Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

PATENTEES' GUIDE TO REPORTING

Forms 1, 2 and 3

of the

Patented Medicines Regulations, 1994

Patented Medicine Prices Review Board

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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*, 1994 (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. Patentees are encouraged to contact the compliance officer assigned to their company.

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 appendix includes the blank reporting forms and the list of codes to be used to complete Form-1 and Form-2.

Blank reporting forms included in this guide may be photocopied for reporting purposes. Additional forms may be obtained from the PMPRB offices.

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.

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.

Alternatives to the Reporting Forms

While the forms are not legally prescribed, the information therein is, and the PMPRB strongly urges their use given the benefit the patentees will receive in the conduct of a more expeditious review. That being said, however, the PMPRB strongly encourages electronic reporting using diskettes. The PMPRB has available on diskette Lotus 1-2-3 spreadsheet templates of the reporting forms. These diskettes are available from the PMPRB at no charge and provide an interactive, menu-driven method of completing the reporting forms. These templates require an IBM-compatible micro computer and Lotus 1-2-3 (Release 2.0). There are no restrictions on copying or distributing these templates. Patentees who wish to report on diskette using a method other than the PMPRB supplied templates should check with PMPRB staff in advance, to ensure that the submitted data will be acceptable in layout and hardware/software compatibility.

If patentees still prefer to report on paper, the PMPRB will consider information submitted in other formats. These could include printouts or other printed reports generated by the patentee. To be considered by the PMPRB, these printouts or other reports should maintain the same general layout as the reporting forms. At a minimum, use the same headings, in the same order, as the official reporting forms. Each page should contain information for no more than one drug product or reporting period. Patentees should consult PMPRB staff about the layout of alternative-format reports or printouts prior to submission. Patentees are responsible for ensuring that these include all the information required under the *Regulations*.

Certain reporting formats are not acceptable:

- Photocopies of price lists that do not have the same general layout and headings of the official report are not acceptable for the Block 5 publicly available prices.
- Price lists in languages other than English or French are not acceptable.
- Reports that show information for more than one reporting period on a single page are not acceptable.

Where to Get Help

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

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
Secretary to the Board

Facsimile:

(613) 952-7626

Communications may be in either official language.

Mailing List

If you would like to be added to the PMPRB's mailing list please complete the following sheet and either mail or fax the relevant information.

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: ( ) -

Please send this completed form to:

Patentees' Guide to Reporting
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Tel: (613) 952-7360
Fax: (613) 952-7626

Patentees' Guide to Reporting
Form-1 - Medicine Identification Sheet

General Information

Purpose

Form-1 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.

Submit a separate Form-1 for each patented drug product within thirty days of it being issued a NOC or being offered for sale in Canada, whichever comes first. Also use Form-1 to report any changes, additions or deletions to information previously submitted on Form-1.

Intent to sell in a new market

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 SCH6: 2, as well as at the back of this Guide.

Who should provide information?

(a) 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 licence 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 licence). 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.

(b) 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 be filed, for drug products not

previously filed, and only for the periods under which the drug products were patented. The Board can request this information within three years of the patent's expiry, if it has reason to do so.

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

Which drug products should be reported?

Once a patentee is issued a NOC for a drug product that has one or more related patents in force, the patentee has 30 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 considered by Health Canada to be "investigational drugs" (including drug products provided under the "Emergency Drug Release" program), that are being offered for sale commercially or otherwise, and for which no NOC has been issued, should also be reported on a Form-1 within thirty days of first being offered for sale.

Changes/Additions/Deletions

Use another Form-1 to forward to the PMPRB any changes, additions and deletions to information previously submitted for a drug product on Form-1. Indicate in the check box at the top of the form that the submission amends an earlier submission. It is not necessary to resubmit all the information submitted on the original Form-1. Block-1, Block-3 and Block-6 should always be completed, as well as amended information in the remaining blocks.

Forward any change to the identity (i.e., name and/or address) of the reporting patentee or former patentee to the PMPRB in writing.

Direct any questions about changes, additions and deletions that cannot be resolved by these guidelines to the officer assigned to your company.

Due Dates

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

i. **30 days** after the Notice of Compliance is issued **or**

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

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.

