USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

*Improved Access. Improved Services. Better Health Outcomes.*

# Review of Pricing Policies and Price Lists Available in Asia Regional Countries

September 2021


USAID
FROM THE AMERICAN PEOPLE

## Recommended Citation

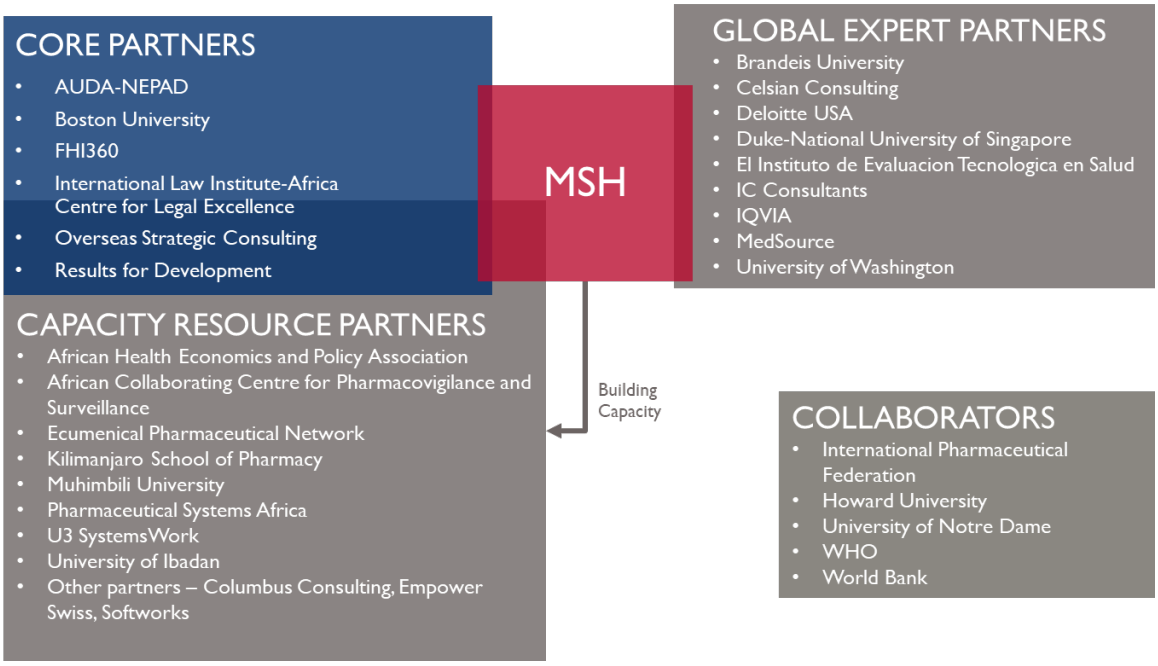
Ursu, I. *Review of Pricing Policies and Price Lists Available in Asia Regional Countries*. September 2021. Prepared for the US Agency for International Development by the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program. Arlington, VA: Management Sciences for Health, Inc.

*This document is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.*

## About the USAID MTaPS Program

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on the appropriate use of medicines to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

## The MTaPS Consortium




**This report is submitted by:**
Ioana Ursu
Pharmaceutical Pricing and Policy Consultant
Results for Development
1111 19th St. NW; Suite 700
Washington, DC 20036

# PROJECT SUMMARY

| | | |
|---|---|---|
| **Program Name:** | | USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program |
| **Activity Start Date and End Date:** | | September 20, 2018–September 19, 2023 |
| **Name of Prime Implementing Partner:** | | Management Sciences for Health |
| **Contract Number:** | | 7200AA18C00074 |
| **MTaPS Partners** | **Core Partners** | Boston University, FHI 360, Overseas Strategic Consulting, Results for Development, International Law Institute-Africa Centre for Legal Excellence, NEPAD |
| | **Global Expert Partners** | Brandeis University, Deloitte USA, Duke-National University of Singapore, El Instituto de Evaluacion Technologica en Salud, IC Consultants, Imperial Health Sciences, MedSource, QuintilesIMS, University of Washington |
| | **Capacity Resource Partners** | African Health Economics and Policy Association, Ecumenical Pharmaceutical Network, U3 SystemsWork, University of Ibadan, University of Ghana's World Health Organizations (WHO) Pharmacovigilance Collaborating Center, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa |
| | **Collaborators** | International Pharmaceutical Federation, Howard University, University of Notre Dame, WHO, World Bank |

# ACKNOWLEDGEMENTS

Ioana Ursu led development of this report. Andre Zida (R4D) and Laurel Hatt (R4D) provided guidance and feedback along the way; Reva Alperson (R4D) finalized and cross-checked all citations.

# Acronyms and Abbreviations

| | |
|---|---|
| ADP | Additional Drug Package |
| AIOCD AWACS | All India Organization of Chemists and Druggists and Advanced Working, Action and Correction System |
| APAC | Asia-Pacific countries |
| API | active principle ingredient |
| ATC | Anatomical Therapeutic Chemical |
| CMS | Central Medical Stores |
| CMSD | Central Medical Stores Depot |
| COBAC | Central Office for Bids and Awards Committee |
| CPA | Complementary Package of Activity |
| DAV | Vietnam's Drug Administration |
| DDA | Department of Drug Administration |
| DGDA | Directorate General of Drug Administration |
| DOH | Department of Health |
| DPCO | Drug Price Control Orders |
| DPRI | Drug Price Reference Index |
| EDCL | Essential Drug Company Limited |
| ERP | external reference pricing |
| FDL | Free Drug List |
| HEF | Health Equity Fund |
| HIB | Health Insurance Board |
| HTA | Health Technology Assessment |
| HWCs | Health and Wellness Centers |
| INN | international nonproprietary name |
| IRP | Internal reference pricing |
| LKPP | Kebijakan Pengadaan Barang Jasa Pemerintah |

| | |
|---|---|
| LMICs | low- and middle-income countries |
| MEA | managed entry agreement |
| MHIF | Mandatory Health Insurance Fund |
| MOH | Ministry of Health |
| MPA | Minimum Package of Activity |
| MRP | maximum retail price |
| MSH | Management Sciences for Health |
| MTaPS | Medicines, Technologies, and Pharmaceutical Services |
| MWP | maximum wholesale price |
| NEML | national essential medicines list |
| NMRA | National Medicines Regulatory Authority |
| NPPA | National Pharmaceutical Pricing Authority |
| NSSF | National Social Security Fund |
| OOP | out of pocket |
| PD | Pharmaceutical Division |
| PNF | Philippines National Formulary |
| SAMES | Service Autonomo de medicamentos e Equipamentos de Saude |
| SGBP | state-guaranteed benefit program |
| SPC | State Pharmaceuticals Corporation |
| SPMC | State Pharmaceuticals Manufacturing Corporation |
| STEP | Health Technology Assessment Unit of the Philippines |
| UHC | universal health coverage |
| USAID | US Agency for International Development |
| WHO | World Health Organization |
| VPB | value-based pricing |

# Contents

# 1. Introduction

Health care expenditures have risen dramatically across the world. In recent years,[1] they have largely outpaced economic growth, and this trend is expected to continue in the future. In countries where health insurance is not yet fully in place, half of health care spending has been taken over by households: in lower-middle and low-income Asia-Pacific countries (APAC), on average, household out-of-pocket (OOP) spending accounted for 48.2% of the total health expenditure in 2015[1]—an increase of one percentage point from 2010—signaling that significant gaps in providing health coverage remain in the region. Pharmaceutical expenditures are a significant driver of increasing health care costs,[2] accounting for one-quarter of all health expenditures in APAC and up to one-third of all health expenditure across lower-middle and low-income APAC countries in 2015.[1] The rising impact of medicines' cost on household budgets can have multiple roots, such as unaffordable prices of medicines, overprescribing and overutilization of treatment, and unregulated marketing. While considerable steps have been taken to increase health coverage in the region by including more medicines, across lower-middle and low-income APAC, most of the spending on pharmaceutical products remains OOP.[1]

In an effort to contain rising health care costs, many Asian countries have developed formal strategies aimed at influencing prices of medicines financed by the public sector.[3] Although there is a fair amount of information on these strategies available in the public domain and on ministry of health (MOH) websites, there are limited documents looking across countries to provide information in one centralized manner. With the support of the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, a review of information was initiated in 11 countries that currently receive USAID Global Health assistance. The goal of the review was to identify the various medicine pricing policies used by APAC public health authorities based on their legislation and on peer-reviewed and grey literature and document key differences in implementation.

This project aims to inform regional regulators, implementing agencies on the ground, and donors on the existing practices and potential medicines pricing interventions to be considered to reach universal health coverage (UHC). The report aims to:

1. Act as a repository of pricing policies used in the targeted countries
2. Document what information is publicly available on manufacturer, wholesale, and retail prices
3. Review the extent to which indexes and international reference pricing rules are being designed and used to standardize purchase prices and negotiate the best value for such products
4. Assess whether country-level pricing policies are normative in nature and are consistently followed and implemented by purchasing organizations

Ultimately, the transversal analysis across countries should highlight which interventions within the continuum of pricing policies are being implemented and which other interventions could be considered.

# 2. Methodology

[1] OECD/WHO. (2019) Health at a glance 2019. OECD Publishing.
[2] Wirtz VJ, Hogerzeil HV, Gray AL, et al. (2017). Essential medicines for universal health coverage. Lancet. 2017;389(10067):403–9.
[3] Verghese NR, Barrenetxea J, Bhargava Y, Agrawal S, Finkelstein EA. (2019). Government pharmaceutical pricing strategies in the Asia-Pacific region: an overview, Journal of Market Access & Health Policy, 7:1, DOI: 10.1080/20016689.2019.1601060.

## 2.1 DESCRIPTION

For the purpose of this report, we have adopted the World Health Organization (WHO) definition of a pricing policy: "a set of written principles or requirements for managing the prices of pharmaceutical products, agreed or adopted by a public institution (e.g., a government authority), a group of purchasing organizations, or individual health services".[5]

There are multiple ways to categorize pricing policies, including direct/indirect price controls, supply/demand, and pricing interventions for reimbursed vs OOP market. In common practice, the term "pricing policies" is used to refer to supply-side interventions that target the price offered by medicine suppliers (e.g., manufacturers, wholesalers, retailers).[5,6]

The WHO Guidelines on Pricing[4] recognize there are also demand-side interventions targeted at the usage of medicines (e.g., generic prescribing) that are likely to have an indirect impact on price. As a result, we have included in our research a quick review of the main demand-side policies that are likely to have an impact on price in the targeted countries while recognizing they are not pricing policies *per-se*. The main focus of work, however, remains on the choices made by the decision makers of the 11 countries with regard to setting the price of medicines in their countries, in line with the mainstream meaning of pricing policies as supply-side interventions.

## 2.2 PRICING POLICIES

The pricing interventions evaluated across the 11 countries stem from the 2020 WHO guidelines on pricing policies and the 2019 WHO report on pricing of cancer medicines.[5] While the pricing guidelines mainly detail the technical elements and required administrative complexity of each of these policies, the WHO 2019 medicines report highlights the impact on price when using each of these policies. From the two reports, we derived a continuum of potential pricing policies that a country can engage in, from less to more complex (figure 1). We recognize there is a high degree of subjectivity on how more or less complex we judged the policy to be, based on:

- Ease of use—the need for trained technical staff able to define and implement the policy (e.g., health economists)
- Need for special regulation (e.g., negotiation procedures, definition of Quality Adjusted Life Years and Incremental Cost Effectiveness Ratio)
- Whether it is part of a combined pricing and reimbursement approach and therefore involving both the central authority and a "payer" (UHC as social insurance implementation)
- Need for tracking—can it be done on paper/Excel or does it require more complex electronic means, such as electronic prescribing and/or dispensing
- Whether it requires additional control monitoring capabilities to ensure correct implementation

[4] World Health Organization. (2020). WHO guideline on country pharmaceutical pricing policies, second edition. ISBN 9789240011878.

[5] World Health Organization. (2019). Technical report: pricing of cancer medicines and its impacts: a comprehensive technical report for the World Health Assembly Resolution 70.12: operative paragraph 2.9 on pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer. World Health Organization. Available at: https://apps.who.int/iris/handle/10665/277190. License: CC BY-NC-SA 3.0 IGO.

**Figure 1: Framework of pricing policies used by national public health authorities as benchmark for assessment of the 11 countries:**[5,6]

### Free pricing

**Definition**: Price determined by the market. It assumes there are multiple suppliers able and interested to be in the market; the good is homogenous (the same or similar, at same quality); there is accurate and complete information with demand and supply having similar level of knowledge about the product sold; and there are (almost) no barriers to entry or exit.
**Applied to**: All products, when there is strong competition or only some products (e.g., only for a category of products with high competition, like over-the-counter medicines).
**Price set at**: Manufacturer, wholesaler, or retail level.

### External reference pricing (ERP)

**Definition**: External reference pricing or international reference pricing refers to the practice of using the price of a pharmaceutical product in one or several countries to derive a benchmark or reference price for the purpose of setting or negotiating the price of the product.
**Applied to**: Most commonly to innovative (single-source/on patent) medicines, as it is easier to compare the same medicine from the same manufacturer.
**Price set at**: Most commonly, manufacturer/importer level (i.e., manufacturer or wholesaler price).

### Generic capping

**Definition**: When the generic version becomes available, its maximum allowed price for the generic is subject to an official maximum proportion of the branded originator price.
**Applied to**: First, second, third...generic. Policy seen in markets where the price of innovative medicines is already regulated through a different method (e.g., external reference pricing or other).
**Price set at**: Most commonly, manufacturer/importer market entry level (i.e., manufacturer or wholesaler price).

### Cost-based pricing

**Definition**: Cost-based pricing, also known as cost-plus pricing, considers the costs associated with the inputs required for the production of goods or services. It requires cost information within the predefined scope (e.g., direct material costs, direct labor costs, overhead costs associated with research and development, manufacturing, regulatory processes and compliance, and other costs of business operation). To determine the final price, the manufacturer and the pricing authority need to come to agreement on profit margin in addition to the estimated costs (i.e., percentage or a fixed amount).
**Applied to**: Innovative or generic medicines or devices.
**Price set at**: Most commonly used to set manufacturer price level for local manufacturers.

### Tendering

**Definition**: A competitive bidding process whereby the winning tenderer would be awarded a contract for supplying a medicine or a set of medicines. Usage of tendering implies that there is an authority with a set budget, as well as minimum of two suppliers for the same medicine.
**Applied to**: Generic and off-patent innovative medicines.
**Price set at**: Wholesale (most common) or retail level.

### Price negotiations

**Definition**: Direct price discussions and agreement between health authorities and supplier; can be face to face or through written communication. Pricing negotiations imply the fulfilment of set behaviors (e.g., criteria for participants, setting what other elements besides price can be negotiated) and can involve one or more products. Price negotiations can be used on their own as a pricing tool or as a final step for other pricing policies (e.g., failure of tenders due to lack of competitors).
**Applied to**: Innovative/single-source, on patent medicines (most common).
**Price set at**: Manufacturer, wholesaler, and/or retail level.

### Supply-chain margins control

**Definition**: A mark-up, or margin, represents the additional charges and costs that are applied to the price of a commodity. In pharmaceutical policy, mark-ups applied are the result of one or a combination of regressive/progressive and/or linear/fixed margins. It is a policy intervention most common in countries where ex-manufacturer prices are set through a different pricing policy (e.g., ERP).
**Applied to**: All types of medicines.
**Prices set at**: Wholesale and retail level as pharmaceutical remuneration.

### Clawback on sales

**Definition**: Health authorities reach an agreement with the pharmaceutical industry present in the country on an acceptable value for overall pharmaceutical spending. Should the overall value of sales of pharmaceuticals surpass the set limit, the amount will be paid back ("clawback") by all suppliers (manufacturers) present in the market. The formula used to calculate how much each supplier owes differs from country to country and reflects the nature of the market and the agreement between the authorities and the industry.
**Applied to**: All types or only certain categories of medicines. A universal clawback rate applied to all products tends to have a negative impact on availability of older, lower-profit margin medicines like generics where there is a risk that the profit margin is lower than the clawback rate.
**Prices set at**: There is no set price for one product, just a capped amount of money/budget.

### Internal reference pricing (IRP)

**Definition**: Internal reference pricing (IRP) implies the creation of groups/clusters of medicines that will be benchmarked against one another (e.g., by Internal Nonproprietary Name [INN] or therapeutic class). IRP signals the maximum cost covered from the insurance budget, for example, with the difference being paid OOP.
**Applied to**: Medicines for which multiple generic versions are already available; classes of medicines with multiple similar treatment options (e.g., statins).
**Price set at**: Most commonly used to set retail-level prices; can also be used to set manufacturer or wholesaler prices during registration of medicines in the country by comparing the requested price to the prices already existent in the country.

**Value-based pricing**

**Definition**: Value-based pricing or value pricing aims to determine the prices of medicines according to the value or worth that patients and health systems attribute to the medicine. In countries where there is a process for assessing the value of medicines (Health Technology Assessment [HTA]), governments or authorized organizations consider the proposed price and costs of a medicine alongside scientific evidence regarding the clinical benefit of the new intervention within a specific context of use.
**Applied to**: Mostly innovative/single-source/on patent medicines.
**Price set at**: Manufacturer level.

**Managed entry/risk sharing agreements**

**Definition**: An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. A managed entry agreement (MEA) has also been referred to as a risk-share arrangement to reflect its intent for sharing the risks—financial risks or uncertainties relating to the performance of the new medicine. It generally implies the existence of a "payer" with well-developed capacity and structures to track and monitor usage and performance of the medicine in real-world settings.
**Applied to**: Mostly innovative/single-source/on-patent medicines.
**Price set at**: Manufacturer level.

It is worth noting that using one policy intervention does not exclude using other types. The WHO 2019 report suggests quite the opposite: in most countries using pricing regulation, multiple types of pricing interventions are used in parallel for different categories of medicines and sometimes for different settings.

### 2.3 RESEARCH APPROACH AND SEARCH TERMS

The review adopted a mix of secondary desk research and qualitative primary research. The desk research targeted English and local-language peer reviewed articles and MOH-issued documentation in 11 Asia Bureau-supported countries that had bilateral missions and were receiving USAID Global Health assistance: Bangladesh, Cambodia, India, Indonesia, Kyrgyz Republic, Myanmar, Nepal, the Philippines, Sri Lanka, Timor-Leste, and Vietnam.[6] WHO and OECD country profiles and PubMed, Medline, and Cochrane databases were searched through September 2020.

Search strategies used the terms 'pharmaceutical pricing policies', 'Asia', 'Asia Pacific', 'reimbursed/covered medicines', 'prescription medicine pricing', and 'essential medicines list' and individual country names. A keyword search was also conducted by combining the terms 'pharmaceutical', 'strategy', 'policy', and 'medicines'; specific policy names (e.g., 'pricing', 'tendering', 'public procurement', 'price negotiation', 'margins', 'generic prescribing', 'generic substitution', 'guideline', 'guideline groups'); and individual country names. An identical strategy was also used to search non-peer reviewed sources, including government websites, newspaper articles, reports from multilateral organizations such as WHO, and white papers. For government websites, Google translate was used to translate from local languages to English when possible. We scanned titles and abstracts to narrow our selection to relevant documents—in total 122 documents across 11 countries, of which 104 were official legislation published by central health authorities. The search was further supplemented by a review of relevant bibliographies for studies that met our criteria but that our search strategy may have missed. Information retrieved from our search included definitions of pricing strategies, countries that are using these strategies, and differences in implementation across countries.

[6] These 11 countries were listed in the approved MTaPS Asia Bureau work plan.

## 2.4 CONFIRMATION OF FINDINGS (PRIMARY RESEARCH) AND PRESENTATION OF RESULTS

A draft country profile was developed for each country that summarized which intervention is used and its design. The draft country report was discussed through a qualitative interview with one policy practitioner in each country. Phone/Skype interviews took place throughout September 2020 on a voluntary basis, with each lasting approximately 90 minutes. To be selected, interviewees had to have been involved in developing pricing policies in the given country or be a well-recognized expert (peer-reviewed author) on pricing policies for the target countries.

As a last step, to allow a quick, visual comparison among countries, a simplified, brief country overview table was developed that shows which intervention is used:


| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Demand-side interventions*** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) generic substitution** | | **Prescribing protocol** | **Prior authorization** | | **Electronic prescribing monitoring tools** | |

Most countries included in this review have different levels of implementation of the above identified pricing interventions (some only apply a policy to public-sector prices, for example). For the country overview and also for easier comparison, we have combined the following symbol system with a color-coding one to be able to highlight at a glance:

1. Policies being used and implemented by both public and private facilities (✓)
2. Policies used but applied only to one part of the market (e.g., only public facilities) (±)
3. Policies defined but not yet implemented (no rules for implementation found) (--)
4. Gap/policy not used – cell shaded in red

Detailed individual country profiles are presented in this report as annexes, providing additional information on each policy being used, to which sector it applies, and for which category of medicines the policy is being used. After presenting each intervention in the given country profile, we highlight the potential gaps in policy versus best practices or limitations as they are explained in the WHO technical report.[7]

## 2.5 LIMITATIONS OF THIS STUDY

The study is based mainly on a review of publicly available legislation for each country and donor country reports. As result, our assessment of the policies does not capture the full spectrum of implementation and/or enforcement of these policies, which can be evaluated though additional primary research on the ground. We considered a policy to be implemented when it was defined in a high-level document (e.g., governmental document) and subsequent implementation documents were issued, or subsequent country reports mentioned the impact of the policy implementation. Furthermore, this study cannot confirm whether the prices resulting from the application of these policies are indeed used in practice.

[7] World Health Organization. (2015). WHO guideline on country pharmaceutical pricing policies. ISBN 978 92 4 154903 5.

Similarly, whether a policy applies to public- and/or private-sector settings is solely based on the data provided in the legislation referenced. The study cannot confirm whether all public and/or private facilities in the given country follow the rules issued through the quoted legislation.

While all efforts have been made to ensure accuracy and detail on the content of each policy and what it addresses, this paper is not able to inform whether the implementation of one particular intervention led to better results than another one. Similarly, this research is not able to provide a rationale as to why certain interventions have been implemented over others. These are valid questions that could warrant further research in the area.

