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CAFE WORKING PAPER NO.36

Centre for Accountancy, Finance, and Economics (CAFE)

The role of Health Technology Assessment in reimbursement decisions and pricing of new medicines across diverse healthcare systems

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June 2025

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Abstract

The rising costs of innovative medicines present a major challenge for public healthcare systems, particularly in countries striving for universal health coverage. Health Technology Assessment (HTA) is critical in guiding reimbursement decisions and negotiating medicine prices, particularly in monopoly markets where pharmaceutical companies hold exclusive rights due to patent protection. This study examines how eight healthcare systems – England, Australia, Canada, Germany, Colombia, Mexico, India, and Brazil – utilise HTA in price negotiations for new medicines. By analysing the integration of HTA into pricing mechanisms, decision-making criteria, and economic evaluation methods, this research highlights significant disparities in terms of socioeconomic context, healthcare system management, and HTA maturity. These insights offer valuable policy recommendations for optimising HTA's role in controlling medicine prices and ensuring sustainable healthcare financing.

Keywords: Health Technology Assessment; medicine pricing; reimbursement decisions; universal health coverage; price negotiation; public healthcare systems; monopoly markets.

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1 Introduction

The provision of medicines is a fundamental component of public health policy and a key priority for governments striving for universal health coverage (WHO, 2023a). However, a major challenge public healthcare systems face in developed and developing countries is the escalating cost of innovative medicines. These medicines, introduced by pharmaceutical companies under patent protection, create a monopoly market where pricing power remains largely with the manufacturers. This situation raises critical concerns regarding affordability, access, and financial sustainability, particularly in healthcare systems where governments make reimbursement decisions on behalf of the population.

Spending on medicines represents a significant proportion of health expenditures worldwide, exerting financial pressure on national healthcare systems. A World Health Organization (WHO) (2020) study reported that medicines account for 20% to 60% of total health expenditures in low- and middle-income countries, compared to 18% in OECD countries. Globally, medicine spending reached $1.5 trillion[2] in 2023 and is projected to grow annually from 3% to 6% until 2027 (IQVIA, 2023). This growing expenditure creates a gap between revenues and spending on health technologies[3], including new medicines, limiting access for a large population segment, notably in developing countries, and driving up out-of-pocket payments. Given these financial constraints, governments must employ effective mechanisms to evaluate the value of new medicines before incorporating them into publicly funded healthcare systems.

Health Technology Assessment (HTA) plays a critical role in guiding government reimbursement decisions for innovative medicines by systematically evaluating their clinical and economic impact (O'Rourke et al., 2020). HTA provides an evidence-based framework that assists policymakers in determining whether a new medicine delivers sufficient therapeutic and economic value to justify public expenditure. The WHO has encouraged countries to adopt HTA methodologies to advance Universal Health Coverage. Reports indicate that approximately 82% of its member states have a systematic, formal health decision-making process at the national, sub-national, or both levels, with 62% of these incorporating an HTA process (WHO, 2021).

Where HTA frameworks are established, the process typically begins with pharmaceutical companies submitting a dossier that includes clinical trial results and proposed pricing (Bertram et al., 2021). HTA bodies then assess the medicine using interdisciplinary methodologies, which follow two primary strands: first, clinical evidence is examined to assess the medicine's risk-benefit balance over the long term; second, economic analysis is conducted to evaluate direct and indirect costs, as well as the potential health benefits, such as extended life years or improved quality of life. In many cases, HTA bodies establish cost-effectiveness thresholds or other criteria to guide reimbursement decisions (Drummond et al., 2008).

Beyond its role in reimbursement decisions, HTA has been increasingly used by governments as a tool for price negotiation with pharmaceutical companies. Given the high costs of patented medicines and the budgetary constraints of public healthcare systems, Ministries of Health (MoHs) leverage HTA outcomes to negotiate prices that align with the medicine's clinical and economic value. Through economic assessments, governments can strengthen their bargaining position by demonstrating willingness-to-pay thresholds and cost-effectiveness ratios, ensuring that public funds are allocated efficiently. Additionally, HTA allows for the implementation of alternative pricing models, such as value-based or outcome-based agreements, which link

[2] Considering the amount spent on purchasing medicines directly from manufacturers before any discounts being applied.

[3] Health technology refers to an intervention developed to prevent, diagnose, or treat medical conditions, promote health, provide rehabilitation, or organize the provision of healthcare. They can be medicines, vaccines, tests, devices, procedures, or medical programmes (HTA Glossary, 2024).

payment to a medicine's actual performance and real-world impact. This fosters transparency and accountability in public procurement practices (Drummond et al., 2022, 2008).

This study examines how MoHs in different healthcare systems utilise HTA in reimbursement decisions and enhance their negotiating leverage in price negotiations for new medicines. The study focuses on eight countries – England, Australia, Canada, Germany, Colombia, Mexico, India, and Brazil – covering a range of socioeconomic contexts. While previous research has primarily focused on HTA outcomes in developed countries, limited attention has been given to the HTA process in developing nations. This study contributes to the literature on public procurement in the healthcare sector by analysing how HTA informs price-setting processes for innovative medicines in monopoly markets, where governments must balance affordability, access, and fiscal responsibility.

By investigating the intersection of HTA, government reimbursement decisions, and price negotiations, this study aims to address the following research question: How do governments in public healthcare systems can utilise Health Technology Assessment (HTA) to negotiate new medicine prices with monopoly suppliers? Specifically, the study explores the role of HTA in shaping economic analyses, decision-making criteria, and negotiation mechanisms that influence medicine pricing in publicly funded healthcare systems.

2 Methodology

This research adopts a multiple case study design, employing a qualitative approach with a descriptive focus. The study uses a deductive method to achieve two main objectives: i) to analyse the role of HTA in new medicines reimbursement decisions within public healthcare systems across different socioeconomic contexts, and ii) to examine the relationship between HTA and price negotiations for new medicines. The methodology was developed in three stages: first, developing a framework to facilitate the analysis and comparison of HTA processes across different contexts; second, selecting the countries for analysis; and third, collecting the data.

In order to develop the HTA analytical framework, a literature review was conducted to find academic articles featuring comparative analyses of HTA across countries. Key studies included Lima et al. (2019), Pinson et al. (2011), Stafinski et al. (2022), Kalo et al. (2016), Rosseli et al. (2017), Drummond et al. (2008), Thokala et al. (2020), Trowman et al. (2021). This review identified and categorised various HTA elements into six themes (Table 1). While several elements were examined to enhance understanding of the HTA process, particular emphasis was placed on economic analysis, decision-making criteria and pricing.

The next step was to select the countries to study their HTA processes. The criteria for selection included: i) having universal health coverage, either fully implemented or in development, as measured by the WHO's Universal Health Coverage Index (UHC) (2023b); ii) exhibiting diverse socioeconomic conditions, as defined by income categories from the World Bank (2023); iii) having innovative HTA practices, initially identified through desk research; and, iv) having publicly available HTA guidelines and manuals. Eight countries were selected: England, Canada, Australia, Germany, Colombia, Mexico, India, and Brazil. Table 2 presents the countries according to the selection criteria.

In the third stage, data and information were gathered through a comprehensive literature review, documentary analysis, and examination of grey literature sourced from government platforms (e.g., laws, decrees, resolutions). Special attention was given to accessing the most recent official manuals and guidelines on HTA. A systematic review of academic articles and reports was also conducted to supplement information unavailable in official sources, particularly regarding new medicines pricing. The collected data was then organised according to the structure set out in the analytical framework for each country (see Table 1).

