Policy Brief

PB

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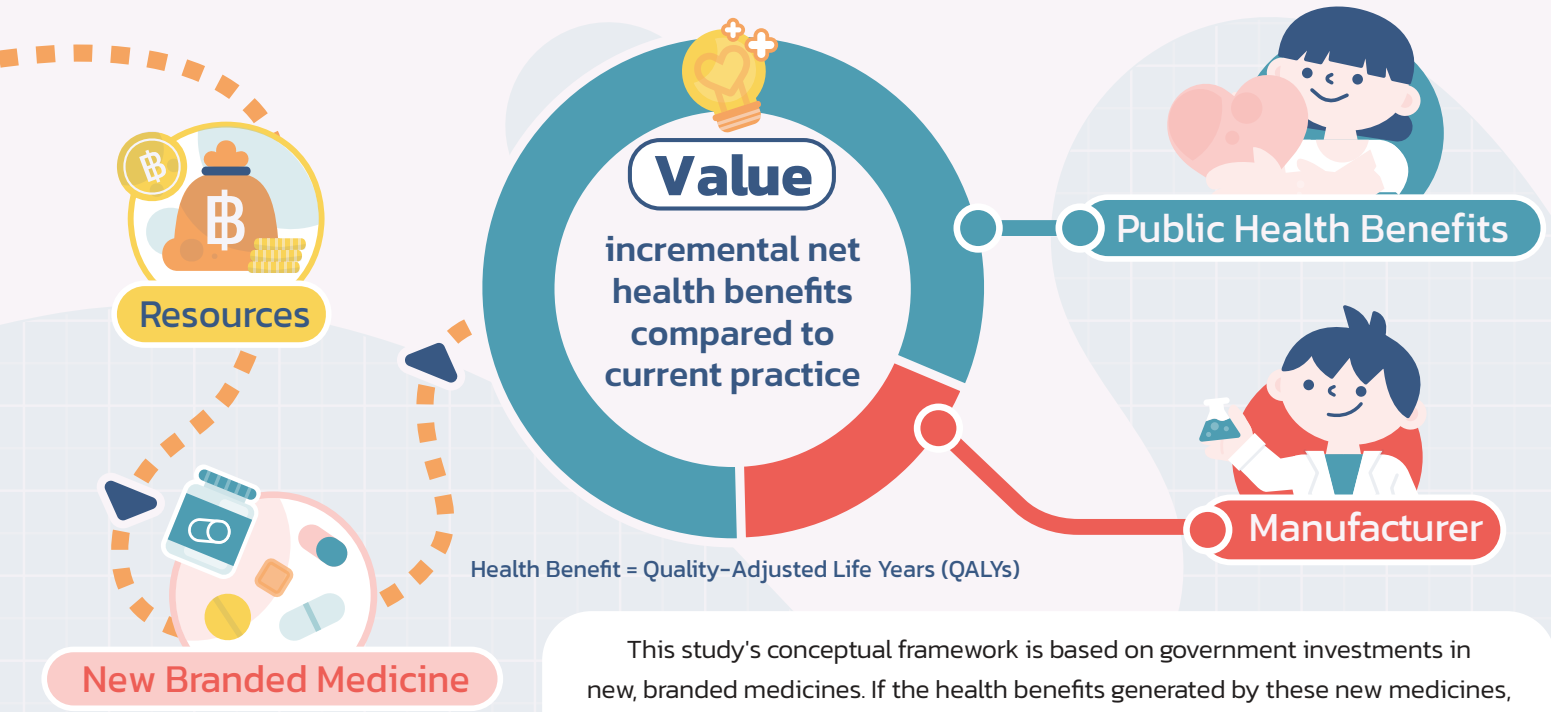
Value Distribution in New Branded Medicines: How Much Benefits Patients Versus Manufacturers?

Highlight

- Thailand has successfully implemented economic evaluation to inform the inclusion of new, branded medicines within its National List of Essential Medicines (NLEM). This method can be used to assess the health value that new medicines will generate for patients after accounting for the health lost due to other healthcare interventions not being funded in order to fund the new medicine.
- New methods for economic evaluation developed by Woods et al. (2021) account for the lifetime value of new medicines, both when the branded version is sold and once generics are available, and enable researchers to determine how much of that lifetime value directly benefits patients in the healthcare system and how much of it goes to manufacturers.
- Thailand applied these new methods for the first time to a low- and middle-income country (LMIC) healthcare system, and was the first country outside the country of origin to apply these methods. The aim was to evaluate how the value of branded medicines funded under the NLEM is distributed between the patients in the Thai healthcare system and originator manufacturers.
- The findings show that in Thailand, delayed adoption of branded medicines and the existence of generic versions result in over 90% of the lifetime value of cost-effective medicines included in the NLEM accruing to the healthcare system with less than 10% going to manufacturers. However, for cost-ineffective medicines included in the NLEM under other considerations, manufacturers accrue more than 100% of the lifetime value in part due to the lack of availability of generic versions of these products to date.