# 3. RESULTS

## 3.1 PRICING POLICIES OVERVIEW – SUPPLY SIDE

**Table 1: Map of supply-side interventions**

| Supply-side Inter-ventions | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Claw-back on sales | IRP | VBP (HTA) | MEA |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Bangladesh | ± | | | ✓ | ✓ | | | | | | |
| Cambodia | ✓ | | | | ✓ | | | | | | |
| India | ± | | | | ✓ | | ± | | ✓ | -- | |
| Indonesia | ± | | | ✓ | ✓ | | ± | | ± | | |
| Kyrgyz Republic | ± | ✓ | | | ✓ | | ✓ | | | | |
| Myanmar | ✓ | | | | ✓ | | | | | | |
| Nepal | ± | | | | ✓ | | | | ± | | |
| Philippines | ± | ✓ | | | ✓ | | ± | | | ± | |
| Sri Lanka | | ± | | | ✓ | | | | ± | | |
| Timor-Leste | ✓ | | | | ✓ | | | | | | |
| Vietnam | | ✓ | | ✓ | ✓ | ✓ | ✓ | | ✓ | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

Table key: Policies being used and implemented by both public and private facilities (✓); Policies used but applied only to one part of the market (e.g., only public facilities) (±); Policies defined but not yet implemented (no rules for implementation found) (--); Gap/policy not used – cell shaded in red

## FREE PRICING

**Free pricing**

**Definition**: Price determined by the market. It assumes there are multiple suppliers able and interested to be in the market; the good is homogenous (the same or similar, at same quality); there is accurate and complete information with demand and supply having similar level of knowledge about the product sold; and there are (almost) no barriers to entry or exit.
**Applied to**: All products when there is strong competition or only some products (e.g., only for a category of products with high competition, like over-the-counter medicines).
**Price set at**: Manufacturer, wholesaler, or retail level.

The region is slowly moving away from free pricing that allows the manufacturer/importer to set the price based solely on competition and market status. The only countries in this report where a "pure" free pricing approach is still taking place are Timor-Leste, Myanmar, and Cambodia.

Over the past three to four years, Bangladesh, the Philippines, and Kyrgyz Republic have introduced the first attempts at regulating the price of a restrained list of molecules—mostly based on their national essential medicines lists (NEMLs).

India and Indonesia have gone one step further, and while they are still allowing manufacturers to set their own prices with the exception of the NEML, they also request all manufacturers to declare the maximum retail price (MRP) at the point of registration/authorization in the country. Furthermore, India has limited the maximum percentage increase year on year from the initial declared price for all medicines in the country, independent of which sector they target (public or private).

Vietnam and Sri Lanka stand out through their decision to implement price regulation for all medicines made available in the market by relying on a combination of ERP and IRP to set their prices.

## EXTERNAL REFERRENCE PRICING[7]

**ERP**

**Definition**: External reference pricing or international reference pricing refers to the practice of using the price of a pharmaceutical product in one or several countries to derive a benchmark or reference price for the purpose of setting or negotiating the price of the product.
**Applied to**: Most commonly to innovative (single-source/on patent) medicines, as it is easier to compare the same medicine from the same manufacturer.
**Price set at**: Most commonly, manufacturer/importer level (i.e., manufacturer or wholesaler price).

Of the 11 countries reviewed in this document, Vietnam and more recently Sri Lanka, Kyrgyz Republic, and the Philippines have implemented an ERP mechanism. Vietnam and the Philippines reference wholesale prices, while Sri Lanka and Kyrgyz Republic reference manufacturer prices.

In all four countries, ERP is used only for specific categories of medicines. Vietnam and Sri Lanka use ERP only for new medicines that don't have a manufacturer/importer already registered in the country with another trade name. Sri Lanka remains open in terms of which countries should be presented by the marketing authorization holder, while Vietnam is more prescriptive and defines the reference

countries as "ASEAN countries where the medicine is registered"[8]—in practice, the most used reference countries are Thailand, Malaysia, Indonesia, the Philippines, and Cambodia.

Kyrgyz Republic has introduced ERP for the 300 medicines (58 active ingredients or INN) that are included in the NEML, which is the basis for the public procurement and state health insurance. Kyrgyz Republic has also defined quite broadly the countries to be referenced, although in practice the most referenced countries seem to be Moldova and Belarus.

The Philippines introduced the new ERP formula in 2020, and it is used to set the prices for 133 medicines (81 INN), mainly in ambulatory settings. According to the new legislation, the Philippines sets both a maximum wholesale price (MWP) and MRP, derived from the wholesale price to which fixed set margins are added. The Philippines references wholesaler prices from eight countries: five Asian (Thailand, Malaysia, Vietnam, India, and Indonesia) and three developed countries (United Kingdom, Australia, and Canada).

**Technical aspects related to implementation of external reference pricing**

In terms of choice of regulation, ERP is a means to cost contain pharmaceutical expenditure independent of the usage and volumes in the market. It acts as a ceiling for what can be the maximal accepted price for a given medicine in comparison to the other nominated countries ("basket countries"). In practical terms, when a country decides to use ERP, it defines specific conditions for the comparison and for the maximum allowed price as result of the comparison. To use ERP, a public authority defines:

1. Which medicines will be used for comparison—for example, most commonly, only the price of the same medicine from the same manufacturer, in the same form/presentation and concentration, are considered for comparison purposes; comparisons at INN level (i.e., the same generic from different manufacturers) are rare, not least due to industry backlash on potential differences in quality, production procedures, or costs of raw materials.
2. Which price will be compared—the manufacturer price (the most common), the wholesaler price, or the retail price.
3. The formula establishing the maximum allowed (manufacturer/wholesale/retail) price in the country versus the compared prices (e.g., maximum equal to the lowest available price/average price/average of the lowest two).
4. Prices set through ERP act as ceiling/reference for the market: suppliers can choose to go below the set price at their level but cannot go above it.

One of the main challenges of ERP is access to current, comparable prices in other relevant markets. This is where regional databases of prices, commonly shared among member states, become particularly relevant. In the absence of such networks and electronic tools, international price indexes can be used as reference, although the issue of prices averaged across manufactures and multiple markets generally impedes countries from using them as actual policy tools. This has also been confirmed by this current research project: Of the 11 countries researched, several quote the MSH Internal Guide on Medicine Prices to compare national prices to an international reference, but none have actually created ERP rules that would reference such databases.

Additional information on the implementation and effects of ERP can be found at:

World Health Organization. (2020). WHO guideline on country pharmaceutical pricing policies, second edition. ISBN 9789240011878.

World Health Organization. (2019). Technical report: pricing of cancer medicines and its impacts: a comprehensive technical report for the World Health Assembly Resolution 70.12: operative paragraph 2.9 on pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer. World Health Organization. https://apps.who.int/iris/handle/10665/277190. License: CC BY-NC-SA 3.0 IGO.

[8] Nguyen TA. Medicine prices and pricing policies in Vietnam. (2011). In: School of public health and community medicine. Sydney: The University of New South Wales.

## GENERIC CAPPING

**Generic capping**

**Definition**: When the generic version becomes available, its maximum allowed price for the generic is subject to an official maximum proportion of the branded originator price.
**Applied to**: First, second, third...generic. Policy seen in markets where the price of innovative medicines is already regulated through a different method (e.g., ERP, VBP).
**Price set at**: Most commonly, manufacturer/importer market entry level (i.e., manufacturer or wholesaler price).

None of the 11 countries included in this report use generic capping, though it is extensively used in other countries like the Republic of Moldova and Jordan. Examples of how this policy would work in practice can be found in Kanavos et al., *A methodological framework and empirical evidence from twelve EU Member States*, Health Policy (2014).[9]

## COST-BASED PRICING

**Cost-based pricing**

**Definition**: Cost-based pricing, also known as cost-plus pricing, considers the costs associated with the inputs required for the production of goods or services. It requires cost information within the predefined scope (e.g., direct material costs, direct labor costs, overhead costs associated with research and development, manufacturing, regulatory processes and compliance, and other costs of business operation). To determine the final price, the manufacturer and the pricing authority need to come to agreement on profit margin in addition to the estimated costs (i.e., percentage or a fixed amount).
**Applied to**: Innovative or generic medicines or devices.
**Price set at**: Most commonly used to set manufacturer price level for local manufacturers.

Of the 11 countries, three engage in cost-based pricing: Bangladesh, Indonesia, and Vietnam. Indonesia and Vietnam use cost-based pricing formulas for establishing maximal retail and wholesale prices for all products coming from their local manufacturers, while in Bangladesh the formula is used to establish the retail price only for essential medicines (117 INN) when they are produced by local manufacturers. Prices established in this manner are applied to both the public and private sectors across all three countries.

## TENDERING

**Tendering**

**Definition**: A competitive bidding process whereby the winning tenderer would be awarded a contract for supplying a medicine or a set of medicines. Usage of tendering implies that there is an authority with a set budget, as well as minimum of two suppliers for the same medicine.
**Applied to**: Generic and off-patent innovative medicines.
**Price set at**: Wholesale (most common) or retail level.

All reviewed countries use tendering as a form of cost containment for medicines procured with public resources. To get a better overview of whether tendering is mostly centralized or localized, see table II

[9] Kanavos P. (2014). Measuring performance in off-patent drug markets: A methodological framework and empirical evidence from twelve EU Member States. Health Policy. Available at: http://dx.doi.org/10.1016/j.healthpol.2014.08.005.

on the types of authorities issuing the tender in the 11 markets reviewed. Red indicates the preferred level for each country.

**Table 11: Types of tenders and medicines tendered**

| Authority issuing the tender | Centralized tender via national pharmaceutical company/ wholesaler* | Centralized tender via MOH* | Local tender (provincial/state or hospital) | Types of medicines tendered | |
|---|---|---|---|---|---|
| | | | | NEML/MOH positive list** | Other medicines allowed** |
| Bangladesh | ✓ | ✓ | ✓ | ✓ | |
| Cambodia | | ✓ | ✓ | ✓ | ✓ |
| India | | | ✓ (state level) | ✓ | ✓ |
| Indonesia | | ✓ | ✓ | ✓ | ✓ |
| Kyrgyz Republic | | | ✓ | ✓ | ✓ |
| Myanmar | | ✓ | ✓ | ✓ | |
| Nepal | | ✓ | ✓ | ✓ | ✓ |
| Philippines | ± | ✓ | ✓ | ✓ | |
| Sri Lanka | ✓ | | ± | ✓ | ✓ |
| Timor-Leste | ✓ | | ± | ✓ | |
| Vietnam | | ✓ | ✓ | ✓ | |

* Centralized tender via national pharmaceutical company/wholesaler – national tenders are conducted through a national, state-owned, private wholesaler/trading company; centralized tender via MOH – national tenders are conducted by the procurement unit of the MOH.
** Tendering is used to procure medicines from a predefined (positive) list issued by the MOH or its agencies, like the NEML. If the country allows procurement through tendering for other medicines outside the predefined list, it is indicated in the last column. ± - policy intervention partially used, only when the other interventions could not be used.

Eight of the analyzed countries try to use the power of pooled procurement to decrease the price of medicines and therefore favor centralized tendering over local (purchase at the local level in India is mainly led by state authorities/companies, and given the size of these states we assume wide pooled procurement is still achieved). For the eight countries, national open tender is the favored method for medicines not included in vertical programs. For the national open tender for the eight countries, donor support may be linked to procurement of commodities through international mechanisms. In case the tenders fail, further price negotiation conditions are defined in Indonesia, the Philippines, Sri Lanka, and Timor-Leste. The only country spelling out separate criteria for price negotiations for single-source medicines in the absence of a tender is Vietnam (see price negotiations below). Myanmar, Cambodia, and Bangladesh do not allow price negotiations, and it remains unclear what happens when there is only one provider or if bids fail due to lack of tender participants.

Across all countries, tender participants have to be registered with the national regulator. In Indonesia, the Philippines, and Bangladesh, national companies are favored over international ones. The Philippines

has set the rule explicitly, while Indonesia does so through the imposed ceiling prices that reflect the agreed cost-based prices with the local manufacturers. Bangladesh requests public facilities to procure 70%[10] of their generics from the state-owned manufacturer, the Essential Drug Company Limited (EDCL).

In 4 of the 11 countries (Cambodia, Kyrgyzstan, the Philippines, and Vietnam), the award criteria are solely based on price (lowest offer); all other countries allow for additional technical requirements to be considered (e.g., shelf life in Myanmar). The quality criteria are not explicitly defined as award criteria in any of the targeted countries; however, in all of the countries, for those medicines procured through **national** tenders, payment of invoices is conditioned on quality confirmation of the delivered lots from a nationally appointed laboratory (generally the laboratory of the national regulator).

With the exception of Vietnam, where tender agreements can cover up to three years, the majority of countries seem to prefer short-term tenders, generally for one year. Experience in more developed systems shows that multi-year agreements, where a minimum volume is guaranteed over a longer period, provide more predictability for the economic agents, allowing them to provide better prices.

Sri Lanka and Timor-Leste stand out for their centralized procurement via a state-owned private company; in Timor-Leste, the *Service Autonomo de medicamentos e Equipamentos de Saude* (SAMES) acts as a centralized procurement, wholesale, and supply system, providing medicines to the districts that then transport them to health facilities. Both SAMES and the State Pharmaceuticals Corporation (SPC) in Sri Lanka can also act also as provider for private-sector facilities; by doing so, the two governments created the possibility to influence and set the price for essential commodities across the whole system, not just public facilities.

Despite the wide use of tendering, transparency in the process differs substantially across countries, and the majority of countries do not explicitly publish who the members of the evaluation committee are or if they were requested to declare any conflicts of interest; awarded prices are also generally kept confidential and only shared with health facilities. Two exceptions are Indonesia and the Philippines. In the former, award-winning prices are published in the e-Catalogue (available online), while the latter provides the Drug Price Reference Index (DPRI), which averages the awarded tender price for each medicine across all public facilities, acting also as benchmark for the maximum allowed tender prices in the following year.

## PRICE NEGOTIATIONS

**Price negotiations**

**Definition**: Direct price discussions and agreement between health authorities and supplier; can be face to face or through written communication. Pricing negotiations imply the fulfilment of set behaviors (e.g., criteria for participants, setting what other elements besides price can be negotiated) and can involve one or more products. Price negotiations can be used on their own as a pricing tool or as a final step for other pricing policies (e.g., failure of tenders due to lack of competitors).
**Applied to**: Innovative/single-source, on patent medicines (most common).
**Price set at**: Manufacturer, wholesaler, and/or retail level.

Of the policy documents reviewed, only Vietnam seems to be engaging in price negotiations as a separate pricing method from tendering for single-source, innovative medicines, with clearly set criteria

[10] WHO SEARO. (2015). Bangladesh Situational Analysis: 13-25 September 2014, Report prepared using the WHO/SEARO workbook tool for undertaking a situational analysis of medicines in health care delivery in low- and middle-income countries.

of when negotiations will be used, who is on the negotiation committee, what data need to be submitted prior to negotiations, what other market-related data will be considered by the negotiation committee, and a general description of the negotiation mechanism. The price set through this method is established at the manufacturer level.

## SUPPLY CHAIN MANAGEMENT CONTROL

### Supply-chain margins control

**Definition**: A mark-up or supply margin represents the additional charges and costs that are applied to the price of a commodity order to cover overhead costs, distribution charges, and profit. In the context of the pharmaceutical supply chain, policies might involve regulation of wholesale and retail mark-ups as well as pharmaceutical remuneration[4]. The regulations may apply mark-ups to a base price (e.g. ex- manufacturer price), based on one or a combination of the following broad structures:
**Regressive**: decreasing amount or percentage of mark-ups with increasing base price
**Progressive**: increasing amount or percentage of mark-ups with increasing base price
**Linear**: same percentage mark-up for all prices
**Fixed**: same amount of mark-up for all prices

Of the 11 countries reviewed, five have developed mechanisms to control the retail price through control of the maximum allowed mark-ups: India, Indonesia, Kyrgyz Republic, the Philippines, and Vietnam. Of these, only Vietnam applies the methodology to all medicines in the market across both public and private pharmacies. In India, the 16% margin only applies to medicines included in the national formulary (the so-called "Scheduled medicines"), while in Indonesia, the 28% margin applied to e-Catalogue prices is only mandatory in public-sector facilities. In Kyrgyz Republic and the Philippines, the regressive margins are applied only to a category of medicines, and the maximum prices should be applied by both public- and private-sector agents.

## CLAWBACK

### Clawback on sales

**Definition**: Health authorities reach an agreement with the pharmaceutical industry present in the country on an acceptable value for overall pharmaceutical spending. Should the overall value of sales of pharmaceuticals surpass the set limit, the amount will be paid back ("clawback") by all suppliers (manufacturers) present in the market. The formula used to calculate how much each supplier owes differs from country to country and reflects the nature of the market and the agreement between the authorities and the industry.
**Applied to**: All types or only certain categories of medicines. A universal clawback rate applied to all products tends to have a negative impact on availability of older, lower-profit margin medicines like generics where there is a risk that the profit margin is lower than the clawback rate.
**Prices set at**: There is no set price for one product, just a capped amount of money.

None of the 11 countries included in the report seem to have considered the use of a clawback approach to limit the impact of pharmaceutical spending in their countries. Examples of how this would work in practice can be seen in the Pharmaceutical Price Regulation Scheme in England, Romania, and Bulgaria.

## INTERNAL REFERENCE PRICING

**Internal reference pricing**

**Definition**: Internal reference pricing (IRP) implies the creation of groups/clusters of medicines that will be benchmarked against one another (e.g., by Internal Nonproprietary Name [INN] or therapeutic class). IRP signals the maximum cost covered from the insurance budget, for example, with the difference being paid OOP.
**Applied to**: Medicines for which multiple generic versions are already available; classes of medicines with multiple similar treatment options (e.g., statins).
**Price set at**: Most commonly used to set retail-level prices; can also be used to set manufacturer or wholesaler prices during registration of medicines in the country by comparing the requested price to the prices already existent in the country.

Four countries in this study use IRP, either by the regulator or the newly set health insurance: India, Indonesia, Nepal, and Vietnam.

In India, IRP is the main pricing methodology used to set manufacturer ceiling prices for scheduled medicines. The ceiling price represents the average of the existing retail price for all of the branded and generic versions for that medicine. To calculate the ceiling prices, the Indian National Pharmaceutical Pricing Authority (NPPA) has contracted public and private agents to provide the data. Prices for scheduled medicines are reviewed annually and can go up or down depending on the ceiling price (see the India country profile for more detail).

Vietnam has taken a different approach for new generics whereby it uses the IRP to set wholesaler prices of a new generic medicine at a maximum equal to the mean historic price for the already existing brands with the same INN, dosage, and concentration. For its calculations, Vietnam's Drug Administration (DAV) relies on mandatory wholesaler annual declared prices.

Nepal is the only example among the 11 countries where the social health insurance scheme (Health Insurance Board [HIB]) uses IRP. For the medicines covered in ambulatory settings, the HIB has set reimbursement ceiling prices by INN and dosage. The reimbursement ceiling is based on the mean price across all the brands available for the same INN; some adjustment may be made based on market size, but the methodology is not very explicit. Should the patient choose a medicine priced above the ceiling price, the difference is paid OOP.

**Technical aspects related to the implementation of IRP**

Similar to ERP, IRP acts as a benchmark (most likely as a ceiling) for setting the price of newcomers at levels similar to the already existent competitors in the market. Two examples of how this works in practice can be seen in India and Vietnam. To implement IRP, an authority needs to define the following elements:

- Which medicines will be used for comparison (e.g., medicines with the same active ingredient, form, and dosage [most commonly used for setting the prices of NEML medicines]) or if price of therapeutically comparable medicines would also be considered
- Which price will be compared—the manufacturer price, the wholesaler price, or the retail price
- The formula establishing the maximum allowed (manufacturer/wholesale/retail) price of the new medicine versus internal existing ones (e.g., maximum equal to the lowest available price/average price/weighted average)
- Prices set through IRP act as ceiling/reference for the market, and suppliers can choose to go below the set price at their level but cannot go above it

As with other pricing policies discussed in this paper, IRP can be used in parallel with other pricing interventions.

IRP can be used as a pricing tool by regulatory agencies, such as when setting the maximum allowed price during the authorization process (India, Vietnam), but it is most well-known for its usage by health financing authorities (i.e., health insurances). A basic example of this can be seen in Nepal, where IRP is used to establish the price to be covered/reimbursed by the health insurance for a cluster of medicines, with the patient paying the difference in price should they choose a more expensive medicine in the cluster. In practice, the steps for this process are:

1. The health insurer defines clusters of equivalent medicines, such as all medicines with the same INN/form/dosage (e.g., clustering at Anatomical Therapeutic Chemical (ATC) classification level 5); less commonly, they can define broader clusters of medicines with a similar therapeutic effect (e.g., clustering at ATC level 3 or 4 for all statins).
2. The health insurer defines the level at which they want to establish the maximum reference price. Most often it is set at the retail level.
3. The health insurer defines a formula that establishes the maximum reference price they would cover for the given cluster of medicines and thus limits the assumed risk (e.g., the average of the three lowest retail prices).
4. Patients or their prescribers are free to use of any of the medicines in the cluster; pharmaceutical companies keep their freedom to price the product independent of the ceiling price set by the insurer.
5. If the price set by the supplier is higher than the reference price set by the health insurance, the patient pays the difference OOP.

## VALUE-BASED PRICING (USAGE OF HTA METHODOLOGY)

**Value based pricing**

**Definition**: Value-based pricing or value pricing aims to determine the prices of medicines according to the value or worth that patients and health systems attribute to the medicine. In countries where there is a process for assessing the value of medicines (Health Technology Assessment [HTA]), governments or authorized organizations consider the proposed price and costs of a medicine alongside scientific evidence regarding the clinical benefit of the new intervention within a specific context of use.
**Applied to**: Mostly innovative/single-source/on patent medicines.
**Price set at**: Manufacturer level.

Of the 11 countries included in this review, only India and the Philippines indicate the use of pharmacoeconomics and cost-effectiveness, although the pricing methodology is far from a fully developed value-based approach.

In India, if, as result of a revision to the NEML, there are new medicines (in terms of active principle ingredient (API)/INN) included in the schedule, the government has to appoint a standing committee of experts "with a view to recommend the retail prices of new drugs on the principles of

*Pharmacoeconomics*".[11] However, the criteria for establishing the price are not clearly laid out. Furthermore, when establishing whether a medicine should be included in the NEML and the schedule, the NEML Committee already takes into consideration cost-effectiveness. At this time, it is not clear if the cost-effectiveness analysis done for the NEML is also used for price setting, and if so, in what manner.

The Health Technology Assessment Unit of the Philippines (STEP) was finalized in 2019; the approach is mainly based on a cost-effectiveness analysis, and it will be focusing initially on high-cost new medicines. HTA will be used as the basis for inclusion in the national formulary, but a final administrative order linking the pricing of these new medicines to the results from HTA has yet to be signed.