Two important clarifications should be noted. First, across all the cases examined, HTA bodies were found to assess various health technologies, including medicines, medical devices, and medical procedures. This study specifically focuses on the HTA process for new medicines, given the variation in evaluation procedures depending on the type of technology under review. Second, each country uses different terminology to refer to the national health authority, such as Departments or Ministries. This study adopts the term Ministry of Health (MoH) throughout for simplicity.

3 HTA and reimbursement of new medicines across healthcare systems

The primary tool the MoHs use to reimburse new medicines within healthcare systems is HTA. Once a medicine receives clinical approval from the HTA body, the next step is to evaluate its economic aspects to determine reimbursement eligibility. This section focuses on the economic analysis conducted by HTA bodies. The key economic factors considered by HTA bodies in the eight selected countries are presented in Table 3.

3.1 England

The National Health Service (NHS) of England, established in 1948, ensures access to healthcare services based on clinical needs rather than financial status (NHS, 2013). Healthcare spending 2019 amounted to 10.2% of GDP, surpassing the European average. Public funding constitutes a significant portion, covering 79.5% of total expenditure, while out-of-pocket payments stood at 17%. Private sector healthcare access is limited but growing, often utilised for services unavailable through the NHS or quicker access to covered services (Anderson et al., 2022; Castle et al., 2023).

The NHS primarily provides prescription medications free of charge, with funding varying based on treatment type (e.g., high-cost medications in specialised services) and setting (primary or secondary care) (DHSC and NHS, 2023). Despite the decentralised procurement of medicines, the NHS remains England's sole financier of healthcare services and products. This centralised healthcare system management enables the implementation of policies to influence medication adoption and usage within the healthcare system (Naci and Forrest, 2023).

The National Institute for Health and Care Excellence (NICE), established in 1999 as an independent advisory body, is responsible for HTA in England. Although NICE is connected to the national government, it operates autonomously and is not a government department. The MoH selects medicines to be assessed based on prioritisation criteria, such as disease burden, impact on resource use, likelihood of influencing public policy, quality of life, and reducing healthcare access disparities (NICE, 2022). The selection of medicines for evaluation may begin up to 24 months before their approval by the Medicines and Healthcare products Regulatory Agency (MHRA) (Castle et al., 2023).

The Technology Appraisal Committee, comprising members from various sectors, including the NHS, industry, academia, and patients, independently conducts the evidence reviews (Thokala et al., 2020). NICE employs Quality-Adjusted Life Years (QALYs)[4] to assess health outcomes across the NHS, facilitating comparisons of intervention effectiveness (NICE, 2023a). The economic

[4] QALY is a unit of outcome of an intervention where gains (or losses) of years of life subsequent to this intervention are adjusted on the basis of the quality of life during those years (HTA Glossary, 2024).

evaluations utilise cost-effectiveness analyses, including cost-utility, employing the Incremental Cost-Effectiveness Ratio (ICER)[5] (Angelis et al., 2018; NICE, 2023a; Thokala et al., 2020).

The decision-making criterion is based on an ICER threshold of £20,000 to £30,000 per QALY (Castle et al., 2023). Since 2017, NICE has implemented a budget impact test to manage access to high-cost medications, with a criterion of £20 million in any of the first three years following the incorporation of the new medication (NICE, 2023b). The use of NICE recommendations is mandatory, with the NHS responsible for covering the new medicine, having up to three months to implement the new medication in the healthcare system (Naci and Forrest, 2023).

The Technology Appraisal Committee evaluates clinical and economic evidence to determine one of five possible recommendations for new medicines: i) Recommended: the medicine is approved based on established criteria for use according to regulatory agency marketing authorisation; ii) Recommended under specific circumstances (optimised recommendation): the medicine is deemed cost-effective at the manufacturer's list price, provided it meets specific clinical and pricing criteria; iii) Recommended with managed access: the medicine has potential cost-effectiveness at the agreed price, but evidence remains uncertain; iv) Recommended only in a research context: evidence of a medicine's clinical effectiveness or its impact on health outcomes is absent, weak, or uncertain; v) Not recommended: there is insufficient evidence of clinical effectiveness, and the medicine is not considered a cost-effective use of NHS resources compared to current practice (NHS, 2022).

3.2 Canada

The Canadian healthcare system, Medicare, operates with decentralised responsibilities among provinces, territories, and the federal government. Provinces and territories manage and provide healthcare services, while the federal government sets national standards and regulations (Government of Canada, 2023). Healthcare spending was 12.3% of GDP in 2021, with 73% from public funds and 27% out-of-pocket payments (CIHI, 2023). There is a significant private involvement, notably in prescription medication costs. Inpatients receive free medications under Medicare, while outpatients' costs are covered by public or private plans (Government of Canada, 2023). Due to gaps in medication coverage, provinces and territories have developed over 100 public drug plans, especially for vulnerable groups, managed by the federal government, reflecting a very administrative complexity (Health Canada, 2019).

The Canadian Agency for Drugs and Technologies in Health (CADTH), responsible for HTA in Canada, was established in 1989 as an independent, non-governmental, non-profit organisation (MacPhail and Shea, 2017). CADTH conducts technology reviews for federal, provincial, and territorial government units, public drug plans, and hospitals across Canada, excluding Quebec, where medication access or reimbursement decisions are handled separately (CADTH, 2023a). CADTH comprises two HTA subgroups: the Common Drug Review (CDR), involving three territorial and three federal public drug plans, and the Pan-Canadian Oncology Drug Review (pCODR), administered by a collaboration of nine provinces (MacPhail and Shea, 2017).

Medicines eligible for assessment must have authorisation from Health Canada (the regulatory agency for health products) or be undergoing review. Authorisation is a prerequisite for completing

[5] ICER is defined by the additional cost of the more expensive intervention compared with the less expensive intervention, divided by the difference between the effects of the interventions on the patients, for example, the additional cost per QALY (HTA Glossary, 2024).

For ICER calculations, NICE recommends using drug tariff prices or estimated prices from electronic pharmaceutical market information tools, NHS reference costs for hospital care, and costs reported by the Personal Social Services Research Unit (PSSRU) for social care.

CADTH's evaluation (CADTH, 2023b). The classification of medicines for assessment is based on a scoring system that establishes a priority order, considering potential clinical impact, budget impact, disease incidence, jurisdictional interest, and equity (CADTH, 2023a).

In economic evaluation, new medicine cost-effectiveness is assessed by comparing it with current healthcare interventions in Canada, potentially involving multiple relevant comparators. (CADTH, 2023b, 2017). CADTH conducts cost-utility and budget impact analyses, measuring health effects in ICER per QALY (CADTH, 2023b, 2017).

CADTH operates expert committees providing recommendations to drug plans, which may advise on reimbursement, limited-time reimbursement, or non-reimbursement of a medication. Limited-time reimbursement depends on future evidence reassessment addressing comparative clinical benefit and cost-effectiveness uncertainty (CADTH, 2023c). Recommendations are not based on willingness to pay but on jurisdictional budgets.

CADTH recommendations are not binding for drug plans, which base reimbursement decisions on CADTH recommendations and other factors, including plan mandates, jurisdictional priorities, and financial resources (CADTH, 2022). Expert committees may suggest inclusion at a lower price if an additional therapeutic benefit is believed compared to comparators or non-inclusion at a specific price if a therapeutic benefit is similar to comparators. The extent of price reduction plans sought is often unspecified, with recommendations not to exceed the cost of an identified comparator in some cases (Husereau et al., 2014).

