Patented Medicine Prices Review Board

Canada

This document contains screenshots of the online filing tool for reference, and includes forms 1, 2, 3, 4, Notification of Intent to Sell, and HTA/Scientific Submission Portal. Glossaries, when applicable, are included.

Patented Medicine Price Review Board

Form 1

IDENTIFICATION OF MEDICINE

Privileged s.87
Patent Act

Form 1 Help Glossary

* **Mandatory field**

* Please Specify ○ Original Filing or ○ Amendment to Original Filing

BLOCK 1: INFORMATION WITH RESPECT TO MEDICINE (Patented Medicines Regulations, s. 3(1))

* Medicinal Name(s)

* Type of Medicine Select

* Rights Holder Name

* Rights Holder Address

* Identify if the Rights Holder is Select

FIRST NOTICE OF COMPLIANCE ("NOC") ISSUED TO MEDICINE

NOC Date yyyy-mm-dd

If no NOC, please choose one of the following

Select

Product Monograph

Note: The Rights Holder is required to file an amended version of the attached document if any changes are made to that document.
Attach Product Monograph or Information similar to that contained in a Product Monograph (PDF document only)

Document Type Select Attach file to form

BLOCK 2: IDENTIFICATION OF MEDICINE BY DRUG IDENTIFICATION NUMBER ("DIN") (Patented Medicines Regulations, s. 3(1),4(1))

* Brand Name * DIN

* Dosage Form * Strength * Unit * Package Unit

Date of First Sale yyyy-mm-dd * Therapeutic use(s) of the medicine approved by Health Canada

Add DIN

BLOCK 3: PATENT NUMBER OF RIGHTS HOLDER'S INVENTIONS PERTAINING TO THE MEDICINE (Patented Medicines Regulations, s. 3(1))

Patent Number	Date Granted	Expiration Date	Certificate of Supplementary Protection (CSP)	CSP Expiration Date
	yyyy-mm-dd	yyyy-mm-dd	○ Yes ◉ No	yyyy-mm-dd

Add Patent

BLOCK 4: CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

* Name

* Title

* Organization

* Date yyyy-mm-dd

* Tel. Number

* E-mail

☐ The e-signature of a duly authorized person for the reporting Rights Holder certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter (PDF Only)

Attach file to form

Pressing "Submit Form" causes an email to be sent with the above-entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Submit Form

Form 1 Online Filing Help

BLOCK 1: INFORMATION WITH RESPECT TO MEDICINE (Patented Medicines Regulations, s. 3(1))

Medicinal Name(s)

State the medicinal name(s) of the drug product to be identified in this form. For medicines that contain 2 or more chemical names, separate them by using a forward slash (/).

Type of Medicine

Indicate in the boxes provided whether the drug product is

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

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

Rights holder Name/Address

State the name and address of the Rights Holder or former Rights Holder.

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

Identity of the Rights Holder

In the boxes provided, check off the description that best describes the status of the Rights Holder or former Rights Holder completing this form.

- Patent holder:
    - is the person ("person" is defined in the Interpretation section) that owns the patent.
- Licensee:
    - A person entitled to the benefits of a patent or to exercise any rights in relation to a patent is a person who has a license or other agreement, whether express or implied, with the patent holder/owner to exercise one or more rights under the patent. This category excludes a person who has a compulsory license, as previously defined under section 39(4) of the Act amended in 1993.

Please note that a patentee may be the patent holder of one patent and the person entitled to the benefits of a second patent on the same DIN. In this case, the combination of Patentee/Licensee should be selected in the dropdown from Block 1.

NOC date

Enter the date on which the first NOC was issued by Health Canada to the Rights Holder or former Rights Holder for the medicine.

If NOC

If no NOC has been issued, use the drop down menu to indicate whether the medicine is being sold under the SAP, a Clinical Trial Application, as an Investigational New Drug, Urgent Public Health Need or Other.

Document Type

Use the drop down menu to indicate whether the document type is either a Product Monograph or information similar to that contained in a product monograph.

An electronic copy of the corresponding document type must be provided in PDF form only.

BLOCK 2: IDENTIFICATION OF MEDICINE BY DRUG IDENTIFICATION NUMBER ("DIN") (Patented Medicines Regulations, s. 3(1),4(1))

Brand Name

State the Brand Name as approved by Health Canada, excluding Trademark (™), Registered (®),Copyright (©), or any other symbols, of the medicine identified in this form.

