Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

PMPRB Outreach Session

Transition Measures for Grandfathered and Gap Medicines

December 10, 2020

Outline

- The focus of this presentation is the transition of Grandfathered and Gap Medicines to the new Guidelines. Topics include:
  - Definitions and Background
  - Price Ceilings
  - Timeline (next 12 months)
  - 2020 Compliance Status Report
  - Reconsideration of the MLP
  - Next Steps for Outreach

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 Maximum List Price ("MLP") will be the lower of the 2020 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 January 1, 2021.
  - (73) The MLP will be the lower of the 2020 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 July to December 2020 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 January 1, 2021 will only have the MLP ceiling calculated.

Timeline (next 12 months)

- January 30, 2021
  - Deadline for patentees to submit data for the July to December 2020 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-March 2021 (45 days from filing deadline)
  - Deadline for PMPRB Staff to send Compliance Status Reports to patentees based on the January to December 2020 price and sale data, and to communicate the MLP.

- December 31, 2021
  - Date by which the list price of all Grandfathered and Gap medicines are expected to be compliant with the MLP.

2020 Compliance Status Report

- For all Grandfathered and Gap medicines, the document will include:
  - The maximum Canadian list price filed by the patentee;
  - The 2020 N-NEAP (Grandfathered/Gap) or MAPP (Gap);
  - The 2020 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 2020.
  - Will be based on the 2020 N-ATP and 2020 N-NEAP (or MAPP), 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 December 31, 2021.

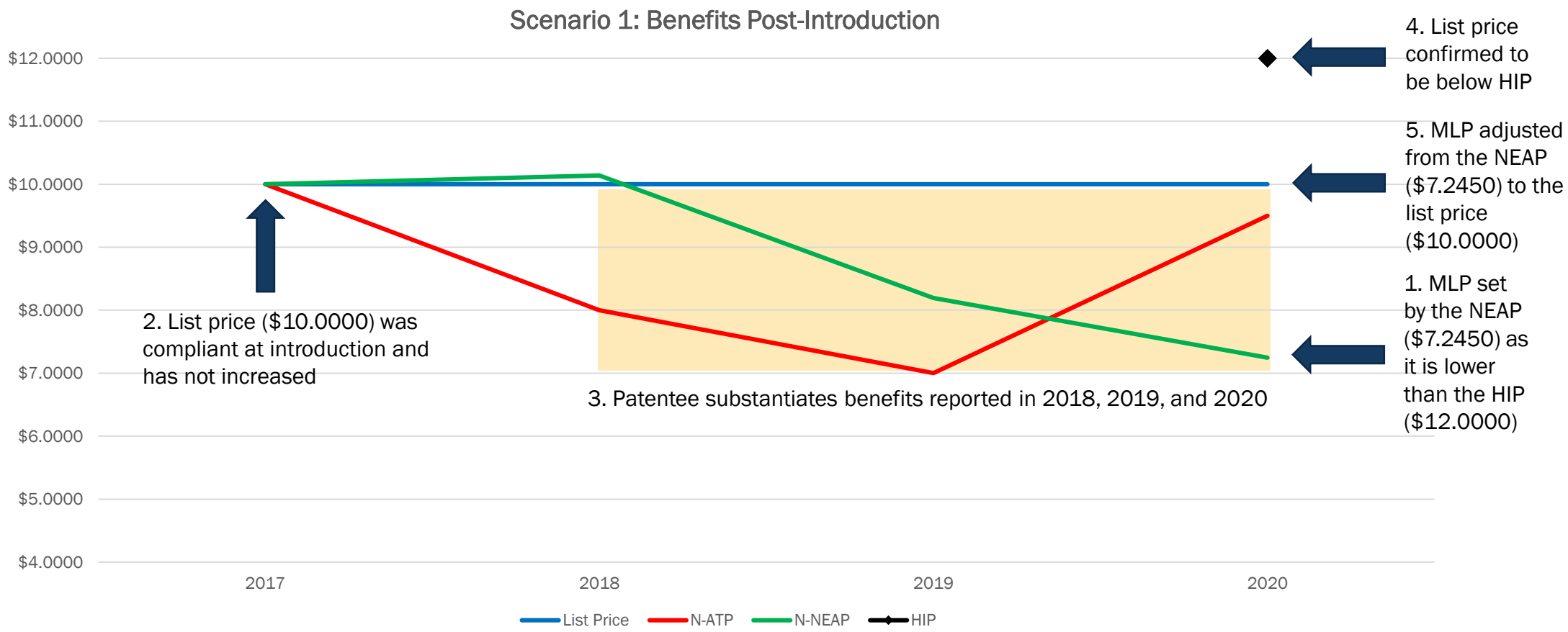
Reconsideration of the MLP

- (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.