3.3 Australia

Australia operates a universal healthcare system, Medicare, established in 1984, comprising two national subsidy schemes administered by the federal government. The Medicare Benefits Scheme (MBS) covers payments for services provided by private healthcare professionals, while the Pharmaceutical Benefits Scheme (PBS) ensures access to essential medications at no cost (Vitry et al., 2015). Despite constitutionally placing health responsibility with the states, federal government funding predominates in the healthcare system. Public sources contribute 73% of healthcare expenditure and 10.5% of Australia's GDP. Individuals contribute 51.5% of non-governmental healthcare expenses, followed by private health insurance providers (26.8%) and other non-governmental sources (21.7%) (Australian Institute of Health and Welfare, 2023).

The Pharmaceutical Benefits Advisory Committee (PBAC), established in 1954 as an independent body, advises on which medications should receive public funding in Australia. With support from the MoH, PBAC recommends which drugs should be included in the PBS (Hailey, 2009). Registering a medicine with the Therapeutic Goods Administration (TGA), Australia's regulatory agency for medicines and medical devices, is a prerequisite for its inclusion in the PBS. PBAC guidelines do not report how medicines are selected and prioritised for assessment (DHAC, 2009; Kim et al., 2021).

Regarding economic evaluation, the PBAC assesses whether new medications efficiently use public resources. If a medication claims clinical superiority, a cost-effectiveness analysis is typically conducted, with a preference for cost-utility analysis. If it claims non-inferiority, a cost-minimisation analysis is performed. The PBAC also examines economic analyses provided by applicants and requires a budget impact model to be presented (DHAC, 2016; Kim et al., 2021; Williams et al., 2023).

While the PBAC does not have an explicit cost threshold, it is assumed that informal standards regarding ICERs per QALY should be applied, varying by therapeutic area (Williams et al., 2023). According to an analysis by the pharmaceutical industry, the PBAC's acceptable threshold from 2003 to 2012 ranged from AUD 45,000 to AUD 60,000 per QALY (Wang et al., 2018). Additionally, if

a medication significantly exceeds the cost of alternative therapies, the PBAC may not recommend its inclusion unless there is evidence of substantial improvement in effectiveness or reduction in toxicity (Williams et al., 2023).

Following a favourable recommendation, the MoH decided to include the new medicine in the PBS. While the PBAC's recommendation is not mandatory, a medicine can only be listed on the PBS if it has been approved by the PBAC (DHAC, 2024).

3.4 Germany

Germany operates a decentralised healthcare system, managed at federal, state, and corporate levels (Blümel et al., 2022). Approximately 86% of Germans are covered by mandatory Statutory Health Insurance (SHI), which includes hospitalisation, outpatient care, mental health, and prescription drugs (The Commonwealth Fund, 2020). The Federal Joint Committee (*Gemeinsamer Bundesausschuss* – G-BA) plays a pivotal role in SHI, defining reimbursable medical services and medications, though the government does not directly provide healthcare (G-BA, n.d.).

In 2022, healthcare spending reached 11% of GDP, with a per capita expenditure of around USD 7,000, making Germany a leading healthcare investor in the European Union. Out-of-pocket household payments contribute 11% of healthcare costs (WHO, 2023c). Most new medications are reimbursed since SHI covers all licensed prescribed drugs (Blümel et al., 2022).

The Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* – IQWiG), established in 2004, is an independent, non-governmental organisation responsible for HTA in Germany. Although IQWiG can initiate investigations independently, most evaluations are prompted by requests from the G-BA or the MoH (Polanczyk et al., 2021).

The selection of medicines for investigation is primarily based on the AOK Research Institute's[6] semi-annual healthcare report, which includes data on prevalence and hospitalisation rates for the 1,500 most common diseases, using information from the SHI Fund. The medicines are then prioritised based on their incidence in the population, meaning they must affect at least 1% of the population at a given time or within a specific year. Only drugs with commercial authorisation can be assessed (Polanczyk et al., 2021; Schaefer et al., 2021).

Germany solely relies on comparative benefit assessment for medication incorporation decisions, i.e. no economic evaluation is conducted (Angelis et al., 2018; Schaefer and Schlander, 2019). The comparative benefit assessment evaluates a medication's efficacy, safety, and clinical quality compared to appropriate comparator therapies (ACT), chosen at the discretion of the G-BA to reflect the current standard of care (G-BA, n.d.; IQWiG, 2015).

The additional benefit is assessed based on the likelihood and extent of benefit, leading to classifications such as "considerable additional benefit," "minor additional benefit," or "no proven additional benefit." While this classification influences the price negotiated between the G-BA and pharmaceutical companies, it does not impact reimbursement, which is determined solely by the G-BA (Akehurst et al., 2017; Angelis et al., 2018; G-BA, n.d.). Budget impact analysis is obligatory and should encompass one-time investments or initial costs for new technology implementation, presented in at least two scenarios (current treatment and new). The budget impact is capped at €1 million annually for common medicines and €30 million for orphan diseases (Reese and Kemmner, 2023; Schaefer et al., 2021).

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[6] The AOK Institute (*Allgemeine Ortskrankenkasse*) is one of Germany's largest and oldest public health insurance providers.

Economic evaluations only come into play when price negotiations falter post-benefit assessment and are contested by the technology supplier or public health insurer. These evaluations are conducted within therapeutic areas and favour a cost-benefit analysis approach using patient-relevant outcomes. The G-BA and IQWiG have dismissed the ICER per QALY as a measure of willingness to pay (Schaefer et al., 2021).

Upon regulatory approval, new medications are automatically accessible to the German population, with the initial price set by the manufacturer. Reimbursement values are determined post-price negotiations, with the possibility of retroactive adjustments following the incorporation decision (Angelis et al., 2018; Polanczyk et al., 2021).

3.5 Colombia

In 1993, Colombia underwent a healthcare system reform that aimed to provide universal public health financing. Establishing the General System of Social Security in Health (*Sistema General de Seguridad Social en Salud* – SGSSS) introduced various forms of contributions from the Colombian population to the Mandatory Health Plan (*Plan Obligatorio de Salud* – POS). Public financing includes the Contributory Scheme, mandatory for those with the means to pay for health insurance, and the Subsidised Scheme, providing coverage for individuals lacking total payment capacity, supported by fiscal funds. Additionally, a segment that caters to uninsured low-income individuals is funded by public resources. The MoH oversees the SGSSS, managing resources from the Contributory and Subsidised Schemes and other funds (Londoño and Frenk, 1997). The Per Capita Payment Unit (*Unidad de Pago por Capitación* – UPC) represents the annual value allocated to each SGSSS affiliate for POS benefits in contributory and subsidised regimes (Ministerio de Salud y Protección Social, 2010).

Since the SGSSS implementation, healthcare insurance coverage has surged from under 20% in 1993 to over 95% in 2022, with 78% of expenses covered by POS and 14% through out-of-pocket payments (OECD, 2023; Rosa and Alberto, 2004). Healthcare spending accounts for 8.1% of Colombia's GDP (OECD, 2023). Free-dispensing medications are part of a list of essential medicines, updated biennially, with 73% financed by POS and 27% covered by a Maximum Budget scheme funded by UPC resources (MinSalud, 2022).

