PMPRB Technical Working Group Meeting

5 February 2019

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Conceptual Framework

- The role of the Working Group was to examine and make recommendations to the Steering Committee regarding a number of specific technical issues. The Terms of Reference specified six distinct areas of focus for the Working Group to consider.
- This Conceptual Framework was drafted by the Chair prior to the final meeting of the Working Group. Its purpose was to guide the Working Group in making consistent recommendations across all six of these areas of focus, while respecting the policy intent and the range of views expressed by members of the Working Group throughout their deliberations.

2

Economic principles

- At any given price, the 'economic surplus' from a good is the sum of two parts:
  - The 'consumer surplus', which is the benefit obtained by consumers because they are able to purchase the good at a price lower than their 'willingness-to-pay';
  - The 'producer surplus', which is the benefit obtained by producers because they are able to sell the good at a price higher than their 'willingness-to-accept'.
- In order to consider the consumer and producer surplus that might arise from the PMPRB setting a ceiling price on a new medicine, we must first specify demand and supply curves.

3

Demand curve for a medicine

- The demand curve reflects society's willingness-to-pay for the medicine in question.
- It is for the PMPRB, rather than members of the Working Group, to define the components of this demand curve. The Working Group therefore defers to the government's policy intent when considering the relevant components of the demand curve.

4

Policy intent

- During the Working Group's deliberations, the PMPRB stated that the most appropriate perspective to adopt is that of *Canada's publicly funded health care systems*.
- The 'Regulatory Impact Analysis Statement' (RIAS) (p.10) states that the *quality-adjusted life year (QALY)*, as used in cost-utility analysis, is regarded as the "gold standard" approach to considering the economic value of new medicines.
- In a July 2018 document prepared for the Working Group, the PMPRB clarified that the purpose of the PMPRB is to ensure that *patentees do not change excessive prices during the statutory monopoly period*.

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Demand curve for a medicine

- In light of this policy intent, a reasonable specification of the demand curve for a new medicine is based upon the net impact upon the health of patients (as measured in QALYs) associated with adopting the medicine within Canada's publicly funded health care systems for the duration of the statutory monopoly period.
- The net impact of a new medicine upon patient health is a function of two components:
  - The gain in health experienced by patients who receive the new medicine;
  - The loss in health experienced by other patients whose health care subsequently receives less funding than it would have done in the absence of the new medicine.

6

Equity weighting

- Although the Terms of Reference required the Working Group to consider potential approaches for allowing higher ceiling prices for some medicines on the basis of specific characteristics (so-called 'equity weighting'), it was agreed by the Working Group that insufficient empirical evidence exists to do this at the present time. For the purposes of this conceptual framework, equity weighting is therefore not applied.

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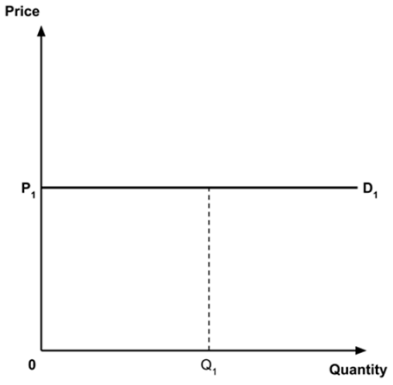
Location of the demand curve

- The demand curve plots the ceiling price at which the incremental cost-effectiveness ratio (ICER) of the new medicine is equal to k



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Supply curve for a medicine

- The supply curve plots the lowest price that a manufacturer would be willing to accept for a medicine. This is sometimes referred to as the 'reservation' (or 'reserve') price of the medicine.
- The supply curve is a function of a number of potential considerations, including the initial costs associated with developing the medicine, the marginal costs of production, and the potential implications for pricing in other jurisdictions as a result of 'reference pricing'.

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Supply curve for a medicine

- The components of the supply curve are complex.
- For the purposes of this framework, the medicine's supply curve will therefore be treated as unknown (and plotted as a dashed line).
- Despite being unknown, we may reasonably expect the supply curve for a medicine to have the following basic properties:
  - A relatively high intercept on the vertical axis, reflecting substantial initial costs associated with developing the medicine;
  - A downwards slope, reflecting a declining per-patient cost of supplying the medicine as the quantity supplied increases. This declining per-patient cost arises from the ability to spread the initial costs of development across a greater number of patients, and also potential economies of scale in the production of the medicine.

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Supply curve for a medicine

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Economic surplus

- The economic surplus is illustrated by the area of the region below the demand curve and above the supply curve, minus any area above the demand curve but below the supply curve, and bounded between the vertical axis and the quantity of medicine adopted.