Drug Identification Number (DIN)

Enter the DIN that applies to the medicine identified in Block 1. Enter only the DIN(s) that identifies a form of the drug product which the Rights Holder or former Rights Holder is selling, has sold or intends to sell in Canada.

If there is no corresponding DIN, leave this space blank. Following receipt of Form 1, the PMPRB may provide an assigned number to any patented drug product that does not have a DIN. The Rights Holder will be asked to use this Assigned Number when completing Form 2 during the subsequent reporting periods until an NOC is issued.

Date of First Sale

Enter the date at which the drug product, identified in the DIN field, is first sold in Canada, whether it is following issuance of an NOC, under the SAP, a Clinical Trial Application, as an Investigational New Drug, Urgent Public Health Need or Other.

Dosage Form

For each DIN(s), indicate the correct dosage form from the dropdown list that best suits the drug product.

Strength

For each DIN(s), indicate the corresponding strength of the drug product. The strength reported by the Rights Holder in the Form 1 should correspond with the strength registered in the NOC.

In the case of percentages, for example, instead of reporting an oral liquid with 1% of active ingredient, report as 0.01 mg/mL, where the mg is the “unit” and mL is the “Package Unit”.

For drug products with more than one active ingredient add the amounts of active ingredients together. For example, 10 mg of active ingredient A + 20 mg of active ingredient B would be reported as 30 mg.

Unit

For each DIN(s), indicate the unit that corresponds to the strength of the DIN from the dropdown list as reported in the NOC, where applicable. The unit is expressed in milligrams (mg), micrograms (mcg) or as appropriate per unit of medicine.

Package Unit

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

Dosage Form	Strength/Unit	Package Unit
J1 Parenteral (J) - Solution	10mg/mL 10mg/vial	Milliliter Vial
S1 Oral Solid (S) – Tablet	10mg/tab	Tablet
T2 Topical (T) – Cream	10mg/gm	Gram
P12 Pulmonary (P) – Aerosol – metered dose	10mcg/dose	Dose

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

State the therapeutic class as provided by Health Canada in the NOC or if an NOC has not been issued, the anticipated therapeutic use(s) of the drug product.

BLOCK 3: PATENT NUMBER OF RIGHTS HOLDER'S INVENTIONS PERTAINING TO THE MEDICINE (Patented Medicines Regulations, s. 3(1))

Patent Number

List the patent numbers for all the Canadian patents that pertain to the medicine identified in Block 1. To add multiple Patent Numbers to the Form 1, click on the ‘Add Patent’ button. List those patents owned by the Rights Holder or former Rights Holder, assigned to the Rights Holder or former Rights Holder, or in respect of which the Rights Holder or former Rights

Holder is or was entitled to the benefit or to exercise any rights (other than through a compulsory license).

Date Granted

For each patent listed, enter the date the patent was granted on the corresponding line.

Expiration Date

For each patent number listed in the first column, enter the corresponding expiry date on the corresponding line.

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

Certificate of Supplementary Protection (CSP) and CSP Expiration Date

For each patent listed in the first column, indicate whether or not a Certificate of Supplementary Protection (CSP) has been granted. If yes, please specify the CSP expiration date.

BLOCK 4: CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

E-Signature

This form must be signed by an authorized individual for the Rights Holder or former Rights Holder. Please provide the name, title, organization, telephone number and email of the duly authorized person who certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter

An optional letter from the Rights Holder can be attached to the Form 1 in PDF format. The letter may include, but not limited to, additional information relating to the medicine, the rational for an amended submission, or any additional information the Rights Holder may find relevant.

Patented Medicine Price Review Board

Form 2

INFORMATION ON THE IDENTITY AND PRICES OF THE MEDICINE

Privileged s.87
Patent Act
Form 2 Help Glossary

* **Mandatory field**

Please Specify ○ Original Filing ○ Amendment to Original Filing ○ First Day of Sale

BLOCK(s) and DIN(s) or ASSIGNED NUMBER(s) WHICH ARE BEING SUBMITTED

Block 4

Attach file to form

Block 5

Attach file to form

Block 3: RIGHTS HOLDER AND CERTIFYING SIGNATURE (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

* Rights Holder Name

* Rights Holder Address

* Name

* Title

* Organization

* Date yyyy-mm-dd

* Tel. Number

* E-mail

☐ The e-signature of a duly authorized person for the reporting Rights Holder certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter (PDF Only) Attach file to form

Pressing “Submit Form” causes an email to be sent with the above-entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Submit Form

Form 2 Online Filing Help

BLOCK 1: ORIGINAL FILING

Reporting Period

Enter the beginning and ending dates of the period to which the information applies. A Form 2 is to be submitted for each semi-annual reporting period – January to June and July to December – as well as the sales data for the first day of sales. Note, there should be only one semi-annual reporting period per Form 2. If you wish to submit for more than one reporting period, please complete one Form 2 per semi-annual reporting period.