HTA in Colombia is overseen by the Institute for Health Technology Assessment (*Instituto de Evaluación Tecnológica en Salud* – IETS), established in 2011 as a non-profit institution involving public and private entities (IETS, 2023a). The MoH identifies new medicines the regulatory body has approved – INVIMA – and aligns with the population's health needs. Eligible drugs are added to a historical list of those identified over time but not yet assessed. Each drug is ranked based on predefined criteria from the Prioritisation Matrix, including disease burden, health status, clinical practice guidelines, first-line treatment, affected population group, and prescription frequency. This ranking ensures an objective, transparent, systematic, and valid prioritisation process. Drugs with the highest potential health impact, as determined by their position in the Prioritisation Matrix, are selected for evaluation by IETS (Ministerio de Salud y Protección Social, n.d.).

The IETS employs three types of economic evaluation: cost-effectiveness analysis, which compares the effectiveness of different medicines to achieve the same health outcome; cost-utility analysis, used when the quality of life is a key outcome, allowing comparisons between healthcare activities; and cost-benefit analysis, applied when non-health-related effects are significant, aiming to compare health programs with those from other sectors of society. Results are typically presented as ICER per QALY, alongside total costs for specific health conditions or population subgroups (IETS, 2014a).

The IETS sets a decision threshold ranging from one to three times Colombia's per capita GDP. A recent study, co-financed by the IETS and the Colombian Ministry of Finance, estimated this

threshold for new medications to be around 14.7 million Colombian pesos for one year of life saved, or approximately 17 million Colombian pesos per QALY, representing roughly one time Colombia's per capita GDP (Espinosa et al., 2022).

Budget impact analysis examines the financial effects of adopting new medications over three to four years, accounting for population changes and price fluctuations. It compares the costs of implementing the new medication to the current standard. A positive impact indicates the need for additional funding, while a negative impact suggests potential savings. Incorporating the new medication may involve replacing current treatments in the public health system if it is more effective or sharing the cost if the effectiveness is similar (IETS, 2014b).

While the IETS deliberates on recommending the inclusion of new medications, the final decision lies with the Committee for Regulation of Benefits, Costs, and Tariffs of Health Insurance, operating under the MoH. HTA is mandatory for medication coverage in the POS (Ministerio de Salud y Protección Social, n.d.).

3.6 Mexico

The Mexican government introduced the Policy for Free Health Services and Medications (*Política para Serviços de Saúde e Medicamentos Gratuitos*) in 2019, managed by the National Institute of Health for Wellbeing (*Instituto de Salud para el Bienestar* – INSABI), aiming to ensure universal free access to healthcare. This policy seeks to streamline healthcare financing and service provision by centralising funding (Block et al., 2020). However, county governments still retain their authority and role as healthcare providers. INSABI's goal is to establish fully funded and integrated public health networks, excluding private outsourcing (INSABI, 2023). In 2019, healthcare spending in Mexico amounted to 5.5% of GDP, with out-of-pocket payments for healthcare rising to 50% over the years (Knaul et al., 2023).

Medication procurement relies on the National Compendium of Health Inputs (CNIS), listing all medications provided by Mexico's public healthcare system (Aguilar-Delfín et al., 2021; Martínez Moreno et al., 2016). Social insurance institutions and MoH facilities dispense medications at no cost to beneficiaries through state-owned pharmacies (INSABI, 2023).

In 2004, the National Centre of Technological Excellence in Health (*Centro Nacional de Excelencia Tecnológica en Salud* – CENETEC) was established under the MoH to provide advisory services aimed at generating relevant information on new medicines to enhance healthcare delivery and health policy implementation (CENETEC, 2023; Gómez-Dantés and Frenk, 2009). CENETEC operates within government programmes requiring HTA but lacks independent decision-making authority in selecting or reimbursing medications into the Mexican healthcare system (Aguilar-Delfín et al., 2021; CENETEC, 2023). A CNIS Commission selects the medicines for evaluation without explicit prioritisation criteria.

In economic evaluation, cost-effectiveness analysis is fundamental, potentially supplemented by cost-utility or cost-benefit analysis. When scientific evidence demonstrates therapeutic equivalence in efficacy or safety among evaluated alternatives, cost-effectiveness analysis can be substituted with cost-minimisation analysis (CSG, 2017). Results are detailed, specifying total average costs, effects, incremental values, and, if relevant, the ICER (CSG, 2023). Budget impact analysis is necessary for discerning if the new input replaces or complements existing treatments, with projected impacts assessed over five years, delineating direct intervention costs and potential savings or costs (CSG, 2023).

Decision criteria vary by economic analysis type. For cost-effectiveness analysis, inclusion is recommended if the new medication is more effective and less costly than the medicine is already in effect in the healthcare system; cost-utility analysis suggests inclusion if the ICER per QALY or

Disability-Adjusted Life Years (DALY)[7] is less than or equal to per capita GDP; cost-minimisation analysis recommends inclusion if the new medication saves costs compared to equally effective alternatives; cost-benefit analysis justifies adoption if medication benefits outweigh costs. Funding for new medication is deemed appropriate if it saves public budget resources or implies up to a 5% increase in the disease-specific treatment budget (CSG, 2023).

The CNIS Commission's decisions are mandatory, ensuring that the Mexican public healthcare system immediately covers all positive recommendations for new medication inclusion through the MoH upon publication (Gobierno de Mexico, 2022).

3.7 India

India has a federal governance structure where national and state governments influence healthcare policies and decision-making. The national government, through MoH, provides oversight, planning, and funding to ensure healthcare service coverage and consistency across states. State governments are prominent in leadership, financing, regulation, and providing primary healthcare. Two-thirds of public health spending comes from state governments, while the central government contributes the remaining share (Selvaraj et al., 2022).

The Indian healthcare system has been chronically underfunded, and universal coverage is under implementation. In 2018, the government launched Ayushman Bharat–PM-JAY, a tax-funded health protection scheme offering free secondary and tertiary care in private facilities, currently covering only 37% of the population. The remaining 63% rely on private health insurance, state government schemes or out-of-pocket payments, with two-thirds spent on medicines (Chokshi et al., 2015; Tikkanen et al., 2020). The current National Health Policy aims to increase public health spending from 1.15% of GDP (2021-2022) to 2.5% by 2025-2026 (Government of India, 2023). Regarding access to medicines, only about 10% of all medications are prescribed and dispensed in government institutions, while the majority rely on the private sector. Although patients are expected to receive free medicines from the National List of Essential Medicines (NLEM), funding shortages often force them to pay out-of-pocket.

As part of its commitment to achieving universal health coverage, the Indian government has implemented a series of reforms to reduce private healthcare expenses and increase public health spending. A key initiative was the establishment of the Health Technology Assessment in India (HTAIn) in 2017. Despite its relatively recent creation, HTAIn has already developed guidelines and methodologies for technology assessments and has conducted several evaluations (Government of India, 2023). The agency operates as a semi-autonomous, publicly funded body under the Department of Health Research within the MoH. HTAIn serves an advisory role, supporting state-level healthcare decision-making by providing reliable, evidence-based information (Tikkanen et al., 2020).

The MoH Procurement Department defines the medicines to be assessed based on their needs. The selection and prioritisation process considers several factors, including the size of the affected population, disease severity, availability of evidence, potential therapeutic benefits, economic impact, and the broader impact on government policy and healthcare resources (Department of Health Research, 2022).

