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Health Policy Analysis

Estimating the Shares of the Value of Branded Pharmaceuticals Accruing to Manufacturers and to Patients in the Thai Healthcare System

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ABSTRACT

Objectives: This article aims to inform which pricing policies for new pharmaceuticals will benefit population health most, and which will not, by drawing out the implications of current pricing policy in Thailand for the value that new, branded pharmaceuticals bring to the population.

Methods: We quantify the lifecycle value in terms of net population health gains of 9 new, branded pharmaceutical and indication combinations by evaluating lifetime health gains and reimbursement costs, considering the availability of generics or biosimilars. We then analyze how the value is shared between the population and manufacturers.

Results: Two-thirds of the pharmaceutical and indication combinations generated net population health gains over their lifecycle, with more than 90% of the total potential net health effects benefiting patients within the Thai healthcare system. However, manufacturers received a low proportion of value. Key factors driving these outcomes included delayed adoption of new pharmaceuticals and entry of generics or biosimilars. Conversely, 2 pharmaceuticals that were approved despite being deemed cost-ineffective resulted in net losses to population health.

Conclusions: Quantification of the lifecycle value of new pharmaceuticals can better inform policies that enhance population health. In Thailand, policies that could improve overall population health include earlier adoption of new pharmaceuticals alongside careful price regulation and expedited generic entry. These approaches could also provide mechanisms to signal research and development priorities effectively.

Keywords: cost-effectiveness threshold, economic evaluation, health economics, pharmaceuticals, willingness to pay threshold.

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Highlights

- Quantification of the total potential net health effects of a new, branded medicine over its lifecycle and how these are shared between the population and manufacturers is key to informing the implications of potential changes to pricing policy.
- In Thailand, driven by late adoption and a cost-effectiveness threshold aligned with evidence about opportunity cost and the timely availability of generics or biosimilars, most new, branded medicines that were assessed generated net population health gains over their lifecycle, with the health system gaining large shares of the available value of new medicines.
- Potentially beneficial policies for Thailand include earlier adoption alongside appropriate price regulation and earlier entry of generics.

Introduction

Economic evaluation methods are often used to assess the health benefits and costs associated with new pharmaceuticals, with a view to informing pricing and reimbursement decisions. Benefits and costs are typically summarized as the ratio of incremental cost per incremental unit of health (relative to the next best alternative), which is referred to as the incremental cost-effectiveness ratio (ICER). The decision to fund a new pharmaceutical is often based, in part, on whether the pharmaceutical's ICER is below a threshold value (cost-effectiveness threshold, [CET]) that represents the maximum a country is willing to pay for gains in health.

Concerns have been raised by a number of commentators that this approach does not take account of the value of the pharmaceutical across its lifecycle and, in particular, that it does not account for the benefits of generic and biosimilar products becoming available at much lower prices.¹ Recent developments have extended economic evaluation methods to consider the costs and benefits of

pharmaceuticals across the lifecycle, including

when generics/biosimilars may become available and how to quantify how the overall benefits of new pharmaceuticals are shared between patients in the healthcare system and manufacturers.²

To date, this framework has been applied only in the United Kingdom.² This article applies the framework to a sample of pharmaceuticals assessed for inclusion in the Thai National List of Essential Pharmaceuticals (NLEM) to estimate how value is shared between manufacturers and patients in the Thai healthcare system. Thailand is one of the few middle-income countries with established universal healthcare coverage (UHC) and a health technology assessment (HTA) system to inform the UHC benefit package, including pharmaceuticals. Policymakers in Thailand, as elsewhere, are under pressure to raise the CET used to evaluate new pharmaceuticals.³ There is a need to understand the implications of current pricing policy in Thailand for how value is shared between the population and manufacturers. This, in turn, can help inform an understanding of the implications of

potential changes to pricing policy, including changing the CET and the use of alternative solutions to ensure that value is shared fairly.⁴

Methods

Following the framework developed by Woods et al² (2021), we measure value using net health effects. We calculate the total potential net health effects a new, branded pharmaceutical offers over its lifetime and report the portion that goes to patients (ie, the total realized net health effects) and the portion that goes to manufacturers (ie, health forgone because of payments to manufacturers).