Quantifying value and how it is shared



This study's conceptual framework is based on government investments in new, branded medicines. If the health benefits generated by these new medicines, compared to current treatments, can be quantified, a portion of the benefits will accrue to the originator manufacturer, while the remaining will go to the public.

Study results

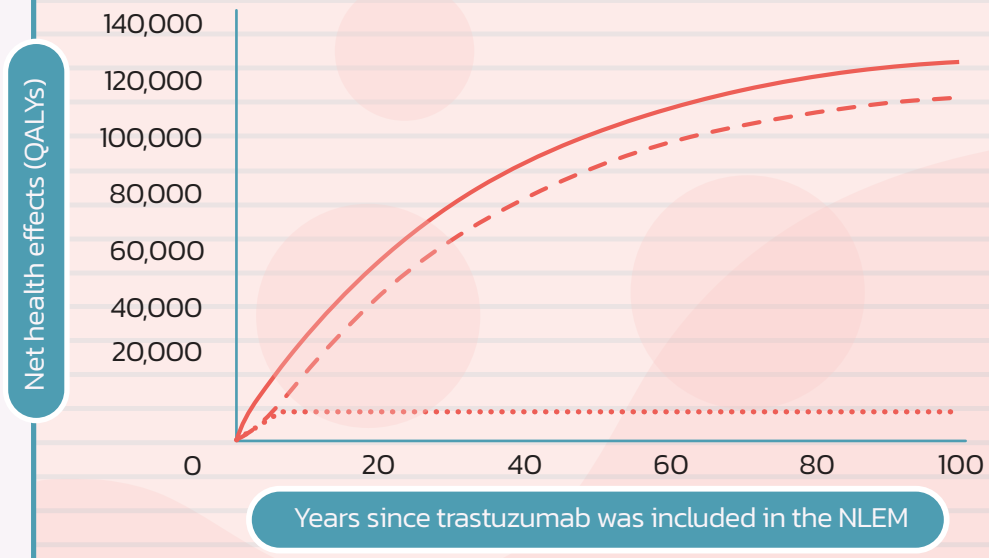
Seven medicines selected from the NLEM's E2 category were categorised into two groups for the analysis based on their cost-effectiveness: 1) cost-effective group 2) cost-ineffective group.

1 Cost-effective medicines

- Factor VIII
- Trastuzumab
- Sofosbuvir + Ledipasvir
- Deferasirox

are cost-effective and results in more **90%** of the overall lifetime value accrues to the population.

Trastuzumab: An example of a cost-effective medicine



Indication
- Patients with early-stage breast cancer

Intervention
- Adjuvant Trastuzumab

Comparator
- Paclitaxel alone

The figure shows an example of a cost-effective medicine, trastuzumab, which **demonstrates a greater share of value accruing to the healthcare system** and a positive long-term impact on population health.

- Total potential net health effects
- Realised population net health effects
- Health forgone due to payments to manufacturers

The HTA report published in 2012 compared the cost-effectiveness of adjuvant therapy with trastuzumab and paclitaxel to paclitaxal alone over a one-year period.

Trastuzumab was included in the NLEM's E2 Category in 2024. It has no patent protection in Thailand, and generic versions have been available since 2019.

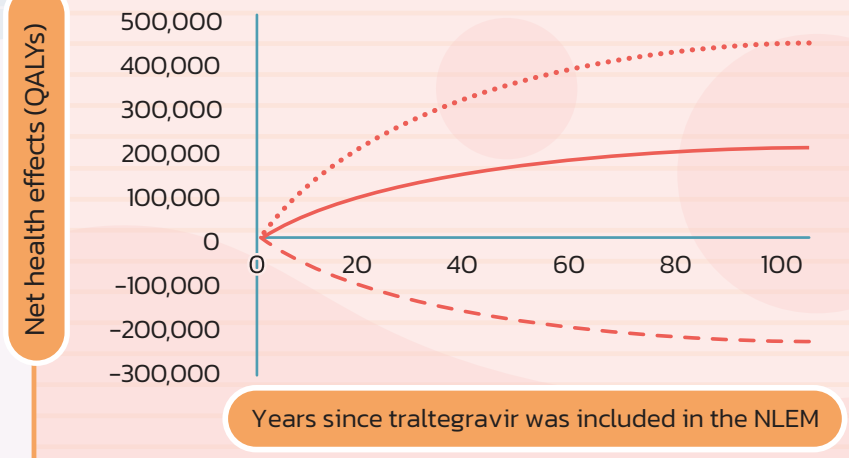
Dasatinib, another cost-effective medicine, presents an unusual exception in that it generates net population health losses over its lifetime. There are net health gains while the originator version is sold, but net health losses once generic versions are sold. This is due to its high non-product costs, such as laboratory tests and follow-up care.