Other attempts at implementing HTA have taken place in the region, although mostly in high- or upper middle-income countries. Malaysia was the first country in the region to establish an HTA program in 1995—the Malaysian Health Technology Assessment Section.[12] However, it was a decade later that South Korea (2006) and Thailand (2007) established HTA programs.[12] India (2019), Indonesia (2014), the Philippines (2019), and Vietnam (2013) have all recently introduced HTA programs.[13] The Malaysia, South Korea, and Thailand programs are well established with dedicated agencies for HTA, and evidence is used for price negotiation[8] More recently, countries such as Indonesia, India, and the Philippines have been formalized with an official agency dedicated to HTA. However, these programs have yet to inform pricing decisions. More nascent ones, such as the several pilots initiated by Vietnam, have not been formalized in the form of an MOH executive document or official institution integrated into the decision making process.

USAID has a long history of investing in pharmaceutical strengthening programs that include systematic priority-setting approaches such as HTA. These programs, including MTaPS, support decision making in health care and promote appropriate resource allocation in low- and middle-income countries (LMICs) to achieve sustainable UHC. This experience includes using evidence-based strategies for rational medicines use and systematic priority-setting approaches to developing NEMLs and standard treatment guidelines. Under the umbrella of these objectives, MTaPS has finalized a policy and guidance document for HTA implementation in LMICs to improve value-based resource allocation decisions for medicines. The document on HTA institutionalization in LMICs, *"A Roadmap for Systematic Priority Setting and Health Technology Assessment (HTA): A Practical Guide for Policy Action in Low- and Middle-Income Countries"*[14] (HTA Roadmap) was published in October 2020. Because there is little guidance for implementing HTA in most LMICs, MTaPS is helping shape the policy agenda and advance the technical foundations and regulation for incrementally implementing systematic priority setting and HTA in these contexts. MTaPS also conducted research on the status of HTA in Asian countries.[13] This helped identify potential challenges and areas for further support in the region. Hence, MTaPS is partnering with the Indonesian HTA Committee to strengthen its HTA process and train researchers on advanced HTA methods. MTaPS will also leverage the stepwise approach in the HTA Roadmap to provide regional training on advanced HTA methods to other countries interested in HTA and value-based pricing. These include

[11] Singh P, Ravi S, Dam D. (2020). Medicines in India: accessibility, affordability and quality, Brookings India Research Paper No. 032020-01. Available at: https://www.brookings.edu/wp-content/uploads/2020/03/Medicines-in-India_for-web-1.pdf.
[12] Liu G, Wu EQ, Ahn J, Kamae I, Xie J, Yang H. (2020). The development of health technology assessment in Asia: Current Status and Future Trends. Value in Health Regional Issues, Volume 21, 39-44. Available at: https://doi.org/10.1016/j.vhri.2019.08.472.
[13] Kumar R, Suharlim C, Amaris Caruso A, Gilmartin C, Mehra M, Castro H. Charting the progress of HTA in Asia: Are we ready for evidence-based decision-making. Arlington, Virginia: USAID/MSH (submitted for publication).
[14] Castro H et al. (2020). Practical Guide for Systematic Priority Setting and HTA Introduction: a Roadmap for Policy Action in Low- and Middle-Income Countries. Arlington, Virginia: USAID/MSH.

Kyrgyz Republic, the Philippines, and Vietnam. While the Philippines and Vietnam have initiated value-based pricing processes, this regional workshop will be a foundational event for Kyrgyz Republic.

***Technical aspects related to the implementation of VBP and HTA***

VPB through HTA is often done through a comparison against the next-best available therapeutic option(s). The assessment may also consider other locally relevant factors, such as disease patterns in the population and budgetary constraints, with a view to establishing the worthiness of that medicine within a specific context of use.

Efforts to establish the price of a medicine based on HTA rely heavily on the capacity of a country to develop a robust assessment framework that can be applied consistently across products, diseases, and settings. Different types of HTA methodologies are used by more sophisticated systems; the most well-known is cost-effectiveness analysis (used by the UK, Australia, Sweden, and the Institute for Clinical and Economic Review in the US); there are also lesser known methodologies like the Service Medical Rendu/Added Service Medical Rendu scales used by HAS in France, the innovation levels used by Germany and Italy, and less complex methodologies used in some of the former Eastern bloc countries.

There are many challenges to the implementation of VBP:

- HTA is only as good as the data used for it. Many new medicines only have clinical trial data and don't have well-established evidence to inform their clinical and economic values at the time when they are being considered for regulatory and reimbursement approvals. These include a lack of data to demonstrate benefits in survival and well-being or the likelihood of generating financial savings through avoidance of hospitalization.
- The relative value of a medicine may appear to be very high when compared to an inefficient current practice even though the absolute magnitude of benefits of the medicine is low (i.e., marginal benefits). This pitfall is known as the so-called straw man comparison, which could result in prices that are higher than the true value.
- It is an intensive, highly specialized resource activity that requires highly trained staff from multiple areas (e.g., clinical specialists, epidemiologists, pharmacists and pharmacologists, health economists, biostatisticians).

## MANAGED ENTRY AGREEMENTS AND USE OF IT INFRASTRUCTURE

**Managed entry/risk-sharing agreements**

**Definition**: An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. A managed entry agreement (MEA) has also been referred to as a risk-share arrangement to reflect its intent for sharing the risks—financial risks or uncertainties relating to the performance of the new medicine. It generally implies the existence of a "payer" with well-developed capacity and structures to track and monitor usage and performance of the medicine in real-world settings.
**Applied to**: Mostly innovative/single-source/on-patent medicines.
**Price set at**: Manufacturer level.

None of the 11 countries included in this report have started introducing managed entry/risk-sharing agreements, although a few countries in the region, including Singapore, Thailand, and South Korea, have implemented such schemes.

***Technical aspects related to the implementation of MEAs***

An MEA has also been referred to as a risk-share arrangement to reflect its intent for sharing the risks—financial risks or uncertainties relating to performance—between payers and manufacturers. There are two broad types of MEAs.

**Financial-based MEAs** typically specify conditions directly relating to price (i.e., price discount and cap); volume; or both. For example, in addition to using value-based pricing, authorities in Italy have implemented price-volume agreements to manage the price of "expensive, innovative drugs that involve large patient populations".[5] The agreements set out a price-volume relationship agreeable to both parties (e.g., half the prices of evolocumab and alirocumab at every increase of 25,000 treated patients).[5] MEAs generally impose confidential terms but broadly entail discounts, rebates, free stock, and capping of utilization to a threshold volume or number of patients.

**Performance-based MEAs** require payments to be contingent on achieving certain pre-agreed health outcomes or other milestones when implemented. For example, an MEA may specify nonpayment or discounts for patients who failed to respond to the treatment. It typically involves data collection through setting up registries or Phase IV trials. For example, the UK's National Institute for Health and Care Excellence entered into an agreement with the manufacturer of bortezomib in which the manufacturer was required to provide retrospective reimbursement to the payers for the costs of using bortezomib in patients who were subsequently identified as nonresponders. In return, the manufacturer would receive payment at the normal price for further doses of bortezomib used in patients who found to be responding to that medicine.[5]

In the 2019 WHO review of pricing methods,[5] discounts, rebates, and reduced prices for treatment initiation were the most commonly used arrangements.

MEAs can be in place for varying durations. The application of MEAs, particularly performance-based MEAs, requires good governance to ensure that the implementation is robust. Specifically, any conditions would need to be operationally manageable without having to dedicate a disproportionate amount of resources for complex monitoring and contract management. The implementation of MEAs requires strong background support from the information infrastructure, including the use of electronic health records to monitor patient health outcomes for the enforcement of performance-based MEA. Other challenges of MEAs include:

- Achieving distribution of risks acceptable to both the manufacturers and regulators (e.g., certainty of future payoffs)
- Linking research measurement in specific clinical contexts to pricing arrangement
- Minimizing potentially high transaction and administrative costs
- Discouraging manufacturers from seeking higher prices in anticipation of an MEA
- Implementing appropriate arrangements that are clinically and politically acceptable to patients/clinicians upon rescinding an MEA due to failure to achieving a pre-agreed milestone

## LIST PRICES AVAILABILITY

One of the aims of this work has been to review whether and how international, regional, or national pricing lists are being designed and used to standardize purchase prices and negotiate the best value for such products, not only in their own country but across the region.

In the context of pharmaceuticals, a medicine price list can be used for two purposes:

- To establish a benchmark (most of the time, a ceiling benchmark) for the price to be used for a given medicine in a specific setting/market (e.g., the maximum tender price)

- To compare the price for a medicine or group of medicines across settings of the same country or in two or more countries

The price listed can be produced using any of the pricing policies (methods) described above or it can reference an international drug index. It is up to the decision maker, based on how and where the list of

prices will be used and whether the list is made public or shared only with the specific setting (e.g., public facilities).

Price indexes represent a normalized average (typically a weighted average) of price relative to a given class of goods in a given region during a given interval of time.[15] Price indexes can be the basis of a price list and can act as benchmarks for suppliers in a specific region.

As presented in the ERP section, there is power in sharing prices across multiple countries of a similar economic level as it can help increase pressure on suppliers to align their prices to those used in other countries in similar conditions. Experience in implementing international reference pricing by most European countries suggests the importance of a regional agreement on what and where the prices are published to ensure comparability of data.

As discussed earlier, international reference pricing is used very little among the 11 countries of the Asia Bureau. Vietnam has the longest experience with the usage of ERP as one of the elements considered when pricing a new molecule and when considering price negotiations. Vietnam mainly references Thailand, Malaysia, Indonesia, the Philippines, and Cambodia, although not all these countries have public price lists. Kyrgyz Republic, the Philippines, and Sri Lanka have introduced international reference pricing in the past one to two years, and in all three cases the majority of countries referenced are regional.

In terms of national indexes, we have found them being used in India and the Philippines. In India, the ceiling price used to calculate the MRP is an index of weighted prices across all competitors in the market for each of the scheduled molecules (INNs). In the Philippines, the DPRI represents the average tender awarded price across all public facilities in the previous year for each of the MOH formulary medicines.

However, even if not all countries use national indexes, the majority of the countries included in this review publish some form of list price to guide the pricing in public, and more rarely in private, facilities. An overview can be found in table III on what price lists are made available across the 11 countries and whether they apply to public- and/or private-sector facilities.

**Table 111: Overview of price lists available publicly across the 11 countries**

| | Price list in public domain | Prices listed for | | Types of prices listed | | | Prices apply to | |
|---|---|---|---|---|---|---|---|---|
| | | All medicine registered | Only certain categories | Manufacturer | Wholesaler | Retail | Public sector | Private sector |
| Bangladesh | ✓ | | ✓ EML [117 INNs] | | | ✓ | ✓ | ✓ |
| Cambodia | x | | | | | | | |
| India | ✓ | ✓ | | | | ✓ | ✓ | ✓ |
| Indonesia | ✓ | | ✓ MOH Formulary | ✓ | | ± Mnf.+ 28% | ✓ | |

[15] Price Index definition. Wikipedia. Available online: https://en.wikipedia.org/wiki/Price_index.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | [e-Catalogue] | | | | | |
| Kyrgyz Republic | ✓ | | ✓ EML [58 INNs] | ✓ | ✓ | ✓ | ✓ | ✓ |
| Myanmar | x | | | | | | ✓ | |
| Nepal | x | | ✓ Free Drug List 70 INNs | | | ✓ | ✓ | |
| Philippines | ✓ | | ✓ MOH Formulary (DPRI) | | | ✓ | ✓ | |
| | | | MRP List 80 INNs | | | | ✓ | ✓ |
| Sri Lanka | ✓ | | ✓ 60 INNs | | | ✓ | ✓ | ✓ |
| Timor-Leste | x | | ✓ EML SAMES | | | ✓ | ✓ | ± |
| Vietnam | ✓ | ✓ | | | ✓ | | ✓ | ✓ |

Of the 11 countries reviewed, 8 publish some form of price list and of these, only India and Vietnam publish the prices for all medicines registered in the country. All other countries only list the price for the category of medicines for which a price control has been put in place. Sri Lanka, Myanmar, Nepal, and Cambodia share the price lists only with public facilities.

An overall view of the prices made publicly available across the 11 countries, the type of price listed, and the pricing method used to establish it are summarized in table IV.

**Table 1V: Overview of publicly available prices and their sources:**

| Country | Price set for | Type of price listed | Pricing method used | Available at |
|---|---|---|---|---|
| Bangladesh | EML [117 INNs] | Retail | Cost-based pricing | Maximum Retail Prices list |
| India | MOH formulary based on EML ("scheduled medicines") | Retail | IRP | NPPA price list |
| | All others ("nonschedule") | Retail | Free pricing at entry; price increases capped annually | |
| Indonesia | e-Catalogue based on MOH formulary | Retail | Tendering (list of awarded prices only) | e-Catalogue |
| Kyrgyz Republic | EML [58 INNs] | Ex-mf/W/R | ERP + capped supply margins | Catalogue of prices |

| | | | | |
|---|---|---|---|---|
| Philippines | DPRI (MOH formulary) | Retail | Tendering (price listed is the average awarded tender price) | DPRI |
| | MRP [80 INNs] | Wholesale/ Retail | ERP + capped supply margins | MRP |
| Sri Lanka | EML [60 INNs] | Retail | External and internal price referencing | NMRA website |
| Vietnam | All new medicines to the market | Wholesale | ERP | List of new prices foreign wholesaler 2019) |
| | All other imported medicines | Wholesale | IRP | List of reconfirmed foreign wholesaler prices 2019 |
| | Local medicines | Wholesale | Cost-based pricing | List of new local wholesaler prices approved 2019<br><br>List of reconfirmed local wholesaler prices 2019 |

As seen above, most of the published prices are set at the retail level rather than manufacturer prices, and this poses an important challenge when trying to compare prices across countries, as retail prices reflect not only starting manufacturer/importer prices but also taxes, distribution, and retail margins, which in turn reflect economic and geographical aspects that are not equal among neighboring countries. It therefore limits the capacity of neighboring countries to leverage the knowledge and create regional pressure on prices from the same manufacturer (the main concept behind ERP).

Despite all countries using a tender system to control the price of medicines in the public sector, the only two countries making the results publicly available (and therefore to private-sector facilities) are Indonesia and the Philippines. The lack of information regarding the results of tenders in the public sector raises many questions on accountability, transparency, and fairness of the process; it also limits the capacity of the market to use the information to pressure the prices downward across both the public and private sectors.

There remains considerable scope in building a regional database of prices to help guide governments in benchmarking their prices. We recognize that confidentiality plays an important role in ensuring better prices, but, as the WHO 2019 study on prices for cancer products shows, there is increased benefit in lowering prices through international benchmarking relative to the potential loss through confidential tenders.

## DEMAND-SIDE POLICIES POTENTIALLY IMPACTING THE PRICE OF MEDICINES

As already mentioned in the methodology section, in the literature, pricing policies mainly refer to supply-side interventions that target the price offered by the suppliers of medicines (manufacturers, wholesalers, retailers).[5,7] Following the WHO Guidelines on Pricing, we have included in our research a quick review of the main demand-side policies that are likely to have an indirect impact on price, while recognizing that they are not pricing policies *per-se*.

**Demand side policies – definitions**

**Treatment guidelines** refer to the issuance of nationally agreed clinical best practices for the diagnostic and treatment of a given disease. Treatment guidelines have an indirect impact on price as they define the place in therapy for each potential medicine to be used; they define the Standard of Care, the medicine that will have most demand (and volume), and they define when other medicines and which ones should be used. Through their systematic placement of generic medicines for the treatment of major diseases, treatment guidelines act as pressure for the system to procure in bulk and therefore decrease the price of these essential commodities.

**Generic prescribing** policies refer to the usage of International Non-Proprietary Name (INN) in prescriptions, rather than of commercial name. When prescribing by INN, the physician gives the pharmacist the right to dispense any of the commercial variants present on the market, taking into account market availability and patient affordability.

**Generic substitution** policies mandate the dispenser (the pharmacy/ drug retailer) to present and/ or dispense to the patient the most affordable generic available.

Prescribing protocols define the conditions in which a specific medicine can be prescribed e.g. placement in therapy such as "only after failure of another medicine"; only in certain settings; only by certain type of physicians or even nominated only specialists etc.

**Prior-authorization** implies the existence of a health authority (generally, a payer) who approves the prescribing and dispensing of a given medicine prior to the act taking place. Given the need to approve usage for each patient at a time, it is an intervention generally used for expensive, highly specialized medicines.

**Table V: Map of demand-side policies**

| Demand-side interventions | Treatment guidelines | Generic prescribing | (Mandatory) Generic substitution | Prescribing protocol | Prior authorization | Other |
|---|---|---|---|---|---|---|
| Bangladesh | ✓ | ± | | | | |
| Cambodia | ± | ± | | ± | | |
| India | ✓ | ± | | | | ✓ |
| Indonesia | ✓ | ± | ± | | | |
| Kyrgyz Republic | ± | ✓ | - | ± | | |
| Myanmar | ± | ± | ± | | | |
| Nepal | ± | ± | | | ± | |
| Philippines | ✓ | ✓ | -- | | | ✓ |
| Sri Lanka | ± | ✓ | ± | | | |
| Timor-Leste | ± | | | ± | | |
| Vietnam | ✓ | ✓± | ✓ | | | |

*Demand-side interventions or provider policies are just beginning to develop in the targeted Asian countries. As the payer and UHC concepts are being developed, demand-side policies tend to become more complex: the payer steps in and can impose new provider conditions through its contracting procedure.*

All 11 countries have evidence-based **treatment guidelines** for vertical programs, relying mostly on WHO decisions in the area. However, only five of the countries studied (Bangladesh, India, Indonesia, the Philippines, and Vietnam) went beyond the vertical programs and developed or adapted evidence-based treatment guidelines for other diseases, covering the whole spectrum of essential medicines used in the country.

**Generic prescribing** has in theory been adopted across countries around the world and the region. Of the countries reviewed, only the ones moving closer to UHC are also enforcing it—the Philippines and Kyrgyz Republic. Vietnam is representative of the main issue surrounding generics: despite a strong policy supporting the prescribing by generic name (the INN), up to 90% of prescriptions are for specific brands, due to lack of trust in the quality of cheaper versions. In countries like Bangladesh and India, where the market is dominated by generics, a general generic prescribing/generic substitution policy is unlikely to lead to cost containment. A more adapted policy intervention along the lines of INN prescribing and mandatory substitution to the lowest price generic available in the pharmacy would probably yield better results.

**Generic substitution** is still far from being implemented in the region. This reflects the lack of not only well-designed retail margins but also a payer that, through pharmacy contracting, would be able to enforce such an intervention in the market.

Cambodia, Kyrgyz Republic, and Timor-Leste stand out for their incipient approach to creating treatment pathways, specific placement in therapy, and nominated specialists prescribing for a few diseases. Cambodia has recently developed 39 benefits packages in which medicines have been clearly nominated and defined in terms of usage and therefore cost impact.

Nepal, through its HIB, has introduced the concept of **prior authorization** for some of the more expensive medicines to be prescribed by highly specialized physicians.

India and the Philippines have also engaged in **another type of market intervention** by creating/developing a state/insurance-owned chain of pharmacies allowed (and subsidized) to dispense only generic essential medicines in the poorer areas of the country—this in turn creates competition for the other retailers, potentially inducing them to lower their own prices.

## 4. Conclusions

Affordable access to safe, quality-assured, and efficacious pharmaceutical products is at the core of global efforts toward achieving UHC. When attentively formulated and properly implemented, pharmaceutical pricing policies could contribute to improving patient access to quality-assured essential medicines and other health products.[4] Strong country pharmaceutical pricing policies can improve the affordability of pharmaceutical products when carefully planned, carried out, and regularly checked and revised according to changing conditions.[16]

[16] Simão MM. Assistant Director General, Medicines and Health Products World Health Organization. Forward to the WHO 2020 guidelines on country pharmaceutical pricing policies.

In an effort to contain rising health care costs, many Asian countries have developed formal strategies aimed at influencing prices of medicines financed by the public sector,[3] with only a handful still adopting a free pricing approach. Even in these countries, for certain categories of medicines, some pricing interventions are being considered.

The most used pricing control tool across all the countries reviewed is tendering that is centralized at the national or regional level and generally coupled with local tendering by public facilities. While tendering offers the advantage of pooled volumes, its impact on prices in the market is limited. As it only applies to certain categories of products and facilities, the winning prices are rarely made available to the whole market, and it offers limited help for those products with few or only one supplier present in the country.

External and internal reference pricing are being put in place in half of the countries reviewed, with Vietnam standing out for its decision to implement them for most of the medicines registered in the country. The main barrier to usage of either reference system remains the lack of transparency with regard to prices inter- and intra-country, and even when published, it is not always clear what price they represent (the ex-factory, wholesale, or retail price). As seen in other regions, ERP can act as an important factor to decrease prices in all markets, but a common agreement needs to be reached on making the set prices transparent to all stakeholders.

One main pricing regulation recommended by WHO in its pricing guidelines is the use of policies that control the margins or the maximum mark-ups that can be added to the manufacturer price throughout the supply chain. Of the countries reviewed, very few have started considering this aspect, with Kyrgyz Republic and Vietnam showcasing good practice policies.

Many other pricing policies could be envisaged, including one that already takes place but only as a result of failed tenders: price negotiations. Establishing a clearer mandate for when negotiations could take place for single-source products, who leads and participates in them, and on what evidence the final price can be set would likely increase access to those medicines for which there is only one supplier.

Value-based pricing linked to a systematic assessment of the clinical and economic evidence (e.g., HTA) is starting to be considered in the region, and we expect to see an increase in countries that engage in HTA and, later on, in pricing related to the value resulting from these assessments. Of the 11 countries, only the Philippines and Vietnam have formalized their HTA in policies. Once HTA and price negotiation procedures are in place, we anticipate that countries will quickly move toward risk-sharing agreements or MEA—a shift that has already happened in Thailand, South Korea, and other countries in the region.

On the demand side, there have been few interventions enforced that would lead to downward price pressure: generic prescribing is in place in almost all of the 11 countries, but it has had little effect, not in the least due to the fact that many of these markets are already dominated by generics. A more adapted approach, such as mandatory substitution to the lowest priced generic available in the pharmacy, would probably yield better results.

As a final objective, this review aimed to provide an instrument for comparison for regional and national regulators, implementing agencies on the ground, and donors to help them evaluate and decide whether there is scope for cross-transfer of best practices. A summary view of where each of the 11 countries is in its approach to price regulation of medicines can be seen below: the placement of countries from left to right takes into account the number of policies and their complexity—the more price strategies are being implemented and the more complex in their approach, the farther to the right the country is placed.


| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Supply-side policies* | Free pricing | ERP | Generic caps | Cost based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP /HTA | MEA |
| ***Demand-side strategies*** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) Generic substitution** | | **Prescribing protocols** | **Prior authorization** | | **Electronic prescribing monitoring** | |

As already highlighted by the WHO report on pricing interventions adopted around the globe, there is no one combination of policies that can be uniformly applied to ensure wide access, affordability, and sustainability of health systems, and any such mix should take into consideration the population's needs, the local market dynamics, and finances available. However, as remarked in the WHO report and in this review, there seems to be a correlation between wider access across a larger number of medicines when more, rather than fewer, pricing interventions are used.