Use the dropdown menu to select the year, month and day. For example:

Period	To	From
First day of sales	2020-05-22	2020-05-22
January to June	2020-01-01	2020-06-30
July to December	2020-07-01	2020-12-31

BLOCK 2: AMENDMENT TO AN ORIGINAL FILING

Reporting Period

Enter the beginning and ending dates of the period to which the amended information applies. There should be only one semi-annual reporting period per Form 2. Use the dropdown menu to select the year, month and day.

Rights Holders submitting data corrections to Block 4 and/or Block 5 of the Form 2 may be asked to provide a written explanation to support any revisions made when filing one or more amendments to Block 4 or Block 5 data. The explanation may be submitted to the PMPRB in a PDF covering letter which can be uploaded at the end of this Form.

BLOCK(s) and DIN(s) or ASSIGNED NUMBER(s) WHICH ARE BEING SUBMITTED

Block 4:

Please upload your completed Form 2, Block 4 Excel file. If you require a blank Form 2, Block 4 template, they can be found here: Template Block 4 (XLS 146 KB)

Block 5:

Please upload your completed Form 2, Block 5 Excel file. If you require a blank Form 2, Block 5 template, they can be found here: Template Block 5 (XLS 121 KB)

BLOCK 3: RIGHTS HOLDER AND CERTIFYING SIGNATURE (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

Rights Holder's name and address

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

E-Signature

This form must be signed by an authorized individual for the Rights Holder or former Rights Holder. Please provide the name, title, organization, telephone number and email of the duly authorized person who certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter

An optional letter from the Rights Holder can be attached to the Form 2 in PDF format. The letter may include, but not limited to, additional information relating to the medicine, the rational for an amended submission, or any additional information the Rights Holder may find relevant.

Patented Medicine Price Review Board

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

Privileged s.87
Patent Act

Form 3 Help Glossary

* **Mandatory field**

BLOCK 1: YEAR TO WHICH INFORMATION APPLIES

* Year: Select Year...

BLOCK 2: IDENTIFICATION OF THE RIGHTS HOLDER

* Rights Holder Name

* Rights Holder Address

BLOCK 3: LICENSEE(S)/OTHER(S)

Name	Address	Revenue
		$ 0.00

Add Licensee/Other

BLOCK 4: REVENUES

	For human use	For veterinary use
Total gross revenues of the reporting Rights Holder from all sales of medicines in Canada	$ 0.00	$ 0.00
Total gross revenues received from all licensees/others in Canada (eg: royalties and/or other fees)	$ 0.00	$ 0.00

BLOCK 5: RESEARCH AND DEVELOPMENT PERTAINING TO MEDICINE

Non-Capital Expenditures Incurred by the Rights Holder

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

TOTAL	$ 0.00

BLOCK 6: TOTAL CAPITAL EXPENDITURES

Building		Equipment	
Annual depreciation (in accordance with section 5 of the Patented Medicine Regulations)	$ 0.00		
Total capital expenditures in the year	$ 0.00	Total capital expenditures in the year	$ 0.00

BLOCK 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	Rights Holder	Other Companies	Universities	Hospitals	Others
Basic-chemical	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Basic-biological	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Manufacturing process	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Preclinical trails I	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Preclinical trails II	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Clinical trials - Phase I	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Clinical trials - Phase II	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Clinical trials - Phase III	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Other qualifying R & D	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

BLOCK 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	Rights Holder	Other Companies	Universities	Hospitals	Others
Basic-chemical	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Basic-biological	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Manufacturing process	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Preclinical trails I	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Preclinical trails II	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Clinical trials - Phase I	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Clinical trials - Phase II	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Clinical trials - Phase III	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Other qualifying R & D	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