Total Potential Net Health Effects

Total potential net health effects for a new branded pharmaceutical represent the value the healthcare system stands to gain from a product if it were sold at the cost of manufacturing and supplying it throughout its lifecycle. This is calculated as the incremental health gain from the drug Δh less its opportunity cost:

$$\Delta h - \frac{\Delta np}{k} - \frac{\Delta mc}{k} \quad (1)$$

Health opportunity costs arise because funding for healthcare is scarce relative to needs; therefore, funding a drug prevents that same money from being used to fund other healthcare. The opportunity cost of a pharmaceutical is the health that could otherwise have been gained if the money required to fund the new pharmaceutical was spent elsewhere in the healthcare system. Health gains are measured in terms of quality-adjusted life-years (QALYs). The drug's incremental nonproduct cost Δnp and the cost of manufacturing and supplying it Δmc are converted into health opportunity costs using an estimate of the opportunity cost of expenditure on healthcare, k . In line with Thai guidance on perspective,⁵ nonproduct costs include medical costs associated with use of the medicine, direct nonmedical costs, and indirect or productivity costs (see [Appendix A](#) in [Supplemental Materials](#)).

The equation below calculates the total potential net health effects over the lifecycle of the pharmaceutical accounting for the size of the population n in each year t . r is the annual discount rate for comparing health interventions accruing benefits and costs over different time frames:

$$\sum_{t=1}^{T=\infty} \frac{n_t}{(1+r)^t} \left(\Delta h - \frac{\Delta np}{k} - \frac{\Delta mc}{k} \right) \quad (2)$$

Total Realized Net Health Effects

The total realized net health effects represent the portion of the total potential net health effects that goes to patients, reflecting the actual price paid for the pharmaceutical (whether it is supplied by the originator manufacturer or generic/biosimilar company). Manufacturers typically charge a price premium additional to the cost of manufacturing and supply to account for research and development (R&D) costs, marketing costs, and profits for shareholders. This is also calculated as the incremental health gain from the pharmaceutical Δh less its opportunity cost. The opportunity cost to the healthcare system arises from the pharmaceutical's incremental price Δp and incremental non-product cost Δnp :

$$\Delta h - \frac{\Delta p}{k} - \frac{\Delta np}{k} \quad (3)$$

The portion of the market purchasing the new, branded pharmaceutical, ρ_t , declines once generics/biosimilars enter the market. The equation presented here departs slightly from the presentation in Woods et al² (2021) but is technically equivalent. This parameterization enables the use of data on the proportion of total sales for each pharmaceutical that are generic versus branded in each year. For the portion of the market purchasing the branded pharmaceutical ρ_t , the pharmaceutical's incremental price Δp is used. For the portion of the market purchasing the generic/biosimilar, $1 - \rho_t$, the generic/biosimilar is assumed to be sold at the cost of manufacturing and supplying. This rests on the assumption that a competitive market operates for generics/biosimilars. Across the lifecycle, total realized net health effects are therefore as follows:

$$\sum_{t=1}^{T=\infty} \frac{n_t}{(1+r)^t} \left\{ \rho_t \left(\Delta h - \frac{\Delta np}{k} - \frac{\Delta p}{k} \right) + (1 - \rho_t) \left(\Delta h - \frac{\Delta np}{k} - \frac{\Delta mc}{k} \right) \right\} \quad (4)$$

Health Forgone Due to Payments to Originator Manufacturer

The originator manufacturer gains the portion of value arising from the incremental price paid for the pharmaceutical Δp less the cost of manufacturing and supplying it Δmc :

$$\frac{\Delta p - \Delta mc}{k} \quad (5)$$

Over the pharmaceutical's lifecycle, the originator manufacturer only accrues value while the branded version is sold. Therefore, the health forgone due to payments to the originator manufacturer over the lifecycle of the pharmaceutical reflects only the portion of the market that purchased the branded pharmaceutical in each year.

$$\sum_{t=1}^{T=\infty} \frac{n_t}{(1+r)^t} \rho_t \left(\frac{\Delta p - \Delta mc}{k} \right) \quad (6)$$

For all pharmaceuticals, the analysis begins from 2014 or the year that a drug is approved for inclusion in the NLEM if it is after 2014.

Scenario Analyses

Earlier generic entry

The patent for Raltegravir in Thailand is due to expire at the end of 2025,⁶ and generics are already available in other countries in the region, such as India. We undertook a scenario analysis in which it is assumed that a generic version of Raltegravir becomes available in Thailand in 2026. The proportion of the market that is generic in each year after entry follows the average year-on-year change in this proportion observed for drugs for which we have these data (see [Appendix B](#) in [Supplemental Materials](#)).

Earlier adoption

Trastuzumab was approved for treating early-stage breast cancer in Thailand in 2014 and entered the market that year. This represents later adoption than in other countries, such as the United Kingdom.⁷ We compare a scenario in which adoption is delayed (meaning that there is no access to Trastuzumab over a 5-year period in which there could have been) and earlier adoption (for which there are 5 additional years of access to Trastuzumab, but at originator prices). For both

scenarios, generics are assumed to enter the market in 2019. The analysis is detailed in [Appendix C](#) in [Supplemental Materials](#).