Given the ability of these countries to rely on one another's experience to move toward UHC, the following annexes provide a practical basis for technical staff and policy makers to continue the exchange of experience in implementing some of these tools and find common solutions to move forward.

# ANNEX A: COUNTRY MEDICINES PRICING PROFILES

# BANGLADESH—MEDICINES PRICING PROFILE

## 1. BANGLADESH—MEDICINE PRICING PROFILE

### 1.1 BACKGROUND INFORMATION

- Bangladesh has a publicly funded health care system that provides consultations at low cost and medicines free of charge to patients; however, anecdotal and limited published evidence suggests that the availability of such medicines is low.[17]
  - This leads to many patients purchasing their medicines OOP.
- Bangladesh's pharmaceutical market is dominated by the presence of domestic manufacturers. There are more than 140 API and generic local manufacturers,[18] and the pharmaceutical industry is considered a national priority. Given the influence of the home market on international price, there is an ongoing lobby from local manufacturers to avoid price regulation of their products in Bangladesh.
  - Only 117 generic INNs[18] of the 1,268 INNs currently registered with the Directorate General of Drug Administration (DGDA)[10] have their price regulated.
  - Generics represent more than 90% of the internal consumption of medicines.[10]
- Self-medication and irrational use of medicines, especially antibiotics, have pushed the government to increase its regulation of the retail market.[17] Since 2016, only pharmacies with a pharmacist on staff have been able to dispense prescription medicines.

### 1.2 PRICING POLICIES OVERVIEW

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ± | | | ✓ | ✓ | | | | | | | |

| ***Demand-side interventions*** | **Treatment guidelines** | **Generic prescribing** | **(Mandatory) Generic substitution** | **Prescribing protocol** | **Prior authorization** | **Electronic prescribing monitoring tools** | **Other** |
|---|---|---|---|---|---|---|---|
| | ✓ | ± | | | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 1.3 PRICING POLICIES DETAILED

[17] Kasonde L, Tordrup D, Naheed A, et al. (2019). Evaluating medicine prices, availability and affordability in Bangladesh using World Health Organisation and Health Action International methodology. BMC Health Serv Res 19, 383. Available at: https://doi.org/10.1186/s12913-019-4221-z.
[18] DGDA website: https://www.dgda.gov.bd/index.php/faqs.

| Supply-side interventions | |
|---|---|
| ***Type of intervention*** | **Details and analysis** |
| **Free pricing (for all local medicines, with exception of 117 generics/INN)** | • For the majority of generics, the price is freely set by the manufacturer.<br>• Bangladesh has some 140 local manufacturers with various "Good Manufacturing Practices" (GMP) levels; the government has explicitly made the local pharmaceutical industry a priority for economic development.<br>• There are 1,268 generic medicines (INNs) registered with the DGDA.[18]<br>• Exception: for 117 generic molecules (INNs) considered essential medicines, the price is set through a cost-based method (see below).<br>***Gaps in policy*:** While the assumption that multiple manufacturers will compete on price does stand to some extent, the increasing prices year on year suggests further attention could be given to ensure affordability and access. |
| **Cost-based pricing (for 117 generics/INN, imported medicines and API)** | • Under the 1982 Drugs Control Ordinance,[19] partially revised in the Price Fixation Procedure issued in 2015,[20] a cost-based pricing mechanism was adopted to ensure access to essential medicines.<br>• According to the 2016 National Drug Policy and the DGDA website, the price is regulated for 117 generic INNs, for all imported medicines, and for all APIs produced in the country.[21,22]<br>• The procedure states that prices are determined by an expert committee using two formulas:<br>  ○ **Local manufactured MRP (without VAT) = [price of RM x (Ac x Exchange Rate) + price of PM] × mark-up**<br>  ○ **Imported medicines MRP = C&F × exchange rate × mark-up**<br>  ○ RM: cost of raw materials (active ingredient and excipients); PM: cost of packaging materials as resulting from invoices, costing sheets, etc.; C&F: cost, freight, and insurance—a term used to define the cost of the product declared at customs; Ac: information not available in the official document<br>• The MRPs are published on the DGDA website.[23]<br>• *Stakeholders involved*: The Pricing Committee and the Pricing sub-Committee sit within the DGDA and are appointed every two years. Their componence is published online.[24] |
| **Tendering at national level through the National Company** (for national EML medicines) | • The 2016 National Drug Policy reinforces the use of NEML medicines as the basis for usage and procurement in all public facilities.<br>• According to the national policy, 70% of all medicines used in public facilities should be supplied by the EDCL, 25% by the Central Medical Stores Depot (CMSD), and the remaining 5% by local purchase.[10]<br>• The EDCL is a state-owned pharmaceutical company that functions under the Ministry of Health and Family Welfare.<br>• According to the 2008 Procurement Law,[25] the preferred method of procurement is national open tender; other types of procurement are allowed but should be conducted only in specific conditions. |

[19] WHO Department of Essential Medicines and Health Products. (2015). WHO guideline on country pharmaceutical pricing policies. ISBN 9789241549035. Available at: https://www.who.int/medicines/publications/pharm_guide_country_price_policy/en/.

[20] Directorate General of Drug Administration (DGDA). (2015). Price Fixation Procedure. Available at: http://www.dgda.gov.bd/index.php/laws-and-policies/87-price-fixation-policy

[21] Bangladesh Government. National Drug Policy 2016. (2016). Available at: http://dgda.gov.bd/index.php/laws-and-policies/261-national-drug-policy-2016-english-version

[22] DGDA. FAQ – Q19: Does the Government control the price of manufactured drugs? Available at: https://www.dgda.gov.bd/index.php/faqs.

[23] DGDA List of Maximum Retail Prices. Available at: https://www.dgda.gov.bd/index.php/search-price.

[24] DGDA Committees. Price Fixation Committees componence. Available at: https://www.dgda.gov.bd/index.php/downloads/committees.

[25] Public Procurement Rules. Available at: https://cptu.gov.bd/upload/policyandprocedure/2017-07-31-16-11-03-Public-Procurement-Rules-2008-Bangla.pdf.

| Supply-side interventions | |
|---|---|
| ***Type of intervention*** | **Details and analysis** |
| | ○ An international tender has to be issued if the value surpasses USD 300,000.<br>• The list of products and their awarded prices is made available to facilities, which order according to their own budget allocation; disbursement of funds then takes place from the Ministry to the EDCL. |
| **Tendering**<br>**CMSD (for national EML medicines)** | • The CMSD is the government procurement unit for all medical supplies, with a particular focus on medical equipment and some EML medicines.<br>○ The CMSD supplies medicines to 64 civil surgeons (in charge of health facilities below the level of district hospital), district hospitals, and public health programs.<br>• The CMSD has various funding sources, including reimbursable project aid, direct project aid, and government development and revenue budgets.<br>• Procurement is done annually on its own quantification estimates based on past supply.<br>• Procurement method:<br>○ A national bidding process is used unless the cost of any single item or package is more than USD 300,000, in which case an international bidding process is used.<br>○ The prices are valid for one year and do not include distribution costs, which are paid separately by the facilities.<br>○ Award criteria: cost-value (lowest price and technical requirements).<br>• *Stakeholders involved*: The Director General of Health Services ultimately approves the procurement plan; the procurement is led by the CMSD. |
| ***Tendering***<br>Local tenders (for any registered medicine) | • Tertiary and specialist hospitals generally do not procure from the CMSD, but they are obliged to purchase from about 40 manufacturers that are prequalified by the CMSD.<br>• For all other facilities at the district level and below, only 5% of the allocated budget is available for local purchase of any registered medicine.<br>• Procurement method:<br>○ Public tender for any procurement above 25,000 Taka [~USD 300] in district hospitals and 15,000 Taka [~USD 180] in Upazila Health Complexes.<br>○ For values below the above-mentioned thresholds, direct procurement can be undertaken.<br>• *Stakeholders involved*: Civil surgeons and district hospital superintendents at district level; hospital directors in specialist and tertiary hospitals |
| **Supply margins control (for 117 local generics and imported medicines)** | • Through the introduction of the 2015 Price Fixation Procedure, the MRP formula defines the value of the maximum mark-ups in relation to the manufacturer price.<br>○ The maximum mark-up is 5%.<br>○ It is expected to cover both distribution and retail.<br>• The formula, and therefore the ceiling mark-up, applies only to the imported medicines and the 117 INNs (local generics) for which prices are regulated.<br>○ There remain 1,151 INNs of local generics that are not regulated. |

| Demand-side interventions | |
|---|---|
| Policy | **Details and analysis** |
| Generic prescribing | • According to the 2016 National Drug Policy, "the supply and use of drugs at all government levels will be encouraged by generic name". |
| Treatment guidelines | • A National Drug Formulary promotes rational use of medicines for all diseases.[26] The development of the Bangladesh National Drug Formulary does not take into consideration the issue of price or availability in the market. |

[26] DGDA. Bangladesh National Formulary (BDNF) 2015. Available at: https://www.dgda.gov.bd/index.php/publications/51-bangladesh-national-formulary-bdnf-2015.

| | |
|---|---|
| Databases of prices publicly available | MRPs (117 generic INNs): https://www.dgda.gov.bd/index.php/search-price |
| Other databases available | National EML: https://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/guidance-documents/219-essential-drug-list-2016 |

# 2. CAMBODIA—MEDICINES PRICING PROFILE

## 2.1 BACKGROUND INFORMATION

- Cambodia has a mixed service delivery system.
- Cambodia has a mixed service delivery system.
- Pharmaceutical expenditure per capita was USD 80.7 according to a 2014 OECD report, representing up to 44% of the total health expenditure/capita. Only 22.5% of this amount was covered by the public expenditure, with 77.5% being paid OOP.[27]
- Public health service delivery is organized through two levels of services:

    1. The Minimum Package of Activity (MPA) provided at health centers.
    2. The Complementary Package of Activity (CPA) provided at referral hospitals.

- Minimum and complementary packages and medicines are subsidized by the government in terms of facilities, equipment, staff salary, and essential medicines, but service users pay consultation and treatment fees and for out-of-stock medicines.

    - User fees vary among services, even within the same operational district.
    - Fees for private services are not government subsidized and are set by each provider with limited regulation.[28]

- The private sector does not deliver minimum and complementary packages. Private practitioners, workplaces, and international nongovernmental organizations deliver a limited range of services.[28]
- Tertiary services are provided by six semi-autonomous national hospitals based in Phnom Penh.
- Health insurance is in its infancy—approximately 20% of the population is covered through Health Equity Funds (HEFs) or the National Social Security Fund (NSSF). HEFs were developed to enable some 3 million low-income people access to public health services by paying public health providers (user fees) on their behalf.[29]

[27] WHO WPRO. (2017). Cambodia Pharmaceutical System Profile. Available at: https://iris.wpro.who.int/bitstream/handle/10665.1/13668/WPR-2017-DHS-004-khm-eng.pdf.
[28] WHO WPRO. (2012). WPRO Cambodia Service Delivery Profile report. Available at: https://time.com/wp-content/uploads/2015/05/service_delivery_profile_cambodia.pdf.
[29] Jacobs B, Bajracharya A, Saha J, et al. (2018). Making free public healthcare attractive: optimizing health equity funds in Cambodia. Int J Equity Health 17, 88 (2018). Available at: https://doi.org/10.1186/s12939-018-0803-3.

- When it comes to regulation of the pharmaceutical sector, Cambodia has been an adopter of free pricing.[30]

- The MOH manages the EML, which comprises the pharmaceuticals required for the MPA and CPA, as outlined in their respective guideline documents.[30,31]

    - The MOH Central Medical Stores (CMS) procure EML medicines centrally and distribute them to districts and then to referral hospitals and health centers.[32]
    - Public facilities rely almost exclusively (80–90%) on EML medicines from the CMS (891 medicines) that, when available, should be free of charge at the point of access.
    - Stock-outs are common, so most patient needs are fulfilled by private-sector retailers where there is no control over their prices; 67.1% of Cambodian patients seek care first in private-sector facilities.[33]

### 2.2 Pricing Policies Overview

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ✓ | | | | ✓ | | | | | | | |
| ***Demand-side interventions*** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) Generic substitution** | | **Prescribing protocol** | **Prior authorization** | | **Electronic prescribing monitoring tools** | | **Other** |
| | **±** | | **±** | | | | **±** | | | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 2.3 Pricing Policies Detailed

| **Supply-side interventions** | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Free pricing (all medicines)** | • The price of medicines on Cambodian territory is not regulated.[32,34] |
| **Tendering Centralized procurement via MOH Medical Supply Store (for EML medicines only)** | • EML medicines should be available for free in public facilities, based on the type of activities the health facility is able to deliver (MPA- or CPA-defined activities).[35]<br>• 90% of EML medicines are procured centrally by the MOH CMS.[36] |

[30] MOH. (2007). Guidelines on minimum package of activities for health center development 2008 ~ 2015. Available at: https://data.opendevelopmentmekong.net/dataset/3173e647-7074-4f9d-96bf-63ba19d1f99c/resource/4e09b8b2-69f5-487e-a4d2-444223a7ae1e/download/mpa-guidelines-2008-2015_eng__2018.01.05.pdf.
[31] MOH. (2006). National guidelines on complementary package of activities for referral hospital development from 2006 to 2010. Available at: https://niph.org.kh/niph/uploads/library/pdf/GL048_HSD_CPA_Guidelines_2006_2010_en.pdf.
[32] MOH. National Medicines Policy 2010. Available at: http://apps.who.int/medicinedocs/documents/s22477en/s22477en.pdf.
[33] World Health Organization/Organisation for Economic Co-operation and Development. (2018). How pharmaceutical systems are organized in Asia and the Pacific. Cambodia profile. Available at: http://iris.wpro.who.int/handle/10665.1/13982.
[34] MOH. Health strategic plan 2016–2020. Available at: http://hismohcambodia.org/public/fileupload/carousel/HSP3-(2016-2020).pdf.
[35] MOH. National list of essential medicines 2018. Available at: https://www.ddfcambodia.com/images/stories/EDB/C-EML_9th%20edition_FINAL_printing%2020_June_2018.pdf.
[36] MOH. Pharmaceutical policy and strategy plan (PSSP) 2013–2018. Available at: http://www.haiasiapacific.org/wp-content/uploads/2015/02/CambodiaPSSP2013-2018FinalDraftOct2012.pdf.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • According to the 2012 Procurement Law,[37] tendering (international, national, or local) is the preferred method of public procurement.<br>  • The price used for tendering of EML medicines is based on historical data, but the results of the previous tender are not publicly available.<br>  • The type of bidding depends on the amount; bids for international competition start for amounts over 5 billion riels.<br>  • The winning bid is established based on lowest price offered, and no allowance is given for quality and/or reliability of supply.<br>  • The awarded prices are not made publicly available.<br>• *Stakeholders involved*: MOH CMS – Director and Deputy Director, vertical programs representatives and/or EML division, with oversight from the Minister or Deputy Minister |
| **Tendering**<br>Local purchasing (EML medicines only) | • Public facilities are paid from governmental subsidies based on their level (e.g., district, provincial, referral), and these subsidies should cover the EML medicines prescribed.<br>• However, the additional user fees paid by HEFs can be used by hospitals to procure medicines; there is no obligation in such cases to use the EML.[38]<br>• Public procurement rules still apply, but the amounts purchased are very small, thus allowing for direct purchase.[39]<br>• In most cases, if there is a stock-out, prescribers prefer to ask the patients to get their medicines from the private sector.[40] |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| Treatment guidelines | • Treatment guidelines are available for the vertical programs. |
| **Generic prescribing** | • Generic (INN) prescribing is mentioned in the medicines policy, but there is no consequence mentioned should this rule not be followed. |
| **Prescribing protocols (incipient)** | • The EML classifies the medicines by the type of facilities that are able to prescribe them. The more complex the type of services provided, the more EML medicines are made available through/to that facility.<br>• *Stakeholders enforcing it*: The Payment Certification Agency and NSSF. The former was created in February 2018, and its main role is expected to be the review of reimbursement claims from providers toward the HEFs. |

| | |
|---|---|
| Other databases of medicines available publicly | National List of Essential Medicines 2018. Available at: https://www.ddfcambodia.com/images/stories/EDB/C-EML_9th%20edition_FINAL_printing%2020_June_2018.pdf |

# 3. INDIA—MEDICINES PRICING PROFILE

[37] Procurement regulation and tenders available at: https://opendevelopmentcambodia.net/topics/procurement/.
[38] Prakas of the inter-ministries No 809 dated on 13 October, 2006 on principle of support for poor patients.
[39] Liverani M, Chheng K, Parkhurst J. The making of evidence-informed health policy in Cambodia: knowledge, institutions and processes. BMJ Global Health 2018;3:e000652.
[40] Ursu I. (2018) Implementation of the GIZ Innovation Fund 2018: The power of data – Improving access to medicines through monitoring systems. German Development Fund (internal report).

### 3.1 Background Information

- The current health system in India is a mixed public-private provider system, with the private sector dominant in urban areas and the public sector dominant in rural areas.

- Due to India's federalized system of government, the areas of governance and operations of the health system have been divided between the union and the state governments.[41]

- WHO's 2016 data on global health expenditures reveal that in terms of OOP expenditure as a proportion of current health expenditure, India has an average of 65%, with some states (e.g., Bihar) reaching up to 80%;[41] between 2011 and 2012, OOP expenditure on health care pushed 3.5% of the population (50.6 million people) below the poverty line and caused further deepening of poverty for already poor people.[42]

    - The share of medicines that were paid for OOP was around 51% in 2013–14 and 43% in 2015–16.[41]
    - Of the total pharmaceutical expenditure incurred by households, 18% is for in-patient treatment and 82% is for outpatient/ambulatory care.[11]

- The Ayushman Bharat Program is a national insurance program launched in 2018 to address the affordability of India's health care though two components:

    - **Health and Wellness Centers (HWCs)** to strengthen and deliver comprehensive primary health care services for the entire population. It is expected that by end of 2022, approximately 1.5 million sub-health centers and primary health centers in urban and rural areas would be transformed to HWCs and deliver comprehensive care for maternal and child services; communicable diseases; and screening and management of noncommunicable diseases such as hypertension, diabetes, and three common cancers (oral, breast, and cervix). Essential medicines and a list of diagnostic tests would be provided for free under this program.[43]
    - **Pradhan Mantri Jan Arogya Yojana** for secondary- and tertiary-level hospitalization services for poorest 40% of families in India. The program aims to provide 1,350 medical insurance packages that cover surgery, medical treatments, and the costs of medicines for eligible members, among other things. The program covers expenses incurred for up to three days of medicines pre-hospitalization and up to 15 days post-hospitalization. Medicine and medical consumables are also listed as covered, but no additional details are available.[44]

- Since 1970, the Drug Price Control Orders (DPCO), issued in accordance with the Essential Commodities Act, have been the main price control regulation in India.

    - The 1995 DPCO created the **NPPA,** which continues to operate today. Its main functions include the annual revision of drug prices, inclusion and exclusion of drugs from price control, and supervision of drug prices outside of price control.
    - The most recent DPCO was issued in 2013 and focuses its selection of prices to regulate based on the essentiality of the medicines: inclusion in the NEML or if there is a public interest. If the

[41] Chokshi M, Patil B, Khanna R, et al. (2016). Health systems in India. J Perinatol. 2016;36(s3):S9-S12. doi:10.1038/jp.2016.184.
[42] Hooda SK. (2017) Out-of-pocket Payments for Healthcare in India: Who Have Affected the Most and Why? Journal of Health Management.;19(1):1-15. doi:10.1177/0972063416682535
[43] Ministry of Health and Family Welfare. (2021). India has crossed a Key Milestone in Universal Primary Healthcare. News available at: https://pib.gov.in/PressReleasePage.aspx?PRID=1706381
Target of Operationalizing 70,000 Ayushman Bharat – Health and Wellness Centres (HWCs)
[44] Ayushman Bharat Pradhan Mantri Jan Arogya Yojana. (2019). "Beneficiary Empowerment Guidebook".

medicines (INNs) are included in the MOH formulary (the "Schedule"), the NPPA can fix the ceiling price for any length of time it considers necessary.[45]
- For nonscheduled medicines, the NPPA still registers MRPs for which the price increase year on year is capped at a maximum of 10% based on specific market criteria.
- As of July 2020, the NPPA was regulating the price of 1,361 medicines.[46]

- The most recent NEML was issued in 2015. In July 2018, the Ministry of Health and Family Welfare called together a Standing National Committee on Medicines to revise the 2015 NEML.