The HTAIn manuals and guidelines do not provide detailed information on clinical and economic evaluations. Economic analysis types include cost-effectiveness, cost-utility, and cost-benefit analyses; however, there is no recommendation on when each method should be applied. There

[7] DALY is a unit of health status where life expectancy according to age is adjusted by the loss of health and years of life due to disability from disease or injury (HTA Glossary, 2024).

is no formal specification of the decision-making threshold. However, the first HTAIn manual mentions that the most commonly used cost-effectiveness threshold is based on the country's per capita GDP. It also suggests using WHO criteria, where interventions that prevent one DALY for less than the average per capita income of a given country or region are considered highly cost-effective; those costing less than three times the average per capita income per DALY avoided are still deemed cost-effective, while those exceeding this level are considered not cost-effective (Department of Health Research, 2022, 2018).

HTAIn also recommends incorporating ICER and budget impact analysis into the decision-making process. The manual on budget impact analysis in India recommends considering multiple payers, including the government and direct patient payments, and a single-payer perspective for universal access. It assumes that large public procurement can reduce prices. However, the manual does not set specific thresholds for budget impact analysis and suggests that the results be considered alongside cost-effectiveness analysis (Prinja et al., 2021). HTAIn can either recommend or not recommend a health technology. However, the recommendation is not mandatory, and there is no set deadline for the medicine's availability following its approval.

3.8 Brazil

Brazil's healthcare system, the Unified Health System (SUS), is a public, universal, and decentralised system designed to provide healthcare services to all residents and visitors, regardless of socioeconomic status. Established in 1988, SUS operates under a shared governance model, with responsibilities divided among federal, state, and municipal levels. The MoH oversees national coordination, including policy development, planning, financing, auditing, and control. State governments manage regional governance, coordinate strategic programmes, and deliver specialised healthcare services not yet decentralised to municipalities. SUS offers services at all levels of complexity – primary, secondary, and tertiary care – alongside prescription drug coverage, funded through tax revenues and social contributions across all three levels of government. While pharmaceutical funding is also decentralised, the MoH centralises procuring strategic and high-cost medicines to strengthen bargaining power in price negotiations. The National List of Essential Medicines (Rename) is regularly updated to optimise health spending and improve access to essential treatments (Massuda et al., 2020; Ortega and Pele, 2023). Despite its comprehensive coverage, SUS faces financial challenges, with health expenditure accounting for 9.9% of Brazil’s GDP. A significant portion of healthcare costs still comes from out-of-pocket payments (22.7%), with medicine expenses representing approximately 34% of total household healthcare spending (IBGE, 2024).

Institutionalising the HTA in Brazil began with the National Policy on Science, Technology, and Innovation in Health (PNCTIS) 2004. In 2011, the Brazilian Network for Health Technology Assessment (Rebrats) was established, comprising collaborating centres and research institutions in the country dedicated to synthesising scientific evidence in the field of HTA (Brasil, 2023a). Subsequently, the National Commission for the Incorporation of Technologies into the SUS (Conitec) was established in 2011 to advise the MoH on its responsibilities regarding the reimbursement, exclusion, or modification of medicines within the SUS, thus proposing updates to the Rename (Brasil, 2023b). In terms of governance, Conitec is linked to the Secretariat for Science, Technology, and Innovation and the Economic-Industrial Complex of Health within the MoH (Brasil, 2023b).

Rebrats and Conitec have complementary functions. While the former provides technical analysis of health technologies' efficacy, safety, and cost-effectiveness, Conitec evaluates and recommends reimbursing new medicines into the SUS. Ultimately, the decision-making process is the responsibility of the SCTIE (Polanczyk et al., 2021).

The Brazilian HTA system includes manuals and methodological guidelines that establish a standardised approach for analysis, outlining procedures and requirements for new medicines. Conitec only evaluates medicines that the regulatory agency, Anvisa, has approved. Additionally, scientific evidence must demonstrate that the new drug is at least as effective and safe as those already available in the SUS for the specified indication. An economic analysis comparing the new drug to existing ones in the SUS must also be provided, along with the price set by the Medicines Market Regulation Chamber (CMED) (Conitec, 2023).

Conceptually, the criteria used by Conitec to recommend the reimbursement of new medicine consider the cost-effectiveness analysis, social needs, scientific evidence, health policy priorities, and the availability of resources. In the case of a positive recommendation, the budget impact is also considered (Conitec, 2023). However, Conitec does not follow an explicit cost-effectiveness threshold, which may affect the validity of the recommendation criteria (MS, 2022). In practice, there is a significant variation in the willingness to pay for Conitec's positive recommendations, with the ICER per QALY ranging from 2,372 to 280,235 Brazilian Reais between 2012 and 2016, and the cost per life year gained ranged from 4,198 to 254,779 Brazilian Reais (inflation-adjusted values) (Ribeiro et al., 2017). A study by SCTIE recommended thresholds of 40,000 Brazilian Reais per QALY and 30,000 Brazilian Reais per life year gained for 2022, with annual updates based on the variation in Brazil's GDP per capita (MS, 2022). Nonetheless, when Conitec makes a positive recommendation for reimbursement, the medicine must be made available to SUS within 180 days.

4 Negotiation mechanisms in pricing decisions

The outcome of the HTA serves as a critical tool for MoHs to strengthen their bargaining power when negotiating the prices of new medicines in a monopolised market. This section examines how different countries utilise HTA to navigate price negotiations. Table 4 presents an overview of the pricing schemes adopted across the eight healthcare systems analysed, highlighting key mechanisms and strategies used to determine new medicine prices.

4.1 England

HTA plays a direct role in determining medicine prices in England. For medicines that fall within NICE's cost-effectiveness threshold (£20,000 to £30,000 per QALY) and meet the budget impact test threshold (up to £20 million in the first three years), pharmaceutical companies can choose between the Voluntary or Statutory Schemes (Naci and Forrest, 2023; NHS, 2022).

The Voluntary Scheme for Branded Medicines Pricing and Access is an agreement between the Association of the British Pharmaceutical Industry (ABPI) and the MoH. It covers most branded products, primarily patent-protected medicines. This scheme sets an annual cap on NHS medicine expenditure growth at less than 2% from 2019 to 2023. Under this scheme, pharmaceutical companies must pay 26.5% if medicine expenditure exceeds the agreed limit (DHSC, 2022). The Statutory Scheme is a government-mandated alternative to the Voluntary Scheme, imposing stricter cost-control measures. It sets a lower cap on NHS medicine expenditure growth, at less than 1.1% per year. Additionally, pharmaceutical companies under this scheme must make a higher payment contribution of 27.5% from 2019 to 2023 (DHSC, 2023).

Alternative contracting options are available for medicines not within the cost-effectiveness or budget impact thresholds. The Patient Access Schemes (PAS) are designed to facilitate patient access to medicines through cost adjustments. These schemes are divided into i) Simple (confidential) schemes with fixed pricing or a percentage discount applied to the list price; ii) Complex (transparent) schemes with more intricate arrangements that require significant

administrative efforts for implementation and monitoring (Naci and Forrest, 2023; NHS, 2022). The Commercial Access Agreements (CAAs) offer various mechanisms to control costs and manage access to medicines within the NHS, including i) Budget caps, establishing a maximum expenditure limit for a product, with centralised discounts applied beyond this threshold; ii) Price-volume agreements, based on patient volume, where initial costs are set, followed by discounts as patient numbers increase or full reimbursement by the manufacturer; iii) Cost-sharing agreements, in which manufacturers subsidise the initial cost of therapy; iv) Start/stop criteria, defining when patients should commence or discontinue therapy; v) Outcome-based agreements/performance-based reimbursement, applying discounts or reimbursements if a medicine does not achieve the expected clinical outcomes (NHS, 2022).