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. If the space provided is not sufficient, add a separate sheet. 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 Valium™ are listed as:

Anxiolytic
Sedative
Muscle Relaxant

Human/Veterinary Use

Indicate in the boxes provided whether the drug product is intended for human or veterinary use. If the drug product is intended for **both** human and veterinary uses, complete a separate Form-1 for each. Veterinary drug products include feed additives (e.g., antibiotics, vitamins) which have been classified as drug products.

Patentees should provide along with either Form-1 or with the notification of intended sale a copy of the product monograph. This material will assist the staff in its review of the new drug product and can expedite the review process by eliminating delays caused by the need to request this information from the patentee at a later date.

BLOCK-2 Notice of Compliance (NOC)

Introduction

The date given for the "Patentees' First NOC" should always be the earlier of:

- the date an NOC was issued to the drug product named in Block-1
- the date the drug product was first offered for sale

Patentees' First NOC

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

Emergency Drug Release Program or Investigational New Drug

If applicable, use the provided boxes to indicate whether the drug product named in Block-1 is being provided under the Emergency Drug Release Program or the Investigational New Drug Program.

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

BLOCK-3 Drug Identification Number (DIN or General Public (GP) Number)

Drug Identification Number (DIN or GP Number)

Enter the DIN (or GP Number) that applies to the drug product identified in Block-1. Enter only the DIN or GP number that identifies a form of the drug product to which the reporting patentee has rights to sell, distribute, etc. If no DIN has been issued, indicate instead when the drug product was first offered for sale in Canada. If the space provided is not sufficient, attach a separate sheet.

Dosage Form

Enter the dosage form that corresponds to the DIN (or GP number) 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, syrup
suspensions
drops
lotions, creams
sprays, aerosols
suppositories

For a complete list of dosage forms, please refer to the Appendix. The Appendix 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 (or GP number) 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 (: g or mcg) or as appropriate per unit of medicine.

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

Dosage Form	Strength
Tablets	10mg / tablet
Oral Liquid	10mg / ml
Injectable	10mg / vial
Cream	10mg / gram
Inhaler	10 : g / metered dose

Do not use percentages; use the style shown above. For example, instead of reporting an oral liquid with 1% of active ingredient, report 10 mg/ml.

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

BLOCK-4 Patent Numbers of Patentee's or Former 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 or former patentee, assigned to the reporting patentee or former patentee, or for which the reporting patentee or former patentee holds a licence (other than a compulsory licence).

Date Granted

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

Expiry Date

For each patent number listed in the first column, enter on the corresponding line in the third column the corresponding expiry date. Until recently, patents expired seventeen (17) years after the date the patent was granted. Patents granted under the revised section 44 of the *Patent Act* will expire twenty (20) years from the date of the filing of the application of the patent in Canada[2].

BLOCK-5 Patentee or Former Patentee Name, Address and Status

State the name and address of the reporting patentee or former patentee. Unless indicated otherwise, questions regarding completeness, accuracy, etc., will be directed to the individual signing the form at the address recorded here. If some other individual or address should receive such communications, complete the "Address for Correspondence" area at the bottom of Block-5.

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 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.

Status of Reporting Patentee or Former Patentee

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

The patent holder is the person ("person" is defined in the Interpretations section at page 2) that owns the patent.

A person holding a licence is a person ("person" is defined in the Interpretations section at page 2) who is licensed by the patent holder to exercise certain rights of the patent. This category excludes a person who has a compulsory licence, as previously defined under section 39(4) of the *Patent Act* amended in 1993.

If the status of the reporting patentee does not fit into either of the situations defined above, then the category "other" should be indicated and the specific status of the patentee should be described.

BLOCK-6 Certifying Signature

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

Signature

The individual signing should indicate if he/she is the patentee, former patentee, or its corporate officer. The individual signing should have the authority to represent the patentee, and be knowledgeable about information reported on the form. Type or print the name of the person signing below the signature.

Date Signed

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

Telephone and Facsimile Numbers

Provide telephone and facsimile numbers for the reporting patentee, former patentee or the corporate officer who signed above.

[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.

Patentees' Guide to Reporting
Form-2 - Identity and Prices of Medicines

General Information

Purpose

Form-2 is a multi-page reporting form on which the patentee provides information on the prices of patented drug products. Submit a separate Form-2 semi-annually for each patented drug product, according to the reporting periods and due dates described on page 12.