Data

We assessed pharmaceuticals approved for inclusion in the NLEM under the E2 category, which includes pharmaceuticals that are of high cost and/or expected to have high budget impact for the Thai healthcare system but are important for groups of patients.⁸ To be included in our analysis, pharmaceuticals must have undergone an economic appraisal to inform the inclusion decision and must have been under patent or have no generics available at the time of the appraisal.

We extracted data on incremental costs (split between product and nonproduct costs), health benefits, and patient numbers from HTA appraisals undertaken by the Health Intervention and Technology Assessment Program Foundation in Thailand (see [Appendix A Table 2](#) in [Supplemental Materials](#)). Health Intervention and Technology Assessment Program is a nonprofit organization, which develops and applies methods for economic evaluation in Thailand and undertakes economic evaluation to inform the inclusion of pharmaceuticals in the NLEM. Product costs in HTA reports reflect the prices offered by the respective pharmaceutical company to the Thai government, accounting for economies of scale if the pharmaceutical is included in the NLEM. These prices are used in economic evaluations but remain subject to negotiation if the pharmaceutical is deemed not to represent value for money or if its budget impact is considered too large for the government to accommodate. The proportion of the market that was generic versus branded in each year was informed by sales volumes data from IQVIA reflecting the volumes sold to public and private hospitals. We assume that the market share also applies to other markets in which the pharmaceutical is sold. In cases in which it was necessary to extrapolate the likely trajectory of branded market share, we applied the average year-on-year change observed across pharmaceuticals for which these data were available (see [Appendix B](#) in [Supplemental Materials](#)). Patent dates were obtained from the Thai Department of Intellectual Property database providing contextual information about the pharmaceuticals market in Thailand.

Obtaining robust evidence on the incremental cost of manufacturing and supply for pharmaceuticals is inherently challenging because of the lack of publicly available data. IQVIA price data are used to provide informative sensitivity analysis for this parameter. See [Appendix D](#) in [Supplemental Materials](#) for base-case values and assumptions and sensitivity analysis.

A measure of opportunity cost k is required to estimate the health forfeited in the wider healthcare system because of payments for a pharmaceutical. To date, no study has been conducted to empirically estimate k using domestic Thai data. Thailand's CET is 160 000 THB, which has been used in making coverage decisions for NLEM E2 since 2013.^{4,9} This threshold falls within the range of estimates of k for Thailand from international data (51 036–279 451 THB).^{10,11} We therefore assume k is equal to 160 000 THB and vary this in a sensitivity analysis (see [Appendix E](#) in [Supplemental Materials](#)).

Costs and health effects are discounted at 3%, as recommended by the Thai guidelines.¹² We assume a lifecycle of 100 years following the same logic applied by Woods et al² (2021) that after 100 years any additional value generated by the drug will be minimal because of discounting.

Results

We obtained data for all parameters for 7 pharmaceuticals, of which 1 was indicated for use in 3 separate patient groups, resulting in 9 pharmaceutical-indication combinations ([Table 1](#)). In 5 of the indications considered, the new pharmaceuticals were cost saving according to the HTA reports. Among the other 4, 2 had ICERs below the CET used at the time of evaluation, whereas 2 had ICERs that exceeded the CET. Imiglucerase (an orphan drug for treating Gaucher disease in children) had an ICER more than 9 times higher than the CET. Gaucher disease is considered an ultrarare disease with approximately 5 children per annum expected to receive this treatment in Thailand. Raltegravir (for treating human immunodeficiency virus infection and acquired immune deficiency syndrome, HIV/AIDS), had an ICER double the CET used at the time of evaluation. There is currently no generic available in Thailand for either pharmaceutical.

[Figure 1](#) shows the cumulative total potential net health effects, realized population net health effects and health forgone because of payments to originator manufacturer over time from pharmaceutical approval to 100 years. The black line represents the total potential net health effects. In cases in which this is more than 0, there is potential for the pharmaceutical to improve overall population health. The realized population net health effects are shown in the long-dashed line. In cases in which this is more than 0, population health is increased by approval of the pharmaceutical under current pricing arrangements, and conversely in cases in which this is less than 0, funding the pharmaceutical on the NLEM reduces overall population health. The short-dashed line shows the health forgone because of payments to the originator manufacturer.

Total potential net health effects are positive for most drugs. For Trastuzumab, between 90% and 100% of the potential net health effects are accrued to patients in the healthcare system for home-based delivery of factor VIII and IX for treatment of early bleeding episodes at home for mild, moderate, and severe hemophilia indications and Sofosbuvir + Ledipasvir ([Table 2](#)). Generics entered the market 5 years after Trastuzumab was approved for inclusion in the NLEM, in the first year of sales under the NLEM for home-based delivery of factor VIII and IX for treatment of early bleeding episodes at home, and within 2 years for Sofosbuvir + Ledipasvir.

