations.

Purpose, Scope and Limitations of the Guide

This Guide is a reference document to help patentees complete Forms 1, 2 and 3. The Guide explains each element of information to be reported, how and when the information is to be submitted to the PMPRB.

This Guide is intended as a reference tool, not an exhaustive interpretation of the reporting requirements of the *Regulations*. The instructions and definitions are intended to assist patentees; they have no legal force and for the formal definitions, reference to the legislation must be made. While every attempt has been made to explain the three reporting forms, it may be necessary to consult directly with PMPRB staff for further guidance regarding complex situations or particular cases.

In the event of a discrepancy between this Guide and the *Regulations*, the *Regulations* shall, in all cases, prevail. Further, the PMPRB has the right to apply such definitions as it considers necessary to administer the *Patent Act* and achieve its purpose and intent in accordance with the law.

This Guide will be revised from time to time to reflect changes in reporting requirements, and to further clarify current requirements.

Layout of the Guide

The Guide consists of five sections: this introduction, three sections relating to the reporting forms, and a glossary. The appendices include the blank reporting forms and the list of codes to be used to complete Form-1 and Form-2.

The reporting forms included in this Guide are for information only. Patentees are required to download the Forms from the PMPRB Web site http://www.pmprb-cepmb.gc.ca/ for purposes of their regulatory filing requirements.

Interpretations

For the purposes of this Guide, please note the following:

Person

For reporting purposes the word “person” means an individual, a company or corporation, or any other legal entity such as a partnership, trust, joint venture or other form of business enterprise

Singular/Plural

All references in the singular case shall include the plural, and references to the plural shall include the singular.

Patentee

Section 79(1) of the *Patent Act* provides the definition of the word “patentee”:

> “in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a license continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, that other person in respect of those rights;”

In other words the word “patentee” is used to mean not only the patent holder, but also any person acting for the patent holder as a seller or otherwise entitled to the benefits of the patent (other than by compulsory license). Patent rights may include manufacturing, distributing, marketing and selling the medicine. The interpretation of “patentee” will depend on the situation; it will generally be the corporate entity that sells the medicine into the distribution chain.

The definition of “patentee” applies whether or not the patentee resides in Canada, as long as the patented medicine is sold in Canada.

Former Patentee

A patentee is referred to as a former patentee once the relevant patents for a particular drug product expire. The *Regulations* require that a Form-1 and Form-2 be filed, for drug products not previously filed, and only for the periods under which the drug products were patented. The Board may request this information within three years of the patent’s expiry.

Reporting Patentee

The “reporting patentee” completing Form-1 and Form-2 is either the patentee or the former patentee.

Confidentiality of Reported Information

Section 87 of the *Patent Act* states that information gathered by means of these reporting forms is privileged, and will not (except when permitted by that section) be communicated, disclosed or made available to any party not legally entitled to such information.

Electronic Filing

The information to be submitted to the PMPRB must be provided using the electronic forms (including layout and file type) that are downloadable from the PMPRB Web site.

Completed forms must be sent to the Board’s e-mail address that is available on the PMPRB Web site: compliance@pmprb-cepmb.gc.ca

Where to Get Help

Please direct questions regarding completion of the reporting forms to the PMPRB by mail, telephone, fax or e-mail:

Address:

Patented Medicine Prices Review Board
Box L40
Standard Life Center
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Telephone:

613) 952-7360
Sylvie Dupont
Secretary of the Board

Facsimile:

(613) 952-7626

E-mail address:

pmprb@pmprb-cepmb.gc.ca

Communications may be in either official language.

Electronic/Mailing List

If you would like to be added to the PMPRB’s mailing list and/or electronic mailing list please complete the following sheet and either mail, fax or e-mail the relevant information.

Electronic/Mailing List Amendment Form

Please make the following change to your mailing list:

Addition [ ]
Deletion [ ]
Revision [ ]

Name: _____

Company/Organization: _____

_____

_____

Title: _____

_____

Address: _____

_____

_____

Postal Code: _____

Telephone: ( ) -
_____

Facsimile: ( ) -
_____

E-mail address: _____

Please send this completed form to:

Patentee's Guide to Reporting
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
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Ottawa, Ontario
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Tel: (613) 952-7360
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Form-1 – Medicine Identification Sheet

General Information

Purpose

Form 1 (see Appendix B) is to be used by patentees to report information on patented drug products for which a Notice of Compliance (NOC) has been issued, or which are being offered for sale in Canada. The PMPRB uses the reported information to identify patentees and patented drug products that are subject to the reporting requirements of the *Regulations*.

Definitions of key terms used in these forms are included in the Glossary (see page 24).

The information to be submitted to the PMPRB must be provided using the electronic forms (including layout and file type) that are down loadable from the PMPRB Web site under Legislation, Regulations and Guidelines / Patentee's Guide to Reporting.

Submit a separate electronic Form-1 for each Drug Identification Number (DIN) of the patented drug product within seven days of it being issued an NOC or being offered for sale in Canada, whichever comes first. An electronic copy of the product monograph (Word or pdf) or information similar to that contained in a product monograph when an NOC has not been issued, must be appended to Form-1.

Completed forms must be sent to the Board's e-mail address that is available on the PMPRB Web site: compliance@pmprb-cepmb.gc.ca

Who should provide information?

The patentee completing Form-1 is the "reporting patentee" who is either the patentee or former patentee.

Which drug products should be reported?

Once a patentee is issued an NOC for a drug product that has one or more related patents in force, the patentee has seven days to submit a Form-1. The patent(s) may be for (among other things) formulation of the medicine, processes involved in making the drug product, dosage forms, preparation of dosage forms, or delivery systems of the drug product. The patent(s) may or may not be used in producing the drug product.

Patented drug products provided under the Special Access Programme or Clinical Trial Application or Investigational New Drug of Health Canada, that are being sold and for which no NOC has been issued, should also be reported on a Form-1 within seven days of first being offered for sale.

Changes/Additions/Deletions

Update the electronic Form-1 to report to the PMPRB any changes, additions and deletions to information previously submitted for a drug product. This includes any change to the identity (i.e., name and/or address) of the reporting patentee.

Indicate in the check box at the top of the form that this update amends the earlier submission.

Due Dates

Form-1 should be submitted to the PMPRB not later than:

i. **7 days** after the Notice of Compliance is issued or

   7 days after a patented drug product has been offered for sale in Canada, whichever comes first; **and**

ii. **30 days** after any changes, additions or deletions are made to the information originally submitted to the PMPRB on a Form-1.

Filing Information

In the appropriate box at the top of the form, specify whether it is an original filing or an amendment. Any amendment(s) must be explained in a letter or e-mail.

Block-1
Names and Use(s) of the Medicine

State the Brand Name and Generic Name of the drug product to be identified by this form. For example:

Brand Name... ...Valium™
Generic Name... ...diazepam

Therapeutic Use of the Medicine

State the therapeutic use(s) (not the indications) of the medicine as approved by Health Canada. *The Compendium of Pharmaceuticals and Specialties* (CPS)[1] provides acceptable therapeutic use descriptions in bold italic at the beginning of each product monograph. For example, the therapeutic uses of ValiumTM are listed as:

Anxiolytic
Sedative
Muscle Relaxant

Human Prescription/ Human Over-the-Counter/Veterinary

Indicate in the boxes provided whether the drug product is:

- **Human Prescription** i.e. prescribed for human use and is a controlled substance as defined in the *Controlled Drugs and Substances Act* or contains a substance listed or described in Schedules C or D to the *Food and Drugs Act* or Schedule F to the *Food and Drug Regulations*;

- **Human Over-the-Counter** i.e. provided over the-counter for human use and is not a controlled substance as defined in the *Controlled Drugs and Substances Act* or does not contain a substance listed or described in Schedules C or D to the *Food and Drugs Act* or *Schedule F to the Food and Drug Regulations*;

- **Veterinary** i.e. intended for veterinary use. Veterinary drug products include feed additives (e.g., antibiotics, vitamins) which have been classified as drug products.

If the drug product is intended for both human and veterinary uses, complete a separate Form-1 for each.

Block-2
Reporting Patentee

State the name and address of the reporting patentee.

Unless indicated otherwise, questions regarding completeness, accuracy, etc, will be directed to the individual signing the form at the address recorded here.

Status of Reporting Patentee

In the boxes provided, check off the description that best describes the status of the reporting patentee completing this form.

The **patent holder** is the person ("person" is defined in the Interpretations section at page 3) that owns the patent.

A **person entitled to the benefits of a patent or to exercise any rights in relation to a patent is a person who has a license or an agreement with the patent** holder to exercise certain rights of the patent. This category excludes a person who has a compulsory license, as previously defined under section 39(4) of the *Patent Act* amended in 1993.