  - The scope of this committee includes revising the NEML and adding medical devices, medical disposables, medical consumables, and other health- and hygiene-related products that it sees fit.
  - The first stakeholder meeting took place in July 2019.[47]

### 3.2 Pricing Policies Overview

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ± | | | | ✓ | | ± | | ✓ | - | | |

| ***Demand-side interventions*** | **Treatment guidelines** | **Generic prescribing** | **(Mandatory) Generic substitution** | **Prescribing protocol** | **Prior authorization** | **Electronic prescribing monitoring tools** | **Other** |
|---|---|---|---|---|---|---|---|
| | ✓ | ± | | | | | ✓ |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 3.3 Pricing Policies Detailed

| **Supply-side interventions** | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Free pricing, with capped annual increases** (nonscheduled medicines) | • Local and foreign manufacturers of nonscheduled medicines (i.e., medicines not listed in the Schedule appended to the 2013 DPCO) have to declare their MRP upon registration and then annually if their price changes.<br>• According to law, the MRP represents the ceiling price or the retail price, plus local taxes and duties as applicable, at which the drug is to be sold to the ultimate consumer.<br>• MRPs have to be listed on the packaging.<br>• The NPPA is mandated to monitor MRPs of all drugs, including nonscheduled formulations.<br>• Once an initial MRP is registered, price increases are capped to a maximum of 10%. *"No manufacturer [can] increase the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months".*[47]<br>• Prices are reviewed annually to ensure that the 10% increase rule has been respected and the updated list is published online by the NPPA.[48] |

[45] DPCO 2013. Available at: http://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf.
[46] Department of Pharmaceuticals. Monthly report. July 2020. Available at: https://pharmaceuticals.gov.in/sites/default/files/Monthly%20Report%20month%20of%20July%2C%202020_0.pdf.
[47] Ministry of Health and Family Welfare. (2018). "Constitution of Standing National Committee on Medicines (SNCM) for revision of National List of Essential medicines (NLEM)".
[48] NPPA prices are available at: http://nppaimis.nic.in/nppaprice/newmedicinepricesearch.aspx.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • *Stakeholders involved*: NPPA—attached office to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The NPPA has an agreement with All India Organization of Chemists and Druggists and Advanced Working, Action and Correction System (AIOCD AWACS) to collect data on prices used by retailers and distributors and provide it to the NPPA on a monthly basis. |
| **Internal reference pricing (Scheduled medicines)** | • For imported or locally manufactured medicines included in the 2013 DPCO formulary (i.e., ***scheduled* medicines**), maximum ceiling prices are set using the following calculations:<br>  • **Step 1**: Calculate the average price to retailer, P(s), using the following formula:<br>  Average price to retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share greater than or equal to 1% of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share greater than or equal to 1% of total market turnover on the basis of moving annual turnover for that medicine)<br>  • **Step 2**: Calculate the ceiling price, Pc, as follows:<br>  P(c) = P(s).(1+M/100), where<br>  P(s) = average price to retailer for the same strength and dosage of the medicine as calculated in step1 above<br>  M = % margin to retailer and its maximum value =16%<br>• The ceiling prices are reviewed annually, and there is an assumption that they will go down as more competitors enter the market for the given medicine/strength/dosage.<br>• In the absence of competition (defined as fewer than five manufacturers) or if the medicine presents a different strength or dosages than the ones published in the schedule, the following formulas are used:<br>  • **Step 1**: Calculate the average price to retailer, P(s), using the following formula:<br>  P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)} where,<br>  Pm = Price to retailer of highest priced scheduled formulation under consideration<br>  Pi = % reduction in average price to retailer of other strengths and dosage forms in the list of schedule formulations with regard to the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms<br>  N = Number of such other strengths, dosage forms, or both in the list of schedule formulations<br>  • **Step 2**: Calculate the ceiling price as in previous situation<br>• Once the ceiling price has been set, the **MRP** of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the government plus local taxes:<br>  • MRP = ceiling price + local taxes as applicable<br>• Ceiling prices are reviewed annually, around April, and revised ceilings have to be applied within 45 days by all manufacturers of scheduled medicines.<br>• Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging to the NPPA. |

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • *Stakeholders involved*: NPPA—attached office to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The NPPA has an agreement with AIOCD AWACS to collect data on prices used by retailers and distributors and provide it to the NPPA on a monthly basis. |
| **Value-based pricing: Pharmacoeconomics (new medicines to be included in the Schedule)** | • If, as result of revisions to the NEML, there are **new medicines included in the Schedule**, the government has to appoint a Standing Committee of Experts "with a view to recommend the retail prices of new drugs on the principles of "*Pharmacoeconomics*".[44]<br>• However, the criteria for establishing the price are not clearly laid out and the constitution order for the standing committee does not spell out which pharmacoeconomics terms are taken into consideration (i.e., budget impact, cost-effectiveness, cost-utility) and how they would influence the resulting price.<br>• In addition, when establishing whether a medicine is included in the NEML, the NEML Committee takes into consideration cost-effectiveness; it is not clear if the cost-effectiveness analysis done by the technical groups for the NEML are also used for price setting or in what manner.<br>• *Stakeholders involved*: Standing Committee of Experts constituted through ministerial order, comprising the NPPA, scientist/expert from the Central Drugs Standard Control Organization, scientist/expert from Department of Health Research or Indian Council of Medical Research, and pharmacoeconomics expert from National Institute of Pharmaceutical Education & Research.[49] |
| **Supply chain margins control (Scheduled and "public interest" nonscheduled medicines)** | • For **all scheduled medicines** appended to the 2013 DPCO, the maximum allowed margin is 16% (see paragraph 7 of 2013 DPCO).<br>• For **nonscheduled products**, paragraph 19 of the 2013 DPCO grants the government power to fix the ceiling or the retail price of any drug for any length of time as long as it is within the public's interest. This power was invoked by the government when it placed a 30% trade margin cap on manufacturers of 42 cancer medications in a February 27, 2019, order.[50]<br>• *Stakeholders involved*: NPPA—attached office to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The NPPA has an agreement with AIOCD AWACS to collect data on prices used by retailers and distributors and provide it to the NPPA on a monthly basis. |
| **Tendering** | • All 53 states have engaged in some form of additional price control of medicines through tendering, either by pooling the needs and overseeing the signing of framework agreements (with invoices and payments done subsequently at the hospital level) or by engaging in a fully developed centralized procurement that pools volumes and resources. In some states, this procurement is done by state authorities, while in others public companies were created to handle the centralized procurement.<br>• Method of procurement:<br>  • Most used is open tender<br>  • Award criteria: most often lowest price, but the law also permits technical aspects to be considered when determining the bid winner<br>  • Price validity: in general, one year<br>  • Price publication: some states make the prices available on their websites, while others keep them confidential and make them available only to local facilities |

[49] Ministry of Chemicals and Fertilizers. (2017). Order on Constitution of a Committee of Experts.F.no. 31015/14/2017 – Pricing. Available at: https://pharmaceuticals.gov.in/sites/default/files/Final%20Expert%20Committee%20by%20DoP.pdf.
[50] Drugs Price Control Order, Notification, February 2019.

# 4. INDONESIA—MEDICINES PRICING PROFILE

## 4.1 BACKGROUND INFORMATION

- The Indonesian health system has a mixture of public and private providers and financing. The public system is administered in line with the decentralized government system in Indonesia, with central, provincial, and district government responsibilities.

- Indonesia introduced a national health insurance program known as JKN in 2014, based on National Social Security Law No. 40. This required integrating the various public health insurance schemes existing at that time into a single insurance system.

- Indonesia faces the challenge of increasing health expenditures, as nominal health spending has been steadily increasing in the last eight years and by 222% overall.[54] The government share of total health expenditure remains low, at only 39%, whereas private, primarily OOP, expenditure is 60%.[54] The majority of this expenditure is for medicines.[55]

- Under the national health insurance, the medicines are covered as long as they are included in FORNAS, the national MOH formulary,[56,57] and provided via the pharmacies within public health facilities (hospitals and puskesmas/primary care facilities).

- Public facilities can procure FORNAS products from the e-Catalogue.[58] The e-Catalogue is an electronic list of awarded national tenders and provides a list of drugs, prices, specifications, and product providers. It contains only medicines that are listed in FORNAS and have won the tender for a given year.

- Maximum prices are regulated in Indonesia and depend on the type of medicine:

  - Innovative medicines – price is set freely
  - Nonbranded generics – price is set through cost-based pricing
  - Branded generics – price is set through IRP rules

## 4.2 PRICING POLICIES OVERVIEW

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ± | | | ✓ | ✓ | | ± | | ✓ | | | |

[54] World Health Organization, Regional Office for South-East Asia. (2017). The Republic of Indonesia health system review. Health systems in transition. Vol-7, Number -1. ISBN 978-92-9022-516-4. Available at: https://apps.who.int/iris/bitstream/handle/10665/254716/97892902251 64-eng.pdf;sequence=1.
[55] Ursu I, Rabovskaja V. (2017). Why pharmaceutical policy matters for Indonesia's social health insurance. Available at: http://health.bmz.de/events/News/why_pharmaceutical_policy_matters/index.html
[56] MOH Indonesia. Minister of Health Regulation No. 32/Menkes/SK/2013. Available at: https://dpmpt.gunungkidulkab.go.id/upload/download/5dc6bdf0e4b4e4285f5df14f183d39fa_sanitarian.pdf.
[57] MOH Indonesia. Minister of Health Regulation No. 159/Menkes/SK/V/2014. Available at: https://www.slideshare.net/bpjskesehatan1/keputusan-menteri-kesehatan-republik-indonesia-nomor-159menkesskv2014-revisi-terhadap.
[58] MOH Indonesia. Minister of Health Circular No. 167 of 2014. Available at: https://farmalkes.kemkes.go.id/en/peraturan/surat-edaran/.

| *Demand-side interventions* | Treatment guidelines | Generic prescribing | (Mandatory) Generic substitution | Prescribing protocol | Prior authorization | Electronic prescribing monitoring tools | Other |
|---|---|---|---|---|---|---|---|
| | ✓ | ± | ± | | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 4.3 Pricing Policies Detailed

| **Supply-side interventions** | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Free pricing (innovative medicines)** | • For innovative medicines and to some extent for branded generics, the MRP is freely set by the manufacturer. |
| **Cost-based pricing (nonbranded local generics)** | • For ***nonbranded local generics***, an MRP has to be declared by the manufacturer and printed on the packaging to obtain market authorization. However, once a medicine has won a tender (e-Catalogue), the printed price on the packaging no longer reflects a nominal value, but the following phrase: "*e-Catalogue price per province + 28% pharmaceutical fee of the e-Catalogue price per province*".[59]<br>• The MRPs for nonbranded generics (local generics) are based on a formula agreed to by the MOH Pricing Committee and local manufacturers; three of the local manufacturers are state owned and represent the biggest share of nonbranded generics in the market.<br>• Annually, local state-owned manufacturers submit their expenses and volumes sold for each medicine to the health authorities.<br>• The MRP allowed is equal to the manufacturing cost multiplied by four and divided by the number of units.[60] |
| **Internal reference pricing (branded imported generics)** | • According to a repealed law from 2011, the MRP for branded generics (generally foreign generics) seems to be three times the price of the nonbranded generic with the same API/concentration on the market.[55] |
| **Tendering at national level/e-Catalogue (MOH formulary medicines)** | • Tendering is applied to all INNs included in FORNAS, whether they are innovator or generic.<br>• Annually, hospitals send their forecasted volumes of FORNAS medicines to the Kebijakan Pengadaan Barang Jasa Pemerintah (LKPP), which is the national procurement agency.<br>• The LKPP can conduct centralized tenders for multiple provinces or for the MOH (e.g., for national programs).<br>  • Methods for procurement:[61]<br>  • Open tender, finalized through framework agreements<br>  • Award criteria: value for money (lowest price)<br>  • Given that nonbranded generics have the lowest prices in the market, almost all tenders are awarded locally. |

[59] MOH Regulation No. 98 of 2015 on the Provision of Information on Highest Drug Retail Price Indonesia. Available at: http://iaijatim.id/wp-content/uploads/2019/11/Permenkes-No-98-thn-2015-ttg-Pemberian_Informasi_Harga_Eceran_Tertinggi_Obat_.pdf.

[60] MOH Indonesia. Minister of Health Regulation no 02.02 / Menkes / 068 / I / 2010 dated January 14, 2010. Available at: http://iai.id/uploads/libraries/Permenkes_No.HK.02.02_MENKES_068_I_thn_2010_ttg_Kewajiban_Menggunakan_Onat_Generik_di_Fasilitas_Pelayanan_Kesehatan_Pemerintah.pdf.

[61] Presidential Decree Number 80 Year 2003 title Guidelines for Implementation of Government Procurement of Goods or Service. Available at: http://luk.staff.ugm.ac.id/phk/adm/keppres80/L1Keppres80.html#:~:text=Keputusan%20Presiden%20RI%20No%2080%20Tahun%202003%20Tentang%20Pengadaan%20Barang%20dan%20Jasa%20Pemerintah&text=1)%20Dalam%20penentuan%20paket%20pengadaan.usaha%20kecil%20termasuk%20koperasi%20kecil

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • Quotations – a minimum of three quotes should be provided; can be used for tenders of up to IDR 100,000,000<br>• Direct procurement – for medicines where only one supplier presents itself to the tender despite the call being made public<br>• Negotiation – for medicines on patent where both cost and technical aspects can be negotiated<br>• The distribution margins vary by province and can be included in the offered price or tendered separately.<br>• The final supply and payment terms are signed by the facilities and the suppliers.<br>• Prices are valid for one or two years depending on the type of medicine.<br>• The prices are included in the e-Catalogue, which provides a list of drugs, prices, specifications, and product providers. The e-Catalogue is shared with all public facilities.<br>• *Stakeholders involved in price setting:* LKPP; support for development of price ceilings from the MOH Pharmacy Division |
| **Tendering Local tenders (MOH formulary medicines)** | • If there are stock-outs, public facilities can lead their own procurement.<br>• Prices are valid for one year; there is no public database of prices obtained through local purchase.<br>• Method of procurement:<br>• A minimum of three quotes should be provided; can be used for tenders of up to IDR 100,000,000<br>• Direct purchase: for medicines where only one supplier presents itself to the tender despite the call being made public<br>• *Stakeholders involved*: Provincial or local facility procurement unit, with support from hospital pharmacies and Hospital Therapeutics Committees |
| **Supply margins control (partial) (MOH formulary medicines)** | • For e-Catalogue products, the MRP is defined as: "e-Catalogue price + 28% pharmaceutical fee of the e-Catalogue price".<br>• The 28% defines a maximum of margin for the pharmacy and wholesaler combined.<br>• The only pharmacies to which this formula applies to are public; there is no margin control for private-sector facilities. |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Generic prescribing** | • Since 2010, an administrative order[60] of the Minister of Health has obliged doctors to prescribe by generic name/INN, but it is limited to government-owned health facilities.<br>• Should the generic version not be available in the hospital facility, the physician can prescribe a branded generic or an innovative medicine with patient consent. |
| **Generic substitution** | • Pharmacists in public health facilities can exchange the branded for nonbranded generics if the patient or physician agrees. |
| **Treatment guidelines** | • There are clinical practice guidelines issued for vertical disease programs, but the guidelines do not include the price and/or cost-effectiveness criteria in their development procedure. |

Databases of prices publicly available e-Catalogue: https://e-katalog.lkpp.go.id/

## 5. KYRGYZ REPUBLIC—MEDICINES PRICING PROFILE

### 5.1 Background Information

- After the collapse of the Soviet Union in 1991, Kyrgyz Republic undertook three major reforms of its health system, each of which aimed to address certain challenges. One major achievement was the introduction of a social health insurance system and the creation of the Mandatory Health Insurance Fund (MHIF).[62]

- To contain costs, in 1996 the state-guaranteed benefit program (SGBP) was instituted to specify which health services patients are entitled to. The introduction of the SGBP represented a shift toward an output-based system with capitation payment in the outpatient sector and case-based payment in the inpatient sector.

    - It is a disease-specific scheme, which ensures access to a defined set of health services (including pharmaceuticals and primary and secondary health care service) for the entire population with certain medical conditions, regardless of their insurance status—acute cardiac infarction, TB, asthma, metastatic cancer, mental disorders (schizophrenia and affective disorders), epilepsy, diabetes, and hemophilia.[62]
    - Medicines for these conditions should be dispensed free of charge in the outpatient sector, but the coverage rate is around 80–90% of the retail price.[62]

- In 2001, the MHIF introduced the *Additional Drug Package* (ADP), which aims to improve affordability and accessibility of pharmaceuticals by limiting the financial burden on the population. It encourages more rational pharmaceutical prescribing and use and aims to reduce hospitalization related to noncommunicable diseases and to shift patients to outpatient facilities, where treatment is considered more efficient.

    - Only those with mandatory health insurance can benefit from the program.
    - Insured members have to enroll with a family general practitioner to receive special prescription forms from their treating doctor. These prescriptions can only be dispensed in pharmacies that have entered into a contract with the MHIF.
    - As of 2015, the ADP listed 60 items (58 INNs and 2 medical devices) for which the MHIF covers the so-called basic price. Patients pay the difference between the basic price and the retail price OOP.[62]

- From 2000 to 2014, the share of households making OOP payments for health care increased substantially. In 2000, 57% of households reported paying for health care OOP; by 2014, this share had risen to 82%. The main drivers of OOP spending were medicines and medical products, which together accounted for more than 50% of household spending in all years.[63]

- Since 1991, prices for the majority of medicines have been set freely.[62]

[62] WHO Europe. (2016). Pharmaceutical pricing and reimbursement reform in Kyrgyzstan. ISBN 978 92 890 5219 1. Available at: https://www.euro.who.int/en/publications/abstracts/pharmaceutical-pricing-and-reimbursement-reform-in-kyrgyzstan-2016.
[63] WHO Europe. (2018). Can people afford to pay for health care? New evidence on financial protection in Kyrgyzstan. ISBN 9789289053648. Available at: https://www.euro.who.int/__data/assets/pdf_file/0007/381589/kyrgyzstan-fp-eng.pdf

- In June 2017, Kyrgyz Republic introduced three new laws focused on medicines and medical devices.[64] The new laws on medicines allow the state to regulate the prices of essential medicines,[65] and as of June 2018, the NEML contains 58 INNs for approximately 300 commercial names.[66]

  - It is considered an integral step on the path to UHC, which Kyrgyz Republic set out to achieve when it adopted the Sustainable Development Goals.
  - Temporary rules for pricing of essential medicines were issued in October 2019 and are valid until December 2021.[67]

### 5.2 Pricing Policies Overview

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ✓ | ✓ | | | ✓ | | ✓ | | | | | |

| ***Demand-side interventions*** | **Treatment guidelines** | **Generic prescribing** | **(Mandatory) Generic substitution** | **Prescribing protocol** | **Prior authorization** | **Electronic prescribing monitoring tools** | **Other** |
|---|---|---|---|---|---|---|---|
| | ± | ✓ | - | ✓ | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 5.3 Pricing Policies Detailed

| **Supply-side interventions** | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Free pricing (for all medicines, except EML)** | • With the exception of essential medicines, the government does not interfere with prices in the pharmaceutical market.<br>• At entry into the market, the price is set freely by the manufacturer/importer for the vast majority of products.<br>• Similarly, there are no rules with regard to maximum margins that wholesalers or pharmacies can apply. |
| **External reference pricing (for EML medicines/ ADP reimbursement list)** | • Since June 2019, pharmaceutical manufacturers or importers of medicines included in the SGBP and ADP reimbursement lists must request a price approval from the Department of Medicines and Medical Devices.<br>• The price request needs to include information on the manufacturer price for given medicine in Kyrgyz Republic and in at least five reference countries, indicating the source of information (with the exception of a domestic manufacturer). In the absence of information on the manufacturer prices in the reference countries, the applicant has to provide information on the manufacturer price for medicinal products in the countries where it has market authorization.<br>• In a second stage, the Department of Medicines and Medical Devices analyzes the requested price according to the following rules:[67] |

[64] WHO Europe. (2019) Improving access to quality essential medicines in Kyrgyzstan. Available at: https://www.euro.who.int/en/countries/kyrgyzstan/news/news/2019/6/improving-access-to-quality-essential-medicines-in-kyrgyzstan.
[65] Government of The Kyrgyz Republic. (2019). Resolution on approval of the temporary rules for regulation of prices for medicines in the Kyrgyz Republic. October 29, 2019 No. 579. Available at: http://cbd.minjust.gov.kg/act/view/ru-ru/157223?cl=ru-ru.
[66] Government of The Kyrgyz Republic. (2018). Resolution on approval of the national list of vital medicines and medical products. June 6, 2018 № 274. Available at: http://cbd.minjust.gov.kg/act/view/ru-ru/11924/10?cl=ky-kg&mode=tekst.
[67] Government of The Kyrgyz Republic. (2019). Interim rules for regulation of prices for medicines in the Kyrgyz Republic. Available at: http://cbd.minjust.gov.kg/act/view/ru-ru/157224.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • If there are fewer than 10 registered competitors (commercial names) for the given INN in Kyrgyz Republic over the past two years, the requested price by the applicant will be compared to the official databases from the reference countries and other databases on prices from countries included in the network of competent authorities collaborating on pricing and reimbursement policies from WHO or other official sources of information from price regulators.<br>• If there are more than 10 registered competitors (commercial names) for a given INN over the past two years in Kyrgyz Republic, the price requested by the applicant will only be compared to the prices in the reference countries.<br>• The comparison is done at ATC level 5/6 across countries, and the products have to correspond in dose, packaging, dosage form, and consumer packaging.<br>• The median price resulting from the price in the reference countries is multiplied by a cost factor of 10%, which includes the costs of logistics, insurance, customs operations associated with the release of goods, and quality assessment.<br>• The resulting price is the estimated price of the medicine. The applicant's requested cannot exceed the estimated price for it to be approved.<br>• If the requested price does not exceed the estimated price, the Department of Medicines and Medical Devices approves and registers the requested price; if the requested price is higher, further steps will follow to allow the manufacturer to decrease the price to the level of the estimated price.<br>• Under no circumstances do the rules allow the approval of prices that are higher than the estimated price.<br>• The approved price is then used to calculate the wholesale and retail maximum prices (see Supply Chain Margins Control below).<br>• Prices are valid for one year, after which a new request for approval has to be submitted.<br>• The approved manufacturer prices and the wholesale and retail maximum prices are published on the department's website.<br>• *Stakeholders involved in price setting:* The Department of Medicines and Medical Devices |
| **Supply chain margin control (all registered medicines)** | • Wholesale prices are established by adding the corresponding monetary wholesale mark-up to the registered price of medicines.<br>• The following wholesale mark-ups apply:<br>• For manufacturer prices up to 50 soms (excluding medicines of domestic manufacturers), the maximum wholesale mark-up is 30%.<br>• Between 51 and 300 soms, the maximum wholesale mark-up is 25%.<br>• Between 301 and 600 soms, the maximum wholesale mark-up is 20%.<br>• Greater than 600 soms, the maximum wholesale mark-up is 15%.<br>• For medicines manufactured locally with a declared price of up to 50 soms, the maximum margin is not established.<br>• Once established, all wholesalers have to comply with the maximum prices within 30 days of their publication of the Catalogue.<br>• Retail prices are set by adding the corresponding monetary retail mark-up to the wholesale price calculated as described above.<br>• The following retail mark-ups apply:<br>• For wholesaler prices up to 200 soms, the maximum retail mark-up is 30%.<br>• Between 201 and 500 soms, the maximum retail mark-up is 25%.<br>• Greater than 500 soms, the maximum retail mark-up is 20%.<br>• Once established, all retailers have to comply with the maximum prices within 45 days of their publication of the Catalogue. |

