Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

Online Filing Tool: Outreach Webinar

June 15, 2021

Agenda

- Online Filing Tool – Log in
- Form 1 – Medicine Identification Sheet
- Form 2 – Information on the Identity of Prices of the Medicine
- Form 3 – Revenues and Research & Development Expenditures
- Form 4 – National Market Size Estimation of Medicine
- Notification of Intent to Sell
- Health Technology Assessment/Scientific Submissions

Online Filing Tool – Log in

- Username and password will remain the same as those currently used
- Forms must be submitted in a single session
- The session will time out after 60 minutes of inactivity
- Issues/concerns? compliance@pmprb-cepmb.gc.ca

Online Filing Tool – Log in Home Screen

- Forms 1 through 4 and Notification of Intent to Sell can be found under the ‘Submit Form’ section
- HTA and Scientific PDF documents can be submitted though the portal beside ‘Submit Form’
- Once submitted, confirmation emails will be sent to the Patentee and to the Compliance Inbox

Form 1 – Medicine Identification Sheet

- Forms 1 are submitted at the medicinal level
- All DINs sold by a Rights Holder will be submitted in a single form
- A help tool is available to provide guidance on how to fill out the form by either using the blue question marks or glossary link at the top of the form

Help Glossary Sample

- The Help Glossary will open in a new tab
- Each Form will have a its own unique Help Glossary
- Provide guidance on how to complete each section along with other pertinent information

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:

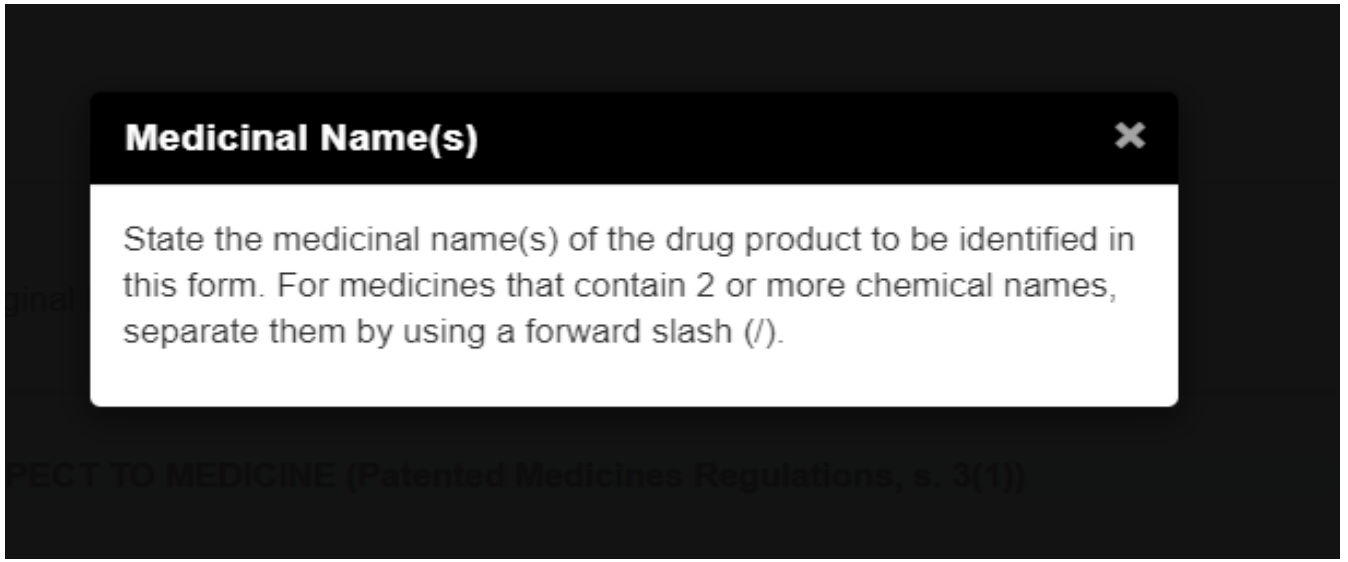
- Human Prescription:
  - i.e. prescribed for human use and is a controlled substance as defined in the *Controlled Drugs and Substances Act* or contains a substance listed or described in Schedules C or D to the *Food and Drugs Act* or Schedule F to the *Food and Drug Regulations*;
- Human Over-the-Counter: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

