Medicines' price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research

Final Report
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*Final Report*
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</tbody>
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Executive summary

The objective of this report is two-fold: (1) to summarize the current evidence on the impact of key price regulatory interventions in the WHO South-East Asia (SEA) Region on access to essential medicines, and (2) identify gaps in knowledge and/or policy implementation practices in the Region. The primary audience of this report are the 11 Member States of the World Health Organization’s South-East Asian Region. These include policy-makers, technical advisers, insurance administrators, industry associations and individual manufacturers and civil society groups.

This report builds on two previously published reports on access to essential medicines in the SEA Region that provide country profiles on key structural and performance metrics of the pharmaceutical sector. Additionally, we used a narrative and analytical literature review, semi-structured interviews with experts and a short expert survey which will be explained in the following sections. Ten experts from nine countries responded to the short survey.

The findings highlight that some pricing policies are very commonly used in all countries, such as the promotion of generic medicines, tendering and free essential medicines in the public sector. All of them are policies that are recommended by the WHO pricing guideline. At the same time is it noteworthy that some pricing policies are only used in a few countries, such as value-based pricing and price negotiation or special price agreements. These particular policies require technical capacity and continuous investment.

Our report shows that there is evidence of unintended and harmful consequences of several SEA Region pricing policies such as cost-plus policies, several mark-up policies, and some external reference pricing policies. Countries are encouraged to review these policies and adjust them to avoid further negative consequences in terms of the health or economic well-being of their population. Some evidence also shows that there was an absence of the intended policy effect. This could be due to a flawed evaluation design or that the policies indeed did not make any difference. Countries are encouraged to invest in studying the effects of their pricing policies. One critical input in such analysis of pricing policies is a pricing survey in both public and private sectors as well as in different levels of care (e.g. primary, secondary and tertiary).

The newly developed app “WHO MedMon” can support countries in their regular pricing surveys. Pricing surveys should be complemented with a variety of other pricing studies such as the evaluation of procurement performance, price negotiation, as well as linking pricing studies with medicines quality assessments and medicines utilization analysis.

Our work indicates that the large differences in country characteristics of Member States of the WHO SEA Region – the region has some of the most populous as well as smallest countries in the world – makes it challenging to consolidate support for pricing policies within the Region. In addition, countries are at very different stages in the roll-out of universal health coverage (UHC), which means that the need for pricing policies will vary depending on the maturity of the pharmaceutical benefit schemes.

Five of the 11 WHO SEA Region countries are “least developed countries” that are currently exempt from World Trade Organization (WTO) medicines patent regulations. This allows at least one of them, Bangladesh, to continue to produce generic versions of...
otherwise patented medicines. Nonetheless, small country markets present a particular policy challenge. One third of all countries in the WHO SEA Region are small pharmaceutical markets where traditional pricing policies such as price negotiation are less effective due to their small purchase volumes. Other regions, such as the WHO European Region (WHO EURO), could provide some useful lessons going forward as European countries with small markets have documented the results of their pricing policies, including some positive outcomes.
1. Background

1.1 Purpose of the report

The purpose of the report is two-fold: a) to summarize the current evidence on the impact of key price regulatory interventions in the WHO South-East Asia Region on access to essential medicines; and b) identify gaps in knowledge and/or policy implementation practices in the Region to be discussed in a regional expert consultation.

The WHO SEA Region includes 11 countries of very different levels of population, size and income (Table 1). On the one hand, three of its countries – India, Indonesia and Bangladesh – are some of the most populous countries in the world. On the other hand, three other Member States – Timor-Leste, Bhutan and Maldives – are some of the world’s smallest countries in terms of population. The size of the rest of the countries in the Region varies between 20–70 million inhabitants. The countries in the Region also differ with respect to their per capita gross domestic product (GDP): Nepal is a WHO SEA Region country that recently moved from low-income to the lower-middle income country classification of the World Bank; and Maldives and Thailand are two countries with the highest GDP per capita in the Region (US$ 10 790 and US$ 7808, respectively).iii

The GDP per capita has a strong influence on the available resources for health, including expenditure on medicines. Five SEA Region countries classify as “least developed”: Bangladesh, Bhutan, Myanmar, Nepal and Timor-Leste. It is noteworthy that these five countries are granted an extended period of time to transition to protect intellectual property under the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).iv As a result, these five countries within the Region can still import lower-cost, off-patent generic medicines as well as import patented medicines via licenses.

Table 1. Country characteristics

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of inhabitants (in millions) in 2019</th>
<th>GDP per capita (US$) in 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>1 366.42</td>
<td>2 099.6</td>
</tr>
<tr>
<td>Indonesia</td>
<td>270.63</td>
<td>4 135.60</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>163.4</td>
<td>1 855.70</td>
</tr>
<tr>
<td>Thailand</td>
<td>69.63</td>
<td>7 808.20</td>
</tr>
<tr>
<td>Myanmar</td>
<td>54.05</td>
<td>1 407.80</td>
</tr>
<tr>
<td>Nepal</td>
<td>28.61</td>
<td>1 071.10</td>
</tr>
<tr>
<td>Democratic People’s Republic of Korea</td>
<td>25.67</td>
<td>-</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>21.81</td>
<td>3 853.10</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>1.29</td>
<td>1 294.20</td>
</tr>
</tbody>
</table>
The countries in the WHO SEA Region also vary widely in the size of their domestic pharmaceutical industry and their dependency on pharmaceutical imports. While some countries have a small local pharmaceutical industry, Thailand and Bangladesh have a sizeable local pharmaceutical industry with about US$ 500–600 million, value-added. Indonesia is a country where the pharmaceutical export value is about 75% of the import value. India is the outlier with the largest pharmaceutical export value of US$ 11 billion, which is 760% times its import value. Among other factors, decision-making regarding pharmaceutical policies including pricing policies are influenced by the size of the pharmaceutical market, including imports and exports.