BLOCK 9: SOURCE OF FUNDS FOR R&D

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

BLOCK 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	Rights Holder	Other Companies	Universities	Hospitals	Others
Newfoundland	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Prince Edward Island	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Nova Scotia	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
New Brunswick	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Quebec	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Ontario	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Manitoba	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Saskatchewan	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

Alberta	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
British Colombia	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
N.W.T,Yukon,Nunavut	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

BLOCK 11: CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

* Name

* Title

* Organization

* Date yyyy-mm-dd

* Tel. Number

* E-mail

The e-signature of a duly authorized person for the reporting Rights Holder certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter (PDF Only)

Attach file to form

Pressing “Submit Form” causes an email to be sent with the above-entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Submit Form

Form 3 Online Filing Help

BLOCK 1: YEAR TO WHICH INFORMATION APPLIES

Indicate the calendar year to which the information applies from the dropdown menu.

BLOCK 2: IDENTIFICATION OF THE RIGHTS HOLDER

State the name and address of the Rights Holder.

BLOCK 3: LICENSEE(S)/OTHER(S)

Provide the names and addresses of all licensees with whom the Rights Holder has a license (including compulsory license) or other agreement that entitles that person to exercise any rights in relation to a patent.

BLOCK 4: REVENUES

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

Report the total gross revenues (net of taxes) from all sales of medicines that have been assigned 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 Programme in accordance with 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. This includes both patented and non-patented medicines, whether sold by prescription or "over the counter".

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

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

Non-Capital Expenditures Incurred by the Rights Holder

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 Rights Holder 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.

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 Rights Holder's behalf. The expression "on the Rights Holder'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 Rights Holder's class of business. Amounts paid to carry out SR&ED on

the Rights Holder'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 Rights Holder'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 Rights Holder's class of business and not included under "E" (designated institutions) or "F" (granting councils) above.

BLOCK 6: TOTAL CAPITAL EXPENDITURES

Buildings – Annual Depreciation

Rights Holders 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 floorspace 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. Since 25% (250 of 1000) of the total floor-space is devoted to SR&ED, calculate annual depreciation based on $100,000 (25% of $400,000). Annual depreciation would be 4% of $100,000 = $4,000.

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

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

Total Capital Expenditures in the Year (buildings)

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

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

Equipment (capital expenditures

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

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

BLOCK 7: 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

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.

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. Rights Holders 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

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

Rights Holder

If you are no longer a Rights Holder but were a Rights Holder during part or all of the year Form 3 covers, you are still required to submit Form 3 information in respect of that calendar year.

Other companies

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

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: EXPENDITURES IN CANADA FOR R&D PERTAINING TO MEDICINES FOR VETERINARY USE, BROKEN DOWN BY TYPE AND WHO CARRIED OUT THE R&D

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

BLOCK 9: SOURCE OF FUNDS FOR R&D

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

Internal Funds

Refers to the internal corporate funds of the reporting Rights Holder. It does not include monies from parent or subsidiary companies if these companies are distinct corporate entities in their own right. Monies from parent or subsidiary companies should be included under “not arm’s-length”.

Arm's-Length Person

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

Not Arm's-Length Person

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

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

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

The above list is a small sample only. Reporting Rights Holders 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 Rights Holder 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 Rights Holder. The amount reported is to be net of amounts repaid to the federal government during the year.

Provincial Government

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

Other

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

BLOCK 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

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

BLOCK 11: CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

E-Signature

This form must be signed by an authorized individual for the Rights Holder or former Rights Holder. Please provide the name, title, organization, telephone number and email of the duly authorized person who certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter

An optional letter from the Rights Holder can be attached to the Form 1 in PDF format. The letter may include, but not limited to, additional information relating to the medicine, the rational for an amended submission, or any additional information the Rights Holder may find relevant.