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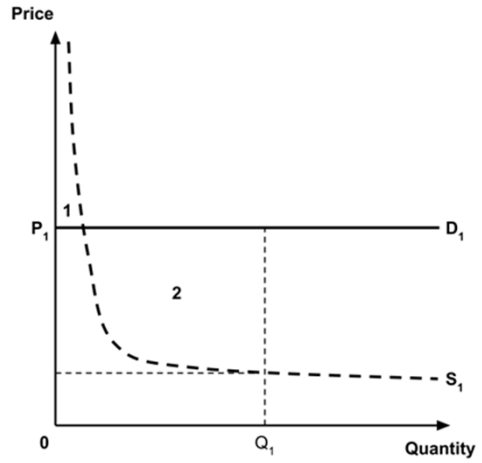
1. Producer receives entire surplus (P1)



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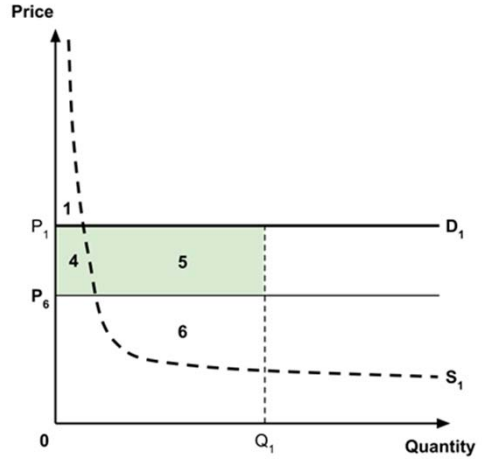
2. Consumers receive entire surplus (P6)



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Topic 1: Options for determining what medicines fall into 'Category 1'

- A Category 1 medicine is one for which a preliminary review of the available clinical, pharmacoeconomic, market impact, treatment cost and other relevant data would suggest is at elevated risk of excessive pricing.
- The following criteria have been identified as supporting a Category 1 classification:
  a) The medicine is 'first in class' or a 'substantial' improvement over existing options
  b) The medicine's opportunity cost exceeds its expected health gain
  c) The medicine is expected to have a high market impact
  d) The medicine has a high average annual treatment cost
- Should other criteria be considered? What are the relevant metrics for selecting medicines that meet the identified criteria and what options exist for using these metrics?

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Topic 1: Summary of Deliberations

- Should other criteria be considered?
  - No additional criteria were suggested by members of the Working Group.
- What are the relevant metrics and what options exist for their use?
  - Criterion B is impractical to implement as a screen.
  - Criterion D should be 'incremental' upon existing treatment.
  - Definitions should reflect practice elsewhere, ideally based upon existing definitions.
  - 'Thresholds' should be clearly specified, to provide a 'clear bright line' for manufacturers.
  - Metrics should result in a manageable number of Category 1 medicines for the PMPRB.

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Topic 1: Draft Potential Recommendations

1. **The PMPRB should not consider any additional criteria.**
2. **The PMPRB should remove Criterion B from consideration.**
3. **Criterion D should be 'incremental' upon existing treatment.**
4. **Metrics for criteria A, C and D should reflect existing Canadian practice (e.g. based on existing definitions of 'substantial' treatment benefit).**
5. **'Thresholds' for each criterion should be determined by the PMPRB, taking into account the capacity for assessing Category 1 medicines, the technical considerations of the Working Group, and the policy intent.**
6. **'Thresholds' for each criterion should be clearly specified, so as to provide a 'clear bright line' to manufacturers.**

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Topic 2: Application of supply-side cost effectiveness thresholds in setting ceiling prices

- Potential approaches for implementing a price ceiling based on a medicine's opportunity cost.
- Potential approaches for allowing price ceilings above opportunity cost for certain types of medicines (e.g. pediatric, rare, oncology, etc)

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Topic 2: Summary of Deliberations (1/2)

- Potential approaches for implementing a price ceiling based on a medicine's opportunity cost
  - An estimate of the 'supply-side cost-effectiveness threshold' ('k') allows for estimation of the health opportunity cost, in terms of forgone QALYs, associated with new medicines.
  - Conceptually, the Working Group expects 'k' to vary across provinces and territories.
  - The only estimate of 'k' currently available for Canada is that by Ochalek et al. (2018), which estimated 'k' to be $30,000 per QALY for Canada as a whole.
  - Concerns were raised about the instrumental variables (IVs) used for in this empirical work, and also the reliance upon UK (rather than Canadian) data.
  - Nevertheless, the $30,000 per QALY estimate of 'k' by Ochalek et al. (2018) is in the same ballpark as recent empirical estimates of 'k' published in other PMPRB12 countries (UK: £12,936 per QALY, Australia: $28,033 AUD per QALY, Spain: €24,870 per QALY).
  - Further empirical research is required to estimate 'k' in Canada - this should use Canadian data, appropriate IVs, and consider variation in 'k' across provinces/territories.
  - Any measure of opportunity cost used for setting a price ceiling should be clearly specified, so as to provide a 'clear bright line' for manufacturers.