In cases where clinical and financial uncertainty poses a challenge to technology appraisals, NICE may recommend that the NHS and the manufacturer negotiate a Managed Access Agreement (MAA) with confidential pricing details. The MAA combine data collection with elements from other access schemes, such as CAA and PAS. These agreements are frequently implemented alongside specific funding initiatives, such as the Cancer Drugs Fund or the Innovative Medicines Fund, to support patient access to promising therapies while collecting real-world evidence on their efficacy and cost-effectiveness (NHS, 2021, 2018). Both funds have an annual budget of £340 million each to reimburse innovative medicines where there is clinical uncertainty (NHS, 2021, 2018).

4.2 Canada

In Canada, CADTH's reimbursement recommendations are non-binding, and it does not negotiate prices. If a medicine receives a negative recommendation due to cost, a lower price may be proposed to secure approval. Since the early 2000s, federal and provincial governments have collaborated to strengthen pricing policies, with the CDR and pCODR standardising reimbursement decisions and acting as informal price negotiation mechanisms (Marchildon et al., 2020).

The Patented Medicine Prices Review Board (PMPRB), established in 1987, regulates new drug prices, assessing whether a medicine is a line extension or a new active substance. Pricing is based on therapeutic value, comparator drugs, median prices in seven reference countries, and CADTH's cost-utility analysis (Government of Canada, 2020; Lexchin, 2015). If a drug is deemed too expensive, provinces negotiate Product Listing Agreements (PLAs), securing confidential discounts linked to expenditure, usage, or health outcomes (Morgan et al., 2013).

In 2010, Canadian provinces established the Pan-Canadian Pharmaceutical Alliance (pCPA) to negotiate drug prices collectively, reducing costs and improving consistency in reimbursement decisions. The federal government joined the Alliance in 2015. The pCPA coordinates PLAs for new medicines, which can also support appropriate use, budget planning, or value-based pricing (Carlson et al., 2010). However, PLAs raise concerns about transparency, administrative costs, and price disparities across provinces and territories (Morgan et al., 2013). For drugs receiving a time-limited recommendation from CADTH, the pCPA's Temporary Access Process allows conditional reimbursement, requiring manufacturers to agree on risk-sharing arrangements and submit new evidence for reassessment. Funding ends if the evidence is insufficient, and manufacturers must cover ongoing patient treatment costs (pCPA, 2023).

4.3 Australia

Once the Pharmaceutical Benefits Advisory Committee (PBAC) recommends adding a medicine to the Pharmaceutical Benefits Scheme (PBS), the Pharmaceutical Benefits Pricing Authority

(PBPA) assesses the proposed price. This evaluation considers the product's brand name, consultations with the manufacturer, the proposed price, international pricing (UK and New Zealand), listed alternatives and their prices, estimated expenditure, cost of goods and margins, pricing calculations, and the PBAC's cost-effectiveness recommendation (Parliament of Australia, 2022).

The Australian government applies automatic price reductions to listed medicines over time to manage PBS expenditure. The Managed Access Program and Risk-Sharing Agreements enable the inclusion of medicines in the PBS at a discounted published price in cases of high unmet clinical need. These schemes allow medicines to be listed despite initial PBAC concerns over clinical and/or economic uncertainties, provided that further evidence is submitted to address these uncertainties. Additionally, the Statutory Price Reduction mechanism enforces automatic price cuts for listed medicines: a 5% reduction in the 5th and 10th year after PBS listing and a 26.1% reduction in the 15th year (until 2026), increasing to 30% from 2027 (DHAC, 2022a, 2022b).

Australia's latest drug pricing agreement, the Strategic Agreement (2022–2027), was established between the government and Medicines Australia, representing the innovative pharmaceutical industry. Key measures include exploring conditional funding agreements through the Managed Access Program, setting clear criteria for reviewing existing funding arrangements and introducing special pricing schemes for innovative medicines with uncertain outcomes. The government also committed to working with Medicines Australia via the Access to Medicines Working Group to develop a new Risk-Sharing Agreement policy following PBAC recommendations (PBAC, 2017, 2015).

4.4 Germany

In Germany, pharmaceutical companies can freely set the price of new medicines for the first six months after market entry. An assessment of the medicine's additional benefits is conducted during this period. Once the Federal Joint Committee (G-BA) publishes its final resolution, confidential price negotiations begin between the pharmaceutical company and the National Association of Statutory Health Insurance Funds (GKV-SV) (G-BA, n.d.).

The main factors considered in price negotiations include the annual costs of the relevant comparative therapy, the level of added benefit determined by the G-BA, the prices of comparable pharmaceutical products within the same therapeutic class, prices in other European countries, and the number of patients. If the G-BA identifies an added benefit, the final price will reflect the cost of the comparator plus a premium for the product's innovative nature. If the G-BA identifies different levels of added benefit for various patient subgroups, the final price will be a weighted average based on the size of each subgroup. If the G-BA concludes that the new drug does not provide the best therapeutic benefits compared to existing treatments for the same condition, its cost must be equal to or lower than the price of other available options (Paris and Docteur, 2008; Polanczyk et al., 2021).

Additionally, if the manufacturer does not provide all the required documentation and data for the drug under evaluation, IQWiG recommends that the reimbursement price not exceed other available therapeutic alternatives. In cases where the data does not meet IQWiG's criteria, such as with drugs with uncertain outcomes, the G-BA may approve reimbursement for a limited period and request additional information from the applicant. A new negotiation will be conducted after this period (Reese and Kemmner, 2023).

If the manufacturer and GKV-SV cannot agree on a price, an arbitration board makes the final decision. Both parties can ask IQWiG for a formal cost-benefit and cost-effectiveness analysis. If the drug is classified as having "no added benefit" and falls within a reference price group, the price is set by the reference pricing system. For innovative drugs outside such groups, the

reimbursement price is negotiated, ensuring the annual cost does not exceed that of the appropriate comparator therapy (Lauenroth and Stargardt, 2017).

4.5 Colombia

In Colombia, pharmaceutical manufacturers can freely set the maximum sale price of a new patented drug upon market entry. They must inform the National Commission for Medicine and Medical Device Prices (CNPMDM) after receiving marketing authorisation from INVIMA. While prices are not controlled at launch, they may later be regulated through International Reference Pricing (IRP). Since 2013, the CNPMDM has imposed price caps when a drug's national reference price exceeds its international reference price (CNPMDM, 2013).

Since 2018, the Colombian government has been working on a value-based pricing (VBP) reform, aligning drug prices with their clinical and societal value. The IETS plays a key role in this new model, which aims to introduce price controls at market entry. In 2023, the IETS published its first manual for defining the therapeutic value category of medicines. Under this system, manufacturers submit registration data to INVIMA, and before approval, the IETS independently assesses the drug's value. It produces three documents to support the CNPMDM in setting a price cap: a therapeutic value classification, a cost-effectiveness evaluation (excluding orphan drugs), and a budget impact analysis. While the latter two are already IETS practices, they are not currently used to determine pricing (Garcia and Rodrigues, 2023; IETS, 2023b).

4.6 Mexico

Since 2004, the Ministry of Economy has set drug prices in Mexico under the Pharmaceutical Industry Modernisation Programme (PROMIF). The pricing system establishes a maximum public price based on an international reference price, calculated using the manufacturer's price in US dollars and weighted by sales volumes in six major international markets where equivalent products are sold. A commercialisation factor covers distribution, storage, promotion, and profit margins across the supply chain, including wholesalers and retailers (González-Pier, 2008).