For Imiglucerase, total potential net health effects are close to 0. This reflects the fact that the lifetime QALY gains are only just enough to make up for the opportunity cost incurred by the pharmaceutical's high lifetime nonproduct cost. As a result, for the health gains from Imiglucerase to outweigh any health losses incurred through the opportunity cost of its purchase price and nonproduct costs, the purchase price would need to be close to 0. Instead, the price paid over a patient's lifetime totals roughly 6 million Thai baht, meaning the realized population net health effects are negative. Although Imiglucerase is not under patent in Thailand, no generic version exists, and there is no expectation that one would come onto the market; therefore, the share of the market that goes to the originator manufacturer remains at 100% over the lifetime of the drug.

There is more potential for the healthcare system to benefit from Raltegravir than Imiglucerase. However, the health forgone because of its high product cost (2.9 million Thai baht over a patient's lifetime) outweighs the health gained, resulting in negative realized net health effects.

Table 1. Characteristics of included drugs (in descending order by ICER).

Drug name	Indication	Annual patient population	Duration of therapy	ICER approved at (THB/QALYs)	CET at time of appraisal	NLEM inclusion year	Generic entry year	Notes	Years sold following NLEM approval before generic entry
Imiglucerase	Symptomatic Gaucher disease type I in children	5	Lifetime	1 184 128	120 000	2013	NA		
Raltegravir	HIV patients resistant to the first- and second-line antiretroviral therapies (ARTs)	733	Lifetime	332 227	160 000	2018	NA	*	
Trastuzumab	Early-stage breast cancer	1761	Time-limited-Continuous	118 572	160 000	2014	2019		5
Factor VIII and IX concentrate (mild)	Mild factor deficiency for both Hemophilia A and B	880	Lifetime	80 542	120 000	2015	2015	†	0
Deferasirox	Transfusion-dependent Thalassemia with iron overload in patients who are more than 6 years old after the failure of deferiprone treatment	64 786	Lifetime	-111 433 (cost saving)	160 000	2018	2019		1
Sofosbuvir and Ledipasvir	Hepatitis C virus (HCV) genotype 3	3726	Time-limited continuous	-165 563 (cost saving)	160 000	2016	2018	‡	1
Factor VIII and IX concentrate (moderate)	Moderate factor deficiency for both Hemophilia A and B	1520	Lifetime	-412 206 (cost saving)	120 000	2015	2015	†	0
Factor VIII and IX concentrate (severe)	Severe factor deficiency for both Hemophilia A and B	1600	Lifetime	-680 801 (cost saving)	120 000	2015	2015	†	0
Dasatinib	Chronic myeloid leukemia (CML) resistant to standard-dose Imatinib (400 mg/day)	1460	Lifetime	-752 776 (cost saving)	120 000	2015	2023	†	8

CET indicates cost-effectiveness threshold; ICER, incremental cost-effectiveness ratio; NA, not applicable; NLEM, national list of essential medicines; QALY, quality-adjusted life-year.

Retrieved from UNITAID MPP.⁶

*Patent protected until 2025.^{1,2}

†Originator entered the market in 2014, before NLEM approval, which may indicate that it was sold under other insurance schemes.

‡Originator entered the market in 2017, analysis begins from 2017 for this drug.

There is also potential for the healthcare system to benefit from Deferasirox. It is the only drug in the analysis for which the realized population net health effects are greater than total potential net health effects for the lifetime of the drug. This anomalous finding results from the fact that both

the product and nonproduct costs used in the HTA are lower than those for the comparator, Deferrioxamine. Deferrioxamine is administered via injection over a period of hours and resultingly has both more direct and indirect medical costs.

Figure 1. Value shares over time. (A) Cumulative total potential net health effects, realized population net health effects, and health forgone because of payments to originator manufacturer. (B) Sensitivity analysis around generic availability for Raltegravir. (C) Sensitivity analysis around early adoption of Trastuzumab.