1 The *Compendium of Pharmaceuticals and Specialties* (CPS) is published and copyrighted by the Canadian Pharmaceutical Association.

Block-3
Notice of Compliance (NOC)

Patentee's First NOC

Indicate the date on which the first NOC was issued to the reporting patentee for the drug product named in Block-1.

Special Access Programme or Clinical Trial Application or Investigational New Drug

If no NOC has been issued, use the provided boxes to indicate whether the drug product named in Block-1 is being provided under the Special Access Programme (SAP) or Clinical Trial Application or the Investigational New Drug Program.

Block-4
Drug Identification Number (DIN)

Drug Identification Number (DIN)

Enter the DIN that applies to the drug product identified in Block-1. Enter only the DIN that identifies a form of the drug product to which the reporting patentee has rights to sell, distribute, etc.

If the drug product has no DIN, leave this space blank. Following receipt of Form-1, the PMPRB will assign a number to all patented drug products that have no DIN. The patentee will be asked to use this Assigned Number when completing Form-2 during the subsequent reporting periods.

Dosage Form

Enter the dosage form that corresponds to the DIN entered in the first column. Write out the dosage form in full – do not use codes.

Examples of dosage forms include:

> tablets, capsules, vials, injectable ampoules, oral ampoules, liquid, solution, suspensions, drops, lotions, creams, sprays, aerosols, suppositories

For a complete list of dosage forms, please refer to Appendix A.

Appendix A provides the list of dosage forms and is not intended to be used for the purpose of identifying comparable dosage forms. The Compendium of Guidelines, Policies and Procedures, Schedule 7, identifies comparable dosage forms.

Strength/Unit

For the DIN in the first column, indicate the corresponding strength of the drug product. Strength is defined as the amount of active ingredient, expressed in milligrams (mg), micrograms (µg or mcg) or as appropriate per unit of medicine.

The unit of medicine is expressed in units of the dosage form such as tablets, milliliters, vials, etc. Be sure to state the units being used. For example:

Dosage Form	Strength/Unit
Tablet	10 mg/tab
Oral Liquid	10 mg/ml
Injectable	10 mg/vial
Cream	10 mg/gm
Inhaler	10 µg/dose

Do not use percentages; use the style shown above.

For drug products with more than one active ingredient, report as above, but with the amounts of active ingredients linked by a "+" sign.
For example:

Dosage Form	Strength/Unit
Tablet	10 mg of active ingredient A + 20 mg of active ingredient B/tab
Oral Liquid	10 mg of active ingredient A + 40 mg of active ingredient B/ml

Block-5
Date of First Sale

Indicate the year, month, day when the drug product identified in Block-1 is first sold in Canada, whether it is following issuance of an NOC, under SAP, a Clinical Trial Application or as an Investigational New Drug.

Block-6
Product Monograph

Patentees must provide an electronic copy of the product monograph along with the Form-1, or if an NOC has not been issued, information similar to that contained in a product monograph.

Block-7
Patent Numbers of Reporting Patentee's Inventions

Patent Number

State the patent numbers for Canadian patents that pertain to the drug product named in Block-1. Patents can be related to (among other things) the chemical formulation of the medicine, processes involved in making the drug product, dosage forms, preparation of dosage forms, or delivery systems for the drug product.

List those patents owned by the reporting patentee, assigned to the reporting patentee, or for which the reporting patentee is entitled to the benefits of a patent or to exercise any rights in relation to a patent (other than a compulsory license).

Date Granted

For each patent listed in the first column, enter the date (year/month/ day) the patent was granted on the corresponding line in the middle column.

Expiry Date

For each patent number listed in the first column, enter the corresponding expiry date on the corresponding line in the third column. Patents granted under the revised section 44 of the *Patent Act* expire twenty (20) years from the date of the filing of the application of the patent in Canada.[2]

Block-8
Certifying Signature

This form should be signed by the reporting patentee (if an individual) or corporate officer[3] (if a corporation).

Signature

The individual signing should have the authority to represent the patentee, and be knowledgeable about information reported on the form. Below the signature, type the name of the person, title and organization. An electronic reproduction of the manual signature of the authorized person is required by the Board and should be copied and pasted in the box reserved to that effect.

Telephone, Facsimile Numbers and E-mail Address

Provide telephone and facsimile numbers as well as the e-mail address for the signatory.

Date Signed

State the date (year/month/day) the form was signed.

2 For patent applications filed before October 1, 1989, the life of the Canadian patent is 17 years from the date the patent was granted. For patent applications filed on or after October 1, 1989, the life of the Canadian patent is 20 years from the date of the filing of the application of the patent in Canada.

3 Corporate officer should be interpreted in the broad sense as meaning any corporate official or employee authorized to sign on behalf of the corporation.

Form-2 – Identity and Prices of Medicines

General Information

Purpose

Form-2 (see Appendix B) is a multi-page reporting form on which the reporting patentee provides information on the prices of patented drug products.

- For Human Prescription drug products (see p. 7 for definition), submit Form-2 semi annually for each patented drug product, according to the reporting periods and due dates described on page 10.

- For Human Over-the-Counter and Veterinary drug products (see p. 7 for definition), submit Form-2 only if the Board sends a request in response to a complaint respecting the price of the medicine.

Definitions of key terms used in these forms are included in the Glossary (see page 24).

Who should provide information?

The patentee completing Form-2 is the "reporting patentee" who is either the patentee or former patentee.

Which drug products should be reported?

Complete a Form-2 for each drug product sold in Canada for which at least one patent related to the medicine pertains. Patent(s) may be for (among other things) formulation of the medicine, processes involved in making the drug product, dosage forms, preparation of dosage forms, or delivery systems for the drug product. The patent(s) may or may not be used in the production of the drug product.

Drug products may be sold pursuant to an NOC, under the Special Access Programme, under Clinical Trial Application or as an Investigational New Drug.

How to Complete the Forms?

For Block-4 and Block-5, please use the format provided by the PMPRB and ensure that each field of each row is filled as specified. Please refer to pages 11 to 14 for additional information on Block-4 and Block-5.

Reporting Periods and Due Dates

The information to be submitted to the PMPRB must be provided using the electronic forms (including layout and file type) that are down loadable from the PMPRB Web site under Legislation, Regulations and Guidelines / Patentee's Guide to Reporting.

Completed forms must be sent to the Board's e-mail address that is available on the PMPRB Web site: compliance@pmprb-cepmb.gc.ca.

(A) Semi-Annual Filing

Report Form-2 information semi-annually. Reporting periods and due dates will be as follows:

	Reporting Period	Due Date*
1	January 1 to June 30	July 30
2	July 1 to December 31	January 30

* If a due date falls on a weekend or statutory holiday the due date shall be the next business day.

(B) Day of First Sale

When a drug product is first offered for sale in Canada by, or on behalf of, the patentee, the following reporting requirements apply:

a) A completed Form-2 must be filed with the PMPRB no later than thirty (30) days after the day on which the medicine is first sold in Canada.

b) The information provided in the completed Form-2 must cover the first day of sale in Canada of the new drug product.

(C) Human Over-the-Counter and Veterinary Drug Products

Form-2 for Human Over-the-Counter and Veterinary drug products must be provided within 30 days after the date on which the Board sends a request and semi-annually for two (2) years following the request, within 30 days after each six-month period.

EXAMPLE:

If a new drug product (Human Prescription) is first offered for sale on March 15, 2007, a completed Form-2 would be due on April 14, 2007. The Form-2 report would report the price and sales of the drug product for March 15, 2007. The next Form-2 would be due on July 30 and would cover the period March 15 to June 30 (it is recognized that some information will be reported twice).

	Reporting Period	Due Date
1	March 15	April 14
2	March 15 to June 30	July 30

Filing Information

In the appropriate box at the top of the form, specify whether it is an original filing or an amendment. Any amendment(s) must be explained in a letter or e-mail.

Block-1
Reporting Period

Enter the beginning and ending dates of the period to which the information applies. For example:

From: 2007/01/01 (year/month/day)
To: 2007/06/30 (year/month/day)

Block-2
Names of the Medicine

Brand Name and Generic Name of the Medicine

Block 2 must be completed when reporting first day of sales or amendments affecting only one drug product. It should be left blank when filing semi-annual reports for multiple drug products.

Brand Name... ...Valium™
Generic Name... ...diazepam

Block-3
Reporting Patentee

State the reporting patentee's name and address; in other words, the name and address of the company or individual completing this form.

Certifying Signature

The individual signing should have the authority to represent the reporting patentee, and be knowledgeable about information reported on the form. Type or print the name of the person signing below the signature. The electronic reproduction of the manual signature of the authorized person is required and should be copied and pasted in the box reserved to that effect.

Date Signed

State the date (year/month/day) the form was signed.

Telephone, Facsimile Numbers and Email Address

Provide telephone and facsimile numbers as well as the email address of the signatory.