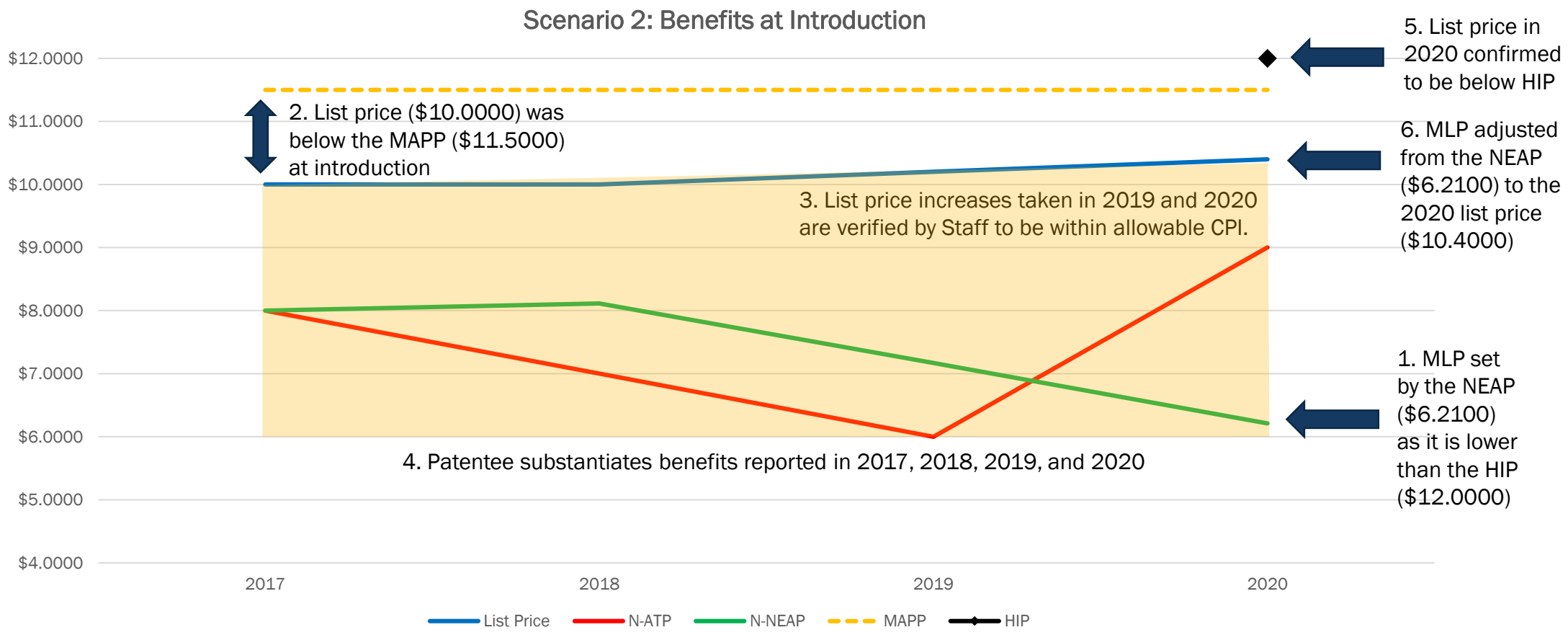
Reconsideration of the MLP

- Patentees may submit requests for reconsideration of the MLP within 30 days of receiving the 2020 Compliance Status Report.
- These requests for reconsideration of the MLP must be submitted to the Senior Regulatory Officer from whom your company received the 2020 Compliance Status Report.
  - Please include the Compliance inbox 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 December 31, 2021. If the list price has not been reduced by this date, the medicine will be subject to investigation and excess revenues from both 2021 and prior reporting periods may be pursued.