<table>
<thead>
<tr>
<th>Country</th>
<th>Export (USD million)</th>
<th>Import (USD million)</th>
<th>% export out of import</th>
<th>Gross value added (USD million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>11,333.18</td>
<td>1,487.41</td>
<td>761.94</td>
<td>17,766.44</td>
</tr>
<tr>
<td>Indonesia</td>
<td>508.89</td>
<td>667.09</td>
<td>76.29</td>
<td>11,419.11</td>
</tr>
<tr>
<td>Thailand</td>
<td>316.26</td>
<td>1,788.64</td>
<td>17.68</td>
<td>544.33</td>
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<tr>
<td>Bangladesh</td>
<td>111.06</td>
<td>219.28</td>
<td>50.65</td>
<td>599.66</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>5.1</td>
<td>316.7</td>
<td>1.61</td>
<td>102.21</td>
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<tr>
<td>Bhutan</td>
<td>0</td>
<td>13.61</td>
<td>0.00</td>
<td>3.5</td>
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<tr>
<td>Maldives</td>
<td>0</td>
<td>Not available</td>
<td>0.00</td>
<td>2.74</td>
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<td>Myanmar</td>
<td>0</td>
<td>392.43</td>
<td>0.00</td>
<td>220.81</td>
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<tr>
<td>Nepal</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
<td>17.97</td>
</tr>
<tr>
<td>Timor Leste</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
<td>0.15</td>
</tr>
</tbody>
</table>


The large differences between these countries makes assessments of these countries in terms of their pricing policies in relation to the country context challenging.

1.2 Target audience

The primary audience of this report are the 11 Member States of the World Health Organization’s South-east Asia Region. These include policy-makers, technical advisers, insurance administrators, industry associations and individual manufacturers and civil society groups.

1.3 Terminology

There are different mechanisms to regulate prices. In general, such policies can target different prices along the distribution chain: manufacturers’ prices, wholesale prices and retail prices or reimbursement prices.

For the purpose of this report we have used the classification used by the WHO Pricing Guidelines that differentiate between the following 10 mechanisms: External reference pricing, internal reference pricing, value-based pricing, mark-up regulation across the pharmaceutical supply and distribution chain, promoting price transparency, tendering and negotiation, promoting the use of quality-assured generic and biosimilar medicines,
pooled procurement, cost-plus pricing for setting the price of pharmaceutical products, and tax exemptions or tax reductions for pharmaceutical products.

2. **Method**

This project made use of existing resources. One key reference are the two reports on access to essential medicines in the SEA Region that provide country profiles on key structural and performance metrics of the pharmaceutical sector. Apart from this resource, we used a narrative and analytical literature review, semi-structured interviews with experts and a short expert survey, which will be explained in the following sections.

2.1 **Narrative and analytical literature reviews**

**Eligibility criteria:** We used all peer-reviewed articles, gray literature and published dissertations from 2000 to the present that describe, characterize and/or evaluate the impact of pharmaceutical policies in the 11 SEA Region countries (names to be included as footnotes) on dimensions of access to medicines. These documents, in all languages, are criteria for eligibility for the review.

**Information sources:** Intended Information sources that were searched between 2000 and the present included PubMed, Embase, EconLit, ProQuest (for dissertations and theses), CINAHL (Cumulative Index to Nursing & Allied Health Literature), Science Direct, Cochrane reviews, WHO library database (WHOLIS), the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (WHOCC) and Web of Science, WHO/Health Action International (HAI) reports, and the Open Grey database, in addition to using the search engine Google Scholar (“snowball” searching using the “cited by” feature).

**Search strategy:** The search strategy that has been used is described in detail in Annex 1.

**Study records:** All citations were stored in RefWorks® and two of the authors (Veronika Wirtz and Warren Kaplan) served as reviewers through each phase of the review (i.e. screening, eligibility and inclusion in the analysis). We created a data extraction form. The method of extracting data was done independently by the team and then reviewed by the authors together.

**Data items:** We were interested in the following descriptive variables: the presence or absence of a named pricing policy, government agency responsible for the policy, implications of the policy, information on actual implementation of the policy, source of funding for the review, time period of policy implementation, barriers and enablers to implementation, and unintended consequences of the pricing policy.

We were interested in the following evidentiary variables: evidence of impact in the public and/or private sector with regard to medicine (i) availability, (ii) affordability, (iii) accessibility (geographical availability), (iv) acceptability (rational selection and use), and (v) medical product quality; evidence of impact on public health generally, and changes in these variables over time; impact evaluation methodology (if present); and other pricing policies in existence at the same time.
2.2 Short online survey asking experts to report on key pricing interventions in countries

We conducted a short online survey asking experts to confirm the presence or absence of key medicines pricing policies in place (e.g. external reference pricing, internal reference pricing, value-based pricing, tendering and negotiations, cost-plus policy) (see draft survey Annex 2). The survey was intended to not take more than 20 minutes to fill out. The survey asked country experts to add the URL of key policy documents in the public domain. It also asked experts about any publication on pricing policy evaluations in their country.