Block-4
Sales of the Medicine by the Reporting Patentee in Final Dosage Form in Canada

Introduction

The detailed information requested in Block-4 relates to quantity and revenues of Canadian sales, in final dosage form, of the drug product named in Block-2. Each field of the row where a DIN is reported should be fully completed to include DIN, brand name, strength/unit, dosage form, package size, number of packages sold,

total number of units sold, net revenue or average price/package, provinces/territories, and class of customer. Use the codes listed in the Appendix A. Use a separate line to report each strength, dosage form and package size. Add as many rows as needed by using the "Insert Row" on the top menu item in Excel or by placing the cursor on the row below which a new row must be added and using the right click/insert function of the mouse. Rows can be deleted similarly either by using the menu item at the top of the screen or by using the right click/delete function of the mouse.

Drug Identification Number (DIN) or Number Assigned by the PMPRB

Enter the DIN that applies to the drug product identified in Block-2. If the drug product has no DIN, use the Assigned Number that the PMPRB provided following receipt of Form-1.

Strength/Unit

Indicate the strength of the drug product. Strength is defined as the amount of active ingredient, expressed in milligrams (mg), micrograms (ig or mcg) or as appropriate per unit of medicine. The unit of medicine is expressed in units of the dosage form such as tablets, milliliters, vials, etc. Be sure to indicate the units being used. For example:

DIN	Strength/Unit	Dosage Form
12345678	10 mg/tab	S1
24681012	10 mg/ml	L1
11223344	10 mg/gm	T2

Avoid using percentages.

Drug products with more than one active ingredient should be reported as above, but with the amounts of active ingredients linked by a "+" sign. For example:

Strength/Unit	Dosage Form
10 mg of active ingredient A + 20mg of active ingredient B/tab	S1
10 mg of active ingredient A + 40 mg of active ingredient B/ml	L1

Dosage Form

Using the codes that appear in Appendix A4, enter in the appropriate column the dosage form code that corresponds to the strength and DIN information entered in the first two columns of the row. For example:

- The dosage form code of a tablet is S1
- The dosage form code of an oral solution is L1
- The dosage form code of a topical cream is T2.

Package Size

In the appropriate space, enter the number of "units" per package. Enter only a numeric value for package size. For example:

DIN	Strength/ Unit	Dosage Form	Package Size
1234567	10 mg/tab	S1	200
2468101	10 mg/ml	L1	100
1122334	10 mg/gm	T2	12

Number of Packages Sold

Indicate for each DIN or Assigned Number the total number of packages sold including quantities distributed for promotions, rebates, free goods, etc. (see Subsections 4(4) and 4(5) of the *Patented Medicines Regulations*) during the reporting period. The date of sale is considered to be the date the product was shipped, not the date payment was received. Returns (i.e., product returned to the reporting patentee for which a refund was provided) are to be included with the data of the reporting period in which reporting patentee received the return. Report only Canadian sales of the drug product in final dosage form.

Net Revenue or Average Price per Package

Record the **Net Revenue whenever possible, otherwise provide the Average Price per Package** that corresponds to the number of packages sold. Report in **dollars and cents** –do not round up to the nearest dollar.

4 Appendix A, on page 29, provides a complete list of dosage forms. It is not intended to be used for the purpose of identifying comparable dosage forms. The Compendium of Guidelines, Policies and Procedures, Schedule 7, identifies comparable dosage forms.

Net revenue consists of actual sales revenue using the accrual accounting method (excluding federal sales tax) for the drug product sold (i.e., shipped) during the reporting period less amounts disbursed for rebates, refunds, or other such type of reduction during the same period (see Subsections 4(4) and 4(5) of the *Patented Medicines Regulations*).

The average price per package is defined as net revenue (excluding federal sales tax) divided by the total number of packages sold (or distributed as part of a promotion, rebate, etc.).

Province/Territory and Class of Customer

Use codes provided in Appendix A to complete these fields (see page 30) or use dropdown menu available in Form 2 Block 4 template (Place your cursor in the cell where you want to enter the code in Province/Territory column or in Class of Customer column and double click to access dropdown menu).

Please note that a breakdown of sales by province must be provided in Block 4. Code 13 can be used only when it is not known in which province the sales have occurred.

Block-5
Publicly available Ex-Factory Prices for Canada and Other Countries

Information in Block-5 covers publicly available ex-factory prices in Canada and in the seven countries listed in the *Patented Medicines Regulations* (France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States), for all final dosage forms of the medicine named in Block-2.

Each field of the row where a DIN or Assigned Number is reported should be fully completed to include the generic name of the medicine, DIN, strength/unit, dosage form, package size, ex-factory price, country or province, and class of customer. Use the codes listed in Appendix A, on page 29 and 30. Add as many rows as needed by using the "Insert Row" in the menu item in Excel or by placing the cursor on the row below which a new row must be added and using the right click/insert function of the mouse. Rows can be deleted similarly either by using the menu item at the top of the screen or by using the right click/delete function of the mouse.

Important: The Canadian reporting patentee must supply public foreign ex-factory price data for all patented drug products that the Canadian patentee sells in Canada. This is necessary even if the Canadian patentee itself does not sell the product in any of the seven foreign countries. Reporting patentees who are unsure of, or have difficulty acquiring, foreign ex-factory price data should contact PMPRB staff for advice.

Use a separate line to report each combination of "strength/dosage form/package size", "country/province" and "class of customer" that applies. If there is only one ex-factory price for all of Canada (i.e., if the ex-factory price is the same in each Canadian province) use the province code "13" to signify all of Canada instead of listing each province separately.

Generic Name of Drug Product

In the first column, provide the generic name of the drug product as identified in Block-2 of Form-2.

Drug Identification Number or Assigned Number

In the second column, enter the DIN that applies to the drug product identified in Block-2 of Form-2. If the drug product has no DIN, use the Assigned Number that the PMPRB provided following receipt of Form-1.

Strength/Unit, Dosage Form, Package Size

Report in the same manner as in Block-4 of Form-2. There is detailed explanation of how to record strength, dosage form and package size in the instructions for Block-4 of Form-2 on pages 11 to 14 of this Guide.

Ex-factory Price

Enter the publicly available ex-factory price per package at which the drug product was sold during the reporting period indicated in Block-1. State the public ex-factory price in the currency of the country in which it was sold.

If there is more than one ex-factory price for a particular country/province and class of customer for a reporting period, use the most recent price for the reporting period.

The public ex-factory price is the price at which a drug product is first sold to wholesalers, hospitals, pharmacies, or others. This price excludes sales taxes and wholesale mark-ups if the wholesale function is not carried out by the reporting patentee.

Country or Province, and Class of Customer

Use codes provided in Appendix A to complete these field (see page 30) or use dropdown menu available in Block 5 template (Place your cursor in the cell where you want to enter the code in Country/Province column or in Class of Customer column and double click to access dropdown menu).

When the publicly available ex-factory price is the same across Canada, use code 13 to report the Canadian price in Block 5.

When reporting the price of the US Federal Supply Schedule (FSS), patentees must enter code 21 in the Country column and code 4-FSS in the Class of Customer column.

Form-3 – Licensees, Revenues and Expenditures

General Information

Purpose

Section 88 of the *Patent Act* requires a patentee of an invention pertaining to a medicine (both patented and non-patented) sold in Canada to provide to the Patented Medicine Prices Review Board (hereafter referred to as the Board) information on scientific research and experimental development (SR&ED). Form-3 is designed to collect information on: the reporting patentee; the names and addresses of all licensees; gross revenue (net of taxes) from sales in Canada; and expenditures in Canada for SR&ED pertaining to all medicines for human and veterinary use.

Who must report?

All reporting patentees of medicines sold in Canada that filed a Form-2 during the calendar year must report gross revenues (net of taxes) and SR&ED expenditures on Form-3. Foreign residency of the reporting patentee does not remove the responsibility to report on Form-3. Foreign persons should report their gross revenues (net of taxes) from sales in Canada and expenditures on SR&ED in Canada as if they were Canadian taxpayers.

Reporting Period and Due Dates

Report Form-3 information annually; the due date is as follows:

Reporting Period	Due Date*
January 1 to December 31	March 1

* If a due date falls on a weekend the due date shall be the next business day.

The information to be submitted to the PMPRB must be provided using the electronic forms (including layout and file type) that are downloadable from the PMPRB Web site, under Regulatory.

Completed forms must be sent to the Board's e-mail address: compliance@pmprb-cepmb.gc.ca

Research and Development

Criteria of Eligibility

Research and development (R&D) expenditures reported on Form-3 must meet the criteria for claiming an **investment tax credit** in respect of scientific research and experimental development as set out in subsections 37(1) and 127(9) of the *Income Tax Act* and section 2902 of the *Income Tax Regulations* as they read on December 1, 1987. The term "Research and Development" as it appears on the reporting forms should be interpreted as meaning Scientific Research and Experimental Development (SR&ED).