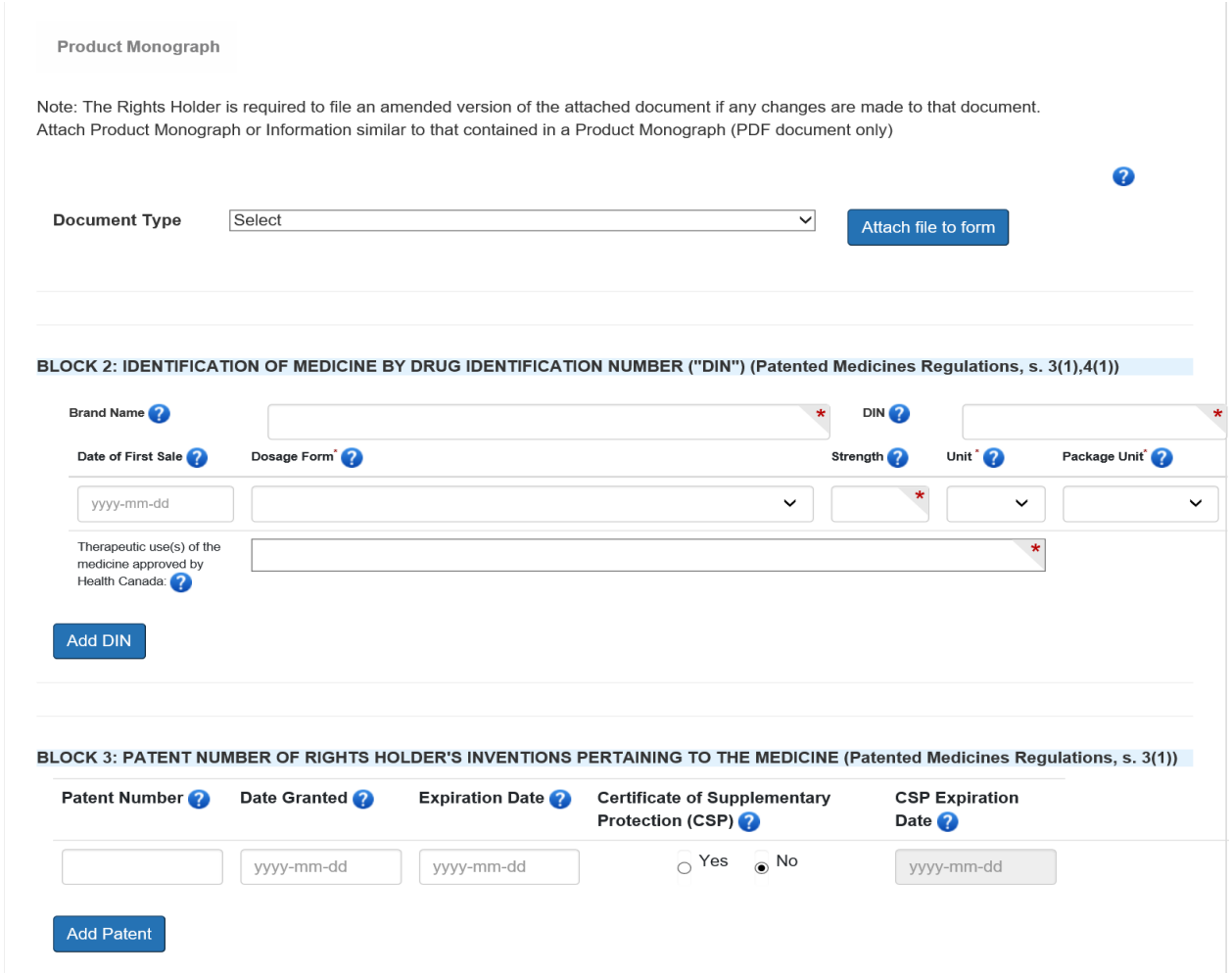
Question mark Sample

- When a ‘question mark’ is clicked, a Help pop-up screen will appear with information pertaining to the particular cell
- The information displayed matches that found in the Help Glossary
- This can be used as a quick reference



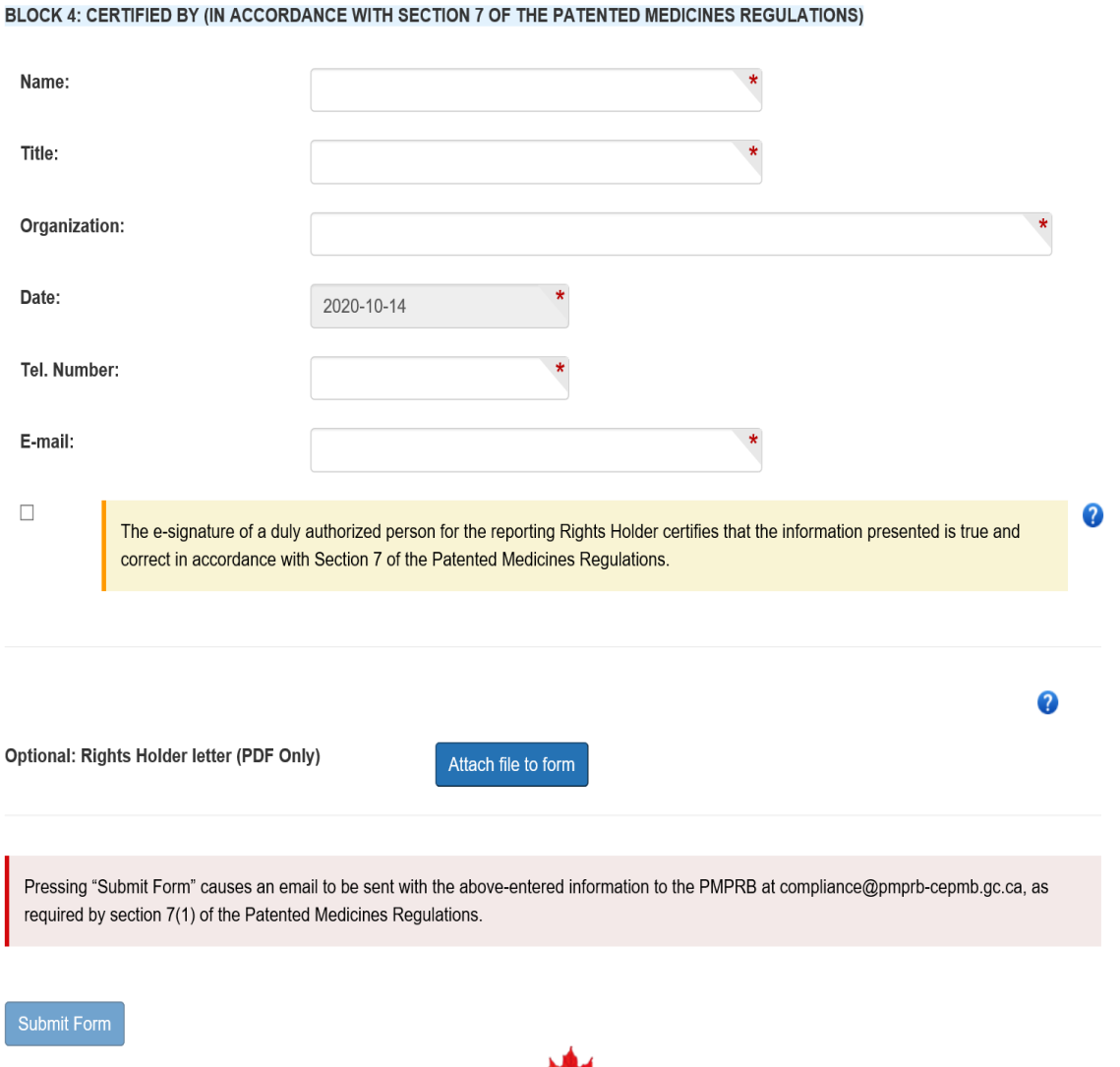
Form 1 - cont'd

- Attached documents are to be PDF only
- Multiple DINs can be added using the 'Add DIN' button
- Likewise for adding additional patents
- Certificate of Supplementary Protection (CSP)