In 2008, Mexico centralised price negotiations for patented or single-source drugs, setting a uniform price for all public institutions nationwide for one year. This led to the creation of the CCNPMIS to address the fragmented public procurement system, which had weakened negotiation power and resulted in inconsistent pricing and purchasing processes. The CCNPMIS is responsible for i) selecting medicines for negotiation, ii) preparing technical and economic assessments for price discussions, and iii) negotiating prices with the pharmaceutical industry for the entire public sector. To qualify for negotiation, a drug must be patented, have a single supplier or no substitutes, and be listed in the CNIS (Gobierno de Mexico, 2018).

The CCNPMIS has three committees coordinated by a Technical Secretariat. The Clinical-Technical Committee assesses the safety and efficacy of medicines, the Technical Evaluation Committee analyses cost-effectiveness and therapeutic alternatives, and the Patent and Pricing Committee reviews data on volume, payment conditions, distribution, and international price comparisons. CENETEC is involved in the first two committees, including indirect participation from manufacturers and pharmaceutical associations (CENETEC, 2012).

4.7 India

The use of HTA in India, particularly for drug price negotiations, is not yet widespread. However, with the establishment of PM-JAY and efforts towards universal health coverage, there are significant opportunities to advance in this area by aligning the efforts of HTAIn and the National

Pharmaceutical Pricing Authority (NPPA). The medicines listed in the National Essential Medicines List are regulated by a maximum price cap set by the NPPA, while other medicines are not monitored, allowing for an annual retail price increase of up to 10% (Sahadeva, 2023). Nonetheless, some initiatives are underway to incorporate cost-effectiveness data into drug price negotiations, particularly for cancer treatments (Chaudhuri, 2021; Ghosh et al., 2023; Prinja and Gupta, 2021). However, no formal agreements have yet been established with manufacturers.

4.8 Brazil

In Brazil, new medicine prices are set before undergoing the HTA process. Price regulation began in 2004 with the establishment of CMED and has followed the same mechanism since then. Pricing is determined using a price-cap model (Miranda, 2023). CMED regulates the entry prices of medicines into the Brazilian market based on specific rules for different types of drugs. Medicines are classified according to their innovation and therapeutic benefit level or as products that contribute to increasing market competition (Dias et al., 2019).

There are five categories for pricing new medicines: i) Patented innovative medicines with therapeutic benefit (category I): prices cannot exceed the lowest manufacturer price in reference countries; ii) New medicines without qualification for category I (category II): prices are based on the treatment cost of existing medicines for the same indication and must not exceed the lowest price in reference countries; iii) New presentation of an existing medicine (category III): the price cannot exceed the arithmetic mean of existing presentations with the same concentration and form; iv) New to the company or in a new pharmaceutical form (category IV): prices must not exceed the weighted average of equivalent presentations available in the market, adjusted by revenue; v) New pharmaceutical form or fixed-dose combination (category V): for new forms, prices align with treatment costs of existing options and cannot exceed the lowest price in reference countries. For fixed-dose combinations, the price must not surpass the sum of the monodrug prices unless justified while ensuring cost-effectiveness. (CMED, 2004).

Therefore, when a new medicine is submitted for evaluation by Conitec, it must already have a price set by CMED. This leaves small room for price negotiation between the SUS procurement department and the pharmaceutical companies. As a result, HTA decisions do not influence medicine pricing in Brazil.

5 Discussion and conclusion

This study analysed HTA processes and medicine pricing mechanisms across eight healthcare systems with universal (or developing) coverage. A key contribution of this research is the exploration of the relationship between HTA and new medicine pricing, a topic that remains underexplored in the literature. At a time when many economies face a public health crisis, struggling to sustain universal coverage as the costs of new treatments rise faster than public budgets (UN, 2025), HTA emerges as a crucial tool to support public healthcare systems. Another significant contribution of this study is bringing the developing countries perspective. Comparative analyses of HTA processes in academic literature often overlook these countries, perhaps assuming they have little to contribute. However, as demonstrated in this study, the four developing countries examined have a HTA procedure in place that warrant closer attention.

A key factor to highlight is the disparity in HTA processes between developed and developing countries. While nations such as England, Canada, Germany, and Australia have well-established HTA frameworks with comprehensive guidelines, clearly defined procedures, and extensive reference materials, countries like Colombia, Mexico, India, and Brazil still face vulnerabilities in this regard. These challenges are evident in the lack of transparency in guideline dissemination

and the overall structure of HTA in these countries. However, significant progress is being made in strengthening HTA frameworks in these developing healthcare systems over the years.

Another distinction is that developed countries tend to have independent or at least autonomous HTA agencies, while developing countries typically have HTA agencies operating under the MoH. One implication of this institutional governance model is its influence on the agency's ability to define prioritisation criteria and establish willingness-to-pay thresholds. However, it is crucial to recognise that developing countries face greater challenges in ensuring access to essential medicines for their populations (Stevens and Huys, 2017). Therefore, aligning HTA processes with the health priorities set by national health policies is particularly important in these contexts.

Regarding economic analysis, there is widespread adherence to cost-effectiveness evaluations, including cost-utility, cost-minimisation, and cost-benefit analyses. All the countries studied, except Germany, assess health effects using a ICER per QALY. Germany, in contrast, employs an additional benefit analysis compared to an appropriate comparator therapy. Additionally, all countries incorporate budget impact analysis in their decision-making for new medicine reimbursement, although not all set explicit thresholds for this impact. While cost-effectiveness analyses are widely used internationally, some studies (Castañeda-Orjuela et al., 2020; Diamond and Kaul, 2009; Mazzucato and Roy, 2019) have highlighted limitations of this method, particularly in its ability to capture the true value of medicines and, consequently, enhance population health access.

Another significant difference in HTA processes across countries relates to decision-making and healthcare system management. Generally, countries with a more centralised healthcare system structure, such as England, Colombia, and Mexico, enforce HTA recommendations as mandatory and have well-defined willingness-to-pay criteria for new medicines. This is because a single governing entity oversees healthcare service provision, reimbursement decisions, and budget allocation. In contrast, countries with decentralised healthcare systems, such as Canada, Australia, and India, involve multiple entities in decisions regarding which health services and products to provide and reimburse, leading to variations in access and potential disparities in healthcare equity (Sapkota et al., 2023; Sumah et al., 2016). There are two exceptions to this pattern. Germany, despite having a decentralised system, mandates HTA recommendations and sets clear willingness-to-pay thresholds. Meanwhile, Brazil also operates a decentralised healthcare system, but decisions on medicine reimbursement remain centralised within the MoH.

The influence of HTA on new medicine pricing appears to be closely linked to the maturity of HTA processes. Countries with more advanced HTA frameworks, such as England, Australia, and Germany, establish a clear and direct link between HTA outcomes and medicine price negotiations. They also implement specialised pricing agreements and are the only ones to adopt uncertainty-based pricing arrangements, typically involving temporary agreements while additional evidence is gathered. England stands out in this regard, offering a range of agreements, including performance-based and risk-sharing schemes. Additionally, the English system has dedicated funds for high-cost medicines, ensuring access to innovative treatments while imposing spending limits on medicines with uncertain benefits. In contrast, developing countries still lack experience integrating HTA into medicine pricing, particularly for treatments with uncertain outcomes. Nonetheless, Colombia is progressing in this area, working towards an innovative pricing model based on HTA recommendations.