2 Cost-ineffective medicines

Imiglucerase **Raltegravir** are cost-ineffective with manufacturers accruing more than **100%** of the medicines' lifetime value.

resulted in net losses to population health

Raltegravir: An example of cost-ineffective medicine



Indication

HIV patients resistant to the first- and second-time antiretroviral therapies (ARTs)

Intervention

Raltegravir + (DRV/r + TDF + 3TC)

Comparator

DRV/r + TDF + 3TC

The figure shows an example of the cost-ineffective medicine, raltegravir, which **demonstrates a greater share of value accruing to the manufacturer** and a negative long-term impact on population health.

- Total potential net health effects
- Realised population net health effects
- Health forgone due to payments to manufacturers

The HTA report published in 2016 compared the cost-effectiveness of adding raltegravir to a standard regimen (DRV/r + TDF +3TC) to the standard regimen alone.

Raltegravir was included in the NLEM in 2018. It remains under patent protection in Thailand with expected expiry date in 2025. Hence, no generic version is currently available in the market.

DRV/r = darunavir, TDF= tenofovir disoproxil fumarate, 3TC = lamivudine

Limitations of raltegravir

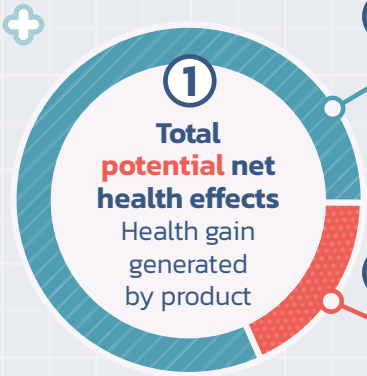
Given the patent protection on raltegravir during the study, a further analysis was conducted to explore the impact of future generic availability. The results indicate that delaying generic availability can lead to continued health losses for the population, even after patent expiration.

About the study

This study applied a framework developed by Woods et al. (2021) to assess how the value of new, branded medicines funded under Thailand's national healthcare is distributed between the healthcare system and manufacturers. The framework uses a lifecycle approach, considering the benefits and costs of these medicines from the time they were included in the NLEM, over the long-term as generic versions of the products may become available.

The study measured the net health benefits over the lifetime of the medicines which account for their direct benefits to the population both while the medicine is sold in as an originator and once generics enter the market.

A positive net health benefit occurs when the expected health benefits of a medicine exceed the health benefits of any healthcare interventions that must be disinvested to fund it. These forgone health benefits represent the opportunity cost of the intervention. In other words, they reflect the value of the health benefits that could have been achieved if the resources allocated to the new medicines had been used for other healthcare interventions.



1. Potential net health effects, referring to the total QALYs generated by medicines over their lifetime if the price for the medicine was zero.

2. Health foregone due to payments to manufacturer refers to the total QALYs forgone due to the price charged by the manufacturer (over and above the cost of production and supply.) Since these payments go to manufacturers, the money can no longer be used to fund other healthcare.

3. Realised population net health benefit are the portion of the potential net health effects (QALYs) that accrues to patients in the healthcare system.

For this study, seven medicines were selected from 35 medicines listed under the E2 category of the NLEM 2022, based on the following criteria: 1) they underwent economic appraisals, 2) only the originators were available at the time of their approval, and 3) the patents for these medicines had either expired or were not granted in Thailand prior to the commencement of this study in 2023. In the case of raltegravir, although it was found that it remained under patent protection after study sample selection, it was still included as a case study.

Data on patent expiration dates were obtained from the Thai Department of Intellectual Property to establish the patent status. Cost and QALYs were derived from the HTA reports used for NLEM inclusion decisions. Market share data for branded and generic medicines was sourced from IQVIA to assess market dynamics.

Scan QR code to follow our research.

This research project, titled "Estimating the shares of the value of branded pharmaceuticals accruing to manufacturers and to patients in the Thai healthcare system", was funded through the University of York internal funding via the Economic and Social Research Impact Acceleration Account and the Policy Support Fund, as well as the Fundamental Fund fiscal year 2024 from the Thailand Science Research and Innovation (TSRI), and the Program Management Unit for Research and Innovation (PMU-B). The objective of this study was to estimate the share of value of the health outcomes currently being given to manufacturers and the public. The project duration was 12 months, spanning from July 2023 to July 2024.

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HITAP Foundation is a research organisation dedicated to studying both the positive and negative impacts of health technologies and policies. Its work supports government health policy decisions, including contributions to the National List of Essential Medicines and the National Health Security Office, as well as evaluations aimed at enhancing public policies.

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