APPENDIX

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]

Patented Medicine Price Review Board

Form 4
NATIONAL MARKET SIZE ESTIMATION OF MEDICINE

Privileged s.87
Patent Act
Form 4 Help Glossary

* **Mandatory field**

BLOCK 1: ESTIMATED MAXIMUM SALES

Medicinal Name(s) Select

Estimated maximum use of the medicine (Patented Medicines Regulations, s. 4.2)

Final Dosage Form / Strength / Package Unit	Drug Identification Numbers	* Total quantity of the medicine (package units)	* Period of time used for the estimate

BLOCK 2: RIGHTS HOLDER AND CERTIFYING SIGNATURE

* Rights Holder Name

* Rights Holder Address

BLOCK 3: CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

* Name

* Title

* Organization

* Date yyyy-mm-dd

* Tel. Number

* E-mail

☐ The e-signature of a duly authorized person for the reporting Rights Holder certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter (PDF Only)

Attach file to form

Pressing "Submit Form" causes an email to be sent with the above-entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Submit Form

Form 4 Online Filing Tool Help

BLOCK 1: ESTIMATED MAXIMUM SALES

Medicinal Name(s)

Select the medicinal name(s) of the medicine being filed. The medicinal names that appear in the dropdown menu are pre-populated to reflect those previously filed in a successfully submitted Form 1.

If the medicinal name(s) does not appear in the Form 4 dropdown list, a Form 1 medicine in question may have not previously been submitted by the Rights Holder.

Total Quantity of the Medicine (Package Units)

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

Period of time used for the estimate

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

BLOCK 2: RIGHTS HOLDER AND CERTIFYING SIGNATURE

Rights Holder Name/Address

State the name and address of the Rights Holder or former Rights Holder.

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

BLOCK 3: CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

E-Signature

This form must be signed by an authorized individual for the Rights Holder or former Rights Holder. Please provide the name, title, organization, telephone number and email of the duly authorized person who certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter

An optional letter from the Rights Holder can be attached to the Form 1 in PDF format. The letter may include, but not limited to, additional information relating to the medicine, the rational for an amended submission, or any additional information the Rights Holder may find relevant.

Patented Medicine Prices Review Board

Canada

Patented Medicine Price Review Board

Notification of Intention to Sell a Patented Medicine
(In accordance with subsection 82(1) of the Patent Act)

* Brand Name

* Type of Medicine

* Dosage Form

* Strength

DIN (if available)

* Date of NOC (anticipated)

* Expected Date of First Sale

* Canadian Patent Number(s)

* Name and Address of Canadian Rights Holder

☐ The e-signature of a duly authorized person for the reporting Rights Holder certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Pressing "Submit Form" causes an email to be sent with the above-entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Submit Form

Patented Medicine Prices Review Board

Canada

Patented Medicine Price Review Board

HTA/SCIENTIFIC SUBMISSIONS

Provided Pursuant to Subsection 88(1) of the Patent Act and Sections 5 and 6 of the Patented Medicines Regulations

Privileged s.87
Patent Act

* Medicinal Name(s)