When returning sheets, fill in the page numbers in the blanks at the top of each page. It is especially important to do so when returning multiple sheets for any of the blocks (generally Block-4 and Block-5).

Definitions of key terms used in these forms are included in the Glossary.

Who should provide information?

(a) 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 licence 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 holder (other than by compulsory licence). 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.

(b) 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-2 be filed, for drug products not previously filed, and only for the periods under which the drug products were patented. The Board can request this information within three years of the patent's expiry, if it has reason to do so.

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

Which drug products should be reported?

Complete a Form-2 for each drug product 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.

Patented drug products considered by Health Canada to be "investigational drugs" (including drug products provided under the "Emergency Drug Release" program), that are being offered for sale commercially or otherwise, and for which no NOC has been issued, should also be reported on a Form-2.

Reporting Periods and Due Dates

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.

Reporting Periods and Due Dates - New Drug Products

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 should be filed with the PMPRB not later than sixty (60) days after the first sale date in Canada of the new drug product.

b) The information provided in the completed Form-2 should cover the thirty (30) day period following the first sale date in Canada of the new drug product.

EXAMPLE:

If a new drug product is first offered for sale on March 15, 1995, a completed Form-2 would be due on May 15, 1995. The Form-2 report would cover the period March 15, 1995 to April 14, 1995. 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).

Submission #	Reporting Period	Due Date
1	March 15 - April 14	May 15
2	March 15 - June 30	July 30

BLOCK-1 Reporting Period

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

From: 1995/01/01
(year/month/day)
To: 1995/06/30
(year/month/day)

BLOCK-2 Names of the Medicine

Brand Name and Generic Name of the Medicine

In this section enter the Brand Name and the Generic Name of the drug product identified on this form. For example:

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

BLOCK-3 Reporting Patentee or Former 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

This form should be signed by the patentee or former patentee or the corporate officer. Indicate in the blank the number of pages returned. This will ensure that PMPRB staff have received all the information.

Signature

The individual signing should indicate if he/she is the patentee, former patentee, or its corporate officer. The individual signing should have the authority to represent the patentee, and be knowledgeable of information reported on the form. Type or print the name of the person signing below the signature.

Date Signed

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

Telephone and Facsimile Numbers

Provide telephone and facsimile numbers for the reporting patentee, former patentee or the corporate officer who signed the above.

BLOCK-4 Sales of the Medicine by the Patentee or Former 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. Figures are required by province and class of customer for each format (strength, dosage form and package size) of the medicine. (Use the codes listed in the Appendix). Use a separate line to report each strength, dosage form and package size.

Drug Identification Number (DIN or GP Number)

Enter the DIN (or GP number) that apply to the drug product identified in Block-2. If no DIN has been issued, state instead when the drug product was first offered for sale in Canada.

Format (Strength/Dosage Form/Package Size)

(1) Strength/Unit

Indicate the strength of this 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, millilitres, vials, etc. Be sure to indicate the units being used. For example:

Dosage Form	Strength/Unit
Tablets	10mg / tablet
Oral Liquid	10mg / ml
Injectable	10mg / vial
Cream	10mg / gram
Inhaler	10µg / metered dose

Avoid using percentages; For example, instead of reporting an oral liquid with 1% of active ingredient, report 10 mg/ml.

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:

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

(2) Dosage Form

Using the codes that appear in the Appendix[4], enter in the appropriate column the dosage form that corresponds to the strength and DIN information entered in the first two columns. For example:

Dosage Form	Dosage Form Code
Tablet	S1
Oral Liquid Solution	L1

[4] For a complete list of dosage forms, please refer to the Appendix. The Appendix 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.

(3) Package Size
In the appropriate space, enter the number of "units" per package. The package size units must be the same as those indicated in the strength of the drug product. For example:

Dosage Form	Strength	Package Size
Tablets	10mg / tablet	200 (tablets)
Oral Liquid	10mg / ml	100 (millilitres)
Injectable	10mg / vial	12 (vials)
Cream	10mg / gram	100 (grams)
Inhaler	10 : g / metered dose	200 (metered doses)
Inhaler	2mg / inhaler	1 (inhaler)

Quantity Sold (Number of Packages Sold)

Indicate for each DIN the total number of packages sold (including quantities distributed for promotions, rebates, free goods, etc.) during the reporting period. On a separate line, identify, the quantity of products provided under a **compassionate program**. 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 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 Revenues or Average Price per Package

Record the **Net Revenues 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.