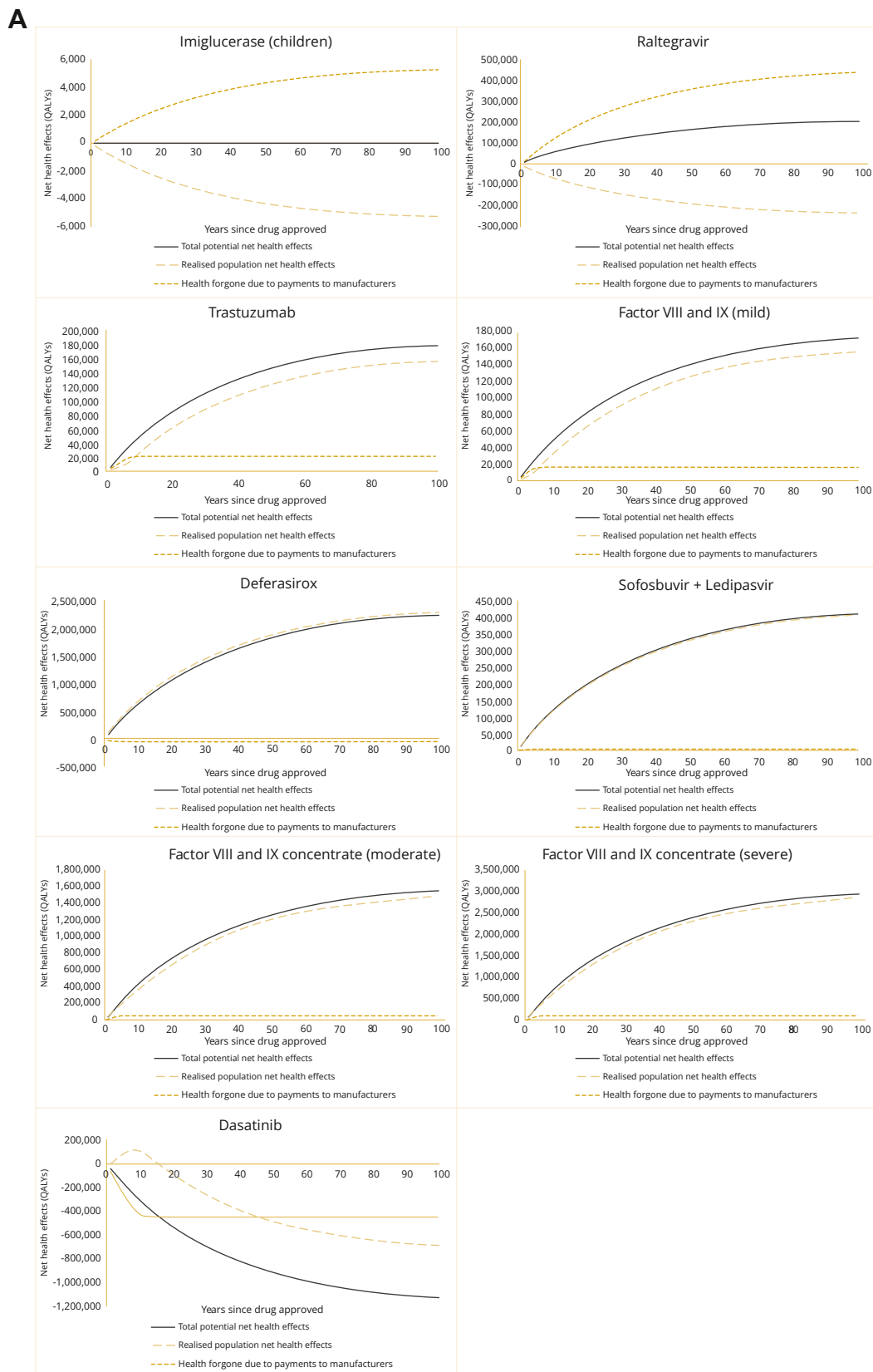
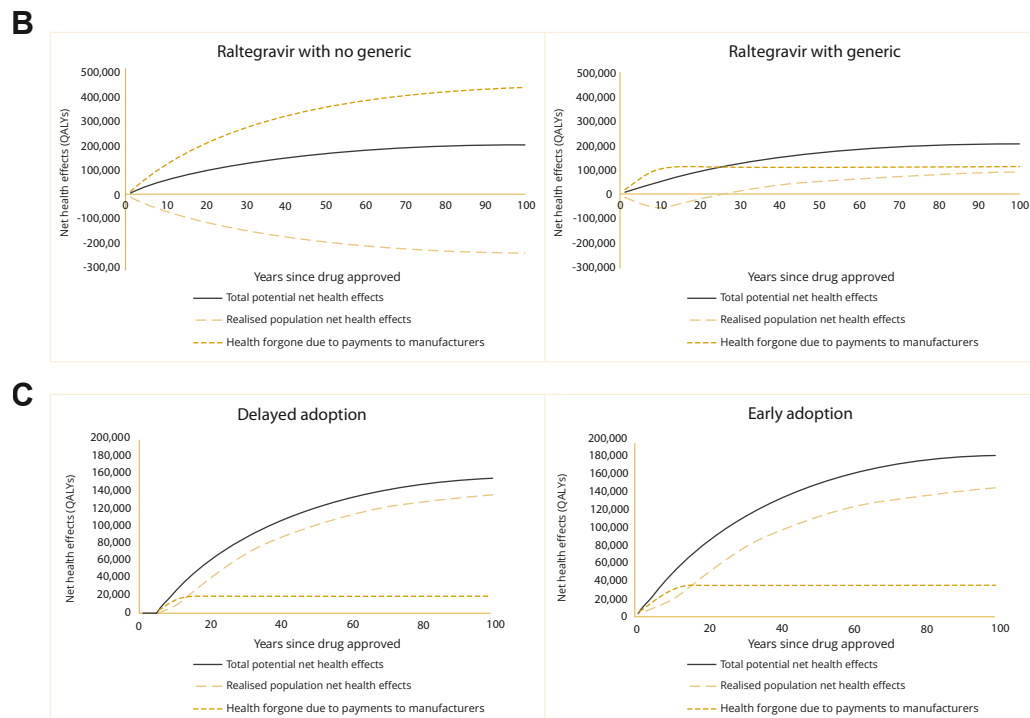