It does not matter if the patentee actually files an income tax return for the reporting year in question, or if any of the research and development tax credits are actually claimed. Individuals and corporations who are not Canadian taxpayers should complete Form-3 as if they were Canadian taxpayers.

Revenue Canada publishes guidelines to claiming an investment tax credit for SR&ED expenditures. Whenever possible, the guidelines outlined in these materials should be used to report SR&ED expenditures on Form-3. Refer to the following documents as they read on December 1, 1987:[5]

Subsections 37(1) and 127(9) of the *Income Tax Act*

Sections 2900 and 2902 of the *Income Tax Regulations*

Revenue Canada Form T661

Interpretation Bulletin No. IT-151R3

Information Circular No. 86-4R2.

5 These documents are available by contacting the Secretary of the Board or the Compliance Officers.

Definition – Scientific Research and Experimental Development

Scientific Research and Experimental Development may be defined as a "systematic investigation or search carried out in the field of science or technology by means of experiment or analysis". Technology refers to the systematic study of the application of scientific knowledge to industrial processes or product development.[6]

There are three main categories:

Basic research
Work undertaken to advance scientific knowledge without a specific practical application in view;

Applied research
Work undertaken to advance scientific knowledge with a specific practical application in view; and

Development
Use of results of basic or applied research to create new materials, devices, products or processes, or to improve existing ones.

Activities such as engineering or design, operations research, mathematical analysis or computer programming, and psychological research are eligible only if such activities directly support basic or applied research, or eligible development activities. Examples of **activities that cannot be included as SR&ED include**:

- market research or sales promotion;
- quality control or routine testing of materials, devices or products;
- research in the social sciences or humanities;
- prospecting, exploring or drilling for, or producing, minerals, petroleum or natural gas;
- commercial production of a new or improved material, device or product, or the commercial use of a new or improved process;
- style changes; or
- routine data collection.[7]

Expenditures – Scientific Research and Experimental Development

Note that only expenditures made **in Canada** on SR&ED carried on **in Canada** are allowed; to qualify as SR&ED expenditures on Form-3, the expenditures must conform to criteria for claiming the investment tax credit for scientific research and experimental development as set out in subsections 37(1) and 127(9) of the *Income Tax Act* and section 2902 of the *Income Tax Regulations* as they read on December 1, 1987.

Amounts that would normally qualify for a deduction (but not an investment tax credit) under subsection 37(2) as it read on December 1, 1987 (Research outside Canada) should not be included on Form-3. Foreign travel expenditures, including the salaries and benefits of a Canadian employee undertaking foreign travel, and any other expenditure that relates to SR&ED carried on outside Canada are all deemed to be "Research outside Canada". Therefore these are not to be included with SR&ED expenditures on Form-3. This is the case even if the expenditures were made in Canada, for example to a Canadian sub-contractor. Patentees who are uncertain as to whether to include certain expenditures as SR&ED expenditures on Form-3 should call Board Staff for advice.

Block-1
Year to which Information Applies

Enter the calendar year to which the information applies.

Block-2
Identification of the Reporting Patentee

State the name and address of the reporting patentee; in other words, the name and address of the company completing this form.

A reporting patentee is either a current patentee or a former patentee (see pages 3 and 4 under Interpretations for further information).

6 Revenue Canada Taxation, Information Circular No 86-4R2, Scientific Research and Experimental Development, August 29, 1988 – para. 2.3.

7 Ibid., para 2.5.

Block-3
Licensee(s)/Other(s)

Provide the names and addresses of all licensees with whom the reporting patentee has a license (including compulsory license) or other agreement that entitles that person to exercise any rights in relation to a patent and which person sells a patented medicine in Canada.

Block-4
Revenues

Total Gross Revenues of the Reporting Patentee from all Sales of Medicines in Canada

Report the total gross revenues (net of taxes) from all sales of medicines[8] sold in Canada for human and veterinary use, that have a Drug Identification Number (DIN) under the *Food and Drug Regulations* or which have been approved for sale to qualified investigators or through Health Canada's Special Access Program under those Regulations. This includes both patented and non-patented medicines, whether sold by prescription or "over the counter" and whether for human or veterinary use.

Gross revenues from the sales of medicines should be reported on an accrual basis, i.e., in the year the product was shipped or left the plant gate.

Total Gross Revenues Received from all Licensees/Others in Canada

Report the total revenues (net of taxes) received (including royalties and license fees) from all licensees/others listed in Block 3, from the sale in Canada of medicines for human and veterinary use.

Revenues from licensees/others, in the form of license fees or royalties may be reported on an accrual basis (i.e., the year in which the medicines were shipped) or on a cash basis (i.e., the year the royalties were actually paid) but reporting should be consistent from year to year.

Block-5
Research and Development Pertaining to Medicines

Non-Capital Expenditures Incurred by the Patentee

Non-capital expenditures do not include general administrative expenses or factory overhead expenses that would have been incurred even if SR&ED had not been carried out. Expenses must all, or substantially all, be linked to SR&ED. All, or substantially all, means at least 90% of the time. For example, if a reporting patentee rents a photocopy machine that will be used approximately 50% of the time for SR&ED; no portion of the rental payments is considered to be an expenditure that is directly attributable to SR&ED. **The following cannot be included as non-capital expenditures in Block-5 under any circumstances:**

- capital expenditures or depreciation expenses (see Block-6)
- entertainment expenses
- advertising or selling expenses
- convention expenses
- legal or accounting expenses
- membership dues or fees
- fines or penalties
- expenditures made to acquire rights in, or arising out of, research and development (e.g., patent or registration fees)

Allowable non-capital expenditures should be broken out into the following categories:

A. Wages and salaries

Only include wages and salaries (and other related costs such as benefits) paid to employees who:

- are actually doing research work
- are directly supervising research work, or
- are directly supporting research work.

These expenditures must:

- include employee benefits and
- exclude bonuses or other remuneration based on the profits of the company.

8 Consult Glossary, on page 26, for definition of "medicine as" it applies to Form-3.

B. Direct material

All costs are to be the net laid-down price after deducting trade discounts, etc.

C. Contractors and sub-contractors

This category only covers contractors hired to carry out SR&ED on the reporting patentee's behalf. The expression "on the reporting patentee's behalf" distinguishes contractors from other expenditure categories such as payments to universities and granting councils.

D. Other direct costs

Include only the incremental general administrative and/or factory overhead costs incurred solely as a result of carrying on SR&ED activities.

E. Payments to designated institutions

Under this category, report payments to an approved university, college, research institute or other similar institution, to be used by that institution for SR&ED related to the reporting patentee's class of business. Amounts paid to carry out SR&ED on the reporting patentee's behalf should not be included here, but under section C pertaining to contractors and sub-contractors.

F. Payments to granting councils

Under this category, report payments to each granting council for eligible SR&ED activities. A granting council is an approved organization that pays an association, institution or corporation to do SR&ED related to the reporting patentee's class of business. Approved granting councils include:

- *Natural Sciences and Engineering Research Council*
- *Canadian Institutes for Health Research (formerly the Medical Research Council)*

G. Payments to other organizations

Include payments to other organizations for SR&ED related to the reporting patentee's class of business and not included under "E" (designated institutions) or "F" (granting councils) above.

Block-6
Total Capital Expenditures

Buildings – Annual Depreciation

Patentees should report annual depreciation of buildings used for SR&ED in Canada. The annual depreciation should be calculated at the rate of 4% of the qualifying capital cost per year over a maximum of twenty-five years. Depreciation is applied beginning with the year in which the building was purchased or acquired.

If a building was built or purchased to be used partly for SR&ED and partly for other purposes, and a **specific area** within the building is allocated solely for SR&ED use, a reasonable portion of the building's original cost can be used to calculate annual depreciation. Calculate the applicable portion of the building's cost by applying the proportion of SR&ED floor-space, to total floors space to the total original cost of the building.

> For example, a 1000 square meter building originally costing $400,000 has a 250 square meter wing allocated entirely for SR&ED activities. Since 25% (250 of 1000) of the total floor-space is devoted to SR&ED, calculate annual depreciation based on $100,000 (25% of $400,000). Annual depreciation would be 4% of $100,000 = $4,000.

If a building was originally used for purposes other than SR&ED, but is converted for SR&ED use, the cost of the conversion may be depreciated as above. However, do not include any part of the building's original cost in the reported annual depreciation.

To calculate the total annual depreciation of all buildings (and eligible conversion costs) dedicated to SR&ED, the annual depreciation of each should be calculated separately, and then totalled.

Total Capital Expenditures in the Year (buildings)

This line refers to capital expenditures made on buildings. Report total capital expenditures made during the reporting year on buildings in Canada to be used for SR&ED. Do not include capital expenditures made on land.