Net revenues consist of actual sales revenues (excluding federal sales tax) received for the drug product sold (i.e., shipped) during the reporting period less amounts disbursed for rebates, refunds, or other such discounts.

Average price per package is defined as net revenues (excluding federal sales tax) divided by the total number of packages sold (or distributed as part of a promotion, rebate, etc.), indicated in the "quantity sold" column.

BLOCK-5 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 *Regulations* (France, Federal Republic of Germany, Italy, Sweden, Switzerland, United Kingdom, United States), for all final dosage forms of the medicine named in Block-2. List figures by "country or province" and "class of customer" for each format (dosage form, strength and package size) of the medicine. Use the codes listed in the Appendix.

The Canadian patentee **must** supply foreign ex-factory price data for all patented drug products that the Canadian patentee sells or offers for sale in Canada. This is necessary even if the Canadian patentee does not sell the product in any of the seven foreign countries listed in the *Regulations*. If any dosage form of the medicine is being sold or offered for sale in Canada, the patentee must report the ex-factory prices of all dosage forms sold in each of the seven foreign countries. Patentees who are unsure of, or have difficulty acquiring, foreign ex-factory price data should contact PMPRB staff for advice.

Restrict reporting of foreign ex-factory prices to the seven countries listed in the *Regulations*. Use a separate line to report each combination of "strength/dosage form/package size," "country/province" and "class of customer" that applies to sales of this drug product. 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

Provide the generic name of the drug product named in Block-2.

Drug Identification Number

Enter DIN (or GP Number) that apply to the drug product identified in Block-2. If the drug product is not sold in Canada, provide the generic name of the drug product instead of the DIN. Ensure that you record the correct DIN numbers.

Format (Strength/Dosage Form/Package Size)

Report format in the same manner as in Block-4. There is detailed explanation of how to record strength, dosage form and package size in the instructions for Block-4 on pages 14 to 16 of this Guide.

Ex-factory Price per Package

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 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 reporting period, use the most recent ex-factory price for the reporting period.

The ex-factory price is the price at which a drug product is first offered for sale "at arm's length" to distributors, wholesalers, hospitals, pharmacies, etc. This price excludes sales taxes and wholesale mark-ups if the wholesale function is not carried out by the patentee. The ex-factory price is generally the "list price" for these drug products.

Patentees' Guide to Reporting
Form-3 - Licensees, Revenues and Expenditures

General Information

Purpose

Under section 88 of the *Patent Act*, a patentee of an invention pertaining to a medicine is required 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 a two-page reporting form designed to collect from the patentee information on the names and addresses of licensees; sales revenues; and expenditures for SR&ED pertaining to medicines.

Who must report

All patentees of medicines sold in Canada **must** report revenues and SR&ED expenditures on Form-3. If you are no longer a patentee but were during all or part of the year Form-3 covers, you are required to report. Under section 79(1) of the *Patent Act* 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 exercising the rights of the patent holder (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 manufacturer who sells the medicine into the distribution chain. The patentee completing this form is the "reporting patentee".

Foreign persons holding Canadian patents

Foreign residency does not remove the responsibility to report on Form-3. Foreign persons should report their revenues from sales in Canada and expenditures on SR&ED in Canada. These foreign persons should report their SR&ED expenditures as if they were Canadian taxpayers. Foreign persons who hold a Canadian patent for a medicine but who had no Canadian revenues or SR&ED expenditures should still report.

Can non-patentees report?

Yes. The Board has a mandate to report on market trends and research and development activities for the pharmaceutical industry as a whole. Canadian individuals or corporations who manufacture, distribute or sell medicines in Canada are encouraged to report. Of particular interest are compulsory licensees and other pharmaceutical companies who are active in the Canadian marketplace.

Non-patentees should follow the same guidelines as patentees when reporting. The term "patentee" refers to the reporting party (i.e., the company or individual completing the form).