We designed the survey in a user-friendly software that allows electronic responses and quick summary overview of the results. The WHO SEA Region supported this work in sending out the survey to their country offices to signal strong endorsement of the survey and its high importance.

2.3 Semi-structured interviews

We interviewed key informants that represent a range of different entities in the pharmaceutical management “ecosystem” such as ministers of health and/or trade, persons involved in procurement, distribution/logistics and use, and NGOs, preferably at both senior and junior levels (see Annex 3, draft interview guide). The recommended list of experts was drawn from a list of participants of two past conferences on medicines prices in the WHO SEA Region over the two years and the survey respondents.

There was very limited information in the literature and no key informant available for the interview with the Democratic People’s Republic (DPR) of Korea.

The interview guide was based on the analytical framework of the updated WHO guidelines on country pharmaceutical pricing policies, 2020.

We asked questions related to the following:

- how many different pharmaceutical pricing policies were/are at play in the country;
- unintended effects on the private and/or public sectors;
- what things would be needed to make the policy more impactful;
- legal and/or economic and/or political implications of pricing policies;
- barriers to implementing and enablers to implementation; and
- presence or absence of current policy evaluations by public/private sector entities.

The interview guide can be found in Annex 3. The responses were analyzed by topics and compared and contrasted with the online survey. If responses contradicted the information in the survey, we consulted the literature and followed up with the interviewees to clarify the reason for any discrepancy.

2.4 Analysis of health and medicines expenditure

Since the country’s health and medicines expenditure are important factors that influence decisions on pharmaceutical pricing reforms, we did an analysis of current health and medicines expenditure for the WHO SEA Region. The data for this analysis was extracted from the World Bank DataBank, a peer-review publication that recently analyzed medicines pricing in the Region, as well as a report published by the World Bank and the World Health Organization on the progress of UHC.
2.5 Analysis of consumer medicines prices

Medicines’ pricing policies aim to promote affordable medicines prices for governments and consumers. Hence, one of the most important outcomes to measure to assess the performance of medicines pricing policies are the prices of medicines that consumer pay. Health Action International along with the World Health Organization has developed a methodology to measure consumer prices at public and private health facilities. The standard methodology allows for comparison of medicines prices across countries. Our literature, mentioned above, identifies 14 such surveys conducted in the Region and published in peer-review journals. We have selected the most recent ones and did a comparative analysis of medicines prices in the WHO SEA Region.

3. Results

3.1 Financing of medicines and universal health coverage

Pricing policies have the goal of making medicines more affordable and hence, promote medicine access as an essential element of universal health coverage. Hence, our diagnostic journey in the WHO SEA Region starts with an analysis of the health and medicines financing by WHO SEA Region countries and the extent to which the countries finance medicines via prepaid financing mechanisms (e.g. taxes, insurances) versus out of pocket. As described above in the Methods section, data on health financing is based on the most recently available information from the World Bank and data on medicines expenditure is based on the WHO SEA Region country reports and a peer-review publication.

The majority of countries in the WHO SEA Region are lower-middle-income countries spending between US$ 36 and US$ 159 per capita on health in 2017 (Fig. 1). Upper-middle-income countries spent US$ 115 (Indonesia), US$ 247 (Thailand), US$ 1007 (Maldives) per capita on health. As in other geographical regions, the higher the GDP per capita, the higher is spending on health per capita (Fig. 2).
Overall, with increasing per capita health expenditure, the proportion of total health expenditure of SEA Region countries on medicines decreases (Fig.3 and 4). The global average is that one of every four dollars (25%) spent on health is on medicines. Indonesia and Sri Lanka are within this average. A somewhat higher-than-the global average
percentage spending on medicines is found in Myanmar and Nepal. A significantly higher proportion of total health expenditure is spent on medicines in Bangladesh and India, both countries with a large domestic pharmaceutical industry.

Timor-Leste and Bhutan stand out as countries with a very low spending percentage on medicines out of their total health expenditure. Excluded from Fig. 4 are two outliers: Thailand, which spent about 55% of its US$ 247 per capita health expenditure on medicines, and Maldives, which spent 9.7% of a total of US$ 1007 per capita health expenditure on medicines, which is about the same percentage as Bhutan but 10 times the per capita total health expenditure of that country.

**Fig. 3.** Pharmaceutical expenditure as percentage of total health expenditure in relation to per capita health expenditure (US$) of WHO South-East Asia Region countries

Health expenditure per capita (US$)

The percentage of total health expenditure that is out-of-pocket is a sensitive indicator to measure the progress countries have made towards universal health coverage where health care is predominantly financed by public funding (either tax or mandatory insurance) as distinguished from out-of-pocket expenditure. Fig. 5 shows that in general, almost all SEA Region countries’ spending on health per capita is below US$ 200 per capita with the exception of Thailand (US$ 247) and Maldives (US$ 1007).

