

# Appendix 2

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## Form-3 – Licensees, Revenues and Expenditures

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### 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](mailto: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:<sup>5</sup>

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.*

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

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## 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.<sup>6</sup>

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.<sup>7</sup>

## 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).

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

<sup>7</sup> Ibid., para 2.5.

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## 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<sup>8</sup> 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.

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

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## 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.

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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.

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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.

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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

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## **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)).

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**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:**

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**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		\$
	<b>TOTAL</b>	<b>0.00</b>

**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	\$

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## 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	\$	\$	\$	\$	\$
<b>Total</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>

## 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	\$	\$	\$	\$	\$
<b>Total</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>

## 9 Source of Funds for R&D

Internal funds	\$
Arm's length person	\$
Not arm's length person	\$
Federal government	\$
Provincial government	\$
Other (specify)	\$
<b>Total</b>	<b>0.00</b>

## 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.	\$	\$	\$	\$	\$
<b>Total</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>

## 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)