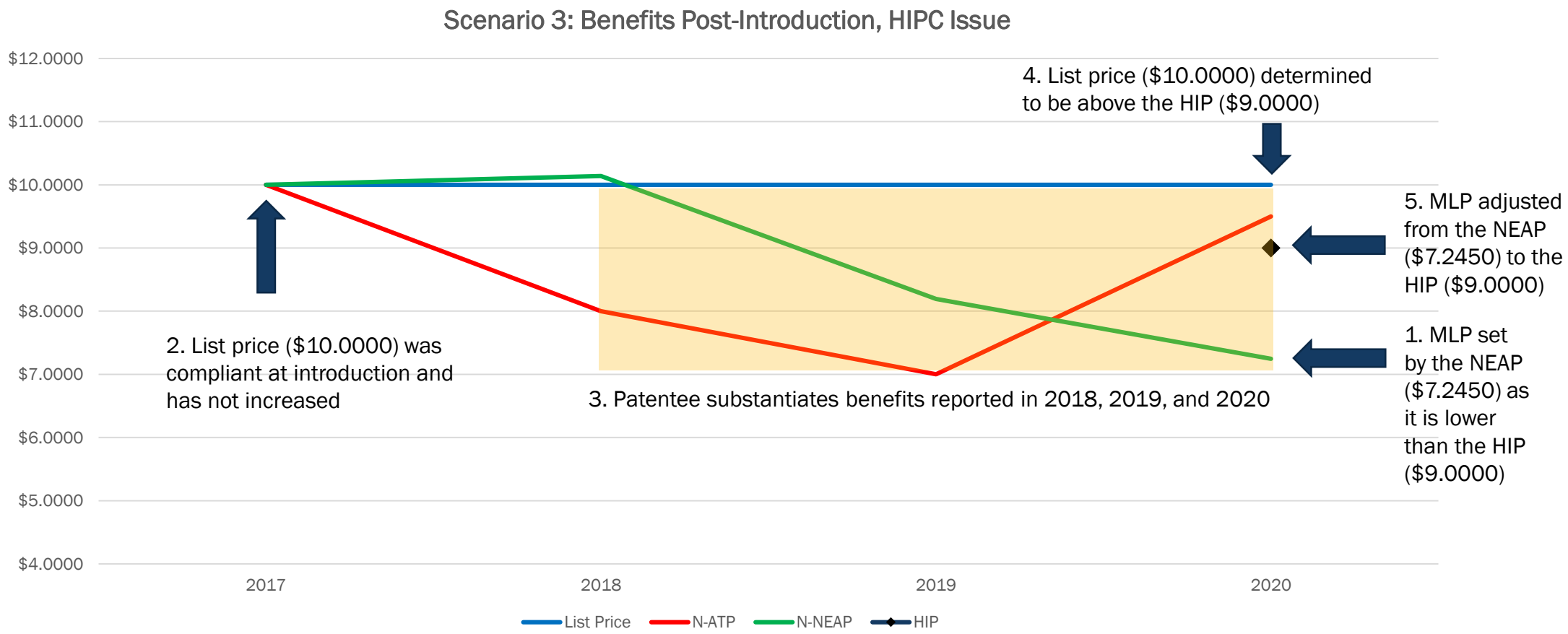
Reconsideration of the MLP



Reconsideration of the MLP



Reconsideration of the MLP



Reconsideration of the MLP

- A form will be made available on the PMPRB website prior to February 1, 2021 that will facilitate and expedite the reconsideration of the MLP by PMPRB Staff by clearly describing the required information.

- The form will be similar to the “DIP” application forms previously used by the PMPRB, and will include 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.

Outreach: Next Steps

- The next Outreach session by the Regulatory Affairs & Outreach (RA&O) branch is tentatively scheduled for spring 2021.
- The focus of that session will be on new medicines that fall entirely under the jurisdiction of the new Regulations, with topics including:
  - Categorization of new medicines based on cost and/or market size;
  - Scientific and introductory price review processes;
  - Annual review of medicines under the new Regulations and Guidelines;
  - Reassessments; and
  - Investigations.
- Following this third Outreach session in the spring, Staff from RA&O will be available for 1-on-1 sessions.

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.