Figure 1. Continued



The total potential net health effects for Dasatinib are negative because the health forgone because of its high incremental nonproduct costs outweighs the incremental health gains it generates. Despite this, the realized population net health effects for Dasatinib are positive while the branded version is sold. This occurs because its product price is lower than that of the comparator pharmaceutical (Imatinib). However, in the postpatent period when generic Dasatinib is compared with generic Imatinib, this cost saving no longer occurs, and over its lifecycle, Dasatinib is associated with negative realized population net health gains. This is an interesting result because at the time of the HTA, Dasatinib dominated its comparator (ie, offered cost savings and health gains), and it emphasizes the importance of considering the costs and benefits of reimbursing pharmaceuticals across the lifecycle.

The results of applying different assumptions for the incremental cost of manufacturing and supply are reported in [Appendix D](#) in [Supplemental Materials](#). Underestimating the cost of manufacturing risks overestimating the total potential net health effects. However, as the health value of the cost of manufacturing is subtracted from both the realized population net health effects and the health forgone to payments to the originator manufacturer, it has a relatively small impact upon how value is shared between patients in the population and manufacturers (see [Appendix D](#) in [Supplemental Materials](#) for a full discussion of these results).

As shown in [Appendix E](#) in [Supplemental Materials](#), varying k has a significant impact on the magnitude of realized net health effects, although for all but 1 pharmaceutical in our sample, these remained positive if they were positive in our base case (see [Appendix E](#) in [Supplemental Materials](#) for a full discussion of these results.)

Scenario Analyses

Earlier generic entry

In the absence of a generic for Raltegravir entering the market in Thailand, the manufacturer obtains 215% of the value of the drug (more than twice the total potential value the drug is forgone to the manufacturer). However, in the scenario in which a generic version of Raltegravir enters the market in 2026, the manufacturer would accrue 55% of the share of the total potential value of the drug with the remaining 45% accruing to patients. [Figure 1B](#) compares the scenario without and with a generic.

Earlier adoption

As shown in [Figure 1C](#), under the current context of delayed adoption, a greater portion of the overall value of Trastuzumab is accrued to the healthcare system, 88% compared with 80% under the earlier adoption scenario. However, under the delayed adoption scenario, the realized population net health benefits are lower, 135 926 compared with 145 779 under the earlier adoption scenario. There is a population net health benefit from earlier adoption of cost-effective pharmaceuticals, as well as a benefit to the manufacturer. See [Appendix C](#) in [Supplemental Materials](#) for details.

Discussion

Informing which pharmaceutical pricing policies will benefit population health the most requires understanding how value is currently shared between manufacturers and patients in the population and how different potential policies could alter this. Our analysis of 9 originator pharmaceutical-indication combinations assessed under E2 criteria and approved for inclusion in the NLEM found that two-thirds generated net population health

Table 2. Estimated share of value (in descending order by ICER).

Drug	Incremental non-product costs (THB)	Total potential net health effects (QALYs)	Realized population net health effects (QALYs)	Health forgone due to payments to manufacturer (QALYs)	Share accrued to the healthcare system (%)	Share accrued to originator manufacturer (%)
Imiglucerase (children)	166 968	64	−5333	5397	−8370	8470
Raltegravir	94 664	206 323	−237 105	443 427	−115	215
Trastuzumab	223 145	181 339	159 159	22 180	88	12
Factor VIII and IX concentrate (mild)	−502 573	170 733	155 010	15 723	91	9
Deferasirox	−24 364	2 239 890	2 295 430	−55 541	102	−2
Sofosbuvir and Ledipasvir	−301 679	410 557	408 649	1909	1	0
Factor VIII and IX concentrate (moderate)	−4 078 981	1 556 545	1 496 342	60 203	96	4
Factor VIII and IX concentrate (severe)	−7 717 764	2 949 321	2 871 031	78 289	97	3
Dasatinib	4 176 023	−1 129 045	−684 698	−444 347	*NA	*NA
Raltegravir (if generic available)	94 664	206 323	92 685	113 637	45	55

NA indicates not applicable; NLEM, national list of essential medicines; QALY, quality-adjusted life-year.