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Internal reference pricing (for all commercial brands of the EML INNs)** | • Since the introduction of the ADP program, the MHIF has created a de-facto IRP intervention: the ADP contains 58 INNs, the same ones as the NEML, for which the MHIF covers the so-called "basic price"; the difference between the basic price and the retail price has to be paid OOP by patients.<br>• Until 2019, the calculation of the basic price was done by the MHIF via analysis of wholesale prices that are extracted from price lists provided by wholesalers (usually the largest, although participation is voluntary) at the MHIF's request. From the prices collected, the three highest and three lowest are excluded and the average of the remaining prices is calculated. To this average two different multipliers are applied—one for pharmacies in urban areas and one for those in remote areas—yielding two reimbursement values with a difference of around 9%. Given the new regulation of wholesale and retail prices, issued in October 2019, the assumption of our interviewee is that the methodology has changed to reflect the new maximal prices from the Catalogue, but no official document was issued explaining the new methodology.<br>• The basic price is likely to act as pressure for further downward decrease of prices.<br>• *Stakeholders involved in internal price setting:* MHIF |
| **Tendering Local purchase (facility level) (all registered medicines, included in EML or not)** | • Health care organizations procure any registered medicines and medical devices for facilities and reimburse the cost of ambulatory drugs within the State Guaranteed Benefit Program and ADP.<br>• Medicines used for inpatient care should be fully covered, but anecdotal information suggests patients' families may still be expected to buy medicines OOP in retail pharmacies around the facilities.<br>• Hospitals form their drugs lists for procurement independent of the NEML. To improve accessibility of drugs and taking into account local and specific needs, hospitals are allowed to include up to 20% of drugs not in the NEML in their procurement drug lists.[68]<br>• Health care organizations are allowed to use any public procurement method, but open tender is the most common.<br>  • Local procurement seems to be riddled with problems (e.g., lack of transparency, accountability, accusations of grift), and there has been an indication from the MOH that a centralized procurement system may be considered moving forward.[69] |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Generic prescribing** | • Prescription by INN is mandatory.[70] |
| **Generic substitution** | • Generic substitution is possible but not mandatory.<br>• Even though the market is mainly generic (originator medicines only account for 3% of the Kyrgyz pharmaceutical market), increasing the use of generic medicines is one of the policy aims stipulated in the National Drug Policy.[71] |

[68] Resolution of the Government of the Kyrgyz Republic № 376 as of "8" July 2014. Program of the Government of the Kyrgyz Republic on development of the area of drugs circulation. Available at: https://www.who.int/medicines/areas/coordination/SDP_eng_July22_2014.pdf?ua=1.
[69] 24kg. (2019). Health Ministry of Kyrgyzstan presents new system of medical procurement. Available at: https://24.kg/english/116344_Health_Ministry_of_Kyrgyzstan_presents_new_system_of_medical_procurement/.
[70] MeTA. Medicine Prices, Availability, Affordability in Kyrgyz Republic. Report of a survey conducted September to October 2015. Bishek, 23 November 2015: Medicines Transparency Alliance. MeTA Project in Kyrgyzstan, 2015.
[71] Vogler S, Schneider P, Dedet G, et al. (2019). Affordable and equitable access to subsidised outpatient medicines? Analysis of co-payments under the additional drug package in Kyrgyzstan. Int J Equity Health 18, 89. https://doi.org/10.1186/s12939-019-0990-6

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Treatment guidelines** | • National specialist hospitals work with the MHIF and contribute to developing clinical guidelines but have no authority or resources for supervising implementation or for monitoring and evaluation in general.<br>• There is little to no connection between the NEML and the MHIF and its Medical Accreditation Commission. As a result, guidelines remain very broad when it comes to defining the treatment that should be provided. |

| | |
|---|---|
| Databases of prices publicly available | Catalogue of prices – approved manufacturer, wholesale, and retail prices for national state beneficiary programs and ADP: http://www.pharm.kg/ru/equipment |

# 6. MYANMAR—MEDICINES PRICING PROFILE

## 6.1 BACKGROUND INFORMATION

- The current health system in Myanmar is a mixed public-private provider system.
- Public health facilities procure mostly essential medicines listed in the NEML and make them available free of charge to patients. If non-NEML medicines are prescribed, the patient has to pay for them OOP.
- Due to stock-outs and prescribing behaviors, a 2014 survey indicated that most patients still buy medicines OOP from retail pharmacies found outside of health facilities.
- The National Medicines Strategy 2018–2021[72] suggests that an ERP mechanism could be considered, but to date no methodology has been issued.[73] There have been ongoing discussions about introducing an MRP, but none have translated into actual policies until now.[74]
- The 2019 National Medicines Policy[75] also suggests that margin controls are likely to be put in place, but specific rules have not yet been issued.
- The only price intervention used in the public sector is tendering, which is mainly led by local authorities or directly by hospitals with more than 200 beds.
- Private-sector facilities are not fully regulated, and prices are established freely.
- There is not yet a mandatory separation between prescribers and dispensers, increasing the likelihood of branded/non-NEML prescribing and purchasing.

## 6.2 PRICING POLICIES OVERVIEW

[72] Ministry of Health and Sports. (2019). National Medicines Policy. Strategy and implementation plan 2018 – 2021. Available at: http://www.doms.gov.mm/wp-content/uploads/2019/12/National-Medicines-Policy-Strategy-and-Implementation-Plan.pdf
[73] Ministry of Health and Sports. (2019). National Medicines Policy 2018. Available at: http://www.doms.gov.mm/wp-content/uploads/2019/12/National-Medicines-Policy.pdf
[74] Myanmar Times. (2016). FDA announces plans to set official medical prices. Available at: https://www.mmtimes.com/national-news/yangon/20829-fda-announces-plans-to-set-official-medical-prices.html.
[75] Holloway KA. (2011). Drug policy and pharmaceuticals in health care delivery, Myanmar. Mission Report 19-26 Oct 2011, WHO-SEARO. Available at: http://origin.searo.who.int/entity/medicines/myanmar_situational_analysis.pdf.

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ✓ | | | | ✓ | | | | | | | |
| ***Demand-side interventions*** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) Generic substitution** | | **Prescribing protocol** | **Prior authorization** | | **Electronic prescribing monitoring tools** | | **Other** |
| | | | ± | | ± | | | | | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 6.3 Pricing Policies Detailed

| **Supply-side interventions** | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Free pricing (all medicines)** | • There is no stated official approach with regard to pricing of essential or nonessential medicines, although there is a generally stated aim of "*ensuring treatment availability and affordability*".[73]<br>• All medicines present in the country have to be registered with the National Drug Administration, but among the data required for registration, price is not stated as a component.<br>• *Stakeholders involved:* Ministry of Health and Sports; National Drug Authority; Department of Medical Services (EML selection) |
| **Tendering a. Centralized procurement (NEML medicines)** | • The 2016 NEML acts as a basis for procurement in public facilities.<br>• Some NEML medicines are procured and distributed by the Drug Purchasing Division under the Department of Medical Services.<br>• Beginning in 2013,[76] there has been a transition from the Central Medical Store Department to decentralized procurement at the state and hospital levels.<br>• The Central Medical Store Department still undertakes central procurement and distribution to health facilities for less than 50% of the volume used.<br>• There is no clear delineation on which medicines are procured centrally and which are led by the state or hospitals.<br>• Method of procurement:<br>- Direct purchase: The Purchasing Division buys in preference essential medicines manufactured by the government-owned Myanmar Pharmaceutical Factory over other manufacturers (approximately 50–70% of medicines are procured centrally).<br>- Open national tender: Annually, through national importers and wholesalers. Award criteria: 95% price, 5% technical performance; mandatory two-year shelf life after delivery; and ability to deposit a tender guarantee that will be forfeited if the contract fails.<br>- All procurement is in Kyat, which is highly volatile, decreasing interest from international players.<br>• The lead time for finalizing the procurement procedure (approximately 140 days) further deters potentially interested parties; this led to continuous stock-outs between 2010 and 2013.<br>• Vertical programs conduct their own procurement and distribution.<br>• *Stakeholders involved in centralized tendering:* The Procurement Committee decides which tenders will be granted and comprises the Director General of the Department of Health Services, Deputy Director General of the Department of Food and Drug |

[76] WHO SEARO. (2014). Medicines in healthcare delivery, Myanmar. Situational analysis: 13-23 October 2014. Available at: https://www.who.int/docs/default-source/searo/hsd/edm/csa-myanmar-2014.pdf?sfvrsn=4a2967da_2.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | Administration, Deputy Director General of the Division of Medical Care, Chief of the Purchasing Division, and Director of Finance within the MOH. |
| **Tendering**<br>**b. State and hospitals with more than 200 beds (mostly NEML medicines)** | • State- and hospital-led tenders are considered to be the main purchase mechanism to ensure medicines in public facilities.<br>- Devolution was implemented in 2013, and increasingly states have taken over the procurement processes.<br>- Procurement done locally is managed by the medical superintendents of hospitals with more than 200 beds or the director of regional/state health authorities.[76]<br>• Method of procurement:<br>- Public tender is issued every six months.<br>- Participants have to be registered with the Food and Drug Administration; approximately 20 wholesalers act as the main suppliers.<br>- Award criteria: price and shelf life.<br>• There has been a loss of economies of scale, and it is likely that medicine prices are considerably higher in such a system than with a central procurement system. A 2014 WHO SEARO study shows that for the three referral hospitals, prices were in general 90% higher than the prices available through the central unit.<br>• However, the shorter lead time for procurement (and payments) of 33 to 35 days has decreased the stock-out rate.<br>• *Stakeholders involved*: The procurement committees generally comprise the state or regional health director or the hospital medical superintendent (hospital procurement), one specialist from each of the major specialties, the matron, a representative of a district and township hospital (in the case of regional/state procurement), a representative from the local medical stores branch (if available), and a representative from transit camps (in the case of regional/state procurement). |
| **Tendering**<br>**c. Vertical programs (EML/WHO-PQ medicines)** | • The majority of vertical programs have financial support from international donor agencies, which ensures that tendering best practices are implemented. The national medicines strategy makes no indication of when and how these programs will be integrated into local financial resources.<br>- Examples include the USAID Global Health Supply Chain Program-Procurement and Supply Management and key commodities such as artemisinin-based combination therapies, long-lasting insecticidal nets, and malaria rapid diagnostic tests. |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Generic prescribing and marketing** | • The National Medicines Policy places generic prescribing as one of the core principles for rational use: "*The government shall encourage production, marketing, prescribing and dispensing of generic medicines. If a drug is marketed under a brand name, the generic name must be displayed prominently on the label*".[75]<br>• However, there is no monitoring indicator developed in the National Medicines Implementation Plan 2018–2021, suggesting there will be little enforcement of it.<br>• Although the NEML should serve as a basis for procurement and use of medicines at public health facilities, there is a need to improve compliance:<br>- The average percentage of non-NEML medicines procured was 29% at public referral hospitals, 20% at public township hospitals, and 14.25% at public primary health centers.[76] |
| **Generic substitution** | • Similar to generic prescribing (above), generic substitution is unlikely to be enforced in the short to medium term: "*Generic substitution shall be allowed as part of the policy, when feasible*".[75] |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| | • The issue is further compounded by the fact that to date regulation still allows for the prescriber to dispense the medicines. |

# 7. NEPAL—MEDICINES PRICING PROFILE

## 7.1 BACKGROUND INFORMATION

- Nepal has a mixed health system, with in-care dominated by public facilities; private clinics and pharmacy retailers are more common for ambulatory settings.

- The public health care system is overseen by the Ministry of Health and Population and broken into 8 central hospitals, 6 regional and sub-regional hospitals, 10 zonal hospitals, 78 district hospitals, 208 primary care centers, 1,559 health posts, and 2,247 sub-health posts.[77]

- In 2007, the country's interim constitution decreed that health care was a basic human right and that essential health care services should be provided for free for Nepalese citizens. Since 2009, all services and medicines provided within public facilities should be free of charge.

- In the initial phases of addressing this goal, the Government of Nepal developed essential services programs and an EML to provide basic health coverage; however, the EML only serves as a guide for health practitioners. There is no financial commitment from the government to provide the medicines and vaccines on the list, which means that they may not necessarily be free of charge or available in public facilities.

- In 2009, a decision was made to ensure free access to 40 medicines, listed separately from the EML, known as the Free Drug List (FDL). The FDL includes mostly EML medicines but differs from the EML in that the government has allocated resources in procuring these products for facilities with fewer than 25 beds, while larger facilities have to provide them at their MRP level (see IRP price intervention below). In its most recent iteration, the FDL included 70 medicines.

- In 2016, a Social Health Security Program[78] was rolled out through the country and led by the HIB. Initially a voluntary program based on family contributions, enrollment has become mandatory for all government and foreign companies' employees since 2017; the poor and very poor are subsidized by the state.[79]

    - Families of up to five members have to contribute NPR 2,500 per year and NPR 425 per additional member; benefits of up to NPR 50,000 per year are available for families of up to five members with an additional NPR 10,000 covered for each additional member. The maximum amount available per household per year is NPR 100,000.
    - As of 2018, the list of medicines covered by the HIB contained 1,441 types of medicines (including the FDL and EML) that are included in the benefit package.

[77] Singh D, Luz A, Rattanavipapong W, Teerawattananon Y. (2017). Designing the free drugs list in Nepal: a balancing act between technical strengths and policy processes. MDM Policy & Practice. 2. 238146831769176. 10.1177/2381468317691766.
[78] Public Health Update. (2020). Social Health Security (Health Insurance) Program in Nepal. Available at: https://publichealthupdate.com/social-health-security-health-insurance-program-in-nepal/.
[79] Thapa G, Amyt A, Maru D. (2017). In Nepal, health insurance for all. Health Affairs. Available at: https://www.healthaffairs.org/do/10.1377/hblog20171027.743636/full/.

- The list of medicines covered by the HIB is considerably more generous than the EML; the selection criteria for the medicines to be included in the benefits package have been mainly physician driven.[80]

### 7.2 Pricing Policies Overview

| Supply-side interventions | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ✓ | | | | | | - | | ± | | | |
| **Demand-side interventions** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) Generic substitution** | | **Prescribing protocol** | **Prior authorization** | | **Electronic prescribing monitoring tools** | | **Other** |
| | ± | | ± | | | | | ± | | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 7.3 Pricing Policies Detailed

| **Supply-side interventions** | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Freely declared price (all medicines, part of registration procedure)** | • The 2018 Drug Act[81] mandates the Department of Drug Administration (DDA) to ensure price regulation for all registered medicines and price transparency; in practice, prices are set by manufacturers and approved by the DDA.[82]<br>• To date, there have been no cases of refusal or cancellation of medicine authorization due to the proposed price.<br>• There are ongoing discussions with regard to imposing price regulation, but it is not clear if the regulation would apply to all medicines registered in the country, the EML, or the Health Insurance list.[83]<br>• The list of approved prices is not available on the DDA website. |
| **Supply chain margin control (all registered medicines)** | • The Drug Act also defines mark-ups for wholesale and retail: up to a 6–10% mark-up for wholesalers and up to a 16% margin allowed for retailers.<br>• In practice, there is little control over the market, in part due to a lack of control capacity, and prices are not monitored.[84] |

[80] German Development Fund GIZ, The Innovation Fund Project. (2019). Nepal – situational analysis of the pharmaceutical sector: how to use IT and novel policies to increase access through social health insurance.
[81] The Drug Act of 2018. Available at: http://www.dda.gov.np/content/drugs-act-2035.
[82] WHO SEARO Report 2014. (internal document).
[83] Government to fix the medicine price, generic name of medicine obligatory – Setopaty online newspaper. Available at: https://setopati.net/social/128954.
[84] Devkota A, Paudel A, Koirala B, Baral D, Gautam S, Sharma SK. Price variation and availability of free medicine for non-communicable diseases. J Nepal Health Res Counc 2018 Apr-Jun;16(39): 118-23. Available at: www.jnhrc.com.np/index.php/jnhrc/article/view/1565/694.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Internal reference pricing (for FDL medicines and HIB list of medicines)** | • MRPs have been set for the 70 molecules included in the FDL.<br>- It is not clear on which grounds the MRP was set, although it seems to represent the average price available in the market for the given medicine per daily drug dose.<br>- In public facilities with fewer than 25 beds, these medicines should be free of charge.<br>- The FDL medicines should be available in all facilities.<br>• In private-sector and public facilities with more than 25 beds, FDL medicines should be charged at MRP level; several studies have pointed out differences of up to 300% in price between various facilities for the same product.[84]<br>• For the 1,141 medicines included in the reimbursement list of the Social Health Insurance Program, the HIB has set reimbursement ceiling prices for each molecule (INN).<br>- The reimbursement ceiling level has been calculated on the mean price across all brands available for the same INN; some adjustments have been allowed for market size.[40]<br>• The list of medicines and prices is made available through an electronic platform set up by the Social Health Insurance Program. |
| **Tendering Centralized procurement (for FDL and EML medicines)** | • **National procurement** through the Medicines Logistics Division:<br>- Before devolution, 70% of hospital medicines were expected to be procured at the national level through central procurement.<br>- The Medicines Logistics Division could procure FDL and EML drugs or other supplies.<br>- Its role has decreased since provinces have received greater autonomy.<br>- Late deliveries and long processes led to frequent stock-outs.<br>- The 70 FDL drugs are still expected to be supplied for free in public facilities with fewer than 25 beds.<br>• **Provincial procurement**<br>- After the move to federalization in 2018, provincial procurement is the main public procurement channel.<br>- Products and quantity are decided by medical officers (there are no provincial Drug and Therapeutics Committees).<br>- Provinces mainly procure EML drugs but now also procure FDL drugs.<br>- There is no regulation preventing the procurement of any registered products if the province approves a physician's requests from their facilities.<br>- Open tendering should be the main method of procurement.<br>- Procurement estimates are based on past consumption.<br>- A call for bids has to be issued for any procurement amount greater than 2 million NPR.<br>- Direct procurement remains the most used procurement method, and prices achieved are, on average, 30% higher than national prices.[82] |

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Tendering**<br>**Local purchasing (for EML medicines, but local formularies allowed too)** | • Local-level municipalities have taken over procurement for facilities such as health posts, primary health centers, and municipal hospitals in their area. Specialized public hospitals and private hospitals are in charge of their own procurement.<br>- Except for FDL medicines, which are procured centrally and distributed for free **only** if the public facility has fewer than 25 beds.<br>• Hospitals should guide their procurement decisions using the EML, but in practice they can procure any drug registered in the country at any price.<br>- The procurement decision is mainly driven by hospital physicians.<br>• Similar to centralized procurement, call for bids should be made public for any procurement amount of more than 2 million NPR.<br>• However, research[84] indicates a preference for direct procurement. |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| Treatment **guidelines** | • Guidelines are in place for major communicable diseases (e.g., HIV, TB, malaria).[85] |
| **Generic prescribing** | • Generic (INN) prescribing is in the policy but not enforced, even by the new health insurance program.[86] |
| **Prior authorization** | • The HIB has introduced the need for a formal request and approval before the prescriber and the facility can dispense a few expensive medicines.[83] |

| | |
|---|---|
| Other databases of medicines available publicly | The FDL:<br>https://publichealthupdate.com/list-of-free-essential-drugs-for-health-institutions-nepal/<br>The Nepalese National Formulary:<br>https://www.dda.gov.np/content/nepalese-national-formulary-nnf |

# 8. THE PHILIPPINES—MEDICINES PRICING PROFILE

## 8.1 BACKGROUND INFORMATION

- The Philippines has a dual health delivery system that includes both the public and private sectors.
- The public sector is largely financed through a tax-based budgeting system in which health services are delivered by government facilities under national and local governments. The Department of Health (DOH) supervises government corporate hospitals and specialty and regional hospitals; at the local level, provincial governments manage and operate district and provincial hospitals, while municipal governments provide primary care, including preventive and promotive health services through rural health units, health centers, and barangay health stations.
- The private sector, which consists of for-profit and nonprofit health care providers, is largely market oriented, where health care is generally paid for through user fees at the point of service.[87]

[85] WHO. (2017). Nepal pharmaceutical profile 2017. Available at: https://apps.who.int/iris/bitstream/handle/10665/274871/2017-Nepal-pharm-profile.pdf?sequence=1&isAllowed=y.
[86] Shrestha M, Moles R, Ranjit E, Chaar B. (2018) Medicine procurement in hospital pharmacies of Nepal: A qualitative study based on the Basel Statements. PLoS ONE 13(2): e0191778. Available at: https://doi.org/10.1371/journal.pone.0191778.
[87] Dayrit MM, Lagrada LP, Picazo OF, Pons MC, Villaverde MC. (2018). The Philippines Health System Review. Vol. 8 No. 2. New Delhi: World Health Organization, Regional Office for South- East Asia; 2018.

- The introduction of social health insurance administered by the Philippine Health Insurance Corporation (PhilHealth) in 1995 aimed to provide financial risk protection for Filipinos. In 2010, the Philippines made an explicit political commitment to achieve universal health care, and in 2019 the Universal Health Care Act was signed into law.

- For insured members, PhilHealth covers all hospitalization costs in public facilities, including medicines; since the signing of the UHC Act in 2019, a two-year pilot study has started testing the reimbursement of Philippines National Formulary (PNF) medicines for ambulatory settings through both public and private medicine retailers.

- The DOH, through its Formulary Executive Committee, is in charge of developing the MOH formulary—the PNF; in its work, the Committee is supported by a Technical Secretariat from the Pharmaceutical Division (PD) and by STEP.

- Public health facilities are only allowed to prescribe, procure, and dispense PNF medicines.[88]

- By law, medicine prices are not regulated in the Philippines unless competition fails and/or there is a public need.[89] For the majority of PNF medicines, with the exception of 86 molecules (see MRP below), the price is not regulated at the manufacturer/distributor or retail level.

- However, winning tender prices for all PNF medicines are indexed in the DPRI and published accordingly. By law, future procurement procedures for public facilities have to be guided by DPRI prices.

- Private-sector prices are not controlled or monitored, with the exception of the 86 medicines (by INN) included in the MRP list.

### 8.2 Pricing Policies Overview

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ± | ✓ | | | ✓ | | ± | | | ± | | |
| ***Demand-side interventions*** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) Generic substitution** | | **Prescribing protocol** | **Prior authorization** | | **Electronic prescribing monitoring tools** | | **Other** |
| | ✓ | | ✓ | | - | | | | | | | ✓ |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 8.3 Pricing Policies Detailed

| **Supply-side interventions** | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Free pricing (all registered medicines)** | • Free pricing is applied to the majority of registered medicines; other pricing interventions are put in place only for those medicines that are also included in the PNF (the MOH formulary) (see below the various tendering interventions and the ERP). |

[88] Ursu I, Carlton A, Reye K. (2018). Situational analysis of the Philippine regulatory landscape and the appropriate enabling environment toward the operationalization of reform. EU-Philippine Health Sector Reform Contract (PHSRC) Contract No. DCI-ASIE/2014/349-774 (internal report).
[89] RA9502 "Cheaper Medicines Act" (2008). Available at: https://mclaw08.wordpress.com/2009/10/06/cheaper-medicines-act-of-2009-ra-9502/.