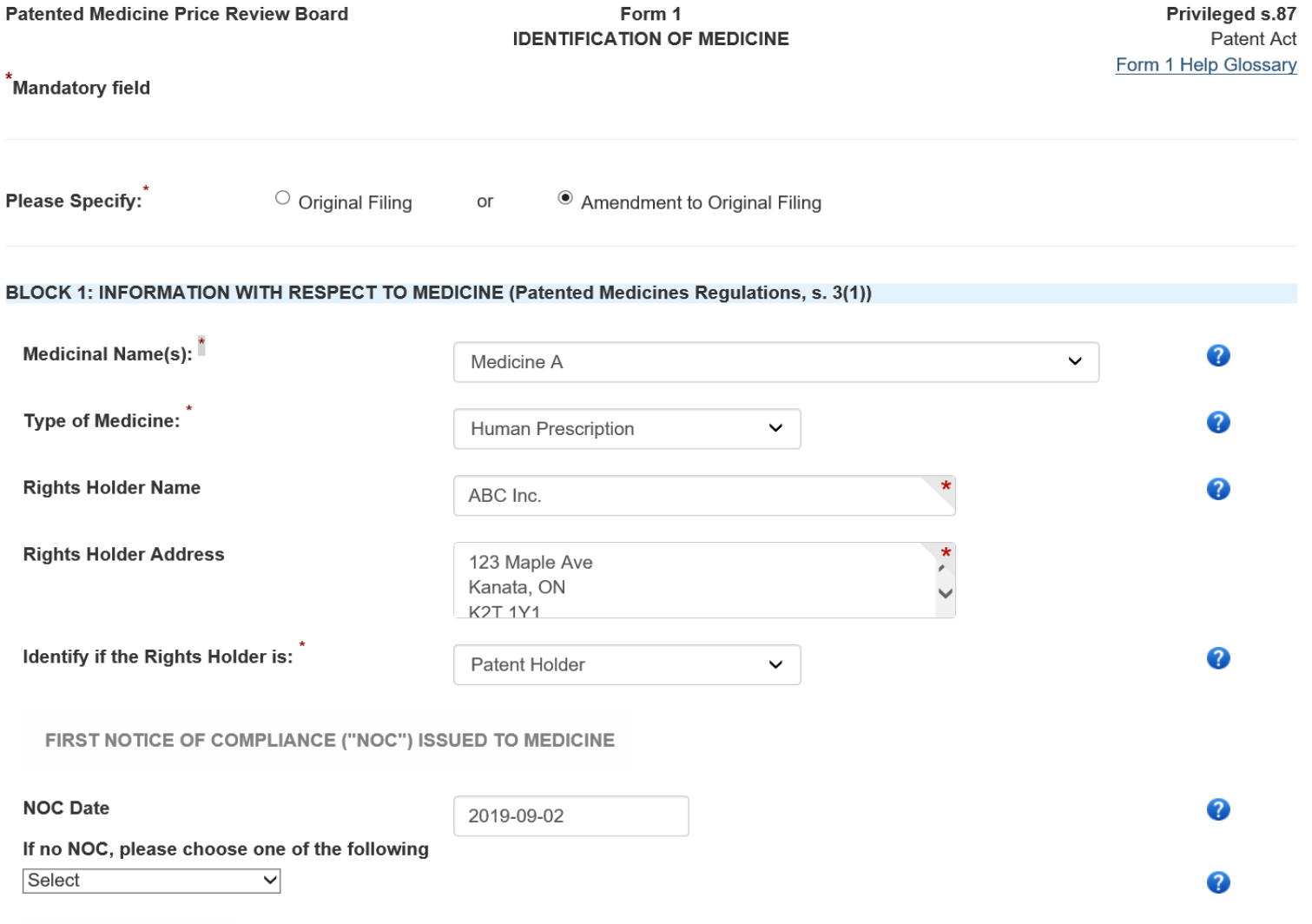
Form 1 - cont'd

- All forms must be certified by a duly authorized person for the reporting Rights Holder (Section 7 of the Patented Medicine Regulations)
- E-signature button must be clicked before you can submit the form
- A Rights Holder letter in PDF can be included on each form



Form 1 - Amendment

- Form 1 amendments are pre-populated with the previously submitted information
- Information may then be amended or updated accordingly