Subsidiaries vs Head Office

Where a foreign parent company carries on SR&ED in Canada but a subsidiary resident in Canada is the seller and distributor, the subsidiary should report the SR&ED on its Form-3, attaching a note with details of its particular situation. The parent should send a letter to the Board, stating that the subsidiary has claimed the SR&ED expenditures. This situation can become more complex when a number of subsidiaries sell and distribute the product in Canada and one parent carries on the SR&ED. Board staff will review each situation to determine the most appropriate reporting method.

Reporting Periods and Due Dates

Reporting periods: The information on Form-3 should be reported by calendar year.

Due dates: All patentees must submit, to the offices of the Board, a completed Form-3 no more than sixty days after the calendar year ends. Generally, this due date will be
March 1.

BLOCK-1 Year to which Information Applies

Information for Form-3 should be reported for the calendar year. Only a calendar year should be indicated in the "reporting period" block on Form-3.

BLOCK-2 Identification of Patentee

Name and Address of Patentee

This should be the name and address of the reporting patentee for correspondence in Canada.

BLOCK-3 Licensees

Patentees should provide names and addresses of all licensees who, by means of a license or other formal arrangement, sell or distribute medicines for which the patentee holds a patent. The names and addresses of voluntary and compulsory licensees should be reported. If necessary, place this list on a separate sheet and attach it to the completed Form-3.

BLOCK-4 Revenues

Total Revenues from all Sales of Medicines in Canada by Patentee

Which revenues should be included? In general, report revenues from sales of medicines[5] that have a Drug Identification Number (DIN) or General Product (GP) number. This includes medicines not under patent and "over the counter" products. There may be some uncertainty as to whether revenues from certain proprietary products should be included. If uncertain, patentees should contact *Board* staff for advice. Other revenues, such as those from investment or real estate, **should not** be included on Form-3.

5 Consult Glossary for definition of 'medicine' as it applies to Form-3.

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 Revenues from Licensees from Sales of Medicines in Canada

On a separate sheet, list total revenues (including royalties and license fees) from sales of medicines in Canada for each licensee (including compulsory licensees) you have listed in Block-3. Revenues from licensees may be reported on an accrual or cash basis (i.e., in the year the royalties were actually paid) but reporting should be consistent. Note that you must report "revenues from all sales of medicines" using the "accrual" method only.

EXAMPLE:

During 1988, Company-X sold Medicine-A under license from Company-Z. For 1988, Company-X had revenues of $100,000 from sales of Medicine-A. Company-X paid Company Z $25,000 as a royalty for the 1988 sales of Medicine-A, of which $7,000 was actually paid in 1989. Company-X should include sales revenues of $100,000 in its report for 1988. Company-Z should include $25,000 under revenues from licensees in the 1988 report if using the "accrual" method. Under the "cash" method Company-Z should include $18,000 under revenues from licensees in its 1988 report and $7,000 for its 1989 report. The following table illustrates this:

	Company-X		Company-Z	
Revenues from:	**1988**	**1989**	**1988**	**1989**
Sales of medicines	100,000	0	0	0
Licensees "accrual"	0	0	25,000	0
or				
Licensees "cash"	0	0	18,000	7,000

Research and Development Pertaining to Medicines

General Note on Research and Development - (Blocks 5-10)

Criteria of Eligibility

R&D expenditures reported on Form-3 must meet the criteria for claiming an **investment tax credit** with respect to Scientific Research and Experimental Development as set out in sections 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" (R&D) 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[6]:

*Sections 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**.

* As they read on December 1, 1987.

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". There are three main categories:

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

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

Development
Use of results of basic or applied research to create new materials, devices, products or processes, or 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
- commercial production of a new or improved material, device or product, or the commercial use of a new or improved process
- style changes
- routine data collection

Expenditures - Scientific Research and Experimental Development

Note that only expenditures relating to SR&ED **in Canada** are allowed; to qualify as SR&ED expenditures on Form-3, the expenditures should conform to criteria for claiming the

[6] These documents are available by contacting the Secretary to the Board or the Compliance Officers.

investment tax credit for scientific research and experimental development as set out in sections 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 section 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 expenditures that relate to SR&ED carried on outside Canada are all deemed to be "Research outside Canada". Therefore these should not 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-5 Non-Capital Expenditures of 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 party 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. Certain other types of expenditures **cannot** be included as non-capital expenditures in Block-5 under any circumstances, even if they are in support of a qualified SR&ED activity. **The following cannot be included as non-capital expenditures:**

- 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)

Break out allowable non-capital expenditures into the following categories:

A. **Wages and salaries**

Only 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
- exclude bonuses or other remuneration based on the profits of the company.