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Topic 2: Summary of Deliberations (2/2)

- Potential approaches for allowing price ceilings above opportunity cost for certain types of medicines (e.g. pediatric, rare, oncology, etc)
  - There is insufficient empirical evidence to implement 'equity weights' at the present time (as would be required to allow price ceilings above opportunity cost for some medicines).
  - There are technical considerations in implementing 'equity weights' in practice, including the need to respect horizontal equity by applying equity weights to all patients affected.
  - Applying equity weights to patients who bear the opportunity cost of new medicines requires an understanding of their characteristics, in addition to an estimate of the magnitude of health forgone (such that an estimate of 'k' is necessary but insufficient).
  - The PMPRB should support future empirical research in this area - this should estimate how 'demand side' willingness-to-pay for a QALY in Canada differs according to the characteristics of the patient, disease and/or technology in question.

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Topic 2: Conceptual Framework

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Pricing across provinces and territories

- Since provinces and territories in Canada have some autonomy in setting health care budgets and prioritizing spending, it follows that k would be expected to vary by province and territory.
- Since the demand curve plots the ceiling price at which the incremental cost-effectiveness ratio (ICER) of the new medicine is equal to k, it follows that the demand curve will be higher in provinces and territories with larger estimates of k.

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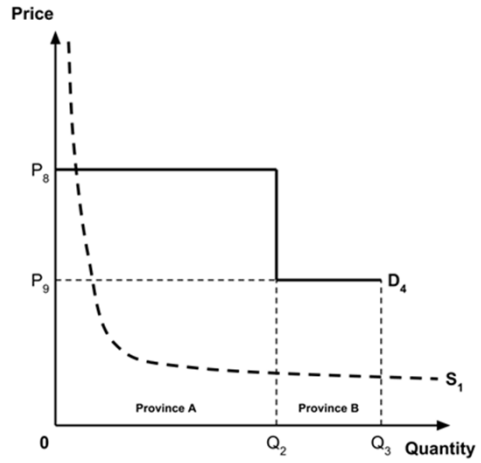
Pricing across provinces and territories



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Approaches for setting a single ceiling price

- The Working Group considered several approaches for setting a single ceiling price across provinces and territories, including:
  1. A ceiling price at which the medicine is 'just' cost-effective in the province or territory with the highest k (such that the ICER equals this highest k);
  2. A ceiling price at which the medicine is 'just' cost-effective in the province or territory with the lowest k (such that the ICER equals this lowest k);
  3. A ceiling price at which the medicine is 'just' cost-effective across Canada as a whole (such that the ICER equals a 'weighted average' of k across Canada).

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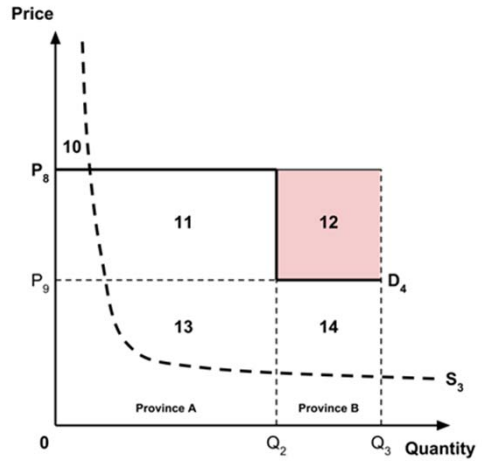
Approach 1: Highest k



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Approach 2: Lowest k

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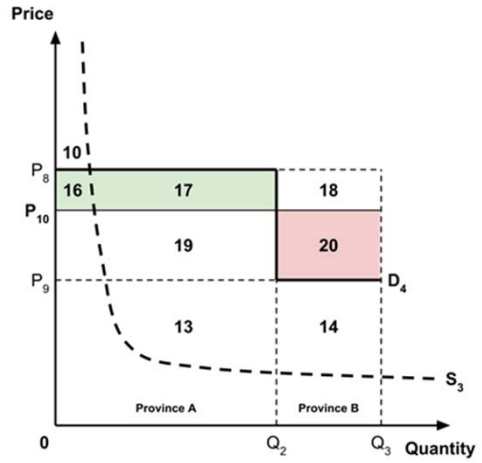
Approach 3: Weighted average k



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Policy implications

- The most desirable approach for setting a single ceiling price across Canada depends upon the government's policy intent.
- *Note that it is not the role of the Working Group to specify the government's policy intent. While the implications of some potential policy objectives are considered below, this should not be construed as an endorsement by the Working Group of any particular policy objective. Also note that this analysis is not exhaustive: there are other potential policy objectives and approaches for setting a ceiling price across provinces and territories.*

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Objective 1: No health loss across Canada

- The first approach is inconsistent with this policy objective. This is because this approach results in diminished population health (negative consumer surplus) in all provinces and territories except that with the highest k (in which consumer surplus is zero), resulting in diminished population health (negative consumer surplus) overall.
- The second approach comfortably satisfies this policy objective (since it results in positive overall consumer surplus), while the third approach only just satisfies this policy objective (since it results in an overall consumer surplus of zero).