When excluding Maldives and expanding the rest of the graph (Fig. 6), there are five SEA Region countries with high proportion of out-of-pocket expenditure to health expenditure: Myanmar, Bangladesh, India and Nepal (Fig. 6). These countries have greater than 50% of total health expenditure being out of pocket and also have low health expenditure per capita (<US$ 70). Two countries, Indonesia and Sri Lanka, have a smaller percentage of out-of-pocket expenditure out of a total health expenditure of between 20%–50%. Three countries – Thailand, Timor-Leste and Bhutan – have a low percentage (<20%) of out-of-pocket expenditure in relation to total health expenditure. The overall trend of the relationship is reverse that of GDP per capita: the lower the total health expenditure per capita in a country in the Region, the higher the out-of-pocket health expenditure as a percentage of the total health expenditure. Outliers in this regard are Timor-Leste and Bhutan with health expenditure per capita of US$ 75–100 and a low percentage of out-of-pocket expenditure.
As one may expect, the relationship between the share of out-of-pocket spending on medicines out of total pharmaceutical expenditure in relation to the per capita health expenditure (Fig. 3) is very similar to that of the percentage of out-of-pocket expenditure with total health expenditure (Fig. 5). There are three countries in the Region with a high percentage of out-of-pocket spending on medicines as a function of health expenditure: India, Indonesia and Myanmar. Four countries – Nepal, Sri Lanka, Timor-Leste and Bhutan – have a medium-range percentage of between 30–55% for out-of-pocket expenditure on medicines vis-a-vis total health expenditure. Two countries, Thailand and Maldives, have a
low percentage (<20%) of out-of-pocket medicine spending out of total pharmaceutical expenditure. We note that with higher per capita health expenditure the percentage of pharmaceuticals financed out of pocket decreases. However, there are some countries that even with relatively low health expenditure (Nepal, Bhutan and Timor-Leste) have achieved lower out-of-pocket expenditure on medicines compared with other countries in the region (Myanmar, India and Indonesia).

Fig. 7. Percentage of out-of-pocket spending on medicines out of total pharmaceutical expenditure in relation to health expenditure per capita (US$)


Generally, the lower the percentage public expenditure out of total expenditure on medicines, the higher is the incidence of catastrophic expenditure out of total consumption or income (Fig. 8). In 2014 one out of seven or fewer dollars spent on medicines was via public funding in Myanmar, India and Nepal (see Y axis: Fig. 1, 5) and more than 10% of households in these three countries spent over 10% of their household income on health including medicines (see X axis: Fig. 8).

In contrast, in Thailand, Bhutan and Timor-Leste, more than 60% of expenditure on medicines is from public sources. These three countries have less than 3% of households who spent over 10% of their income on health. Outliers are the Maldives where one in five households incur catastrophic expenditure on health. Indonesia with a low proportion of public expenditure on pharmaceuticals has only 1.7% of households incurring a catastrophic expenditure on health annually.
In summary, countries in the WHO SEA Region differ largely in the amounts of health and medicines expenditure per capita. This means countries with a very low per capita spending on medicines will struggle to provide an essential basket of medicines required to satisfy the health needs of the population. Member States of the WHO SEA Region also vary largely in the proportion of public financing of health and medicines and the degree to which their public investment is translating into financial protection. In particular, countries with comparatively low per capita expenditure on medicines combined with very high out-of-pocket expenditure on medicines and catastrophic expenditure such as over 10% of their household expenditure on medicines will need to review their current financing and pricing policies to accelerate their progress towards achieving universal health coverage.

The following section will focus on the pricing policies that countries in the WHO South-East Asia Region have implemented, and its intended and unintended consequences.

### 3.2 Medicine pricing policies in the WHO South-East Asia Region

As seen from the analysis above, some countries in the WHO SEA Region rely predominantly on households to finance medicines (Bangladesh, India, Myanmar and Nepal) compared with countries where medicines are predominantly financed by the government (Bhutan, Thailand, and Timor-Leste). How medicines are financed — either predominately via governments or households — has important implications on the development, implementation and enforcement of pricing policies.

When medicines are predominantly financed by households ensuring affordability of medicines in the retail sector is important as this sector is the main avenue for the purchase of medicines by the population. When medicines are predominantly financed by governments, ensuring their affordability through selection of medicines for reimbursement, government procurement and price negotiation on behalf of the government is especially
relevant as provision of medicines through the government is the main route by which the population accesses medicines.

Table 1 presents the main pricing policies under consideration by countries of the WHO SEA Region. Before describing the policies that countries have developed and implemented in the WHO SEA Region it is important to keep in mind that the selection of these pricing policies shown in Table 1 was in accordance with the WHO Pricing Guideline published in September 2020. The guideline identifies 10 pricing policies commonly considered in countries: cost-plus pricing, tax exemption or tax reduction, internal reference pricing, external reference pricing, mark-up regulations, promoting the use of quality-assured generic and biosimilar medicines, tendering and price negotiation, pooled procurement, value-based pricing and promoting price transparency.

We have two additional policies: wherein the countries offer free essential medicines in the public sector and where a particular state agency’s responsibility is assigned for the price regulation. It is noteworthy that the agency responsible for price regulation is not responsible for all the pricing policies in the country, but for a relevant number of pricing policies which have to do with price regulations. Both these aspects (free medicines in the public sector and agency responsible for price regulations) are based on the WHO SEA Region country profiles.