<table>
<tr><th colspan="2">Supply-side interventions</th></tr>
<tr><th>Type of intervention</th><th>Details and analysis</th></tr>
<tr><td></td><td>• Prices in public-sector medicine retailers or clinics are not regulated with the exception of the 86 medicines included in the MRP list (see below).</td></tr>
<tr><td>External reference pricing and supply chain-controlled margin<br>(86 INN)</td><td>
• Through Executive Order No. 104[90] of February 17, 2020, the Philippine government imposed MRPs and/or MWPs on 86 medicines (INNs)/133 formulations.<br>
• The 86 molecules were chosen based on burden of disease; whether they affect special and disadvantaged populations (e.g., orphans, patients with rare cancers); or medicines for which there is limited competition (e.g., on patent).[91]<br>
• The MRP and/or MWP take into consideration prices from:<br>
- Asian countries: Thailand, Malaysia, Vietnam, India, and Indonesia<br>
- Developed countries: United Kingdom, Australia, and Canada<br>
• The MRP is determined through ERP plus a regressive mark-up:[92]<br>
- MRP = PER + $m$<br>
- PER = min{mid{Pac}, min{Pdc}}<br>
- Where: PER External Reference Price (Prescribed Wholesale Price)<br>
- $m$ Mark-up, value identified below<br>
- Pac is the median price per SKU of the reference Asian country (ac)<br>
- Pdc is the median price per SKU of the reference developed country (dc)<br>
• Depending on the value of PER, a regressive mark-up schedule has been imposed:
<table>
<tr><th colspan="2">External Reference Price/<br>Prescribed Wholesale Price (PER)</th><th rowspan="2">Mark-up $m$</th></tr>
<tr><th>Over (PHP)</th><th>But not over (PHP)</th></tr>
<tr><td>0</td><td>50</td><td>40%</td></tr>
<tr><td>50</td><td>100</td><td>Php 20 + 30% of the excess of Php 50</td></tr>
<tr><td>100</td><td>1,000</td><td>Php 35 + 20% of the excess of Php 100</td></tr>
<tr><td>1,000</td><td>10,000</td><td>Php 215 + 10% of the excess of Php 1,000</td></tr>
<tr><td>10,000</td><td>(...)</td><td>Php 1,115 + 5% of the excess of Php 10,000</td></tr>
</table>
• The MRP calculated using the formula above is VAT inclusive unless otherwise stated; the MWP is VAT exclusive.<br>
• The MRP and MWP apply to all medicines specifically referred to and annexed under EO 104 and its subsequent iterations.<br>
• The MRP is “imposed on all public and private retail outlets, including drugstores, hospitals and hospital pharmacies, health maintenance organizations, convenience stores, supermarkets, and the like”.[92]<br>
• The MWP is “imposed on all manufacturers, wholesalers, traders, distributors, and the like”.[92]<br>
• The MRP and MWP are publicly available and must be included in the package labelling.<br>
Stakeholders involved: DOH PD, Drug Price Advisory Council
</td></tr>
<tr><td>Tendering/setting maximum ceilings: DPRI (MOH formulary medicines)</td><td>• The DOH PD has developed a pricing methodology that aims to control the demand-side price by imposing ceilings on the tenders issued by public-sector facilities.[93] The stated aim of the DPRI is “to guide all public health facilities in the fair pricing of essential medicines and to increase efficiency of the drug procurement process in the public sector”.[94]</td></tr>
</table>

[90] Executive Order No. 104 on “Improving Access to Healthcare through the Regulation of Prices in the Retail of Drugs and Medicines” (“EO No. 104”) dated 17 February 2020. Available at: https://www.officialgazette.gov.ph/downloads/2020/02feb/20200217-EO-104-RRD.pdf.
[91] DOH Administrative order no 2020-0039 on Guidelines for the Implementation of Maximum Retail Price (MRP) on Drugs and Medicines. Available at: https://law.upd.edu.ph/wp-content/uploads/2020/09/DOH-Administrative-Order-2020-0039.pdf.
[92] Annexes C and E of AO 2020-0039. Available at: https://www.doh.gov.ph/sites/default/files/policies_and_laws/MRP%20AO%20(Draft)%20as%20of%20Jul%2023%2019_0.pdf.
[93] DOH. Department Order No. 2014-0146. Available at: https://dpri.doh.gov.ph/download/do2014-0146.pdf.
[94] DOH. Administrative Order no 20015-0051. Available at: https://dpri.doh.gov.ph/download/ao2015-0051.pdf.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • All DOH and government hospitals and regional offices have to adhere to a price ceiling (the DPRI) when procuring drugs listed in the PNF.[94]<br>• The DPRI represents "*the final acquisition cost to government health facilities which should include the landed cost, packaging, drug content, quality assurance, manufacturing overheads and FDA fees. The DPRI excludes other costs such as pharmacy services, preparation and storage fees and applicable taxes to medicines (i.e. VAT) and other reason-able pharmacy mark-ups to be determined by the DOH*".[94]<br>• The DPRI methodology has yet to demonstrate its ability to control prices in the medium to long term. Wong et al.,[95] note a failure rate of approximately half of the tenders issued at DPRI prices, and despite the need to follow DPRI prices even for all other forms of procurement, in general, prices achieved through alternative procurement means were higher than DPRI prices. |
| **Tendering**<br>**Centralized procurement DOH (MOH formulary medicines)** | • All commodities procured with DOH funding are handled by the Central Office for Bids and Awards Committee (COBAC). COBAC's role is largely executive and administrative. It applies and complies with the Public Procurement Law[96] and acts based on decisions signed by the Secretary of Health.<br>• Product dependent, procurement can go through a national tender or alternative procurement (international purchase through donors).<br>- The technical specifications and the quantities of the commodities to be procured and the points of delivery are defined by the DOH requesting office.<br>- The maximum price is based on the DPRI, market price averages, or international price for UNICEF products.<br>- Distribution costs may or may not be included in the tender, based on whether the supply will be at the national level, CMS, or regional/provincial level.<br>• Bids are awarded to the lowest calculated bid and subject to post-qualification checks. The bids should be executed within 15 days of award.<br>- According to the revised rules of procurement issued in 2016, "the Procuring Entity shall give preference to materials and supplies produced, made and manufactured in the Philippines, subject to the conditions herein below specified. The award shall be made to the lowest Domestic Bidder, provided his bid is not more than fifteen percent (15%) in excess of the lowest Foreign Bid".[97]<br>• The contracts can have a duration of only one year, although in 2018 two medicines were being piloted for framework agreements of two years.<br>• Bids are considered failed when no bids are received or no bid qualifies as the lowest calculated responsive bid.<br>- After the first bid failure, the process of advertising and re-opening the bid can be resumed, allowing for higher maximal prices, but only as long as the overall amount of the bid stays the same (i.e., decreasing volumes to be procured).<br>- Should the bid fail a second time, a procedure of negotiated procurement can be initiated, but the price proposed can only exceed the initially proposed price by up to 20%. |
| **Tendering**<br>**Local procurement** | • Public hospitals can **only procure and dispense medicines listed in the PNF**. |

[95] Wong J, Apostol GL, Modina CAE, Bagas J. A Study on Factors Influencing Drug Prices Among National Public Hospitals. Epimetrics, June 30, 2017.
[96] GOVPH. The 2016 Revised Implementing Rules and Regulations of Republic Act No. 9184, Otherwise Known as the Government Procurement Reform Act. Available at: https://www.officialgazette.gov.ph/2016/08/29/implementing-rules-and-regulations-of-republic-act-no-9184/.
[97] Lam H (project leader). A Study on Drug Procurement Practices of Selected Local Government Units (LGUs) in Luzon. Final Report Approved Version (as of May 31, 2018). Report copy provided by the Pharmaceutical Division (internal document).

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **(MOH formulary medicines)** | • For all **PNF medicines** that are not procured and delivered by the DOH, or if additional volumes are needed, hospitals have to conduct their own procurement process.<br>• Similar to the national level, the purchasing decision is split between the hospital chief as a representative of the Drug and Therapeutics Committee and the local procurement offices. The rules and regulations for hospital procurement are the same as the ones followed by COBAC.<br>• However, the loss of economies of scale compared to a nationwide procurement seems to result in multiple bid failures. Lam et al.,[97] found in half of the hospital surveyed that "most frequent source of failure of bidding was that few or no suppliers submitted their bids".<br>• If the tenders fail, alternative procurement options can be considered in line with the Procurement Act, including negotiated procurement, direct contracting, local shopping, emergency procurement, small-value procurement (up to 50,000 Php), and consignment.<br>- All should in theory abide with the DPRI maximal procurement. |
| **Value-based pricing: Use of HTA (for innovative/ expensive medicines requesting inclusion in MOH formulary)** | • Since 2016, there has been increasing effort to set up the pharmacoeconomics capacity in the country and more specifically in the DOH. STEP was officially put in place in March 2019.[98]<br>• The unit is capable of reviewing a minimum of 10 to 12 in-depth HTAs per year, in addition to further technical reviews and information briefs delivered as the need arises.<br>• Given the relatively small number of assessments that can be done by the HTA group, a decision was made to target HTA for high-ticket items with potentially high budget impact on DOH programs or PhilHealth.<br>• The latest draft AO foresees the relation between the outputs of this unit in relation to the other functions of the system, and HTA should inform DOH formulary decisions and provide support for price negotiations. |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Treatment guidelines** | • Since 2018, there has been an ongoing effort to update most guidelines in the country according to formulary medicines and evidence-based approaches.[90] |
| **Generic prescribing** | • INN prescribing in policy but not enforced.[88]<br>***Gaps in policy***: The policy is not enforced. |
| **Other** | • Since 2018, the DOH through the PD has set up the barangay pharmacies program of drugstores where good quality, nonbranded generics can be made available "at affordable prices" for the poorer population.[88] |

| | |
|---|---|
| Databases of prices publicly available | Drug Price Reference Index – average awarded tender prices:<br>https://dpri.doh.gov.ph/index.php?page=downloads<br>List of Maximum Retail Prices (MRP) – 80 INNs/133 formulations:<br>https://www.officialgazette.gov.ph/downloads/2020/02feb/20200217-EO-104-RRD.pdf |

# 9. SRI LANKA—MEDICINES PRICING PROFILE

[98] Ursu I. Development and institutionalization of the HTA unit in the Philippines. EU-Philippine Health Sector Reform Contract (PHSRC) Contract No. DCI-ASIE/2014/349-774 (internal report).

### 9.1 Background Information

- The health care system in Sri Lanka is a mix of public and private providers, with governmental facilities dominating the in-care setting. The outpatient setting is equally split between public and private providers.[99]

- The government health care delivery system, including medicines, is free to all citizens at the point of delivery, and it has been the commitment of successive governments of Sri Lanka to maintain this policy.

- Patients frequently pay OOP for prescribed medicines and laboratory tests when they are not readily available in public facilities. For the past decade, OOP expenditure has been consistently above 40% of the total health expenditure.[100]

- Sri Lanka has been faced with rising costs of medicines since pharmaceutical price controls were abolished in 2003. In 2015, the National Medicines Regulatory Act was passed as the main legislation with regard to medicines in Sri Lanka. The National Medicines Regulatory Authority (NMRA) is tasked with ensuring the quality, safety, and efficacy of medicines and reserves the right to consider the need for and price of a medicine before granting market authorization.

- In 2016, a new pricing methodology was established for 48 essential medicines (by INN) enabling a maximum retail (ceiling) price; the list and prices are reviewed annually. In 2019, there were 60 medicines (by INN) in the list of medicines for which a maximum ceiling price was established.

- In addition, the government has been able to limit drug price increases in the public sector through the SPC, established in 1971 to provide high-quality, safe, effective, and affordable medicines. The SPC imports, distributes, and sells pharmaceuticals throughout the country. It is the largest distributor in Sri Lanka. The SPC can secure lower prices through competitive global tenders and generic and bulk purchasing.

- In 1987, the State Pharmaceuticals Manufacturing Corporation (SPMC) was founded. It is now the largest drug manufacturer in Sri Lanka, providing 43 drugs to the Department of Health Services (MOH) at low profit margins. In 2015, the SPMC and local manufacturers accounted for 15% of the total pharmaceutical market in Sri Lanka.

### 9.2 Pricing Policies Overview

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ✓ | | | ✓ | | | | ± | | | |
| ***Demand-side interventions*** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) Generic substitution** | | **Prescribing protocol** | **Prior authorization** | | **Electronic prescribing monitoring tools** | | **Other** |
| | ± | | ✓ | | ± | | | | | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

[99] Ursu I. Development and institutionalization of the HTA unit in the Philippines. EU-Philippine Health Sector Reform Contract (PHSRC) Contract No. DCI-ASIE/2014/349-774 (internal report).
[100] WHO, Country Office Sri Lanka. (2016). Sri Lanka's success: ensuring affordable essential medicines for all. Available at: https://nmra.gov.lk/images/PDF/affordable_essential_medicines_policy_brief1.pdf.

### 9.3 PRICING POLICIES DETAILED

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **External/internal reference pricing (60 EML medicines)** | • The 2015 NMRA[101] introduced the concept of price regulation at the retail level for medicines entering the country as part of the marketing authorization procedure: "*the NMRA reserves the right to consider the need and the price of a medicine before granting market authorization, as part of the evaluation procedure: the MEC shall take into consideration the efficacy, safety, quality, need and cost of each medicine, in the process of evaluation and may consider pharmacoeconomic analysis where necessary*".[101]<br>• For the purpose of determining the **retail price** of a new medicine, *"the Authority shall consider the prices in the region, the benefit of the new product and the cost effectiveness, as well as the prevailing market prices of similar products within the same therapeutic class, International Reference Prices and other factors as may be prescribed"*.[101]<br>• For a set of 60 essential medicines (by INN), a maximum retail ceiling price has been imposed since 2016 that must be respected by all stakeholders in the market, public or private. The list is reviewed annually.<br>• A new pricing policy issued in 2019[102] requests that all manufacturers/importers who want to register a product propose an introductory price that considers "*prevailing market prices in Sri Lanka and any other countries of similar products within the same therapeutic class, regional and international reference prices and any other factors determined by the Pricing Committee including information from any other relevant sources, the cost, insurance and freight value of the medicinal products and the applicable exchange rate*"; for manufacturers who want to register an essential medicine, a price equal or lower than the maximum retail (ceiling) price has to be proposed.<br>• Once an MRP has been approved as part of the registration or reregistration procedure, it cannot be changed without NMRA approval.[103]<br>• Given the novelty of the pricing law, the exact implementation rules are still to be published. It is unclear which countries would be used as external reference, at which ATC level (5 or 3) the therapeutic comparison is established if the comparison is made only on prices from the same manufacturer registered in the other countries, or if prices of medicines produced by different manufacturers would be allowed as reference. Currently, the exact methodology used to propose an introductory price or request a change is left to the manufacturer to decide on and calculate.<br>• To date, there is no publicly available information on whether manufacturer proposed retail prices have been refused by the Pricing Committee and, if so, on what grounds.<br>• Recent news suggests that the NMRA has issued notices of cancellation of registration for medicines where the declared maximum retail (ceiling) price has not been respected.[104]<br>• *Stakeholders involved in price setting:* Pricing Committee (nominated by the Minister) and the Consumer Affairs Authority as per Consumer Affairs Authority Act No. 9 of 2003. |

[101] Parliament of the Democratic Socialist Republic of Sri Lanka. (2015). The National Medicines Regulatory Authority Act, No. 5 of 2015. Available at: https://www.srilankalaw.lk/YearWisePdf/2015/NATIONAL_MEDICINES_REGULATORY_AUTHORITY_ACT,_No._5_OF_2015.pdf.

[102] Pricing Regulations (2019). Regulations made by the Minister of Health, Nutrition and Indigenous Medicine under section 142 Read With Section 118 of the National Medicines Regulatory Authority Act, No. 5 of 2015. Available at: https://nmra.gov.lk/images/PDF/gazzet/nmraGazzete/Pricing-Regulations--Gazette-No--2146-3.pdf.

[103] National Medicine Regulatory Authority. Guideline on registration of medicines. October 15, 2019. Available at: https://nmra.gov.lk/images/PDF/draft_guidelines/Guideline-on-registration-of-medicine.pdf.

[104] Daily Mirror. (2020). NMRA issues cancellation notices to five pharmaceutical companies. Available at: http://www.dailymirror.lk/print/front_page/Registration-and-import-licenses-NMRA-issues-cancellation-notices-to-five-pharmaceutical-companies/238-192147#.XxKCvsjRjxY.whatsapp.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Tendering Centralized procurement via state-owned company (mostly EML medicines)** | • The SPC procures through national and international tendering procedures (with quality safeguards) and sells to DOH programs and facilities at a fixed mark-up of 10%, which makes their products the most affordable in the market. It can also sell to private-sector facilities (e.g., clinics, pharmacies), but the 10% mark-up is no longer imposed.<br>• The tenders are awarded considering the following factors:[105]<br>- Price quoted<br>- Past performance<br>- Quality of samples submitted for the offered product<br>- Registration status<br>- Local manufacturers<br>• The technical evaluation committee evaluates the tender (if it costs between 50 and 100 million SL rupees) and recommends procurement. This committee comprises the MOH Medical Supply Division Deputy Director General (chair), two medical consultants, one person from the MOH Finance Department, and one person from the SPC. High-volume and high-cost tenders (more than 200 million SL rupees) will be sent to the MOH cabinet for approval. Those less than 50 million SL rupees will be evaluated by an in-house evaluation team of pharmacists.[106]<br>• Tenders are generally issued for one year. There is lack of transparency on the amount spent, the type of medicines, and awarded prices.<br>• The SPC also owns a nationwide chain of retailers (*Rajya Osu Sala*) to ensure quality assured products at affordable prices in the private sector.[107]<br>• Most of the medicines procured through the SPC are essential medicines to be delivered to public facilities via the Medical Supply Division, but some nonessential medicines are also procured for the *Rajya Osu Sala.*<br>• Public facilities have less than 10% of their allocated budget for direct procurement needs; all budgeting and procurements are dealt with centrally by the MOH Medical Supply Division and the SPC.<br>• *Stakeholders involved:* MOH Medical Supply Division; SPC |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Generic prescribing** | • Every medical practitioner, dentist, and veterinary surgeon is expected to prescribe by generic name (INN).[107]<br>• However, "*he may in addition to the generic name write a particular brand name of the medicine in the prescription. They may write only the brand name of a medicine in the prescription where the medicine prescribed is a combined medicine for which the generic name is not available*",[107] thus granting the prescriber considerable power to not follow the policy. |
| **Generic substitution** | • If the brand name of the medicines prescribed is not available or affordable to the patient, the pharmacist may dispense any other generic medicine with the consent of the patient.[107]<br>• The pharmacist is expected to inform the patient on the range of generic medicines with or without brand names available in the pharmacy and their prices, thus enabling the patient to buy the medicine of their choice.<br>• A pharmacist who fails to disclose the generic medicines with or without brand names available in the pharmacy and their prices at the time of sale commits an offense.[107] |

[105] State Pharmaceutical Corporation of Sri Lanka website: http://www.spc.lk/tenderDisplay.php.
[106] WHO SEARO. (2015). Medicines In Health Care Delivery in Sri Lanka. Situational analysis report: 16-27 March 2015. Available at: http://origin.searo.who.int/entity/medicines/sri_lanka_mar_2016.pdf.
[107] Art 56. National Medicines Regulatory Authority Act, No. 5 of 2015. Available at: https://nmra.gov.lk/images/PDF/Legislation/5e_nmdra_07.pdf.

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| | • *Stakeholders involved*: NMRA inspectors |

| | |
|---|---|
| Database of prices publicly available | The list of essential medicines for which there is a maximum retail (ceiling) price is published annually on the NMRA website: https://nmra.gov.lk/index.php?option=com_content&view=article&id=74&Itemid=184&lang=en#maximum-retail-prices-of-60-selected-medicinal-product-formulation-2019 These prices are valid in both the public and private sectors. |

# 10. TIMOR-LESTE—MEDICINES PRICING PROFILE

## 10.1 BACKGROUND INFORMATION

- Timor-Leste has a tax-based health system in which health services in the public sector are provided free at the point of use, including vital essential medicines.
- Utilization of health services and free treatment is affected by a set of behavioral, social, and economic issues, including the availability of medicines, distance to a service access point, and access to affordable and reliable transportation.[108]
- Stock-outs of essential medicines are common—in 2016, they seemed to be at a level of 30% of needed stocks.[109] The current government program aims to decrease stock-outs to less than 20% for centrally procured essential medicines and to less than 10% for locally procured medicines.[110]
- In 2014, the share of OOP spending on medicines was 37%.[111,112]
- There is no price control at the point of entry. The prices of the essential medicines made available free of charge to patients in public-sector facilities result from national- or local-level tenders.
- Non-EML medicines in public facilities or medicines procured in the private sector are paid OOP at nonregulated prices.

## 10.2 PRICING POLICIES OVERVIEW

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ✓ | | | | ✓ | | | | | | | |

| ***Demand-side interventions*** | **Treatment guidelines** | **Generic prescribing** | **(Mandatory) Generic substitution** | **Prescribing protocol** | **Prior authorization** | **Electronic prescribing monitoring tools** | **Other** |
|---|---|---|---|---|---|---|---|
| | ± | | | ± | | | |

[108] Guinness L, Paul RC, Martins JS, Asante A, Price JA, Hayen A, Jan S, Soares A, Wiseman V, Determinants of health care utilisation: the case of Timor-Leste, International Health, Volume 10, Issue 6, November 2018, Pages 412–420. Available at: https://doi.org/10.1093/inthealth/ihy044.
[109] Netfarma. PM timorense garante que stock de medicamentos no país é suficiente. 2016. Available at: https://www.netfarma.pt/pm-timorense-garante-que-stock-de-medicamentos-no-pais-e-suficiente/.
[110] Programa do VIII Governo Constitucional. Available at: http://timor-leste.gov.tl/?cat=39#prog2.
[111] WHO. Timor-Leste medical products profile. 2019. Available at: https://apps.who.int/iris/bitstream/handle/10665/328932/medicines-profile-tls-eng.pdf?sequence=1&isAllowed=y.
[112] World Health Organization. National Health Accounts, Timor-Leste. Geneva. Internal communication, April 2017.