5.1 Implications for public policies.

The findings of this study offer valuable insights for shaping public policies. First, the integration of HTA into pricing decisions should be strengthened, and decision-making should be centralised. Governments should ensure clear decision-making criteria, and budget impact assessments are central to reimbursement and price-setting processes. Centralising medicine pricing negotiations

within the Ministry of Health enhances bargaining power by allowing for coordinated procurement strategies and stronger price control mechanisms. Second, implement formalised risk-sharing agreements. Like England's approach, countries should introduce managed entry agreements for medicines with uncertain long-term benefits, ensuring prices reflect real-world effectiveness and reducing financial risks for public health systems. Implementing this practice would require a formal governance framework to ensure transparency in risk-sharing objectives, establish accountability rules, and mitigate potential conflicts, as it involves multiple stakeholders with differing interests and requires the evaluation of complex outcomes. Third, transparency in price-setting and stakeholder engagement should be increased. Strengthening public accountability and negotiation processes will ensure fair pricing strategies that balance affordability with incentives for pharmaceutical innovation. Lastly, it enhances regional and international collaboration. Governments should engage in cross-country cooperation on HTA methodologies and pricing benchmarks, particularly in developing economies, facilitating knowledge exchange and improving public procurement efficiency.

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Tables

Table 1: Analytic framework: Theme and item of HTA

Theme	Item
Programme Structure	Body/entity responsible for HTA.
	Website
	Year of establishment
	Role of HTA in relation to decision making
	Institutional governance
	Scope
	Target audience
	Financing
	Annual budget
	Capacity building
	Stakeholder involvement
Topic Selection	Topic identification
	Topic refinement
	Topic prioritisation
Evidence Synthesis	Clinical evaluation
	Economic evaluation
	Entities conducting evidence reviews
	Appraisal process
	Types of recommendations
	Evidence gathering
Decision Making (reimbursement)	Decision-making process
	Decision-making bodies
	Decision-making criteria
	Use of recommendation
	Appeals process
	Public consultations
Transparency	Public documents
	Timeline
Implementation	HTA products
	Medication reimbursement timeframe
	HTA review
Pricing	Influence of HTA on pricing
	Pricing model
	Special agreements

Source: Own elaboration based on Lima et al. (2019), Pinson et al. (2011), Stafinski et al. (2022), Kalo et al. (2016), Rosseli et al. (2017), Drummond et al. (2008), Thokala et al. (2020), Trowman et al. (2021).

Table 2: Country selection criteria

Selected countries	UHC Index	Socioeconomic condition	Innovative experience in HTA	HTA guidelines availability
England	88	High income	X	X
Canada	91	High income	X	X
Australia	87	High income	X	X
Germany	88	High income	X	X
Colombia	80	Middle-high income	X	X
Mexico	75	Middle-high income		X
India	63	Middle-low income		X
Brazil	80	Middle-high income		X

Source: Own elaboration based on WHO (2023b) e World Bank (2023).

Table 3: Comparison of medicines HTA processes in the selected countries

Country	England	Canada	Australia	Germany	Colombia	Mexico	India	Brazil
Healthcare system manag	Centralised	Decentralised	Decentralised	Decentralised	Centralised	Centralised	Decentralised	Decentralised
HTA governance	Autonomous governmental organisation	Independent, non-governmental and non-profit	Independent statutory body	Non-governmental, autonomous and non-profit institution	Non-profit institution with mixed private and public participation	Autonomous institution linked to the MoH	Semi-autonomous body, part of the MoH	Governmental commission linked to the MoH
Criteria for prioritising topics	Disease burden, impact on resource use, likelihood of influencing public policy, quality of life, and reducing healthcare access disparities	Consultation with federal, provincial, and territorial jurisdictions through advisory committees assessing topic relevance	Not reported	Topics affecting at least 1% of the population at a given time or within a specified year	Disease burden, clinical practice guidelines, first-line care, affected population group, and prescription frequency	No explicit criteria	Population size, disease severity, potential therapeutic benefit, economic impact, evidence availability, and health policy priorities	Not reported
Type of economic analysis	Cost-effectiveness and cost-utility; and budget impact	Cost-utility; and budget impact	Cost-utility and cost-minimisation; and budget impact	Budget impact	Cost-effectiveness, cost-utility, and cost-benefit; and budget impact	Cost-effectiveness, cost-utility, cost-benefit, and cost-minimisation; and budget impact	Cost-effectiveness, cost-utility, and cost-benefit; and budget impact	Cost-effectiveness, cost-utility, cost-benefit, and cost-minimisation; and budget impact
Decision-making (threshold)	£20,000–£30,000 ICER per QALY; budget impact up to £20 million in the first three years	Not defined	Not defined. Budget impact up to AUD 20 million per year	Additional benefit over an appropriate comparator therapy. Budget impact up to €1 million per year for common medicines or up to €30 million for orphan diseases	1 to 3 times GDP per capita. Budget impact not defined	More effective and less costly medicines than comparators. ICER per QALY or DALY equal to or lower than GDP per capita. Budget impact up to 5%	DALY lower than up to three times GDP per capita (not explicit). Budget impact not defined	Not defined
Use of recommendation	Mandatory	Not mandatory	Not mandatory, except for decisions not to recommend inclusion	Mandatory	Mandatory	Mandatory	Not mandatory, except for decisions not to recommend inclusion	Mandatory
Type of recommendation	Recommended; Optimised; Recommended with managed access; Recommended in a	Reimburse; limited-time reimbursement; Do not reimburse	Recommended; Not recommended	Indication of substantial additional benefit; Indication of minimal additional benefit; No additional benefit (evidenced)	Recommended; Not recommended	Approved or Maintain current medication	Recommended; Not recommended	Recommended; Not recommended

	research context; Not recommended							
HTA Timeline	12 to 14 months	90 to 120 days	17 weeks	Two stages of three months each	Not reported	60 days	Not reported	180 days (extendable by 90 days)
Timeframe for medicine dispensing	3 months	Not defined	Not defined	Automatically available after marketing approval, but reimbursement granted after price negotiation	Not defined	Immediate	Not defined	180 days

Source: Own elaboration.

Table 4: Medicines pricing in the selected countries

Country	Influence of HTA on Pricing	Standard Pricing Model	Special Pricing Agreements	Special Agreements for Medications with Uncertain Outcomes
England	Direct	Voluntary and Statutory Scheme	Patient Access Schemes (PAS); Commercial Access Agreements (CAAs)	Managed Access Agreements (Cancer Drugs Fund and Innovative Medicines Fund)
Canada	Direct	Potential Maximum Average Price	Product Listing Agreements (PLAs)	Temporary Access Process
Australia	Direct	Reference Pricing Statutory Price Reduction	Special Price Agreement; Strategic Agreement	Managed Access Program; Risk-sharing Agreement
Germany	Direct	Reference Group Pricing	Based on additional clinical benefit (comparator therapy cost + premium)	Limited-time Reference Group Pricing and Renegotiation
Colombia	Direct under implementa-tion	International Reference Pricing	Value-based pricing (therapeutic value and international reference prices)	NA
Mexico	Indirect	Maximum Retail Price	Price agreements for a one-year period	NA
India	Indirect	Maximum ceiling for essential medicines	NA	NA
Brazil	None	Set by CMED/Anvisa, before HTA decision	NA	NA

Source: Own elaboration.