Some of the 10 WHO Pricing Guideline policies displayed in Table 3 (these are marked in gray) have the objective of lowering medicines prices in the public sector: tendering and price negotiation, pooled procurement, and value-based pricing. Hence, these policies are particularly relevant to and have an impact on countries where most of the population obtain medicines via the government (e.g. Bhutan and Thailand).

Table 3. Summary of pricing policies implemented in WHO South-East Asia Region countries

<table>
<thead>
<tr>
<th>Bangladesh</th>
<th>Bhutan</th>
<th>DPR Korea</th>
<th>India</th>
<th>Indonesia</th>
<th>Malaysia</th>
<th>Nepal</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Timor-Leste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-plus</td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
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<td>Tax exemption</td>
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**Cost-plus pricing**

Cost-plus pricing is a cost-based method for setting prices of medicines, whereby the production costs, research and development (R&D), administrative costs, overheads and profit, and promotional expenses are summed to determine the final price. According to the survey of experts, this policy is implemented by Bangladesh and Indonesia. In Bangladesh, the Government is determining the prices of essential medicines based on cost of raw materials, packaging materials and a mark-up. In Indonesia, the production costs together with the anticipated volume are taken into consideration for setting ceiling prices of generic medicines which are reimbursed. According to the WHO Pricing Guideline, this policy is no longer recommended.

**Tax exemption or reduction**

According to the WHO Pricing Guidelines, “tax is a compulsory transfer of money from private individuals, institutions or groups to the government. There are two main categories of tax: direct taxes, which are levied by governments on the income of individuals and corporations, and indirect taxes, which are added to the prices of goods and services”. WHO suggests that countries consider exemption or reduction of tax on medicines. Indeed, seven of the 11 countries of the WHO SEA Region are using this policy as a strategy to lower prices of medicines. Indonesia and Bangladesh did not report using tax exemption or reduction.

The literature about India’s pricing policies confirms that medicines are not tax exempt but recent efforts has reduced taxes on several pharmaceuticals including insulin (which is now 5% from the 12% earlier), and contraceptives and human blood products are tax exempt.xvi For the countries currently not exempting taxes on medicines, it is an opportunity to promote more affordable prices, including in the private sector, which is of high relevance to Bangladesh and India as medicines are largely financed out of pocket.

**Internal reference pricing**

Internal reference pricing (IRP) is the practice of setting or negotiating reimbursed medicine prices by referencing the prices of medicines within the country that are identical, similar, or therapeutically equivalent. Among countries of the SEA Region, only Thailand uses internal reference pricing.xvii Thailand can use this pricing policy as medicines are predominantly financed through the government. For many other countries where medicines are largely financed out of pocket, internal reference pricing used for medicines
predominantly financed through public or social insurance would not significantly impact the affordability of medicines at the household level.

**External reference pricing**

**Bangladesh, Indonesia and Thailand** reported using external reference pricing. Nepal does not use “external reference pricing” in the traditional sense but does not allow marketing of products having prices that exceed the price of medicines from the country Nepal imports from. According to the expert in Bhutan, a country that heavily relies on medicine imports, the country is not using external reference pricing, but the manufacturer must register the maximum retail price with the medicine regulatory authority before receiving market approval. In order to have the desired effect on making the prices of medicines affordable, the WHO Pricing Guideline highlights the need to obtain reference prices from verifiable data sources, account for all forms of discounts, rebates and taxes with a high degree of confidence, and make adjustments and choose jurisdictions that are comparable in terms of market size, national income and purchasing power. Additionally, adequate resources and skilled personnel are necessary but not sufficient to guarantee adequate implementation that is appropriate to the country context.

**Regulating mark-ups**

Generally, mark-ups are the additions to the medicine manufacturer’s or importer’s supply price to cover the costs of wholesale and retail activities, including overheads, distribution costs and profit margins for wholesalers or other distributors and retailers. Four out of 11 SEA Region countries report regulating mark-ups. **India, Indonesia and Bangladesh** have fixed mark-up regulations in place to help control prices of medicines. Bangladesh implements a fixed mark-up range of 150% to 340%, depending on the formulation. In Indonesia, generics have lower mark-ups compared with originator brands which allows for higher returns on lower cost generic medicines.

The pricing policy in India is more complex than the pricing policy in many other SEA Region countries. In India, the regulated mark-ups of wholesalers and retailers are incorporated into the formula for calculating maximum retail price (MRP). Retailer mark-ups are set at 16% and for wholesalers at 8%, which are at levels lower than the industry standards. India’s National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling price of 860 (out of 954) formulations on India’s EML from 2013 till December 2019. Furthermore, India also makes use of regressive mark-ups whereby higher cost medicines receive lower mark-ups, thus influencing incentives within the pharmaceutical supply chain. There may be large variations in mark-ups in different Indian states, particularly for branded generics, e.g. as high as 600% in the case of anti-hypertensive and anti-diabetic drugs and 1800% for anti-cancer drugs in urban Tamil Nadu.

Five countries report setting a ceiling for retail prices, which we classify for the purpose of this document under mark-ups: **Bhutan, India, Maldives, Nepal and Sri Lanka**. India uses market-based data to fix ceiling prices. This is done by taking a simple average of the prices of all brands having a market share of more than or equal to 1%. Nevertheless, significant inter-brand price variations for branded generic medicines still exist in the Indian pharmaceutical market. The NPPA has recently asserted that its price rationalization initiated in February 2019 has led to price reductions in anti-cancer drugs of “up to 90%”.