B. **Direct material**

All costs should 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 party's behalf. The expression "on the reporting party's behalf" distinguishes contractors from other expenditure categories such as payments to universities and granting councils.

D. Other direct costs

Includes only the **incremental** general administrative and/or factory overhead costs incurred solely as a result of carrying on SR&ED activities. Provide a breakdown of these costs on a separate sheet.

E. Payments to designated institutions

Under this category, report payment to an approved university or other similar institution, to be used by that institution for SR&ED related to the reporting party's class of business. Amounts paid to carry out SR&ED on the reporting party's behalf should not be included here, but under "C" (Contractors…) above.

Approved institutions include:

- universities
- colleges
- research institutes
- other similar institutions

F. Payments to granting councils

A granting council is an approved organization that pays an association, institution or corporation to do SR&ED related to the reporting party's class of business. Approved granting councils include:

- *Natural Sciences and Engineering Research Council*
- *Medical Research Council*
- *Social Sciences and Humanities Research Council*

G. Payments to other organizations

Payments to other organizations for SR&ED related to the reporting party's class of business and not included under "E" (designated institutions) or "F" (granting councils) above. Provide a list of the organizations to which payments were made.

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. Patentees should attach details of the calculation of annual depreciation.

If a building was built or purchased 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 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 floor-space to the total original cost of the building.

For example, a 1000 square metre building originally costing $400,000 has a 250 square metre wing allocated entirely for SR&ED activities. As 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 should 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 not be included unless it can be demonstrated that **all, or substantially all** of the equipment's use is for SR&ED, where "all, or substantially all" means at least 90% of the time during the useful life of the equipment.

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 of "type of research" and "who carried out the research". These definitions also apply to Block-8.

Type of R&D

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.

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, clinical and preclinical trials often overlap. Some drug evaluations may not follow the phases of evaluation described here. Reporting parties 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." Provide details of all expenditures included in this category.

Categories Describing Who Carried Out Research

Patentee
For Form-3, patentee refers to the reporting party completing this form. If you are no longer a patentee but were during part or all of the year Form-3 covers, you are required to report. Because all pharmaceutical companies and drug manufacturers are encouraged to complete Form-3, some reporting parties will not hold a patent on a medicine. Therefore, the reporting party is not necessarily a true patentee as defined for Form-1 and Form-2.

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

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

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 by hospital or university for research carried out in a teaching hospital or when scientists doing the work are affiliated with both a hospital and a university. These considerations may be useful: 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. Patentees should attach details on expenditures.

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, should 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 source of funds total reported in this block should 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 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 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 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. 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 patentee. The amount reported should be the 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. Attach a list detailing these "other" sources and amounts to the completed Form-3.

BLOCK-10 Information for R&D in Each Province

Provide a provincial 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 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 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).

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]

Glossary
(Patentees' Guide to Reporting)

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 28.

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.

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 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)

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 Health Protection 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.

Emergency Drug Release (EDR) Program: A program operated by Health Canada to provide access to practitioners to drugs that are not approved or otherwise available for sale in Canada for the treatment of patients. Health Canada may authorize the sale of a quantity of drug for human or veterinary use in the treatment of a patient under the care of that practitioner.

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.

General Public (GP) number: A number that Health Protection Branch of Health Canada assigns to proprietary medicines which are registered according to the requirements of Division 10 of the Food and Drug Regulations. These products may be sold in non-pharmacy outlets in certain provinces.

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 Drugs (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 licence 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 licence fees or royalties to the patent holder for use of the patented invention.

With the exception of those compulsory licences 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 licences 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

labelling.

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 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 Protection 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* on September 15, 1988, and amended effective November 7, 1994 and published in Part II of the Canada Gazette on November 30, 1994. 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 licence 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 1994*, 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.