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):* Medicine A

Type of Medicine:* Human Prescription

Rights Holder Name: ABC Inc.*

Rights Holder Address: 123 Maple Ave
Kanata, ON
K2T 1Y1 *

Identify if the Rights Holder is:* Patent Holder

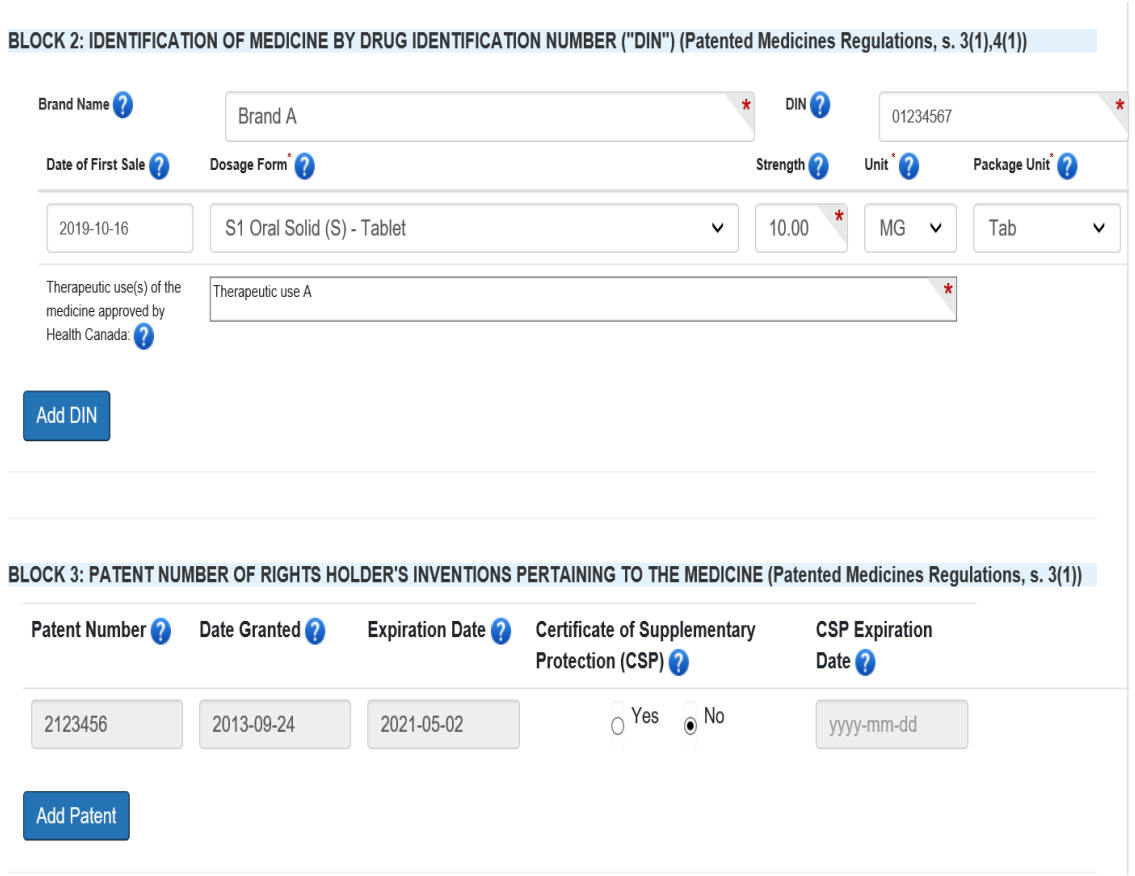
FIRST NOTICE OF COMPLIANCE ("NOC") ISSUED TO MEDICINE

NOC Date: 2019-09-02

If no NOC, please choose one of the following
Select

Form 1 – Amendment Cont'd

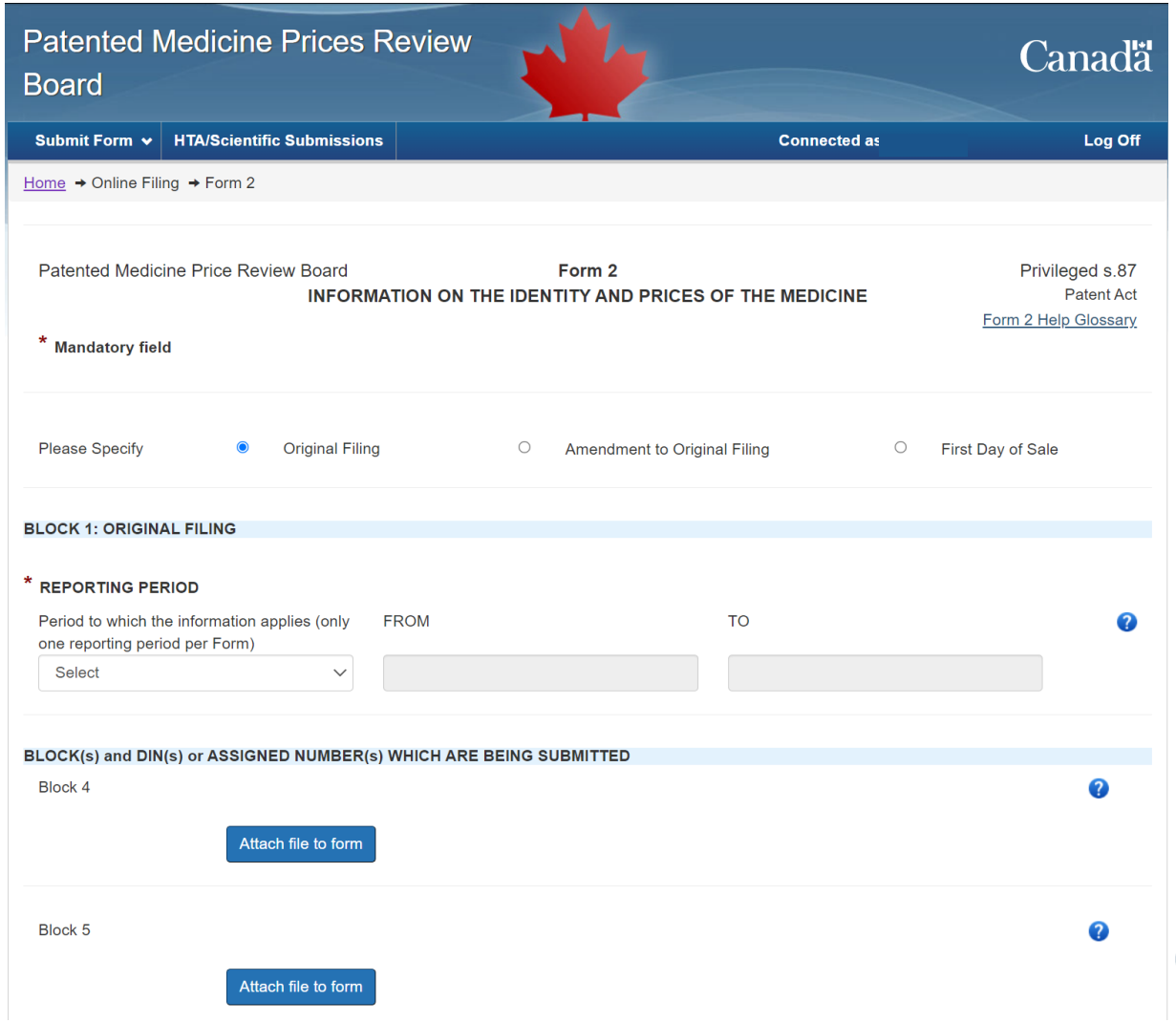
- Additional DINs can be added/amended in Block 2
- Additional patents can be added in Block 3 of the amended form; however, any changes required to previously filed patents must be done through an email request sent to compliance@pmprb-cepmb.gc.ca



Form 2 – Information on the Identity of Prices of the Medicine

- Form 2 Block 4/5 will continue to be filed at the DIN level

- Semi-annual Excel filing templates for Blocks 4 and 5 will be distributed in both official languages to the Rights Holder no later than 45 days before the filing deadlines



Block 4 Filing Template – Sales of the Medicine by the Reporting Rights Holder in Final Dosage Form in Canada

Patented Medicine
Prices Review Board

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

Privileged s.87
Patent Act

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

Reporting Period: _____

4 SALES OF THE MEDICINE BY THE RIGHTS HOLDER IN FINAL DOSAGE FORM IN CANADA [1]

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

Drug Identification Number
Enter Numeric DIN Value

Block 5 Filing Template – Publicly Available Ex-Factory Prices for Canada and Other Countries

Patented Medicine
Prices Review Board

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

Privileged s.87
Patent Act

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

Reporting Period: _____

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

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

Generic Name
Enter Chemical Name of Product Consistent with the Provided Template

Form 3 – Revenues and Research & Development Expenditures

- No changes to content of Form 3 R&D filing
- Reporting period remains January 1st to December 31st
- Previously filed in Excel
- Annual Form 3 filing deadline remains March 1st
- Available January 1st, 2022

Form 3 – Revenues and Research & Development Expenditures - Cont'd

- Blocks input are identical to those previously filed in Excel format
- Blocks are self-totalling

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

Form 4 – National Market Size Estimation of Medicine

- New Form stemming from filing requirements of amended Patented Medicine Regulations (into force August 21, 2019)

Patented Medicine Prices Review Board

Canada

Submit Form | Health Technology Assessment/Scientific Submissions | You are logged in as | Log Off