*NA for drugs for which the total potential net health effects are negative. In this case, there is an argument to not include the drug in the NLEM, and it is possible that the total realized net health losses will exceed the potential net health losses (as is the case for Dasatinib).

gains over their lifecycle, with more than 90% of the total potential net health effects accruing to patients within the Thai healthcare system. The 2 pharmaceuticals that were approved despite being found to be cost-ineffective resulted in net losses to population health. One pharmaceutical had negative potential net population health effects due to its incremental nonproduct costs.

The variation in realized population net health effects across products may reflect processes, policy choices, and market conditions that affect the pricing and timing of adoption of new pharmaceuticals. For example, Thailand is a relatively late adopter of new pharmaceuticals compared with many high-income countries. This has the effect of reducing the period over which Thailand pays for the branded version of the pharmaceutical, increasing realized population net health effects and the share of total potential net health effects that accrue to the population. Furthermore, in Thailand, manufacturers submit a price to the Ministry of Public Health before the HTA process begins. An HTA is then commissioned by the Health Economics Working Group including an economic evaluation of the drug, which is undertaken independently.^{9,13} With limited information a priori of the findings of the economic modeling conducted within the HTA, manufacturers may not have a good sense of what the highest “cost-effective” price that can be charged is and therefore price conservatively to improve their chances of approval. Lower prices reduce the amount of health forgone to manufacturers, increasing realized population net health effects.

Woods et al¹⁴ (2024) suggest that the optimal share of the value of new pharmaceuticals to offer to manufacturers to incentivize socially optimal levels of R&D under coordinated global pricing is roughly 20% (range: 6%–51%). Although this benchmark provides a reference point for interpreting national value shares within the global context, it should not be viewed as a target for any single country. If a country is paying too high a share (as was found in the United Kingdom²), unilateral price reductions (achieved through policies such as encouraging the development and promoting the use of generics or lowering the CET) may be warranted to align with the national objective to improve population health. However, for an individual country,

such as Thailand, which represents a small fraction of the global market, unilaterally raising prices to meet this benchmark would be an inefficient policy. It would be unlikely to meaningfully influence global R&D incentives, while certainly reducing population health by imposing high opportunity costs on the Thai health system. Therefore, for products with a low manufacturer's share, our study results suggest that the CET (the policy threshold used to assess whether the product's ICER was deemed cost-effective or not⁴), should not be adjusted upward to meet an external benchmark. Instead, the CET should primarily reflect the health opportunity cost within Thailand. To address the systemic lack of innovation incentives for lower-revenue markets, solutions lie in international collaboration and collective negotiation, as exemplified by the Medicines Patent Pool, a centralized form of voluntary licensing.¹⁵ These models decouple R&D funding from high prices in individual countries, ensuring that innovation is appropriately incentivized while safeguarding access and population health in lower-revenue settings. Further research on this would be valuable.

Policies such as earlier adoption of new pharmaceuticals, raising the CET so that more pharmaceuticals meet the approval criteria and earlier generic entry have been raised in Thailand as potential levers to improve population health and access to new pharmaceuticals.^{3,8} As observed in the scenario analysis for Trastuzumab, earlier adoption of the originator can benefit both manufacturers and population health under the condition that the pharmaceutical's ICER is below the estimated opportunity cost threshold. As such, when considering policies to promote early adoption, health systems should consider carefully how the additional value generated by early adoption should be shared. A desired share can be achieved through use of appropriate CETs in the context of early adoption, or other forms of price regulation (as a reduced price will mean a higher share goes to patients).

Thailand has raised its CET twice since it was first decided at 100 000 THB per QALY in 2008.³ Although we did not model changes in the CET itself, our results suggest that if a higher CET were to lead to higher prices, a greater portion of the potential net health effects would be forgone to manufacturers, underscoring the importance of aligning pricing and threshold policies

with opportunity costs. Currently, the CET used for decision making in Thailand is relatively close to the best available estimate of the opportunity cost of healthcare spending in Thailand.^{3,9,10} Evidence from this study was presented at a public policy forum on CET in Thailand. It served as a key input for the policy statement issued in January 2025 by the decision-making bodies responsible for developing the country's UHC benefit packages for pharmaceuticals and medical devices in collaboration with relevant stakeholders, which recommended that the current CET of 160 000 THB per QALY gained be maintained and that future adjustments to the CET should be based on robust academic evidence, particularly estimates of health opportunity costs within the Thai health system.