In Nepal, the ceiling price of a drug is decided by taking the mean or median prices of products in the market and comparing them with the international reference price.
This is similar to an external reference pricing, but a true external reference price regulation would not set a ceiling price at the point of sale. In other words, Nepal does not allow marketing of products having prices exceeding the exporting country price. Mentioning the maximum retail price (MRP) is mandatory on the label of every medicine. Nepal has fixed MRP of certain selected essential medicines as per the provisions of Section 26 of the Drug Act 1978.

Though the Maldives price control regulations are under review, prices are set by manufacturers who import to the Maldives and these prices need to be approved by the Maldives FDA. Additionally, the Maldives Food and Drug Administration is working with the Ministry of Economic Affairs to set a maximum retail price for their medicines. In 2016 Sri Lanka introduced a price ceiling for 48 essential noncommunicable disease medicines. These 48 medicines listed in the Extraordinary Gazette by the Government should be sold below this ceiling price at all times.

Regulating mark-ups received a conditional recommendation as a pricing policy by the WHO Pricing Guideline. There are a series of challenges for countries to effectively implemented it. We discuss the undesirable effects of mark-ups in a subsequent section of this report.

Promotion of generic medicines (private and public sector)

According to the WHO Pricing Guideline this is the only policy that received a strong recommendation. Governments should encourage patients, prescribers and dispensers to promote the use of quality assured generic medicines or similar biological medicines. According to our survey carried out for this report, almost all countries in the WHO SEA Region promote the use of generic medicines through a variety of strategies. The most common reported strategies include mandatory prescription by International Nonproprietary Name (INN) and either voluntary or mandatory generic substitution. Interestingly, three countries – Indonesia, Nepal and Timor-Leste – report that the government has introduced visuals on the product package to indicate that it is a generic product, which would support consumers to easily identify them and address the asymmetry of information as a barrier to improving the use of generic medicines. In Sri Lanka, the State Pharmaceutical Corporation (a government-owned organization responsible for the procurement of pharmaceuticals and other health products for the public sector) sells low-cost generics via its retail franchise network, called Rajya Osu Sala outlets, with fixed mark-ups and at affordable prices.

India promotes the use of affordable quality generics through specific outlets at lower (50%–90% less) prices than in private pharmacies. This is the Jan Aushadhi Scheme (JAS) (Public Medicine Scheme). The Indian government provides incentives to medicine outlets with an assistance of Indian rupees (INR) 200 000 to INR 5 000 000 (INR 100 000 is equivalent to about US$ 1500) and also provides a 16% discount in medicine purchase. In Indonesia, the Ministry of Health fixes the prices of generics which have lower mark-ups to promote their use. We provide more information about the unintended consequences of generic promotion policies below.

Tendering

Tendering is a process whereby the government engages manufacturers to submit quotations for a particular contract usually in a competitive bidding process. Tendering is used by most countries of the Region, including Bangladesh, Bhutan, India, Indonesia,
Maldives, Nepal, Sri Lanka and Thailand. In the country survey Myanmar and Timor-Leste did not report using tendering; however, there are literature reports on the use of tendering in both countries. SAMES (Servico Autonomo de Medicamentos e Equipamentos de Saude) is a public institution within the Ministry of Health in Timor-Leste. The core functions of SAMES are the procurement, storage and distribution of drugs and medical supplies for the health facilities of Timor-Leste. In recent years, the tendering practices have been reformed and improved with the help of various NGOs. In Timor-Leste, drugs are procured via local and international tenders. These bids are evaluated based on the criteria of lowest price.

Bangladesh procures medicines through national and international competitive bidding. In Sri Lanka, tenders are printed in newspapers worldwide, scheduled according to ascending prices and evaluated technically. It is a single bid system.

Indonesia procures generic drugs through local tendering. They use the e-catalog system, which is an electronic information system that provides the list of all reimbursed medicines. The price of a medicine procured through the e-catalogue in Indonesia is 10% less than the price through procurement without e-catalog.

India makes use of competitive tendering (two-bid system) although different Indian states use slightly different variations. In the Tamil Nadu model, an autonomous public sector body (Tamil Nadu Medical Services Corporation) procures generic medicines through a transparent bidding system, which is then supplied to public health facilities. West Bengal uses a public-private partnership (PPP) framework where the contracts are offered to private pharmaceutical retailers through online bidding depending on the percentage of discount for each hospital. The bidder with the highest discount gets the contract. In Myanmar, medicines are mainly procured from the Myanmar Pharmaceutical Factory and through national competitive tenders. Government hospitals in Thailand employ tenders for generic drugs and report savings due to generic competition.

As a general matter, it is useful to know if a particular country is purchasing medicines directly from manufacturers or from wholesalers. Small countries with no local production mostly rely on wholesalers and prices may well be less competitive.

**Negotiating special pricing agreements**

For the purpose of this report we defined price “negotiations of special pricing agreements” as the development and implementation of a legal contract between the government and the manufacturer that allows payers and pharmaceutical companies to align on value, speed of reaching the market, and/or risks involved. An example of a special pricing agreement is a so-called “managed entry agreement” (quite common in Europe) where the payer and the manufacturer participate in risk-based or outcomes-based contracts, i.e. a (conditional) marketing authorization is granted based on early evidence of the positive benefit-risk profile of the medicine, with a proactive plan for additional evidence generation in place to support the initial license.