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Objective 2: No health loss in any province

- Both the first and third approaches are inconsistent with this policy objective. This is because both approaches result in diminished population health (negative consumer surplus) in at least one province or territory.
- The second approach would only just satisfy this policy objective, since consumer surplus is zero in the province or territory with the lowest k.

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Objective 3: Max health gain across Canada

- Consideration should be given to the location of the supply curve.
- Since the location of the supply curve is uncertain, this is challenging.
- Key assumption: a medicine will not be launched if producer surplus is negative.
  - If a medicine is not launched, the pharmacoeconomic value is zero since there is no resulting net gain in QALYs.
  - For the pharmacoeconomic value to be positive, the medicine must be launched at a ceiling price that results in positive consumer surplus.
- *The mandate of the PMPRB is to protect consumers from excessive pricing, not to ensure that products are launched into the market.*

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Objective 3: Max health gain across Canada

- If the supply curve is understood to be sufficiently low that the medicine would be profitable at the ceiling price arising under the second approach (P9), then maximizing population health requires setting a ceiling price below P9, so as to maximize consumer surplus subject to producer surplus being non-negative.
- However, since the true location of the supply curve is uncertain, any reduction in the ceiling price carries a risk that producer surplus might become negative, such that the medicine would not launch at all. In such circumstances, consumer surplus would be zero, whereas at a higher ceiling price of P9 the new medicine would have launched and consumer surplus would have been positive.

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Topic 2: Draft Potential Recommendations

1. **The Working Group regards the current evidence base with respect to the opportunity cost of adopting new medicines within Canada's public health care systems as highly uncertain. The PMPRB should be aware of limitations with the empirical work by Ochalek et al. (2018), including the reliance on UK data and the choice of instrumental variables (IVs) used. However, the direction of any resulting bias is unknown. Furthermore, the authors' $30,000 per QALY estimate of 'k' is in line with published empirical estimates of 'k' for other PMPRB12 countries.**
2. **The PMPRB should support further empirical research to estimate a 'supply-side cost-effectiveness threshold' ('k') for Canada. This research should consider and report on potential variation in 'k' across provinces and territories.**
3. **There is insufficient empirical evidence to implement 'equity weights' at the present time, as would be required to allow price ceilings above opportunity cost for some medicines but not others.**
4. **Any determinants of the price ceiling should be clearly specified, so as to provide a 'clear bright line' to manufacturers.**

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Topic 3: Medicines with multiple indications

- Options for addressing medicines with multiple indications (e.g. multiple price ceilings or a single ceiling reflecting one particular indication).

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Topic 3: Summary of Deliberations

- Indication-specific pricing is desirable in principle, since it would allow the price of each medicine to more closely reflect the medicine's value to patients in each indication.
- However, other countries which have implemented indication-specific pricing have a sophisticated IT infrastructure to support this, which Canada lacks.
- As a result, it is not feasible to implement indication-specific pricing in Canada at the present time.
- Rebenching of prices over time causes instability and uncertainty for manufacturers.
- Since manufacturers may choose the order in which indications are launched, and may avoid launching in specific indications altogether, any approach to pricing across indications may give rise to concerns of 'gaming' by manufacturers.

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Topic 3: Conceptual Framework

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Pricing across indications

- Where a medicine is available for multiple indications, this has implications for specification of the demand curve for a new medicine.
- If the per-patient health gain from the new medicine is different in each indication, then the ceiling price at which the ICER is equal to k will also differ across indications.
- It follows that the demand curve will generally be different for each indication, with a relatively higher ceiling price corresponding to an ICER of k for those indications in which the medicine has a relatively greater per-patient health gain.