Home → Online Filing → Form 4

Patented Medicine Price Review Board

Form 4
NATIONAL MARKET SIZE ESTIMATION OF MEDICINE

Privileged s.87
Patent Act
Form 4 Help Glossary

*Mandatory field

Type of Form: Original Filing or Amendment to Original Filing

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

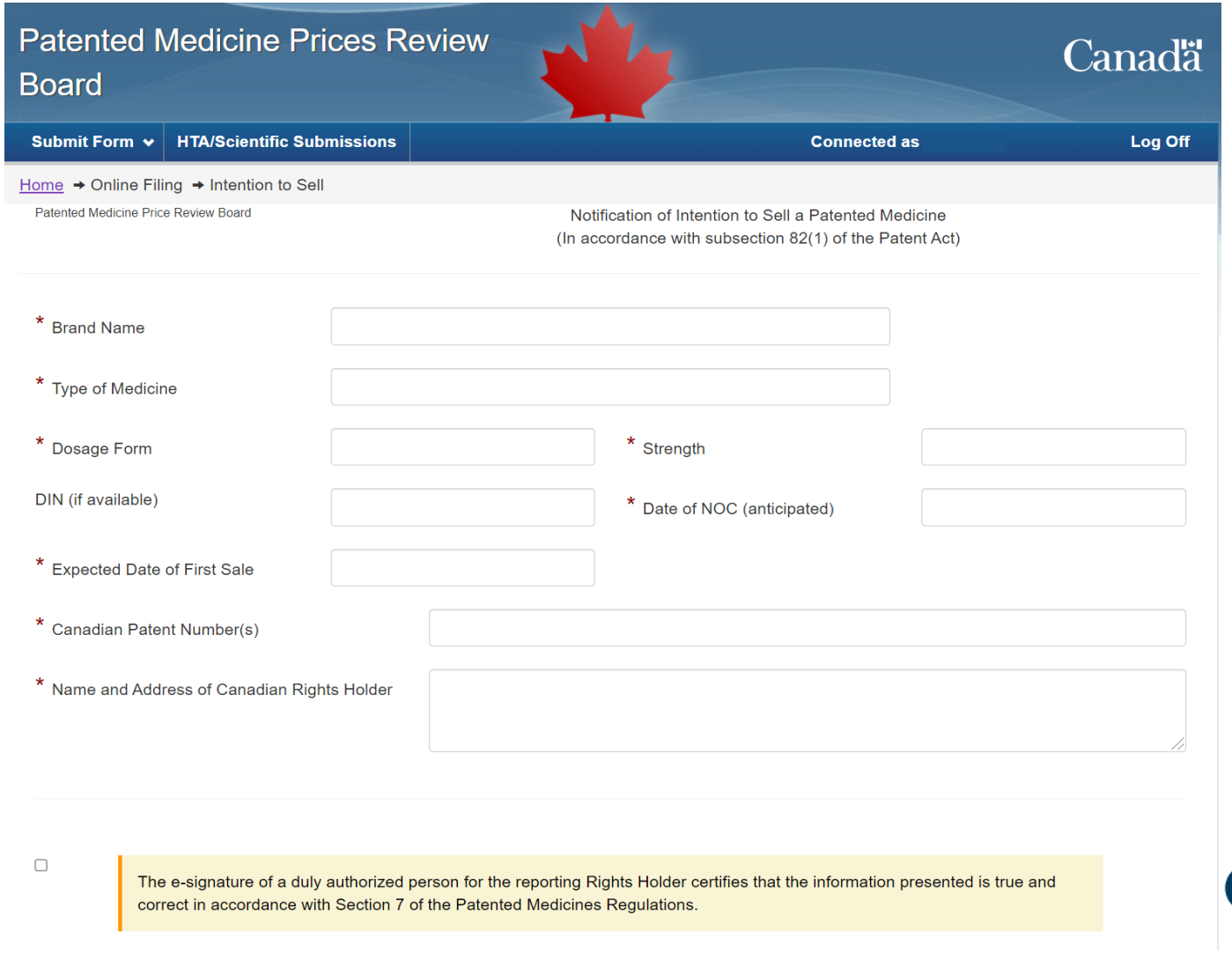
BLOCK 2: RIGHTS HOLDER AND CERTIFYING SIGNATURE

Rights Holder Name *

Rights Holder Address *

Notification of Intent to Sell

- Under subsection 82(1) of the *Patent Act*, a Patentee is required to notify the PMPRB as soon as practicable, of its intention to sell a patented drug product in Canada, and the date on which the patentee intends to offer the drug product for sale.



Patented Medicine Prices Review Board

Canada

Submit Form | HTA/Scientific Submissions | Connected as | Log Off

Home ➔ Online Filing ➔ Intention to Sell

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

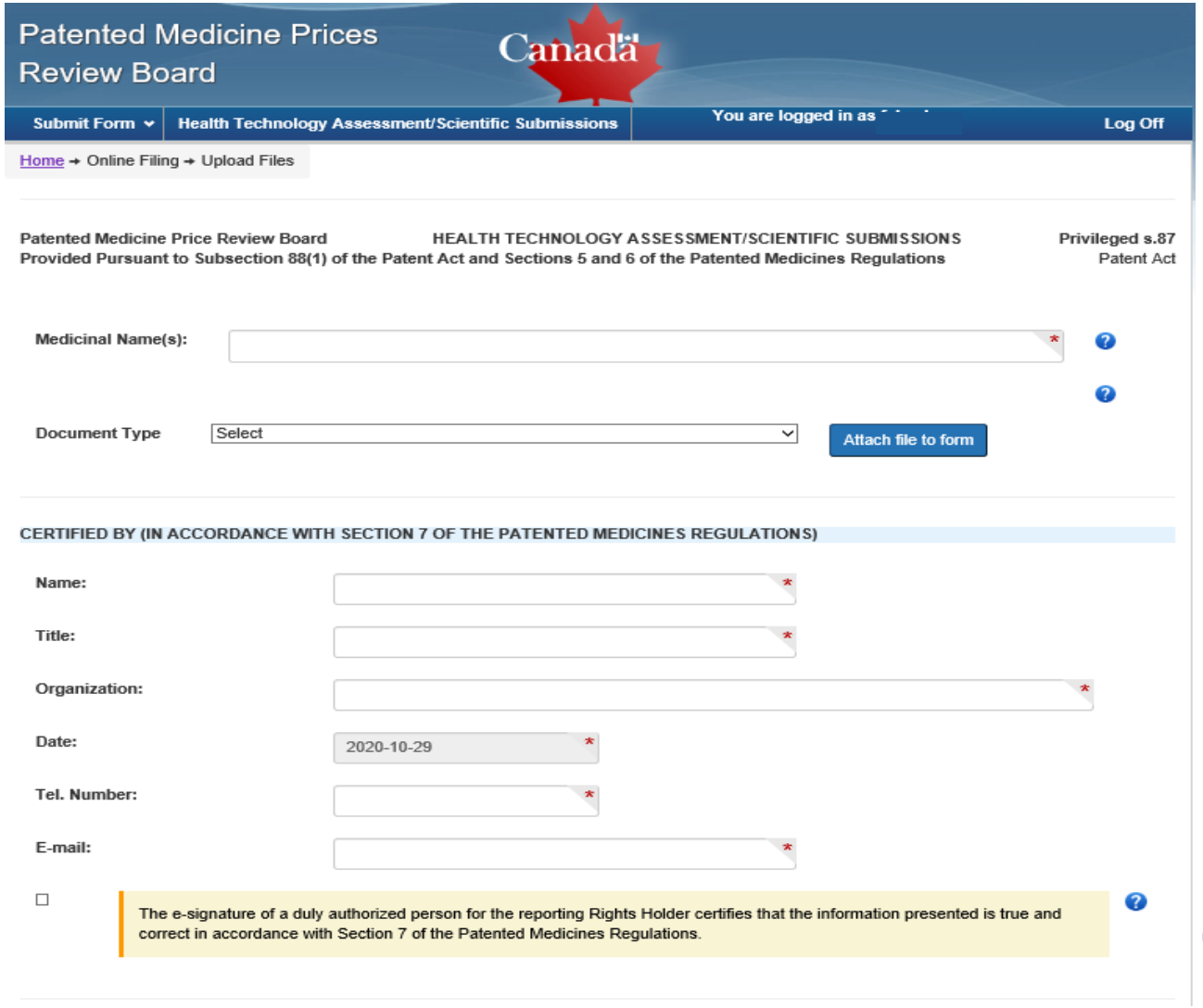
* Canadian Patent Number(s)

* 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.

