# Modelling of lifecycle pricing in HTA: methodological considerations

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PNS267

## Introduction

- Health technology assessments (HTAs) using cost-utility modelling typically rely on comparison of intervention and comparator(s) prices at time of introduction of the intervention. However, this approach does not take account of changes in price throughout the lifetime of the drug.
- Cost-effectiveness analysis assumes that the price of a drug in real terms will remain constant over time. However, a number of studies have shown that the real price of individual therapies decreases over time.[1,2]
- The long-term price of a drug can be affected by several factors including:[3]
  - On-patent competition from products in the same or related therapeutic classes.
  - Off-patent generic competition.
- Lifecycle pricing may be a bigger determinant of the incremental cost-effectiveness ratio (ICER) than many of the other assumptions currently discussed in HTA decisions.
- It has been proposed that the changes in the costs of a drug over its lifetime should be incorporated into cost-effectiveness analysis.
- Modelling future changes in drug price has the potential to affect HTA outcomes.

## Objectives

- The objective of this study was to assess the methodological arguments for and against consideration of lower future prices of therapies following patent expiration within economic evaluations.

## Methods

- A targeted literature review was performed to identify publications describing factors which affect the long-term cost of drugs and the arguments for and against incorporating changes in costs over the lifetime of a drug into economic evaluations.
- Databases searched included PubMed, Ovid Embase, EconLit, and Google Scholar.

## Results

### Arguments for and against lifecycle pricing in HTA

- There is a large body of evidence assessing the market dynamics of patent expiration and impact on pricing. However, literature on incorporation of these future price reductions within HTA is limited.

**For**

- **Hoyle (2008)[1]:** consideration should be given to the impact of lifecycle pricing in economic models in order to capture the true cost of a new drug.
- **Guertin et al. (2015)[4]:** the likelihood of the ICER being underestimated or overestimated will be dependent on whether the intervention and/ or comparator lose patent protection during the timeframe under consideration in the economic model. Where generic versions of the comparator are already used, overestimation of the ICER will depend on the following factors:
  - Timing of the introduction of generic versions of the intervention.
  - Price difference between the branded drug and the generic version.
  - Discount rate applied to future costs.
- **Lakdawalla et al. (2017)[5]:** drug prices for a wide variety of diseases, including 132 therapeutic classes and 259 drugs, were examined before and after patent expiration in the US.
  - Estimation of the long-term cost of prescription drugs to patients, accounting for patent expiry and medical cost offsets predicted that the average price of a prescription was 6% lower in the year generics entered the market, 55% lower at 5 years, and 71% lower at 10 years, meaningfully lowering the average cost per prescription over the drug's lifetime.
  - Generics captured 33% market share in the year they entered the market and after 5 and 10 years, market share was 74% and 77%, respectively.

**Against**

- **Lee et al. (2016)[6]:** decision makers should only consider whether a technology currently represents a cost-effective use of healthcare resources. Adopting lifecycle pricing may lead to bias in the true estimation of the value of a drug, resulting in sub-optimal allocation of resources.
- However, in the case of chronic conditions, where decisions affect the lifetime of the patient, we cannot consider only current cost-effectiveness as Lee et al. (2016) argue, but should consider cost-effectiveness over the model time horizon.

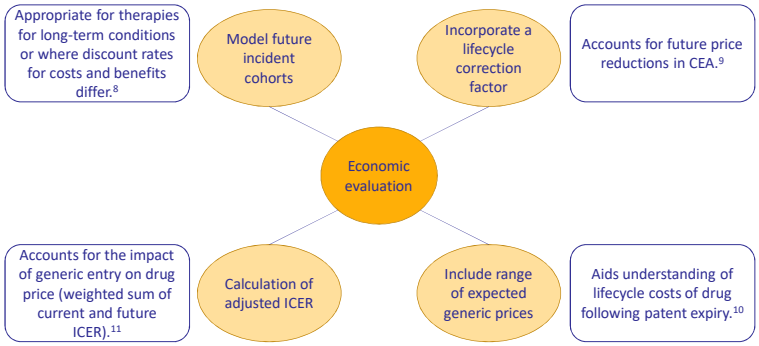
**Sources of uncertainty**

- **Vondeling et al. (2018)[7]:** a published systematic literature review (SLR) assessed the impact of patent expiry on drug prices across a number of countries including the US, Canada, Australia, and the EU5. The findings of the SLR showed that drug prices decrease significantly after patent expiry. However, the extent of price reductions varied by drug and country. Further country-specific research was recommended to reduce uncertainty regarding the prediction of future price developments after patent expiry.

### Proposed methodology

- Proposed methods identified in the literature for incorporating expected price reductions over the lifecycle of a drug are shown in **Figure 1**.

**Figure 1: Methodological considerations for incorporating drug lifecycle price reductions within economic evaluations**




CEA, cost-effectiveness analysis; ICER, incremental cost-effectiveness ratio.

- **Modelling future incident cohorts[8]:** modelling the costs and benefits of all patients who will become eligible for the treatment in the future (future incident cohort) as well as patients who are currently eligible for the treatment (prevalent cohort) will capture all patient-related benefits and costs in cost-effectiveness analysis. Modelling future incident cohorts may be particularly appropriate for therapies for chronic conditions or where the discount rates for costs and benefits differ.
- **Incorporating a lifecycle correction factor[9]:** considers the assumptions made about the pricing of a drug over its lifecycle together with assumptions about the future usage pattern of the drug. These assumptions are incorporated into the cost-effectiveness calculation, accounting for future price reductions in CEA.
- **Including a range of generic prices[10]:** a panel of health economic experts recommended that a range of expected generic prices be included as part of an economic evaluation of a new drug to support understanding of the lifecycle costs of the drug.
- **Calculation of an adjusted ICER[11]:** considers the future cost-effectiveness of a drug. The adjusted ICER is calculated as a weighted average between the current standard ICER and the future ICER when the new drug patent expires. Calculation of a standard ICER may over- or underestimate the cost-effectiveness of drugs with a high level of therapeutic competition, a long off-patent useful life, and strong brand loyalty. Under these circumstances, calculation of an adjusted ICER may be appropriate.

## Conclusion

- Several studies report that drug prices will decrease after patent expiry. However, there is uncertainty in both the extent and timing of price reductions which are likely to vary by both indication and country.
- Focusing only on current drug prices may overestimate the true cost over the lifecycle of the drug and underestimate long-term cost-effectiveness.
- The arguments against inclusion of future price reductions within models appear to be based more on practical considerations of data availability and extent of price reductions to be considered rather than whether inclusion of future price reductions is methodologically appropriate.
- The impact of lifecycle pricing on cost-effectiveness is likely to be dependent on both treatment duration and life expectancy of the modelled population as well as the size of post-patent price reductions.
- There does not appear to be a strong methodological rationale for excluding future price reductions from consideration within all HTAs. We believe that discussion should focus on which HTAs should consider this issue and the magnitude and timing of future price reductions to be modelled.

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