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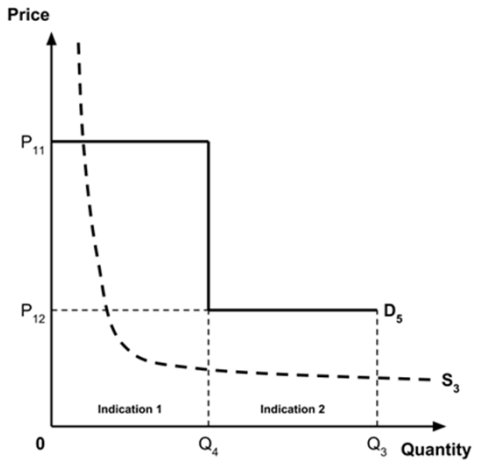
Pricing across indications



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Approaches for setting a single ceiling price

- The Working Group therefore considered various approaches for setting a single ceiling price across multiple indications, including:
  1. A ceiling price at which the medicine is 'just' cost-effective in the most cost-effective indication (such that the ICER equals k in this indication);
  2. A ceiling price at which the medicine is 'just' cost-effective in the least cost-effective indication;
  3. A ceiling price at which the medicine is 'just' cost-effective across all indications (such that a 'weighted average' of the ICER across all indications equals k);
  4. A ceiling price at which the medicine is 'just' cost-effective in the first indication considered by the PMPRB (such that the ICER equals k in this indication).

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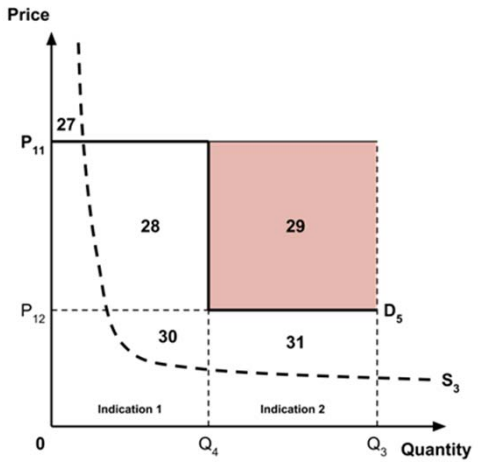
Approach 1: Most cost-effective indication



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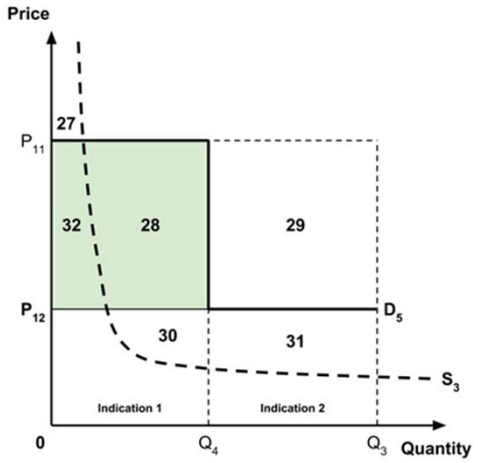
Approach 2: Least cost-effective indication



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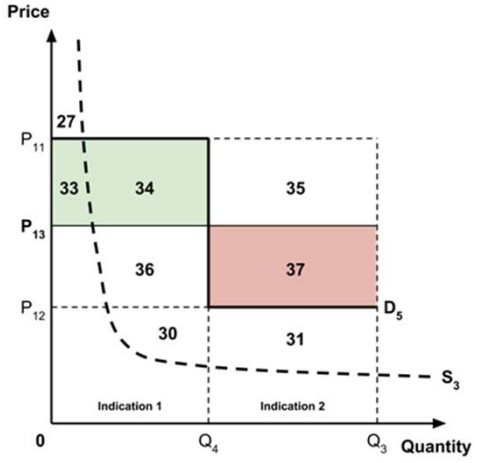
Approach 3: 'Weighted average' of indications



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Approach 4: First indication considered

- This approach is the simplest to administer, since it does not require rebenching of ceiling prices in future if and when additional indications are launched.
- However, because producer surplus is unambiguously greater at a ceiling price of P_{11} than P_{12}, this approach provides an incentive for the manufacturer to launch in the most cost-effective indication first to secure a higher ceiling price for future indications.

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Approach 4: First indication considered

- If manufacturers act upon this incentive and are perfectly strategic, then this approach would have the same implications for consumer surplus as Approach 1.
- If manufacturers do *not* act upon this incentive, then in some cases consumer surplus from additional indications will be positive (if a less cost-effective indication is launched first) and in other cases consumer surplus from additional indications will be negative (if a more cost-effective indication is launched first). If the decision as to which indication to launch first is truly random, then a reasonable expectation would be that the *expected* consumer surplus associated with additional indications is zero. This would have equivalent implications for consumer surplus as Approach 3.
- It follows that this approach may be considered as lying somewhere between Approach 1 and Approach 3, with expected consumer surplus ranging between negative (if manufacturers are in any way strategic) to zero (if manufacturers are not strategic at all).