If a building was built or purchased to be used partly for SR&ED and partly for other purposes, and a **specific area** within the building is allocated solely for SR&ED, a reasonable portion of the building's total cost can qualify as a capital expenditure on SR&ED. If part or all of an existing building is converted for SR&ED, the conversion costs may qualify as a capital expenditure on SR&ED. However, no part of the building's original cost or of its un-depreciated capital cost is eligible.

Equipment (capital expenditures)

Capital expenditures on equipment must be made in Canada. When an asset is purchased from a supplier outside Canada and is imported and used for SR&ED in Canada, the expenditure is considered to be made in Canada. Normal accrual accounting principles will apply to capital expenditures for SR&ED.

Expenditures on equipment partly used for SR&ED and partly used for other purposes may be included only if it can be demonstrated that **all, or substantially all** of the equipment's use is for SR&ED. "All, or substantially all" means the equipment is used at least 90% of the time throughout its expected useful life for SR&ED.

Block-7
Type of Research and Development – Medicine for Human Use

List expenditures (non-capital only) on SR&ED in Canada for medicines for human use according to "type of research" and "who carried out the research". The following definitions may help in interpreting the meaning of the categories "type of research" and "who carried out the research". These definitions also apply to Block-8.

Type of R&D

Basic Research

Basic – chemical
Systematic investigation undertaken to advance knowledge in chemistry by means of experimentation or analysis, without any practical application in view.

Basic – biological
Systematic investigation undertaken to advance knowledge in biology by means of experimentation or analysis, without any practical application in view.

Applied Research

Manufacturing processes
Experimental development of new or improved manufacturing processes in support of basic or applied research.

Note: Preclinical and Clinical Trials
Generally, preclinical trials involve animal testing while clinical trials involve human subjects. However, preclinical and clinical trials often overlap. Some drug evaluations may not follow the phases of evaluation described here. Reporting patentees should strive to report according to the phases defined below.

Preclinical Trials I
- Acute toxicity – single administration to two or more animal species
- Detailed pharmacological studies (main effect, side effects, duration of effect, etc.)
- Specifications or analysis of active substance
- Stability of active substance
- Specifications of inactive substances

Preclinical Trials II
- Pharmacokinetics
- Chronic toxicity (two animal species)
- Reproduction toxicological studies
- Mutagenicity and carcinogenicity studies
- Synthesis of active substance on technical scale
- Development of final dosage form(s)
- Analytical evaluation of final dosage form(s)
- Stability of final dosage form(s)
- Production of clinical samples
- Sub-chronic (sub-acute) toxicity (other animal species)
- Supplementary animal pharmacology
- Carcinogenicity trials
- Supplementary animal pharmacology

Clinical Trials Phase I
- Tolerance in healthy volunteers
- Pharmacokinetics in humans

Clinical Trials Phase II
- First controlled trials on safety and efficacy in patients
- Chronic toxicity

Clinical Trials Phase III
- Therapeutic large scale trial at several trial centres for final establishment of therapeutic and safety profiles
- Proof of efficacy and safety in long term administration
- Demonstration of therapeutic advantages, if any
- Clarification of any interactions with concomitant medication
- Chronic toxicity (if required)

Other Qualifying R&D

This includes eligible research and development expenditures that cannot be classified into any of the preceding categories of "type of research and development."

Other qualifying research includes drug regulation submissions, bioavailability studies and Phase IV clinical trials.

Categories Describing Who Carried Out Research

Reporting Patentee
Reporting patentee is either a current patentee or a former patentee (see definitions on pages 3 and 4 under Interpretations). If you are no longer a patentee but were a patentee during part or all of the year Form-3 covers, you are required to report as a former patentee.

Other companies
Include corporations, resident in Canada, undertaking research on behalf of the reporting patentee, or research in the same class of business as the reporting patentee. Corporations carrying out the research do not have to be at arm's-length from the reporting patentee.

Universities
Include universities, colleges and other institutions, such as research institutes, approved under the *Income Tax Act*.

Hospitals
A facility licensed, approved or designated as such by a federal, provincial or territorial government.

Note: Hospital vs. University

There may be some uncertainty as to whether to classify, as hospital or university, research carried out in a teaching hospital or when scientists doing the work are affiliated with both a hospital and a university. If it can be ascertained where the monies for the research are being handled/managed (i.e., through the university or through the hospital), then these amounts should be assigned to reflect this. When payment is made directly to a scientist or other researcher with dual affiliations, the amounts should be included under the category that best describes the setting where the research took place.

Others
This category is reserved for expenditures that do not logically fit into any of the other categories.

Block-8
Type of Research and Development – Medicine for Veterinary Use

Expenditures (non-capital only) on SR&ED in Canada, pertaining to medicines for veterinary use, are to be listed according to "type of research" and "who carried out the research". The definitions in Block-7 above may help you interpret the categories of "type of research" and "who carried out the research".

Block-9
Source of Funds for R&D

Detail sources of funds for non-capital expenditures and capital equipment expenditures according to the categories described below. The total source of funds reported in this block is to correspond to the total of non-capital expenditures and capital equipment expenditures (Block-5 and Block-6 (Equipment)).

Internal Funds
Refers to the internal corporate funds of the reporting patentee. It does not include monies from parent or subsidiary companies if these companies are distinct corporate entities in their own right. Monies from parent or subsidiary companies should be included under "not arm's-length".

Arm's-Length Person
An "arm's-length person" is an individual, corporation or other legal entity that is not related to the reporting patentee. If in doubt, refer to the *Income Tax Act* for a definition of "arm's-length". Examples of "not arm's-length" relationships are given in the following section.

Not Arm's-Length Person
A "not arm's-length person" is an individual, corporation or other legal entity that is related to the reporting patentee. There are many types of "not arm's length" relationships. It is beyond the scope of this document to list them all. However, some examples of "not arm's-length" relationships of corporations follow.

Corporations are related (i.e., not at arm's-length) to each other if:

- one is controlled by the other
- one corporation is a member of a related group that controls the other
- they are controlled by the same person or persons ("person" can mean an individual or a corporation)

The above list is a small sample only. Reporting patentees should consult the *Income Tax Act* if there is doubt as to whether a relationship is, or is not, at arm's-length.

Federal Government
This category includes all monies received during the year from departments and agencies of the federal government of Canada. These monies include, among other things, all assistance paid during the year to a patentee under the terms of an *Appropriation Act* for SR&ED expenditures. Such assistance includes, among other things, any grant, subsidy, reimbursement or forgivable loan (including a contingently repayable loan) received by the reporting patentee. The amount reported is to be net of amounts repaid to the federal government during the year.

Provincial Government
Include all monies received from provincial or territorial government departments or agencies.

Other
Include all monies received by the patentee from sources that do not logically fall into any of the above categories.

Block-10
Information for R&D in Each Province/Territory

Provide a provincial/territorial distribution of SR&ED expenditures (non-capital only), by each of the "who carried out the research" categories. Definitions of the "who carried out the research" categories are in the definitions for Block-7. The total expenditures reported in Block-10 should correspond to total non-capital expenditures (Block-5).

Block-11
Certifying Signature

This block is for the signature of the reporting patentee (or authorized corporate official). The individual signing should be knowledgeable about the information reported on the form.

Reconciling Expenditures and Sources of Funds

To verify the accuracy of information reported on Form-3, ensure that the "expenditures" and "source of funds" figures can be properly reconciled.

The sum of all non-capital expenditures (Block-5) should be equal to the sum of Block-7 and Block-8, as well as to the total of the expenditures provided in the provincial/territorial breakdown in Block-10. The sum of non-capital (Block-5) and capital equipment expenditures (Block-6 equipment only) should equal the total source of funds (Block-9).
For summary table, see page 22.

In summary:

[Block-5] = [Block-7] + [Block-8]

[Block-5] = [Block-10]

[Block-9] = [Block-5] + [Block-6 (equipment only)]

Columns reconciliation:

Patentee [Block-7] + [Block-8] = Patentee [Block-10]

Other companies [Block-7] + [Block-8] = Other companies [Block-10]

Universities [Block-7] + [Block-8] = Universities [Block-10]

Hospitals [Block-7] + [Block-8] = Hospitals [Block-10]

Others [Block-7] + [Block-8] = Others [Block-10]

Notification of Intent to Sell

The 1993 amendments to the *Patent Act* require patentees to notify the PMPRB, as soon as this is possible, of an intention to sell a patented drug product in a new market in Canada, and the date on which the patentee intends to offer the drug product for sale. The form for providing the required information can be found in the Compendium of Guidelines, Policies and Procedures, Schedule 6, page 38, as well as at the back of this Guide on page 32.