Health Technology Assessment/Scientific Submissions

- Portal specific to Health Technology Assessment and Scientific submissions
- PDF format only
- Multiple documents can be filed in a single submission



Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

PMPRB Outreach Session

Transition Measures for Grandfathered and Gap Medicines

June 15, 2021

Outline

- This presentation is a refresher on the transition of Grandfathered and Gap Medicines to the new Guidelines. Topics include:
  - Coming into Force (CIF) Delay; Notice and Comment
  - Definitions and Background
  - Price Ceilings
  - Timeline (next twelve months)
  - 2021 Mid-Year Compliance Status Report
  - Reconsideration of the MLP

CIF Delay; Notice and Comment

- On December 29, 2020, Health Canada delayed the CIF date for the amended *Patented Medicines Regulations* to July 1, 2021.
  - In response, the PMPRB initiated a Notice and Comment period on January 15, 2021.
- This consultation process solicited feedback on two proposed amendments to the Guidelines in response to the CIF delay:
- (1) The definition of Gap Medicines.
  - The Board decided that the window for gap medicines would be extended to those first sold in Canada prior to July 1, 2021, rather than prior to January 1, 2021.
- (2) The compliance timeline for Grandfathered and Gap medicines.
  - The Board decided to maintain the December 31, 2021 deadline for Grandfathered and Gap medicines to comply with the Maximum List Price (MLP).
  - In April 2021, in response to additional feedback the Board revised this decision to allow for a compliance deadline of June 30, 2022.

Background

- Grandfathered Medicines:
  - (33) All dosage forms and strengths of medicines for which the patentee was assigned a DIN prior to August 21, 2019 regardless of whether those dosage forms and strengths have been approved for new indications (without a DIN change) after August 21, 2019.
  - (71) The MLP will be the lower of the 2021 National Non-Excessive Average Price (N-NEAP) and the PMPRB11 Highest International Price (HIP) based on the Form 2, Block 5 information filed by the patentee.
- Gap Medicines:
  - (35) Medicines for which a DIN was assigned on or after August 21, 2019 and first sold in Canada prior to July 1, 2021.
  - (73) The MLP will be the lower of the 2021 Maximum Average Potential Price (MAPP) or N-NEAP, whichever is appropriate, and the PMPRB11 Median International Price (MIP) based on the Form 2, Block 5 information filed by the patentee.
- Note: the HIP & MIP will be based on the January to June 2021 filing.

Price Ceilings

- The list prices of Grandfathered and Gap Medicines are expected to comply with the MLP. There is no interim MLP (iMLP).
- The MLP will be static based on the “lower of” rules described in paragraphs 71 and 73 of the Guidelines, unless:
  - (83) For Grandfathered medicines, “… if the prevailing HIP is lower than the MLP for two consecutive reporting periods, the MLP will be reset by the prevailing HIP.”
  - (82) For Gap medicines, “… if the prevailing MIP is lower than the MLP by more than 10% for two consecutive reporting periods, the MLP will be reset by the prevailing MIP”.
- The Maximum Rebated Price (MRP) ceiling will not be applied.
- Line extensions of Grandfathered and Gap medicines that both receive a DIN and are first sold on or after July 1, 2021 will only have the MLP ceiling calculated.

Timeline (next twelve months)

- July 30, 2021
  - Deadline for patentees to submit data for the January to June 2021 reporting period.
  - Reminder: this is the first reporting period for which patentees will be filing Form 2, Block 5 data for the new schedule of comparator countries.
- Mid-September 2021 (45 days from filing deadline)
  - Deadline for PMPRB Staff to send Mid-Year Compliance Status Reports to patentees based on the January to June 2021 price and sale data, and to communicate the MLP.
- January 30, 2022
  - Deadline for patentees to submit data for the July to December 2021 reporting period.
- Mid-March 2022 (45 days from filing deadline)
  - Deadline for PMPRB Staff to send 2021 Year-End Compliance Status Reports to patentees offering a status update on compliance with the MLP.

Timeline (next twelve months)

- June 30, 2022
  - Date by which the list price of all Grandfathered and Gap medicines are expected to be compliant with the MLP.
- July 30, 2022
  - Deadline for patentees to submit data for the January to June 2022 reporting period.
- Mid-September 2022
  - Deadline for PMPRB Staff to send 2022 Mid-Year Compliance Status Reports to patentees.
  - Compliance with the MLP will be evaluated at this time.
  - Investigations will be commenced based on non-compliance and patentees will be notified.

2021 Mid-Year Compliance Status Report

- For all Grandfathered and Gap medicines, the document will include:
  - The maximum Canadian list price filed by the patentee;
  - The 2021 N-NEAP (Grandfathered/Gap);
  - The 2021 HIP (Grandfathered) or MIP (Gap) of the PMPRB11;
  - The MLP, as determined by the lower of the two respective numbers; and
  - Other relevant pricing information.
- Excess revenues will be calculated for the first half of 2021.
  - Will be based on the 2021 N-ATP and N-NEAP, not the list price or MLP;
  - Will not be immediately pursued, and new investigations will not be commenced.
- Excess revenues and existing investigations will be carried over.
- All accrued excess revenues may be pursued by PMPRB Staff if the patentee does not comply with the MLP by June 30, 2022.

Reconsideration of the MLP

- (75) Patentees will have the opportunity to request a reconsideration of the MLP by PMPRB Staff if the MLP was set by the NEAP and the NEAP had been significantly impacted by the reporting of benefits. If they elect to do so, patentees will be required to provide:
  - Evidence of the benefits provided, i.e., details on any contracts or agreements which led to a discounted price, invoices for free goods, etc.;
  - A comparison of the historic list price changes to the CPI-Adjustment Methodology; and
  - Any other material requested by PMPRB Staff during the analysis.
- (75) If the requisite information supports a reconsideration of the MLP, it will be adjusted to the lower of the applicable international price test for the PMPRB11 (HIP for Grandfathered; MIP for Gap) and the highest compliant list price.

Reconsideration of the MLP

Part A: Background, Description of the Benefit, and Certification

Paragraph 75 of the Guidelines:

"For Grandfathered, Line Extension and Gap medicines, if the MLP is set by the medicine's NEAP and if there is evidence that its calculation was significantly impacted by the reporting of benefits, the patentee may submit a request for the MLP to be set higher. Any such request must include details and supporting documentation of the reported benefits and, where available, a history of the medicine's list price changes, as well as any other relevant information requested by Staff. If the requisite information supports a reassessment, the MLP will be adjusted to the lower of (i) the applicable international price test for the PMPRB11 countries for which the patentee has provided information, or (ii) the highest compliant list price of the medicine under the Guidelines as they were prior to the issuance of these Guidelines."