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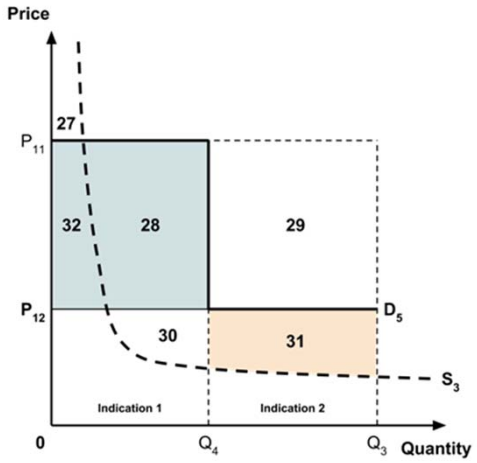
Potential for strategic behaviour



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Objective 1: No health loss across Canada

- The first approach is inconsistent with this policy objective
- The second approach comfortably satisfies this policy objective (since it results in positive overall consumer surplus)
- The third approach only just satisfies this policy objective (since it results in an overall consumer surplus of zero)
- The fourth approach satisfies this policy objective *if manufacturers are not strategic*, but if manufacturers behave strategically then the expectation would be that consumer surplus is negative overall, in which case this approach would *not* satisfy this objective.

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Objective 2: No health loss in any indication

- Both the first and third approaches are inconsistent with this policy objective. This is because both approaches result in diminished population health (negative consumer surplus) in at least one indication.
- The second approach would only just satisfy this policy objective, since consumer surplus is zero in one indication and positive in all others.
- The fourth approach satisfies this policy objective *if manufacturers always launch in the least cost-effective indication first*, otherwise it does not satisfy this objective

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Objective 3: Max health gain across Canada

- The most desirable ceiling price under this policy objective is the lowest ceiling price at which producer surplus is non-zero.
- Depending upon the location of the supply curve, this might be at a ceiling price below P_{12}, leading to greater consumer surplus than that resulting from any of the four approaches considered above.
- However, as before, lowering the ceiling price to extract additional consumer surplus carries a risk that producer surplus may become negative, such that the medicine is not launched and consumer surplus is zero.

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Topic 3: Draft Potential Recommendations

1. **Since indication-specific pricing is not currently feasible, the PMPRB should specify a single ceiling price for each medicine that applies across all indications.**
2. **This ceiling price should be consistent with the government's policy intent with regards to the allocation of consumer and producer surplus.**
3. **The PMPRB should support efforts to develop the necessary infrastructure to allow for indication-specific pricing in future.**

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Topic 4: Accounting for uncertainty

- Options for using the CADTH and/or INESS reference case analyses to set a ceiling price.
- Options for accounting for and/or addressing uncertainty in the point estimate for each value-based price ceiling.

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Topic 4: Summary of Deliberations

- Options for using the CADTH and/or INESSS reference case analyses to set a ceiling price
  - CADTH guidelines (4th edition) describes principle methods, but differences between the CADTH and INESSS reference cases, and between each analyst's consideration of uncertainty, may lead to different point estimates of the ICER
  - PMPRB could specify its own 'reference case', including a preferred 'threshold' & perspective
  - PMPRB could set up a committee to review the economic evidence
  - Price adjustments may be needed as real world evidence changes
- Options for accounting for and/or addressing uncertainty in the point estimate for each value-based price ceiling.
  - CADTH currently reports a range for the reference case ICER, not a point estimate
  - 'Price reduction tables' reported by CADTH not subject to peer review
  - CADTH methods (4th edition) mandate probabilistic analysis
  - Use the expected values or the upper/lower end of the range?

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Topic 4: Conceptual Framework

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Uncertainty

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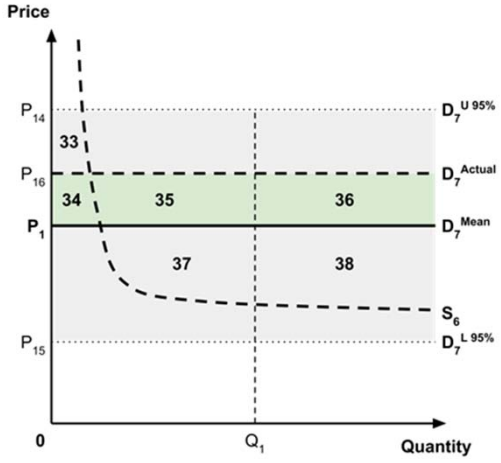
Actual demand curve higher, drug launched