Only Sri Lanka and Thailand reported currently considering special pricing agreements. Both use “Managed Entry Agreements”. According to the literature, in Indonesia product-specific price negotiations directly with the manufacturer are only used for those drugs that are still under patent and imported in the country. Thailand is also using risk-sharing agreements and price volume agreements. In Thailand, a maximum volume threshold is calculated for high-cost, on-patent medicines by estimating the number of eligible patients.
and the duration of the intervention. Costs exceeding this threshold are covered by the manufacturer.¹

Having special pricing agreements is particularly relevant for countries where the majority of the population obtains medicines through the public sector and where institutions have the technical capacities to implement such agreements with the manufacturers.

**Pooled procurement**

Pooled procurement is a formal arrangement where financial and non-financial resources are combined across various purchasing authorities to create a single entity for purchasing health products (e.g. medicines) on behalf of the individual purchasing authorities. In **India**, several states have a centralized pooled procurement model such as Tamil Nadu, Kerala, Odisha and Rajasthan.³³² Maharashtra follows the system of centralized tendering and procurement and decentralized purchasing where the suppliers directly deliver the medicines to the facilities.³³³

In Tamil Nadu, medicine quantities are also pooled at the state level and payments are also processed at the state level upon receipt of laboratory quality-assurance reports on the medicines. Tamil Nadu had suppliers for 100% of the drugs on their procurement list at the end of the procurement processes in 2006, 2007 and 2008.³³⁴

Currently, **Nepal** has a central tendering and procurement process after which medicines on the Free Drugs List in the country are distributed as determined by facility category, with all drugs provided at district hospitals, fewer medicines at primary healthcare centres, and even fewer medicines at health posts (HPs). Nepal moved from the unitary system to a three-level federal system of government in 2015 with health-care decision-making including procuring of medicines at all three levels of administration: the federal, provincial and local governments.¹x Hospitals are also entitled with certain funds to procure medicines at the institutional level. Although tendering at the federal level is still ongoing, the ability of local bodies to manage drug procurement and general logistics requires adequate human resources in local health-care centres. This is an ongoing challenge.

In January 2009, the **Thailand** National Health Security Office (NHSO) collaborated with the Government Pharmaceutical Organization (GPO) to introduce the ‘high-cost medicines E2 access program’ as a part of the National List of Essential Medicines to increase patient access to medicines. This was to make medicines more affordable through central procurement for high-cost E2 medicines used under the Universal Coverage insurance system. Pooled procurement resulted in lower prices of high-cost E2 medicines.¹xi

**Value-based pricing**

Value-based pricing relies on the results of pharmacoeconomic (PE) assessment that evaluates the cost and effects of purchasing/using a pharmaceutical product. Only India and Thailand report using PE assessments. India has price ceilings based on pharmacoeconomic (PE) assessments for new products with a 16% retail mark-up.¹xiv However, there is little evidence to describe how it is implemented in the country.³³³

Thailand also conducts pharmacoeconomic assessments for reimbursement and a health technology agency (Health Intervention and Technology Assessment Programme (HITAP)) is responsible for evidence-based evaluation of health technologies and programmes, including pharmaceuticals, medical devices, interventions, individual and community health promotion, and disease prevention, as well as social health policy, to inform policy decisions in the country.¹xii According to the WHO Pricing Guidelineº
adequate resources and skilled personnel are necessary but not sufficient conditions for implementation of value-based pricing.

**Promoting price transparency**

We defined price transparency as the sharing, disclosure and dissemination of information related to prices of pharmaceutical products to relevant parties and the general public to ensure accountability. Full price transparency includes the publication of prices at all price types (e.g. ex-factory prices, pharmacy retail prices), the disclosure of the net transaction prices between the suppliers (e.g. manufacturers, service providers) and the payers/purchasers (governments, consumers). WHO SEA Region countries were asked in the survey that was carried out for this report to indicate whether their country was promoting price transparency. Six countries indicated partial price transparency and publishing of the maximum retail price. **Thailand** reported full price transparency through publishing both the retail price and the ex-factor price. Although there is limited evidence on the effectiveness of price transparency, WHO recommends countries to consider this strategy in their policy toolbox to promote affordable medicines.

**Free essential medicines in the public sector**

According to the WHO SEA Region report on access to medical products 2019, policies to provide free essential medicines exist in all South-East Asia Region countries.

In India, the Free Essential Drugs Initiative is aimed at providing essential medicines free of cost in all public health facilities. The initiative provides funding to individual states for strengthening/setting up of robust systems of procurement, quality assurance, IT-backed supply chain management systems such as Drugs and Vaccines Distribution Management Systems (DVDMS), warehousing, prescription audit, grievance redressal, information, education and communication (IEC), training, and dissemination of Standard Treatment Guidelines. The states of Tamil Nadu and Rajasthan have implemented free medicines scheme in all public hospitals.

Medicines are provided free of cost in the public sector in both Sri Lanka and the Democratic People’s Republic of Korea. In Nepal, medicines are available free of cost up to the district level. A maximum of 70 essential medicines are provided free of charge from health posts, primary health care centres and district hospitals.