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

### 10.3 PRICING POLICIES DETAILED

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **Free pricing (all medicines)** | • There is no requirement to register a price when requesting market authorization; if the price is supplied, it is not made public and the supplier is not bound to it. |
| **Tendering a. Central Procurement through medical stores (SAMES) (for EML medicines)** | • The **EML** is used to plan procurement, supply, and clinical use of drugs. This provides a prioritized list for medicine supply for all referral hospitals, primary care facilities, and the national wholesaler (SAMES).[113]<br>• The government has established a national wholesaler—SAMES—as a centralized procurement, wholesale, and supply system that provides EML medicines to the districts, which then transport them to health facilities. SAMES can also act as a supplier for private pharmacies, but there are no rules on which margins they are allowed to use in such cases.<br>• Methods for procurement:<br>- Public tender, required in acquisitions in excess of USD 1,000,000 where any interested national or international party may submit a proposal, provided that they meet the participation criteria indicated in the tender document.<br>- Restricted bidding for purchases between USD 500,000 and 1,000,000, where only prequalified bidders can submit proposals.<br>- Request for quotations, for acquisitions of less than USD 500,000, where three prequalified or previously contracted bidders are invited to submit proposals.<br>• Prequalification of bidders takes place yearly at the call of SAMES; international suppliers registered with UN agencies are prequalified through a simplified procedure.<br>• Award criteria: the best combination of services/cost (in practice, lowest price offered, provided the supplier is prequalified and able to meet the quality conditions). The winning price for each item is not made public, although an overall amount of the offer and the technical conditions will be published for each awarded contract.<br>• In cases of emergency, the MOH can also conduct central procurement, as can referral hospitals and laboratories.[114,115]<br>• Direct procurement, regardless of the financial value, can be considered if:<br>- There is only one supplier and no suitable alternative in the market.<br>- A product is under patent.<br>- When, having performed the procedures for public open tender or restricted bidding twice or made a request for quotations, SAMES does not receive proposals that meet the award criteria.<br>- Emergency situations (e.g., natural disasters).<br>• There are no publicly set maximum margins for storage and distribution done by SAMES.<br>• There are no rules on the starting price for bidding; there is no indication of how the tender evaluation committee is expected to decide (e.g., consensus, majority vote); the winning price for each tender is not publicly available; and there are no rules to guide the negotiations and discussions taking place in the case of direct procurement. |

[113] MOH Timor Leste. List of Essential Medicines 2010. Available at: http://moh.gov.tl/sites/default/files/SAUDE%20BOOK%20ENGLISH.pdf.
[114] Alteração Ao Decreto-Lei N.° 2/2009, De 15 De Janeiro (Regime Jurídico Especial DeAprovisionamento Do SAMES). Available at: http://www.mj.gov.tl/jornal/public/docs/2016/serie_1/SERIE_1_NO_18.pdf.
[115] Decreto-Lei N.° 2/2009 de 15 de Regime Jurídico Especial de Aprovisionamento do Serviço Autónomo de Medicamentos e Equipamentos de Saúde, E.P (SAMES). Available at: http://www.mj.gov.tl/jornal/public/docs/2009/serie_1/serie1_no2.pdf.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • *Stakeholders involved in price setting:* The Permanent Commission for the Evaluation of Proposals (CPAP) decides the bid winners. CPAP members are appointed by the Minister of Health, on the proposal of the Director General of SAMES for a period of one year; the Commission comprises three or five permanent members and three alternate members, of whom one is the President of the Commission or his/her substitute in cases of absence. At least two members of CPAP are MOH employees, and at least one member belongs to the Procurement Department of SAMES. CPAP decisions must be validated by the SAMES Executive Council before proceeding to contracting. |
| **Tendering**<br>**b. Local purchase (for EML medicines)** | • Procurement **of EML medicines** can also be done at the individual public facility level but should be limited to emergency cases or where there are stock-outs from SAMES.<br>• There is no public database of prices obtained through local purchase.<br>• Method of procurement:<br>- Request for quotation—facilities must obtain a minimum of three quotations from suppliers registered with the government prior to procurement.<br>- Direct purchase—independent of value, when there is an emergency and SAMES cannot provide the necessary medicines. |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Treatment guidelines** | • Guidelines issued by WHO for vertical programs (malaria, TB, immunizations) are recognized and implemented.<br>• There are initial guidelines on mental health and eye health. |
| **Prescribing protocols** | • The 2010 National Medicine Policy indicates that "*mechanisms should be established, including active implementation of standard treatment guidelines, in hospital therapeutic committees*" to promote rational, safe, and cost-effective use of medicines.[115]<br>- These mechanisms have not been laid out; we assume some hospitals have, through their Therapeutics Committees, issued such protocols, but they are not nationally set, nor is it clear how they are monitored and enforced. |

# 11. VIETNAM—MEDICINES PRICING PROFILE

## 11.1 BACKGROUND INFORMATION

- The current health system in Vietnam is a mixed public-private provider system. In 2009, the Vietnamese government introduced the New Health Insurance Law for universal coverage by 2020.
- The public system is organized under an administrative hierarchy, with the central level under the MOH and local levels under provincial and municipal authorities.
- Pharmaceutical retail units remain the preferred first point of access, especially in rural areas; there are 10,250 private pharmacies nationwide and 44,000 drug retailers in both the public and private sectors.[116]

[116] Phamax AG. (2015). Healthcare Market Access Vietnam. Available at: https://www.phamax.ch/wp-content/uploads/bsk-pdf-manager/02082016040344AM_7.pdf

- In theory, Vietnam practices a free pricing approach, as it aims to encourage competition to ensure affordable prices. However, since the price hikes in the early 2000s, multiple price stabilization interventions have been tried,[8] including external and internal reference pricing, tendering, cost-based pricing, and price negotiations.

- Except for some preventive products (e.g., vaccines for children under age 5), medicines are paid OOP unless the patient is covered through the National State Insurance or private health insurance.

- The pharmaceutical market in Vietnam is mainly driven by (branded) generics: in 2013, 71% of the pharmaceutical expenditure was on generics, with imported, foreign ones being favored over locally manufactured products.[116] Across the market, from providers to pharmacies and patients, there is an overall perception of "expensive is good",[116] which impairs ongoing efforts to curb medicine spending.

- Price interventions target mainly the imported and wholesaler/distributor level across all types of medicines (generics or innovative); only since 2017 have regressive maximum retail margins been imposed for public-sector pharmacies. The impact of these policies remains unclear, due in part to the absence of a strong regulation enforcement capacity; a shortage of pharmaceutical inspectorate personnel; and a weak, inconsistent, and unclear sanction system.[116]

    - All medicines, locally manufactured or imported, have to declare a maximum price as part of the registration procedure.[117] Any price increases after registration require a new price declaration (and approval) from the DAV. The type of pricing intervention applied at registration depends on whether the active ingredient has been already registered in the country. Should the medicine be included in the "National Listing", the price will undergo further tendering or negotiation.
    - There are three National Lists: medicines centrally procured through tendering (MOH programs and projects); medicines for which there will be national price negotiations; and medicines locally procured through tendering.
    - The presence of a product in the NEML does not warrant its inclusion in one of the first two National Lists; however, should provinces and city-level health authorities engage in local tendering, they can only do so for NEML medicines.[116]

## 11.2 PRICING POLICIES OVERVIEW

| *Supply-side interventions* | Free pricing | ERP | Generic caps | Cost-based price | Tenders | Price negotiations | Supply chain margins control | Clawback on sales | IRP | VBP (HTA) | MEA | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ✓ | | ✓ | ✓ | ✓ | ✓ | | ✓ | | | |
| ***Demand-side interventions*** | **Treatment guidelines** | | **Generic prescribing** | | **(Mandatory) Generic substitution** | | **Prescribing protocol** | **Prior authorization** | | **Electronic prescribing monitoring tools** | | **Other** |
| | ✓ | | ± | | ± | | | | | | | |

ERP – external reference pricing; IRP – internal reference pricing or usage of Therapeutic Class comparison; VBP – value-based pricing (usage of HTA approaches); MEA – managed entry agreement

## 11.3 PRICING POLICIES DETAILED

[117] Hien Thi Thu Vu and Mai Thi Le, Tilleke and Gibbins. (2020). Pharmalegal Handbook: Vietnam. Available at: https://pharmaboardroom.com/wp-content/uploads/2020/03/PLH_VIETNAM_Final-new-design-pdf.io_.pdf

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| **External reference pricing (for all new medicines/INN not previously registered in Vietnam)** | • Pharmaceutical manufacturers or importers of new medicines or generics that are not present on the market must declare their wholesaler medicine prices to the DAV.[117]<br>• The declared prices should not be higher than the average wholesale price of the same drug in ASEAN countries where such drugs are marketed. Informally, the DAV nominates Thailand, Malaysia, Indonesia, the Philippines, and Cambodia as reference countries.[8]<br>• The Interdisciplinary Council on Drug Prices advises the Minister of Health on the reasonableness of drug prices declared in the following cases:<br>- Medicines with different API concentrations than the ones present in the market<br>- Medicines with different administration forms than the ones already present in the market and that declare a price higher than the highest approved price in the past three years for the medicines with the same API and concentration<br>- New medicines<br>- Medicines included in the National Listing (see centralized procurement and price negotiations interventions below)[118]<br>• Any change in the declared price must be redeclared to the DAV.<br>• Distributors and retailers (if retail price is declared) must not sell drugs at prices higher than the declared prices.<br>• The list of declared and approved prices is updated annually and can be found online.[119] A call for price revision/resubmission was announced in August 2020.<br>• The list of medicines for which the declared price has not been approved is also published annually.<br>• It is not clear what database or prices are being referenced from other countries (e.g., wholesaler, retail, indexes).<br>• The current text of Governmental Decree No. 54/2017 / ND seems to allow higher prices should the Interdisciplinary Council agree, but there are no clear guidelines on how the Council reaches its decision.<br>• *Stakeholders involved in price setting:* Drug Price Management Department; DAV; and Interdisciplinary Council on Drug Prices comprising representatives from the MOH, the Ministry of Finance and Vietnam Social Insurance, and other relevant agencies and units advising the Minister of Health |
| **Internal reference pricing (for imported generics)** | • Generic manufacturers or importers for which a similar medicine (same API/concentration/form) is already registered on the market must also declare their medicine prices to the DAV. As part of the marketing authorization process, the importer/manufacturer must declare the estimated wholesale/distributor price and (optionally) the estimated retail price for the drug before the first lot enters Vietnam.[116]<br>• Prices declared are assessed for reasonableness and approved if:<br>- The price declared is not higher than the previous declared price for the same or a different trade name from the same manufacturer.<br>- The price declared is not higher than the highest declared price in the past three years for the same API/concentration/form, taking into account the inflation rate declared by the General Statistics Office.<br>• Any change in the declared price must be redeclared to the DAV.<br>• Distributors and retailers (if retail price is declared) must not sell drugs at prices higher than the declared prices. |

[118] Governmental Decree No. 54/2017 / ND-CP. Decree Detailing a Number of Articles and Measures for Implementation of Pharmaceutical Law. Hanoi, 8 May 2017. Available at: https://thuvienphapluat.vn/van-ban/the-thao-y-te/Nghi-dinh-54-2017-ND-CP-huong-dan-Luat-duoc-321256.aspx.s

[119] Announcements of the Drug Price Management Department. Available at: https://dav.gov.vn/quan-ly-gia-cn11.html.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • The list of declared and approved prices is updated annually and can be found online. A call for price revision/resubmission was announced in August 2020.[119]<br>• The list of medicines for which the declared price has not been approved is also published annually.<br>• *Stakeholders involved in internal price setting*: Drug Price Management Department, DAV |
| **Cost-based pricing (for local generics):** | • For local manufacturers, the wholesaler price must also be registered with the DAV.<br>• To establish the ex-factory price, the following formula applies:<br>- Direct costs of raw materials, fuels, tools, tools, and energy<br>- (+) Direct labor costs<br>- (+) Other discounted costs<br>- (+) Direct loss of machinery and equipment<br>- (+) Overhead<br>- (+) Financial costs (if any)<br>- (+) Selling expenses<br>- (+) Administrative costs<br>- (-) Costs allocation for byproducts (if any)<br>• The wholesaler maximal prices registered with the DAV will reflect the ex-factory prices calculated as per the formula above, to which the maximal wholesaler margins are being applied (see details in control of supply margins). The formula relies heavily on the accuracy of data submitted by the manufacturer, with limited/no capacity to check its veracity. The formula does not seem to incorporate research and development expenses or shift in types of medicines and subsequent change/update in equipment (e.g., shifting from chemical synthesis to biosimilar production).<br>• *Stakeholders involved*: Drug Price Management Department, DAV |
| **Tendering MOH central tenders (for the National List)** | • As a result of the revision of the Pharmacy Law in 2016, medicines included in National List will undergo price control via tendering or negotiation.<br>• Circular no 15/2020/TT-BYT[120] defines three types of lists:<br>- The list of medicines centrally procured through bidding<br>- The list of medicines locally procured through bidding<br>- The list of medicines for which there will be price negotiations<br>• Centrally led tenders are required for the following products:<br>- Medicines used for national programs, projects, and MOH units<br>- Drugs that satisfy all of the following criteria:<br>- Medicines registered in Vietnam that are not on the list of medicines for which there will be price negotiations<br>- Medicines requiring intense resources in terms of either value or quantity used in health facilities across the country<br>- Medicines that have at least three certificates of free sale from at least three manufacturers meeting the technical criteria<br>• Method of procurement:<br>- Quotation from at least three marketing authorization holders pertaining to at least three manufacturers<br>- Award criteria: value for money (lowest price)<br>- Starting price for tendering: DAV declared price<br>- Winning prices are submitted to the Interdisciplinary Council for approval; tenders are valid for a maximum of three years |

[120] Circular no 15/2020/TT-BYT. Circular issuing the list of drugs tendered centrally and locally, list of drugs to which price negotiation applies. Hanoi, August 10, 2020. Available at: https://luatminhkhue.vn/thuoc-dau-thau--thuoc-dau-thau-tap-trung--thuoc-dam-phan-gia.aspx.

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • *Stakeholders involved*: The tenders are managed centrally by the MOH Procurement Division with support from the DAV. There are no clearly laid out criteria for the selection of Tender Committee members. |
| **Tendering**<br>**Local purchase at provincial and city levels**<br>**(for EML medicines not procured centrally)** | • Provincial- and city-led tenders are considered if all of the following criteria are met:<br>- Medicines are registered with the DAV and are not included in the list of medicines centrally procured or the list of medicines for which there are price negotiations<br>- Medicines are included in the MOH EML<br>- Medicines have three providers for the given administration form or three manufacturers of the same API/form/concentration<br>- Medicines have a large utilization rate in terms of value or quantity in health facilities of the province or city<br>- Medicines are used by multiple local facilities and at multiple specialization levels<br>• Procurement is done at the individual province and city levels with funds from the province, health insurance, or other rotating funds from facilities.<br>• Prices are valid for one year; prices are declared to the MOH but there is no public database of prices obtained through local purchase.<br>• Method of procurement:<br>- Quotation: facilities must obtain a minimum of three quotations from suppliers able to provide the same API/concentration but different forms or quotations from three manufacturers of the same API/form/concentration.<br>• *Stakeholders involved*: The tenders are managed by the local Tender Selection Committee. There are no clearly laid out criteria for the selection of Tender Committee members. |
| **Price negotiations (for the National List)** | • Medicines included on the list of medicines subject to price negotiation must satisfy one of the following criteria:<br>- Innovator/originator medicines registered with the MOH and DAV<br>- Rare (low-stock) medicines as defined by the MOH<br>- Medicines that have only one or two manufacturers registered in Vietnam<br>• For price negotiations, the manufacturer/representative should prepare a dossier consisting of:<br>- The ex-factory price, the import price, and the selling price for medical facilities in the manufacturing country and in the ASEAN countries where the manufacturer has such a contract<br>- The ex-factory price, the import price, and the selling price for medical facilities in Vietnam<br>- Evidence on the requested treatment indication and assessment of clinical efficacy resulting from clinical trials or real-world evidence<br>- Report comparing the clinical efficacy of the new medicines versus current standard of care (if any)<br>- Pharmacoeconomics data: cost-effectiveness, cost-benefit, and cost-utility provided by the contractor (if any)<br>• The National Drug Procurement Centre prepares a negotiation plan summarizing the information on the pharmacological effects, the proposed price, the price of drugs with the same API/concentration/form but different manufacturer (if any), and the list of drugs and their prices of the same pharmacological class that can be substituted (if any). The technical evaluations are not made public, although the initial documents submitted are. |

| Supply-side interventions | |
|---|---|
| **Type of intervention** | **Details and analysis** |
| | • Prices negotiated are valid for a maximum of 36 months.[121]<br>• *Stakeholders involved in negotiations*: The Drug Price Negotiation Council is established by the Minister of Health, who also specifies the functions, tasks, powers, and operation mechanism of the Drug Price Negotiation Council. The Council is chaired by the Minister of Health, with two vice chairs: the president of Vietnam Social Insurance and the director of the National Drug Procurement Centre. Other council members are representatives from the MOH, the Ministry of Planning and Investment, the Ministry of Finance, Vietnam Social Insurance, and independent experts in the evaluated disease areas. |
| **Control of supply margins (all medicines available in** public **pharmacies)** | • Annually, the DAV publishes and updates the list of approved declared prices comprising wholesale and some retail prices.<br>• Declared prices act as price ceilings for wholesalers and retailers.<br>• For public pharmacies (within public health facilities), the following retail margins apply on top of the purchase price (as resulting from invoices/tenders):<br>- For medicines with a purchase price calculated on the smallest packaging unit that is less than or equal to 1,000 VND, the maximum retail margin is 15%.<br>- For medicines with a purchase price calculated on the smallest pack from more than 1,000 VND to 5,000 VND, the maximum retail margin is 10%.<br>- For medicines with a purchase price calculated on the smallest pack from more than 5,000 VND to 100,000 VND, the maximum retail margin is 7%.<br>- For medicines with a purchase price calculated on the smallest package from more than 100,000 VND to 1,000,000 VND, the maximum retail margin is 5%.<br>- For medicines with a purchase price calculated on the smallest pack of more than 1,000,000 VND, the maximum retail margin is 2%.[122] |

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| **Generic prescribing** | • According to Circular no 52/2017,[123] single and generic prescribing is recommended, but it should not overcome the goal of a safe, reasonable, and effective treatment.<br>• Perception of higher quality of branded medicines, whether originator or branded generics, means there is little enforcement of the policy.<br>• Results from a qualitative study showed that 40–60% of the price of off-patent medicines in Vietnam was typically spent to induce prescribers to use the medicines or to procure them (within hospital procurements).[124] |
| **Generic substitution** | • The pharmacist can exchange the prescribed medicine (whether generic or trade name) as long as it is the same API/concentration/form. |

[121] CIRCULAR No 15/2019 / TT-BYT. Regulations on medicine tendering in public health institutions. Hanoi, July 11, 2019. Available at: https://thuvienphapluat.vn/van-ban/dau-tu/Thong-tu-15-2019-TT-BYT-quy-dinh-viec-dau-thau-thuoc-tai-cac-co-so-y-te-cong-lap-351102.aspx.

[122] The smallest pack is considered as follows: a) If the dosage form is tablet, the smallest pack is a pill; b) If the dosage form is liquid, the smallest package unit is a pre-filled tube, bottle, bag, or syringe.; c) If the dosage form is powder for injection, the smallest package unit is a pre-packed syringe, bottle, or bag; d) If the dosage form is in the form of powder or cereal for drinking, the smallest pack is a package, bottle, jar, or bag; e) If the dosage form is cream, oil, or gel for topical use, the smallest package unit is a tube or jar; f) If the dosage form is a paste, the smallest package unit is a patch; g) If the dosage form is an aerosol, the smallest package unit is a spray bottle or medicine bottle for an aerosol machine; h) If the dosage form is a kit, the smallest packaging unit is a kit.

[123] Circular no 52/2017/TT-BYT. Regulations on Drug Prescription Form for Medicines, Biological Drugs in Outpatient Treatment. Available at: https://thuvienphapluat.vn/van-ban/the-thao-y-te/Thong-tu-52-2017-TT-BYT-don-thuoc-va-ke-don-thuoc-hoa-duoc-sinh-pham-trong-dieu-tri-ngoai-tru-372634.aspx.

[124] Nguyen TA, Knight R, Mant A. et al. (2018). Corruption practices in drug prescribing in Vietnam – an analysis based on qualitative interviews. BMC Health Serv Res 18, 587. Available at: https://doi.org/10.1186/s12913-018-3384-3.

| Demand-side interventions | |
|---|---|
| **Policy** | **Details and analysis** |
| | • The patient should sign that they have been informed and agreed prior to procuring.<br>• The perception of higher price leading to higher quality does mean pharmacists may recommend switching to a more expensive medicine; the imposition of regressive margins will likely help curb this practice. |
| **Treatment guidelines** | • Treatment guidelines have been issued by the MOH on infectious diseases, cancer, and diabetes, and a new clinical pharmacy practice guideline was issued in October 2019 that details treatment pathways and recommends specific medicines in given lines of treatment.[125,126]<br><br>***Gaps in policy***: To ensure maximization of resources, the guidelines should focus more on mainly using medicines from the National Lists (tendered or negotiated). |

| | |
|---|---|
| Databases of prices publicly available | List of new wholesaler prices approved for local manufacturers (May 2019):*<br>https://dav.gov.vn/tong-hop-ke-khai-thuoc-san-xuat-trong-nuoc-theo-nghi-dinh-so-155_nd_cp-cap-nhat-den-ngay-30042019-n2478.html<br>List of reconfirmed wholesaler prices approved for local manufacturers (April 2019)*<br>https://dav.gov.vn/tong-hop-ke-khai-lai-thuoc-san-xuat-trong-nuoc-theo-nghi-dinh-so-155_nd_cp-cap-nhat-den-ngay-30042019-n2476.html<br>List of new prices wholesaler approved for importers/foreign manufactures (April 2019):*<br>https://dav.gov.vn/tong-hop-ke-khai-thuoc-nhap-khau-theo-nghi-dinh-so-155_nd_cp-cap-nhat-den-ngay-30042019-n2477.html<br>List of reconfirmed wholesaler prices approved for importers/foreign manufactures (April 2019):*<br>https://dav.gov.vn/tong-hop-ke-khai-lai-thuoc-nhap-khau-theo-nghi-dinh-so-155_nd_cp-cap-nhat-den-ngay-30042019-n2475.html<br>*A call for the annual review was issued on August 21, 2020; once finalized, the new lists will likely be announced and published here: https://dav.gov.vn/quan-ly-gia-cn11.html |

[125] MOH. The Ministry of Health publishes the first National Guidelines for Clinical Pharmacy Practice. (2019). Available at: https://moh.gov.vn/chuong-trinh-muc-tieu-quoc-gia/-/asset_publisher/7ng11fEWgASC/content/bo-y-te-cong-bo-tai-lieu-huong-dan-au-tien-cap-quoc-gia-ve-thuc-hanh-duoc-lam-sang.

[126] MOH. National Guidelines for Clinical Pharmacy Practice. (2019). Available at: https://kcb.vn/wp-content/uploads/2019/11/H%C6%B0%E1%BB%9Bng-d%E1%BA%ABn-th%E1%BB%B1c-h%C3%A0nh-d%C6%B0%E1%BB%A3c-l%C3%A2m-s%C3%A0ng-cho-D%C6%B0%E1%BB%A3c-s%E1%BB%B9-trong-m%E1%BB%99t-s%E1%BB%91-b%E1%BB%87nh-kh%C3%B4ng-l%C3%A2y-nhi%E1%BB%85m.pdf.