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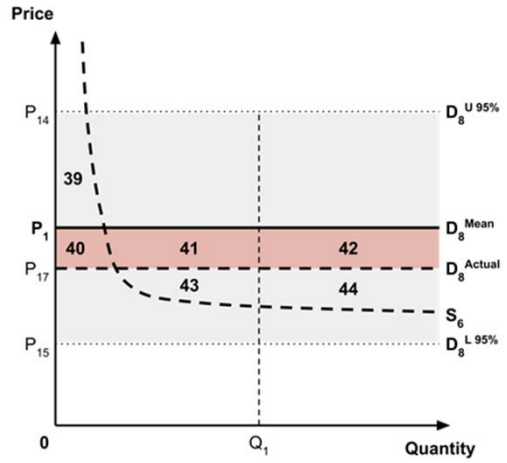
Actual demand curve lower, drug launched



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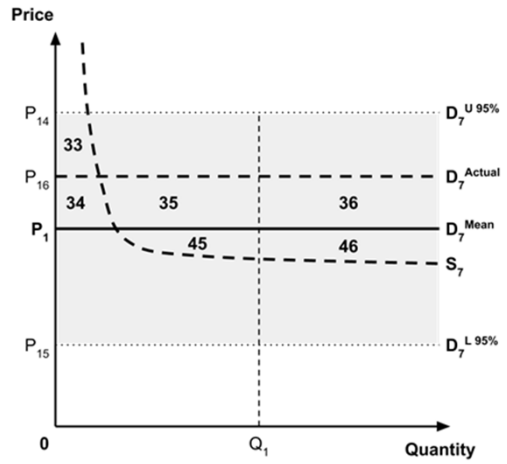
Actual demand curve higher, not launched



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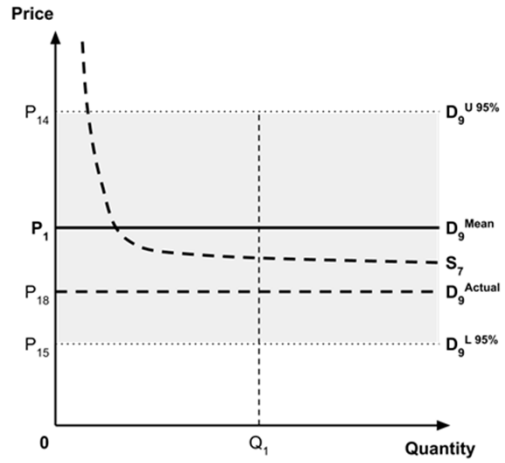
Actual demand curve lower, not launched



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Implications of uncertainty

- If the medicine is launched at a ceiling price coinciding with the expected demand curve then the expected consumer and producer surplus is zero.
- If the medicine is unprofitable at a ceiling price coinciding with the expected demand curve, and is also unprofitable at a ceiling price coinciding with the actual demand curve, then consumer surplus is zero.
- If the medicine is unprofitable at a ceiling price coinciding with the expected demand curve, but would have been profitable at a ceiling price coinciding with the actual demand curve, then the impact of uncertainty is to diminish the total economic surplus such that the impact upon expected consumer surplus at a ceiling price coinciding with the expected demand curve is negative.

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Value of information analysis

- In conventional pharmacoeconomics, the expected loss that results from uncertainty is estimated using 'value of information' (VOI) analysis.
- Since the focus of conventional pharmacoeconomic analysis is making a yes/no decision regarding adoption of a new medicine, conventional VOI analysis considers the expected loss associated with making the 'wrong' decision (e.g. approving a medicine that would otherwise have been rejected, or *vice versa*).
- In the context of the PMPRB using 'pharmacoeconomic value' as a factor when considering the ceiling price for a new medicine, the expected loss as a result of uncertainty comes not from making the 'wrong' yes/no decision, but from setting the 'wrong' ceiling price.

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Value of information analysis

- In principle, VOI analysis could be used to estimate this expected loss, and hence the value associated with obtaining additional sample information for one or more uncertain parameters. The results of these analyses could then be used to apply a reduction to the ceiling price of the medicine to reflect the diminished expected pharmacoeconomic value as a result of uncertainty.
- However, conducting such VOI analyses would require an understanding of the location of the supply curve, since this is required to estimate the expected loss in economic surplus, and in practice the location of the supply curve is unknown. Although, in principle, the supply curve could be modelled with a probability distribution in order to permit VOI analysis to take place, methods for estimating the parameters of such a distribution are undeveloped. It may therefore be infeasible to conduct VOI analyses of this type at the present time.

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Topic 4: Draft Potential Recommendations

1. **The PMPRB should consider its attitude towards risk**
2. **If the PMPRB is risk-neutral, the *expected* values of the incremental costs and QALYs and k should be used when considering the ceiling price**
3. **If the PMPRB is *not* risk-neutral, values above or below the expected values may be appropriate, depending upon the risk attitude**
4. **The value of obtaining additional information for uncertain parameters should not be routinely considered by the PMPRB at the present time**

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Topic 5: Perspective

- Options to account for the consideration of a public health care system vs societal perspective, including the option of applying a higher value-based price ceiling in cases where there is a 'significant' difference between price ceilings under each perspective.
- How to define a 'significant' difference in price ceilings between each perspective.