* Document Type — Select — Attach file to form

CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

* Name

* Title

* Organization

* Date

* Tel. Number

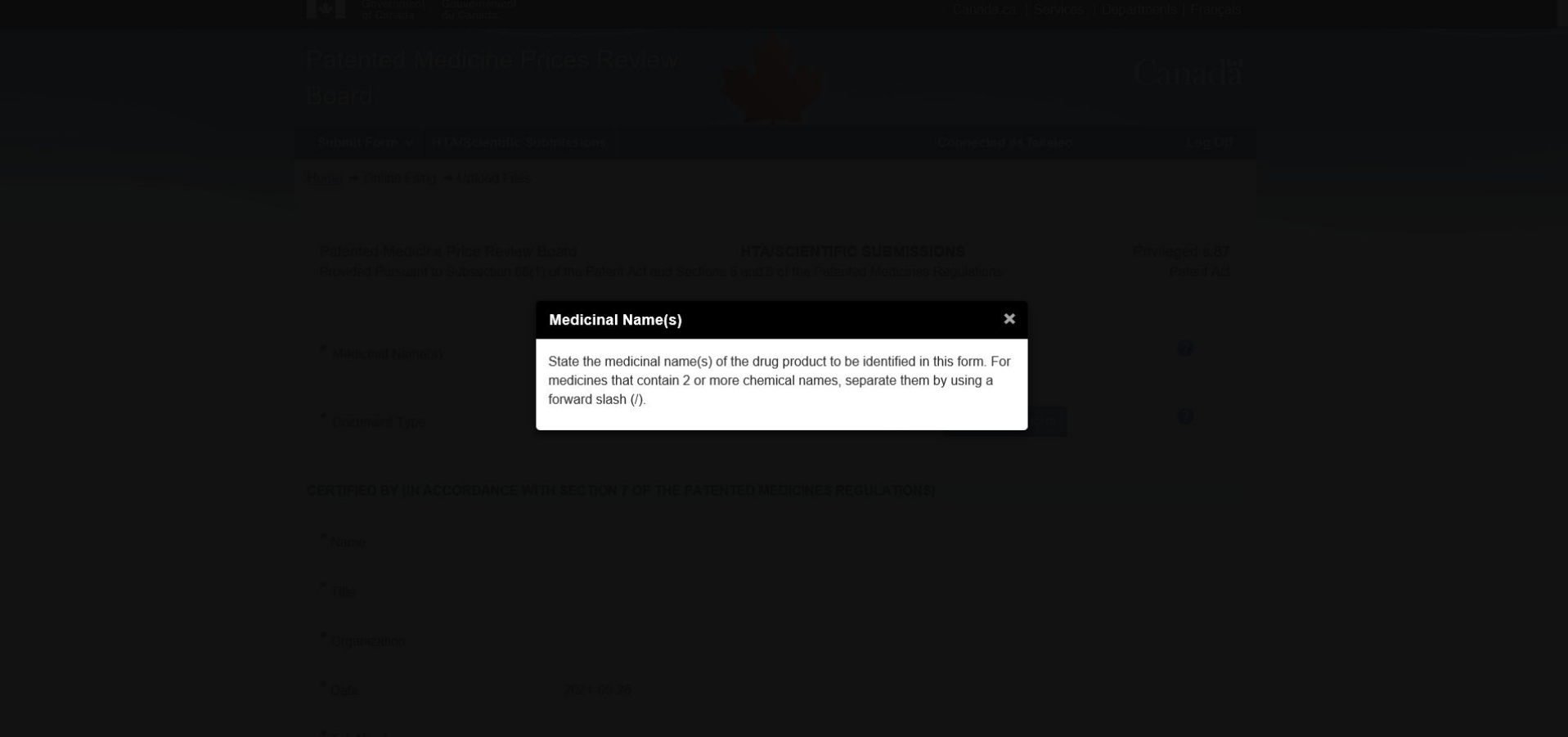
* E-mail

☐ The e-signature of a duly authorized person for the reporting Rights Holder certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

Optional: Rights Holder letter (PDF Only) Attach file to form

Pressing “Submit Form” causes an email to be sent with the above-entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Submit Form


Medicinal Name(s)
State the medicinal name(s) of the drug product to be identified in this form. For medicines that contain 2 or more chemical names, separate them by using a forward slash (/).

Patented Medicine Prices Review Board

Canada

Patented Medicine Prices Review Board
Provided Pursuant to Subsection 65.1(1) of the Patent Act and Sections 4 and 5 of the Patented Medicines Regulations

HTA/SCIENTIFIC SUBMISSIONS

Privileged s.87 Patent Act

* Medicinal Name(s)

* Document Type

CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

* Name

* Title

* Organization

* Date 2021-05-26

Document Type ×

Use the drop down menu to indicate whether the document type is either a Product Monograph or information similar to that contained in a product monograph.

An electronic copy of the corresponding document type must be provided in PDF form only.

* Title

* Organization

* Date 2021-05-25

* Tel. Number

* E-mail

The a signature of a duly authorized person for the complete Rights Holder confirms that the information provided is true and correct in accordance

Optional: Rights Holder letter (PDF

Pressing "Submit Form" causes an email to be sent with the above entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Terms and conditions | Transparency

This form must be signed by an authorized individual for the Rights Holder or former Rights Holder. Please provide the name, title, organization, telephone number and email of the duly authorized person who certifies that the information presented is true and correct in accordance with Section 7 of the Patented Medicines Regulations.

CERTIFIED BY (IN ACCORDANCE WITH SECTION 7 OF THE PATENTED MEDICINES REGULATIONS)

* Name

* Title

* Organization

* Date 2021-05-28

* Tel. Number

* E-mail

The e-signature of a [illegible] entered is true and correct in accordance

Optional: Rights Holder letter (PDF Only)

Pressing "Submit Form" causes an email to be sent with the above entered information to the PMPRB at compliance@pmprb-cepmb.gc.ca, as required by section 7(1) of the Patented Medicines Regulations.

Optional: Rights Holder letter (PDF Only) ×

An optional letter from the Rights Holder can be attached to the Form in PDF format. The letter may include, but not limited to, additional information relating to the medicine, the rational for an amended submission, or any additional information the Rights Holder may find relevant.