Adoption of policies to encourage earlier generic entry may improve realized population net health effects (as demonstrated by the scenario analysis for Raltegravir). In cases in which it is unlikely that a generic will be developed (eg, as may be the case for some biologic or specialist drugs), there is a case to negotiate lower prices for originator drugs. Crucially, approving a drug for inclusion in the NLEM that is cost-ineffective at the originator price reduces overall population health. If it is not possible to reduce the price such that the lifetime realized population net health benefits are not negative, then approval could be reserved for the most cost-effective subgroups, delaying access for other subgroups (or all patients) until a cost-effective generic version is available, or, as a last resort, compulsory licensing.^{16–18}

Another consideration when determining appropriate pricing policy, is the potential for impacts on companies' decisions to launch products within the Thai market. The argument that low shares for manufacturers could reduce the likelihood of new products being launched in Thailand presumes that manufacturers make launch decisions based on expected returns. However, because pharmaceutical R&D costs are sunk by the time of launch and because originator prices typically far exceed marginal production costs, as demonstrated by large price drops after generic entry, it is unlikely that small differences in value share would deter launch in the short term. Nevertheless, this remains an empirical question and deserves further research. Importantly, any potential benefits of additional launches resulting from a higher CET must be weighed against the system-wide health losses incurred from higher prices across all products. Understanding and monitoring the share of value accruing to manufacturers and patients remains critical to designing policies that support both population health and sustainable access to innovation.

Our study highlights the importance of considering net health effects over the lifecycle of a new pharmaceutical. At the point of launch, Dasatinib is cost-effective compared with Imatinib because of its lower product costs; however, once biosimilars are available for both medicines, Dasatinib is no longer cost-effective because of its high nonproduct costs. The lifecycle negative realized population net health gains associated with approving Dasatinib could be mitigated by reverting to the use of Imatinib in the long run, but this would require consideration of these lifecycle effects and a mechanism for reappraisal or revision of recommendations that have been made. Guidance on general principles for decision makers to develop proportionate processes in the context of evolving treatments, prices, and evidence can be found in Woods et al.¹⁹ Historically, the CET has been used to negotiate new prices with manufacturers; the lifecycle approach could help provide more comprehensive information for future negotiations around price and the timing of access.⁹ However, this would require additional assumptions and extrapolation to predict key aspects of lifecycle value, such as when biosimilars/generics are likely to become available and how much they might cost.

The case of Imiglucerase, an orphan drug used to treat Gaucher disease in children, raises important considerations for the application of standard value attribution frameworks to rare disease treatments. Deliberative processes can help incorporate additional attributes of value, such as disease severity, lack of alternatives, and ethical obligations to identifiable patients, which fall outside traditional cost-effectiveness analysis.^{20,21} However, it is essential that these deliberations reflect societal preferences regarding the trade-offs between those who benefit from treatment and those who bear the opportunity costs.²² Evidence from economic evaluations can support the transparency of these processes by making such trade-offs explicit.²¹ Recent experience in Thailand illustrates how market dynamics can alter these trade-offs: the introduction of Velaglucerase, a therapeutic equivalent, led to a reduction in the price of Imiglucerase by more than 25%, and a Velaglucerase-first treatment policy is now likely. These developments highlight the importance of fostering competition even in markets for rare diseases.¹⁸

Our analysis has some limitations. Assumptions were required to extrapolate disease incidence and generic/biosimilar market share data over time. Additionally, our analysis uses HTA-submitted or appraised prices. These may be subject to further negotiations between government and manufacturers after the HTA, and if lower prices are negotiated, our analysis will underestimate value to the healthcare system and overestimate value to the manufacturer. In Thailand, for medicines deemed to be cost-effective, the submitted price generally becomes the final price because no further negotiation is required.⁴ In contrast, for medicines found to be cost-ineffective, price negotiations, which may involve volume-based discounts, may occur to bring the product into alignment with cost-effectiveness requirements. Furthermore, we assume k does not vary over time. Finally, Thai guidelines for HTA recommend taking a societal approach when undertaking economic evaluation. Reporting costs falling on the healthcare system and on individuals separately would enable fuller consideration of opportunity costs associated with a pharmaceutical's approval.

Conclusions

The framework provides a novel way to assess the value of a pharmaceutical being considered for inclusion in the NLEM. In Thailand, for many pharmaceuticals the combination of late adoption and timely entry of generics means that overall population health is improved by most cost-effective pharmaceuticals that are funded on the NLEM, but a low proportion of value goes to manufacturers. Within Thailand, policies to promote early generic entry would improve realized net population health effects, as would policies promoting earlier adoption of new pharmaceuticals under certain conditions.

Author Disclosures

Author disclosure forms can be accessed below in the [Supplemental Material](#) section. The views expressed are those of the authors and not necessarily those of the funders.

Supplemental Material

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