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Topic 5: Summary of Deliberations

- **PMPRB intervened to state that public payer perspective is preferred**
- Prior to this, the Working Group considered how reforms have implications for private payers and individuals paying out of pocket
- A broad 'societal' perspective is problematic for reasons of principle (e.g. equity) and practicality (specifying productivity, spillover effects, caregiver burden, etc.)
- Concern that excluding productivity would impact private payers
- Cash paying customers will be excluded from the confidential MRP ceiling price
- Benefits to private payers might not be transferred back to end users

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Topic 5: Draft Potential Recommendations

1. **Given the policy intent, the public payer perspective should be adopted**
2. **The PMPRB should be aware of the potential implications of its reforms for private payers and individuals**

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Topic 6: Application of the market size factor in setting ceiling prices

- Approaches to derive an appropriate affordability adjustment to a medicine's ceiling price based on an application of the market size and GDP factors (e.g. based on the US 'ICER' approach).

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Topic 6: Summary of Deliberations

- Different payers have different tolerances for expenditure growth
- In the UK, NICE recently agreed to cap expenditure growth on new medicines by 2% per annum
- Members considered the US ICER approach, which moved away from considering GDP factors when setting prices
- Market size is distinct from 'net budget impact'
- Particular implications for whether orphan drugs are profitable
- Market size not always known at launch (uncertainty)

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Topic 4: Conceptual Framework

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Market size

- The PMPRB has proposed that a 'market size adjustment' may be applied to the ceiling price for some Category 1 medicines. This includes a potential upwards ceiling price adjustment for medicines with small market size and (independently) a potential downwards ceiling price adjustment for medicines with large market size.
- The first of these would have the effect of increasing the producer surplus (at the expense of consumer surplus) for medicines with small market size. The second would increase the consumer surplus (at the expense of producer surplus) for medicines with large market size.

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Without market size adjustment

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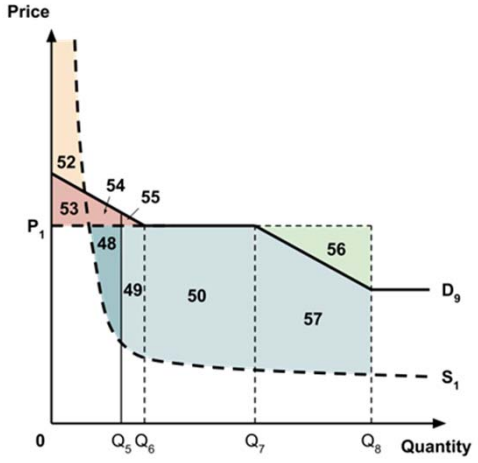
With hypothetical market size adjustment



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Implications of a market size adjustment

- Increased consumer surplus from medicines with large market size
  - The reduction in the ceiling price for medicines with large market size results in an increase in consumer surplus and a reduction in producer surplus
- Reduced consumer surplus from medicines with small market size
  - A higher ceiling price for medicines with small market size results in greater producer surplus and a loss in consumer surplus
  - Since (in this example) consumer surplus was zero prior to the market size adjustment, consumer surplus is now negative for medicines with small market size.
- Increased profitability for medicines with small market size
  - Medicines with a market size between Q5 and Q6, which were unprofitable prior to the market size adjustment, now have positive producer surplus.
  - This might result in greater access to medicines with small market size.

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Potential risks and disincentives

- If the reduction in ceiling price for medicines with large market size is large, then manufacturers may be incentivized to reduce the quantity supplied so as to avoid the reduction in the ceiling price. This risk is particularly acute if the medicine in question has multiple indications, and if pricing across all indications is based upon the least cost-effective indication - as discussed earlier, this pricing approach might already provide an incentive for manufacturers to avoid launching in one or more indications, and the addition of a market size adjustment might exacerbate this risk.
- By providing a higher ceiling price for medicines with low market size, a market size adjustment would also relatively incentivize the development of such medicines. Over time, a reduction in medicines with large market size and an increase in medicines with small market size might result in progressively smaller gains and progressively larger losses in consumer surplus as a result of the market size adjustment.

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Topic 6: Draft Potential Recommendations

1. **The PMPRB should ensure that any market size adjustment results in the MRP changing smoothly with the market size**
2. **The PMPRB should consider the implications for consumer and producer surplus, and ensure these are consistent with the policy intent.**
3. **The PMPRB should consider potential disincentives that might result from application of a market size adjustment**

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