Medicinal Information:

Patentee:	
Medicine:	
Brand Name:	

Pricing Information (insert additional rows as required):

Strength	DIN	Year of Introduction	Medicine Type	2021 Highest List Price	2021 NEAP (or MAPP)	Relevant IPC Test*	MLP

*Note: the IPC test is based on the January to June 2021 Form 2, Block 5 filing of the PMPRB11. It is the HIP for Grandfathered, and MIP for Gap medicines.

Description of the Benefit:

Have additional supporting documents (contract details, invoices, etc.) been attached:	**Yes**	
	No	

Part B: Historic List Prices

Paragraph 75 of the Guidelines:

"For Grandfathered, Line Extension and Gap medicines, if the MLP is set by the medicine's NEAP and if there is evidence that its calculation was significantly impacted by the reporting of benefits, the patentee may submit a request for the MLP to be set higher. Any such request must include details and supporting documentation of the reported benefits and, where available, a history of the medicine's list price changes, as well as any other relevant information requested by Staff. If the requisite information supports a reassessment, the MLP will be adjusted to the lower of (i) the applicable international price test for the PMPRB11 countries for which the patentee has provided information, or (ii) the highest compliant list price of the medicine under the Guidelines as they were prior to the issuance of these Guidelines."

Medicinal Information:

Patentee:		**Strength:**	
Medicine:		**DIN:**	
Brand Name:		**Date of First Sale:**	

List Price(s):

Step 1: For each unique list price, note the jurisdiction/province(s) to which this list price applies in the provided field.
Step 2: Provide the list price that was in place in that jurisdiction/province at the end of the calendar year.
Step 3: Calculate the year-over-year increase in the list prices.

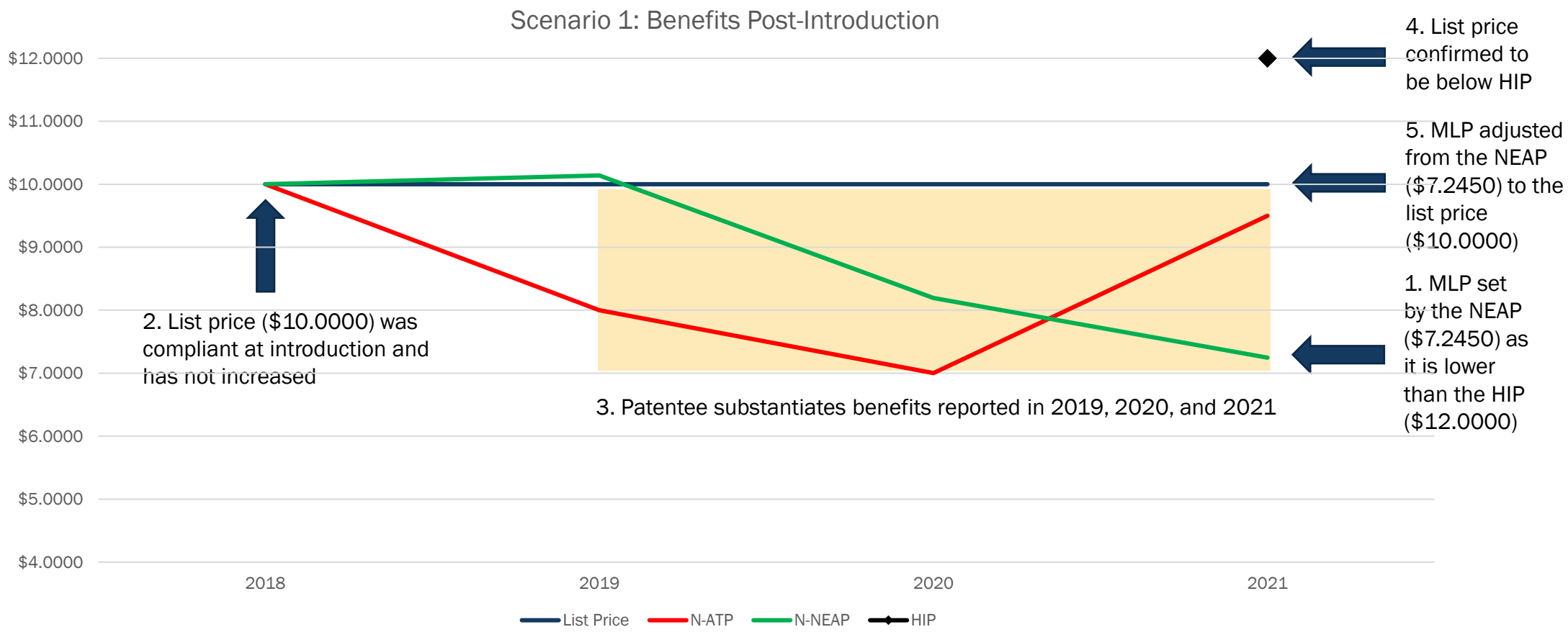
In its analysis, PMPRB Staff will compare these list prices to the MAPP and CPI-Adjustment Methodology. As noted above, the highest compliant list price will be used in the reconsideration.

Year	Jurisdiction/Province (1)		Jurisdiction/Province (2)		Jurisdiction/Province (3)	
	List Price (1)	% Increase (1)	List Price (2)	% Increase (2)	List Price (3)	% Increase (3)
2021						
2020						
2019						
2018						
2017						
2016						
2015						
2014						
2013						
2012						
2011						
2010						