Glossary

Note to Reader: This glossary is included for the convenience of the reader. For more detailed information and definitions please refer to the *Patent Act*, the *Patented Medicines Regulations* and the Compendium of Guidelines, Policies and Procedures, or contact the PMPRB.

Accrual accounting: Under the "accrual" accounting method, revenues should be reported in the year in which they are earned, regardless of when payment is received. Expenditures should be reported in the year in which they were incurred, whether or not they were paid in that period. With the exception of "Revenues from licensees" on Form-3, all revenues and expenditures must be reported using normal accrual accounting methods.

Active Ingredient: Chemical responsible for the claimed pharmacologic effect of a drug product.

Arm's-length person: An "arm's-length person" is an individual, corporation or other legal entity (see also: definition of "Person") that is not related to the reporting patentee. If in doubt, patentees should refer to the *Income Tax Act* for a definition of "arm's length". Generally, "arm's-length" persons (individuals or corporations) are persons that have no corporate or other direct connections with each other, and thus act each in their own self-interest. Examples of "not arm's-length" relationships are given in the definition of "not arm's length" on page 21.

Persons normally operating at "arm's length" may have a "not arm's-length" relationship for a particular contract. However, if outside this contract there is not special duty, obligation or relationship to each other, then the two persons may be considered to be at "arm's length".

Assignee: An assignee is a person (individual or corporation or other legal entity) that enjoys some or all of a patentee's rights with respect to a patented medicine. Such rights may include manufacturing, distributing or selling a patented medicine. The assigned rights may have time and geographic limitations. The assigned rights are generally the outcome of a contractual agreement between the patentee and the assignee. Compulsory licensees are not considered to be assignees.

Assigned Number: Number attributed by the PMPRB for reporting purposes to a patented drug product that has no DIN. This number will be assigned once the completed Form-1 for the patented drug product with no DIN has been filed and should be used on Form-2 for all subsequent reporting periods.

Average price per package: Average price per package is defined as net revenues divided by the total number of packages sold (or distributed as part of promotion, rebate, etc.) when net revenues consist of actual sales revenues (excluding sales tax) less any amounts disbursed for benefits or promotions such as rebates, refunds, or gifts.

Cash Accounting: Under the cash accounting method revenues are reported in the year in which they are actually received. Only "Revenues from Licensees" on Form-3 may be reported using the cash method; all other revenues and all expenditures must be reported using normal accrual accounting methods.

Clinical Trial Stages: Generally, preclinical trials involve animal testing while clinical trials involve human subjects. However, there is often overlap of the clinical and preclinical trials. Some drug evaluations may not have followed the phases of evaluation described in these definitions. Reporting parties should strive to report according to the phases defined under the headings "clinical trials" and "preclinical trials".

Clinical Trials Phase I:

- Tolerance in healthy volunteers
- Pharmacokinetics in humans

Clinical Trials Phase II:

- First controlled trials on safety and efficacy in patients
- Chronic toxicity

Clinical Trials Phase III:

- Therapeutic large-scale trial at several trial centers for final establishment of therapeutic and safety profiles
- Proof of efficacy and safety in long term administration
- Demonstration of therapeutic advantages, if any
- Clarification of any interactions with concomitant medication
- Chronic toxicity (if required)

Corporate officer: For reporting purposes, corporate officer is interpreted in the broad sense as meaning a corporate official or employee authorized to sign on behalf of the corporation. Corporate officials signing the reporting forms on behalf of their corporation should be knowledgeable about the contents of the forms.

Drug Identification Number (DIN): A registration number that the Health Products and Food Branch of Health Canada assigns to each prescription and non-prescription drug product marketed under the Food and Drug Regulations. The DIN is assigned using information in the following areas: manufacturer of the product; active ingredient(s); strength of active ingredient(s); pharmaceutical dosage form; brand/trade name; and route of administration.

Drug Product: A particular presentation of a medicine characterized by its pharmaceutical dosage form and the strength of the active ingredient(s).

Efficacy: The ability of a medicine to produce the purported effect as determined by scientific methods.

Special Access Programme (SAP): The SAP provides access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada.

Ethical (medicine): Generally, the term “ethical” is used in the pharmaceutical industry to describe products that require a prescription and are not usually advertised to the public. By contrast, the term “proprietary” is used to describe products for which no prescription is required and which may be promoted directly to the public.

Ex-factory price: The price established for the first sale (during the reporting period) of the product “at arm’s length” to distributors, wholesalers, hospitals, pharmacies, etc. This price always excludes sales taxes, and wholesale mark-ups when the wholesale function is not carried out by the patentee. The ex-factory price is generally the “list price” for medicines. The ex-factory price can also be the price that is agreed on between the patentee and the regulatory body of the country in which it is sold by the patentee.

Format (of medicine): Also referred to as the “presentation”. The format of a medicine is the particular combination of active ingredient strength, dosage form and package size (i.e., units of medicine per package).

Former patentee: A patentee is referred to as a former patentee once the relevant patents for a particular drug product expire. The Regulations require filing of information for drug products not previously filed. The filing should only cover the periods during which the drug product was patented. The Board can request this information within three years of the patent’s expiry, if it has reason to do so.

Generic Product: A pharmaceutical product that is a copy (i.e., the same active ingredient, strength and dosage form) of a brand-name drug product.

Hospital: A health care institution licensed, approved or designated as a hospital by a provincial or territorial government or is owned or operated by the Government of Canada to provide continuing medical care and supporting diagnostic and therapeutic services.

Indication: An indication is a specific condition, manifested by the presence of disease or medical signs or symptoms that the medicine treats or cures, as approved by the Health Protection Branch of Health Canada.

Investigational New Drug (IND): A drug that has been approved for clinical evaluation (i.e., testing on humans) but that is not yet approved for sale for the indication under study.

In vitro: In relation to a medicine or patented medicine, the use or application of such medicine or patented medicine in a laboratory or other environment that is not associated with its direct application to, or use for, humans or animals.

In vivo: In relation to a medicine or a patented medicine, the application or administering of such medicine or patented medicine, as the case may be, into or upon the living body of humans or animals.

Licence, Compulsory: A license granted by the Commissioner of Patents that permits the licensee to import, make, use or sell a patented invention pertaining to a medicine. The compulsory licensee pays license fees or royalties to the patent holder for use of the patented invention.

With the exception of those compulsory licenses issued prior to December 20, 1991, which continue to be in effect, the 1993 amendments to the *Patent Act* repealed the compulsory licensing regime effective December 20, 1991. Accordingly all compulsory licenses issued after December 20, 1991 cease to have effect.

Licence, Voluntary: A contractual agreement between a patent holder and a licensee under which the latter is permitted to exploit certain of the otherwise exclusive patent rights of the patentee, usually for some consideration (i.e., royalties in the form of a share of the licensee's sales).

Manufacturing: All operations involved in the production of a medicine, including processing, compounding, formulating, filling, packaging, and labeling.

Medicine: Any substance or mixture of substances made by any means, whether produced biologically, chemically, or otherwise, that is applied or administered in vivo in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans and or animals, however administered.

For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used *in vivo*, regardless of delivery mechanism (e.g., transdermally, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, *in vitro* diagnostic products and disinfectants that are not used *in vivo*.

Net Revenues: Net revenues consist of actual sales revenues (excluding sales tax) for medicine sold (i.e., shipped) during the reporting period less amounts disbursed for benefits or promotions such as rebates, refunds, or gifts.

Not arm's-length person: A "not arm's-length person" is an individual, corporation or other legal entity that is related to the patentee. For example, a foreign owned corporation and its Canadian subsidiary do not have an arm's-length relationship with each other. However, there are many types of "not arm's-length" relationships. It is beyond the scope of this document to list them all. However, some examples of ways in which corporations may have relationships that are not at arm's-length are:

- if one corporation is controlled by the other
- if one corporation is a member of a related group that controls the other
- if they are controlled by the same person or persons ("person" can mean individual or corporation)

The above list is a small sample only. If there is any doubt as to whether a relationship is, or is not, at arm's-length, patentees should consult the *Income Tax Act*.

Notice of Compliance (NOC): A notice in respect of a medicine issued by the Health Products and Food Branch of Health Canada under section C.08.004 of the *Food and Drug Regulations*. The issuance of an NOC indicates that a drug product meets the required Health Canada standards for use in humans or animals and that the product is approved for sale in Canada.

Patent: An instrument issued by the Commissioner of Patents in the form of letters patent for an invention that provides its holder with a monopoly limited in time, for the claims made within the patent. A patent gives the patentee the exclusive right to make, sell or otherwise exploit the invention for the term of the patent.

***Patented Medicines Regulations*:** A federal regulatory instrument promulgated under the authority of the *Patent Act*. The *Regulations* specify the information patentees must report to the Board relating to the medicine, price and sales of the medicine, revenues and research and development expenditures as well as the timing of the filing.

Patentee: For purposes of subsection 79 to 103 of the Act, "the person for the time being entitled to the benefit of the patent for that invention (pertaining to a medicine) and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a license continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, that other person in respect of those rights;"

Pharmacokinetics: The rate of drug action, particularly with respect to absorption, distribution, metabolism and excretion of the drug and its metabolites.

Pharmacy or Drugstore: An establishment licensed by a provincial licensing body to dispense or sell drugs, pharmaceuticals, patented medicines and drug sundries to patients.

Preclinical Trials I:
- Acute toxicity – single administration to two or more animal species
- Detailed pharmacological studies (main effect, side effects, duration of effect, etc.)
- Specifications or analysis of active substance
- Stability of active substance
- Specifications of inactive substances

Preclinical Trials II:
- Pharmacokinetics
- Chronic toxicity (two animal species)
- Reproduction toxicological studies
- Mutagenicity and carcinogenicity studies
- Synthesis of active substance on technical scale
- Development of final dosage form(s)
- Analytical evaluation of final dosage form(s)
- Stability of final dosage form(s)
- Production of clinical samples
- Sub-chronic (sub-acute) toxicity (other animal species)
- Supplementary animal pharmacology
- Carcinogenicity trials
- Supplementary animal pharmacology

Proprietary Drug: The term "proprietary" is used to describe products for which no prescription is required and which may be promoted directly to the public.

Quality control: All measures designed to ensure the output of uniform batches of drugs that conform to established specifications of identity, strength, purity, and other characteristics.

Research and Development (R&D): Basic or applied research for the purpose of creating new, or improving existing materials, devices, products or processes (e.g., manufacturing processes).

Research and Development – Applied Research: Work that advances scientific knowledge with a specific practical application in view such as creating new or improved products or processes through manufacturing processes or through preclinical or clinical studies.

Research and Development – Basic Research: Work that advances scientific knowledge without a specific application in view.

Research and Development – Clinical Research: The assessment of the effect of a new medicine on humans. It typically consists of three successive phases, beginning with limited testing for safety in healthy humans then proceeding to further safety and efficacy studies in patients suffering from the target disease.

Research and Development – Preclinical Research: Tests on animals to evaluate the pharmacological and toxicological effects of medicines.

Research and Development Expenditures: For the purposes of the *Patented Medicines Regulations*, in particular sections 5 and 6, research and development includes activities for which expenditures would have qualified for the investment tax credit for scientific research and experimental development under the *Income Tax Act* as it read on December 1, 1987.

Sale: A "sale" is the transfer of property rights from one person to another for money, money's worth, or other consideration. On Form-2, information is requested on the revenues from sales of patented medicines only, while on Form-3, information is requested on revenues from the sales of all medicines.

More specifically, the sales to be reported are for any product for which a DIN has been issued under the *Food and Drug Regulations* or which has been approved for sale to qualified investigators under the said regulations; AND

that is used in the diagnosis, treatment, mitigation or prevention of disease, disorder, abnormal physical state or the symptoms thereof, or in the modification of organic functions in human or animal; AND

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

Wholesaler: An person (individual, corporation or other legal entity) primarily engaged in buying merchandise for resale to retailers; to industrial, commercial, institutional, farm or professional business users; to other wholesalers or in acting as an agent or broker in buying merchandise for, or selling merchandise to, such persons or companies for a commission.

Appendix A – List of Codes

Comparable Dosage Form Codes (to be used in Form 1 Block 4, and in Form 2 Block 4 and 5)

Topical (T)	Nasal (N)/Pulmonary (P)	Oral Solid (S)
T1 Aerosol T2 Cream T3 Gel T4 Liquid T5 Ointment T6 Paste T7 Powder T8 Shampoo T9 Spray T10 Patches T11 Disks T12 Dressings T99 Other	N1/P1 Drops N2/P2 Aerosol N3/P3 Spray N4/P4 Solution N5/P5 Powder N6/P6 Gas N7/P7 Metered dose preparations N99/P99 Other	S1 Tablet S2 Capsule S3 Modified release tablets S4 Modified release capsules S5 Effervescent powder S6 Effervescent tablets S7 Effervescent granules S8 Caplet S9 Modified release caplets S99 Other
Oral Liquid (L)	**Vaginal (V)**	**Parenteral (J)**
L1 Solution L2 Powder for solution L3 Powder for suspension L4 Suspension L5 Drops L6 Modified release liquid L99 Other	V1 Suppository V2 Cream V3 Tablet V4 Douche V5 Foam V6 Cone V7 Ovule V8 Gel V9 Tampon V10 Sponge V11 Insert V99 Other	J1 Solution J2 Powder for solution J3 Suspensions or Emulsions J4 Modified release injections J5 Implant J99 Other
Otic (E)/Ophthalmic (Y)	**Rectal (R)**	**Dental – Sublingual Buccal (M)**
E1/Y1 Liquid E2/Y2 Powder for solution E3/Y3 Drops E4/Y4 Suspension E5/Y5 Ointment E6/Y6 Gel E7/Y7 Modified release ocular devices E99/Y99 Other	R1 Suppository R2 Cream R3 Ointment R4 Enema R5 Suspension R6 Foam R99 Other	M1 Mouth wash M2 Solution M3 Suspension M4 Powder for suspension M5 Lozenge M6 Gel M7 Gum M8 Modified release buccal tablets M9 Sprays – Sublingual M10 Sprays – buccal M11 Sublingual tablets M12 Tooth paste M13 Tooth powder M99 Other

Form 2 Block 4

Province/Territory Codes	Class of customer Codes
1 NL 2 PE 3 NS 4 NB 5 QC 6 ON 7 MB 8 SK 9 AB 10 BC 11 NT 12 YT 13 CANADA (when province / territory is not known) 14 NU	1 Hospital 2 Drugstore or Pharmacy 3 Wholesaler 4 Other

Form 2 Block 5

Country or Province Codes	Class of customer Codes
13 CANADA (when public price is the same in ALL provinces/ territories) otherwise use same codes as in Block 4 for each province/ territory 15 GERMANY 16 FRANCE 17 ITALY 18 SWEDEN 19 SWITZERLAND 20 UNITED KINGDOM 21 UNITED STATES	1 Hospital 2 Drugstore or Pharmacy 3 Wholesaler 4 Other 4-FSS The price of a drug product on the US Federal Supply Schedule should be coded as follows: use code 21 in the column Country or Province and “4-FSS” in the column Class of Customer

Appendix B – Reporting Forms

Patented Medicine
Prices Review Board

FORM 1
MEDICINE IDENTIFICATION SHEET

Privileged s.87
Patent Act

Use one form per DIN

Please Specify ☐ Original Filing or ☐ Amendment to Original Filing

1 NAME(S) AND USE(S) OF THE MEDICINE

Brand Name: _____

Generic Name: _____

Therapeutic use(s) of the medicine approved by Health Canada: _____

☐ **Human Prescription**

(The medicine is for human use and contains a controlled substance as defined in the *Controlled Drugs and Substances Act* or contains a substance listed or described in Schedules C or D to the *Food and Drugs Act* or in Schedule F to the *Food and Drug Regulations*)

OR

☐ **Human Over-the-Counter**

(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 Schedules C or D to the *Food and Drugs Act* or in Schedule F to the *Food and Drug Regulations*)

OR

☐ **Veterinary**

2 REPORTING PATENTEE

Patentee Name

Patentee Address _____

Identity if the reporting patentee is: ☐ the patent holder ☐ person entitled to the benefits of a patent or to exercise any rights in relation to a patent

3 NOTICE OF COMPLIANCE (N.O.C.)

First N.O.C.		
Y	M	D

Check if applicable

☐ Special Access Programme
or
☐ Clinical Trial Application or Investigational New Drug

4 DRUG IDENTIFICATION NUMBER (DIN)

Drug Identification Number	Dosage Form	Strength/Unit

5 DATE OF FIRST SALE

Date of 1st Sale		
Y	M	D

6 PRODUCT MONOGRAPH

☐ Product Monograph (Copy Included) ***OR*** ☐ Information similar to that contained in a Product Monograph (Copy Included)

Patented Medicine
Prices Review Board

FORM 1
MEDICINE IDENTIFICATION SHEET

Privileged s.87
Patent Act

7 PATENT NUMBER OF REPORTING PATENTEE'S INVENTIONS PERTAINING TO THE MEDICINE

Patent Number	Date Granted			Expiration Date		
#	Y	M	D	Y	M	D

8 CERTIFIED BY: (in accordance with Section 7 of the Patented Medicines Regulations)

I hereby certify that the information presented is true and correct.

Signature of duly authorized person for the reporting patentee.