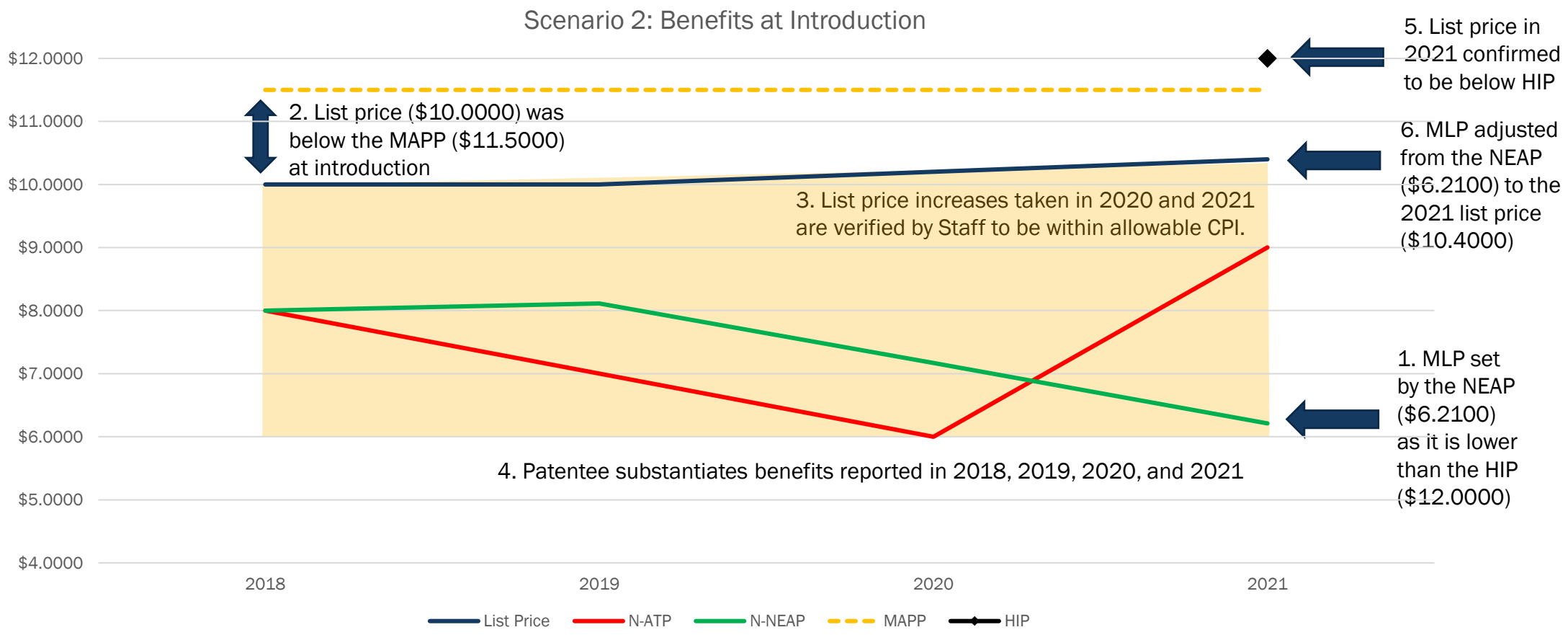
Reconsideration of the MLP

- Patentees may submit requests for reconsideration of the MLP within 30 days of receiving the 2021 Mid-Year Compliance Status Report.
- These requests for reconsideration of the MLP must be submitted to the Senior Regulatory Officer from whom your company received the 2021 Mid-Year Compliance Status Report.
  - Please include Compliance (compliance@pmprb-cepmb.gc.ca) as a CC on these requests.
- Patentees will be notified of the results of the reconsideration by email.
- (76) Compliance with the MLP – original or reconsidered – is required by June 30, 2022. If the list price has not been reduced by this date, the medicine will be subject to investigation and excess revenues current and prior reporting periods may be pursued.

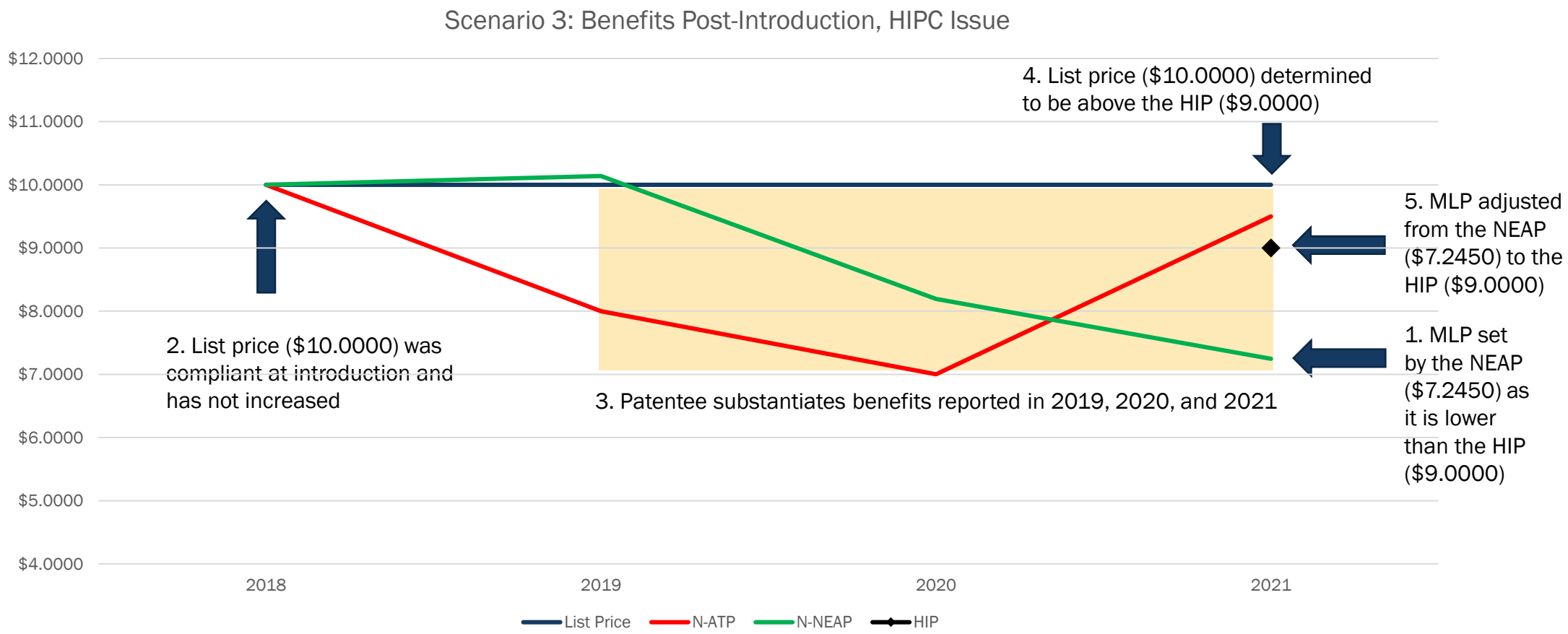
Reconsideration of the MLP



Reconsideration of the MLP



Reconsideration of the MLP



Reconsideration of the MLP

- The form will be included with the 2021 Mid-Year Compliance Status Report that will facilitate and expedite the reconsideration of the MLP by PMPRB Staff by clearly describing the required information.

- The form is similar to the “DIP” application forms previously used by the PMPRB, and includes fields to provide details on the nature of the benefits, the direct impact of the benefits on the N-NEAP, changes to any Canadian list prices, and the international prices.

- The form should be sent to the Senior Regulatory Officer assigned to your company, with any additional information deemed relevant (invoices, international sources, etc.), by the provided deadline.

Questions?

- Reminder:
  - Questions should be focused on the content of this presentation only. Any questions outside the scope of the transition period for Grandfathered and Gap medicines will not be answered.
    - Staff will not be answering questions about on-going Legal cases.
    - Staff will not be answering questions about policy decisions.
    - Staff will not be answering questions about hypothetical scenarios.