Name:

Title:

Organization:

Date:

Tel. Number: ( )

Fax Number : ( )

E-mail:

Please send completed Form 1 to: compliance@pmprb-cepmb.gc.ca

FORM-1 Medicine Identification Sheet (XLS)

Patented Medicine
Prices Review Board

FORM 2
INFORMATION ON THE IDENTITY AND PRICES OF THE MEDICINE

Privileged s.87
Patent Act

Please Specify ☐ Original Filing or ☐ Amendment to Original Filing

1 REPORTING PERIOD

Period to which the information applies:	FROM Y M D	TO Y M D

2 NAMES OF THE MEDICINE

Brand name of the medicine
Generic name of the medicine

3 REPORTING PATENTEE*

Patentee Name
Patentee Address

*Please see section 79(1) of the *Patent Act* for the definition of a "patentee". Note that a patentee is any person entitled to the benefits of a patent or to exercise any rights in relation to a patent. This includes patent holders, licensees or others.

CERTIFIED BY: (in accordance with Section 7 of the Patented Medicines Regulations)

I hereby certify that the information presented is true and correct.

Signature of duly authorized person for the reporting patentee

Name:

Title:

Organization:

Date:

Tel. Number: ( ) Fax Number : ( )

E-mail:

Please send completed Form 2 including the cover sheet, Block 4 and Block 5 to:
compliance@pmprb-cepmb.gc.ca

FORM-2 Information on the Identity and Prices of the Medicine (XLS)

FORM-2 Sales of the Medicine by the Reporting Patentee in Final Dosage Form in Canada (XLS)

Patented Medicine
Prices Review Board

FORM 2 (continued)
INFORMATION ON THE IDENTITY AND PRICES OF THE MEDICINE

Privileged s.87
Patent Act

(1) Each line of information should be fully completed to include DIN or Assigned Number, Strength/Unit, Dosage Form, Package Size, Number of Packages Sold, Net Revenues, Average Price/Package, Province, Class of Customer
(2) For drug products with no DIN, use number assigned by the PMPRB for reporting purposes
(3) Use a separate line for each strength/unit, dosage form and package size
(4) See attached and/or the Patentee's Guide to Reporting for codes to be used
(5) Insert only numeric values
(6) Please provide net revenue whenever possible, otherwise provide the average price per package

Reporting Period: ____________________

4 SALES OF THE MEDICINE BY THE REPORTING PATENTEE IN FINAL DOSAGE FORM IN CANADA [1]

Drug Identification Number (DIN) or Assigned Number (2)	Strength/Unit (3)	Dosage Form (3,4)	Package Size (3,5)	Number of Packages Sold (5)	INDICATE EITHER (6)		Province (4)	Class of Customer (4)
					Net Revenue	AVG Price/Package		

FORM-2 Publicly Available Ex-Factory Prices for Canada and Other Countries (XLS)

Patented Medicine
Prices Review Board

FORM 2 (continued)
INFORMATION ON THE IDENTITY AND PRICES OF THE MEDICINE

Privileged s.87
Patent Act

(1) Each line of information should be fully completed to include Generic Name, DIN, Strength/Unit, Dosage Form, Package Size, Ex-Factory Price, Country or Province, Class of Customer
(2) For drug products with no DIN, use number assigned by the PMPRB for reporting purposes
(3) Use a separate line for each strength/unit, dosage form and package size
(4) See attached and/or the Patentee's Guide to Reporting for codes to be used
(5) In currency of the country in which the medicine is sold

Reporting Period: _____

5 PUBLICLY AVAILABLE EX-FACTORY PRICES FOR CANADA AND OTHER COUNTRIES [1]

Generic name of medicine	Corresponding Canadian DRUG IDENTIFICATION NUMBER (DIN) when sold in Canada, or Assigned Number (2)	Strength / Unit (3)	Dosage Form (3,4)	Package Size (3)	Ex - Factory Price (5)	Country Province (4)	Class of Customer (4)

Form 3 - Revenues and Research and Development Expenditures
Provided Pursuant to Subsection 88(1) of the *Patent Act* and Sections 5 and 6 of the *Patented Medicines Regulations*, *1994*

1 Year to which Information Applies:

2 Identification of the Reporting Patentee*

Patentee Name:
Patentee Address:

* **Please see section 79(1) of *Patent Act* for the definition of a "patentee." Note that a patentee is any person entitled to the benefits of a patent or to exercise any rights in relation to a patent. This includes patent holders, licensees or others.**

3 Licensee(s)/ Other(s)**

Name:	Name:
Address:	Address:

Name:	Name:
Address:	Address:

Name:	Name:
Address:	Address:

Name:	Name:
Address:	Address:

** **Those persons with whom the reporting patentee has a license (including compulsory license) or other agreement that entitles that person to exercise any rights in relation to a patent.**

4 Revenues

	For human use	For veterinary use
Total gross revenues of the reporting patentee from all sales of medicines in Canada	$	$
Total gross revenues received from all licensees/others in Canada (eg: royalties and/or other fees)	$	$

5 Research and Development Pertaining to Medicines

Non-Capital Expenditures Incurred by the Patentee		
A. Wages and salaries		$
B. Direct material (expenditures on material and supplies directly used)		$
C. Contractors and subcontractors	Universities	$
	Other	$
D. Other direct costs (other expenditures that are directly attributable to R&D)		$
E. Payments to designated institutions (university, college, research institute or other)		$
F. Payments to granting councils		$
G. Payments to other organizations		$
	TOTAL	**0.00**

6 Total Capital Expenditures

Building		Equipment	
Annual depreciation (in accordance with section 5 of the Regulations)	$		
Total capital expenditures in the year	$	Total capital expenditures in the year	$

7 Expenditures in Canada for R&D pertaining to medicines for human use, broken down by type and who carried out the R&D

Type of R&D	Patentee	Other Companies	Universities	Hospitals	Others
Basic - chemical	$	$	$	$	$
Basic - biological	$	$	$	$	$
Manufacturing processes	$	$	$	$	$
Preclinical trials I	$	$	$	$	$
Preclinical trials II	$	$	$	$	$
Clinical trials Phase I	$	$	$	$	$
Clinical trials Phase II	$	$	$	$	$
Clinical trials Phase III	$	$	$	$	$
Other qualifying R&D	$	$	$	$	$
Total	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**

8 Expenditures in Canada for R&D pertaining to medicines for veterinary use, broken down by type and who carried out the R&D

Type of R&D	Patentee	Other Companies	Universities	Hospitals	Others
Basic - chemical	$	$	$	$	$
Basic - biological	$	$	$	$	$
Manufacturing processes	$	$	$	$	$
Preclinical trials I	$	$	$	$	$
Preclinical trials II	$	$	$	$	$
Clinical trials Phase I	$	$	$	$	$
Clinical trials Phase II	$	$	$	$	$
Clinical trials Phase III	$	$	$	$	$
Other qualifying R&D	$	$	$	$	$
Total	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**

9 Source of Funds for R&D

Internal funds	$
Arm's length person	$
Not arm's length person	$
Federal government	$
Provincial government	$
Other (specify)	$
Total	**0.00**

10 Expenditures in Canada for R&D pertaining to medicines for both human and veterinary use, broken down by province/territory and who carried out the R&D

Province where R&D was performed	Patentee	Other Companies	Universities	Hospitals	Others
NFLD.	$	$	$	$	$
P.E.I.	$	$	$	$	$
N.S.	$	$	$	$	$
N.B.	$	$	$	$	$
QUE.	$	$	$	$	$
ONT.	$	$	$	$	$
MAN.	$	$	$	$	$
SASK.	$	$	$	$	$
ALTA.	$	$	$	$	$
B.C.	$	$	$	$	$
N.W.T.,Yukon and Nunavut.	$	$	$	$	$
Total	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**

11 Certified By: **(in accordance with Section 7 of the *Patented Medicines Regulations, 1994*)**

I hereby certify that the information presented is true and correct.	
Signature of duly authorized person for the reporting patentee	
Name	
Title:	
Organization	
Date:	
E-Mail:	
Telephone Number:	Fax Number:

FORM-3 Revenues and Research and Development Expenditures Provided Pursuant to Subsection 88(1) of the *Patent Act* (XLS)

Noti cation of Intention to Sell a Patented Medicine *(In accordance with subsection 82(1) of the Patent Act - http://lois.justice.gc.ca/en/showtdm/cs/P-4)*	
Brand Name:	
Generic or Chemical Name:	
Dosage Form:	Strength:
DIN (if available):	Date of NOC (anticipated):
Expected Date of First Sale:	
Canadian Patent Number(s):	
Name and Address of Canadian Patentee:	
Authorized signing of cer: *Signature*	*Name and Title*

NOTIFICATION OF INTENT TO SELL – pursuant to Subsection 82(1) of the *Patent Act* (as published in the Compendium of Guidelines, Polices and Procedures) (XLS)