Nepal developed an EML, which is a generic guide to public sector procurement. However, not all EMLs may be free of charge or even available in public facilities. In 2009, the coverage was expanded so that all citizens would have access to 40 drugs on a separate list known as the Free Drug List (FDL). The FDL has recently been expanded from 40 to 70 drugs, although the process of review or updating of the list remains unclear.

**3.3 Evidence of undesirable consequences of pricing policies**

Many of the pricing policies implemented in the SEA Region could lead to possible unintended consequences. In this section of the report, we highlight some evidence documented in the peer-review and grey literature on such unintended and often undesirable consequences of pricing policies. Identifying these unintended consequences is very relevant to assess their effects and implement corrective actions if necessary. The following section can support WHO SEA Region countries in learning from examples in the Region where pricing policy implementation could be improved.
Cost-plus pricing

The cost-plus pricing method requires manufacturers to provide extremely detailed pricing information, which is likely considered intrusive and is also sometimes highly resisted, leading to possible manipulation and delay in provision of data. As the prices are based on the “lowest common denominator”, they tend to be clustered within a narrow band, thus limiting the space for the entry of a new product at an uncovered price. Thus, cost-plus pricing policy can disincentivize price competition and create shortages, as well as lead to inefficient R&D and inefficient manufacturing of medicines.

As mentioned above, the WHO Pricing Guideline discourages countries from using this policy. In Indonesia, currently the national pricing committee seems to rely mostly on the sales volumes and production costs declared by the manufacturers. There is no cross-referencing with the consumption data from the primary health insurer. This in turn is likely to create various distortions in the market, as drugs with declared high volumes may eventually not be used in reality, and potentially the production costs can remain uncovered. Reversely, not enough volume of a drug may be produced, thus encouraging a higher price due to higher demand.

Internal reference pricing

There appear to be relatively few unintended consequences documented for internal reference pricing. Patients for whom the reference-priced product is ineffective face either higher copayments or nonoptimal insurance coverage, leading to health risks if they switch their medicine. Some authors suggested that if patent medicines are grouped together with off-patented medicines there is a risk that lower prices of patented medicines would reduce the incentives for R&D. However, there is not much rigorous evidence to support that notion.

External reference pricing

Qualitative evidence suggests that external reference pricing (ERP) using reference countries with lower prices could cause potential launch delays and product withdrawals in those countries that are referencing against such lower prices. These delays and withdrawals are used to avoid prices being reduced in the referencing country, with the alleged potential for parallel exports to higher priced countries. These delays could also be due to slow registration procedures and lack of access to reliable price information.

It has been argued that external reference pricing can also lead to lower prices which could hamper investment in innovation; however, there is no rigorous evidence that support that claim. At least with respect to the available literature on middle- and high-income countries, there is some evidence on the impact of ERP on affordability of medicines within a country, but little was identified in terms of quantifying the actual extent to which this affordability of medicines would be affected as a result of ERP policies.

One important unintended consequence of external reference prices in the SEA Region is the use of an inappropriate benchmark, for instance, list prices that do not reflect the actual purchase price. If SEA Region countries benchmark against upper-middle or high-income countries that do not disclose confidential rebates, for example, then the Region’s Member States may end up paying more than the countries they use as benchmarks.

Regulating mark-ups

Mark-up regulations could lead to price convergence towards the maximum regulated prices and may potentially increase demand by suppliers for medicines with higher mark-up margins. Hence the World Health Organization is suggesting regressive rather fixed
mark-up. In India’s Odisha state, the largest contributor to add-on cost for pediatric medicines is the retailer mark-up, which also includes the operating cost of transportation, storage and dispensing of medicines.

A high price variability between private sector outlets is likely the result of low market competition and absence of proper price regulation. At least in Odisha state, operating costs of transportation, storage, and dispensing of medicines could not be separated from the mark-ups at the wholesale and retail stage. Further, bonus or free medicines are often offered by manufacturers, which could result in supplier-induced demand for products with higher mark-ups.\textsuperscript{1} In India, as of 2012, profit margins applied to medicines in the private sector are not regulated. This is probably contributing to create an unfavorable environment for the private sector, since small businesses are unlikely to survive in a system where a few vertically integrated groups (importers with their own retail pharmacy) control market prices (and practices).\textsuperscript{li}

Manufacturers can shield themselves from price control by producing therapeutically inappropriate medicine combinations so that they do not come under the purview of price control, but consumers are inundated with such inappropriate combinations that push up the cost but delay the course of treatment.\textsuperscript{5} In Bangladesh, where fixed mark-ups are implemented, the prices of key essential drugs differed widely by brands (sometimes by a margin of 500% or above), seriously compromising the affordability of poor people.\textsuperscript{lii}

The WHO Pricing Guideline\textsuperscript{7} highlights the challenges of implementing mark-up regulations across the pharmaceutical supply chain since it is often very complex and characterized by a lack of transparency. According to the literature, many countries in the WHO SEA Region face challenges in promoting price transparency across the supply chain. An exception to the lack of price transparency is the retail price — many countries have made it mandatory to print it on the product package. However, the publication of the maximum retail price is insufficient for effective regulation across the supply chain.

**Promotion of generic medicines**

In 2010, Indonesia’s policy stated that public sector health-care facilities must procure and use unbranded (INN) generic medicines. Indonesia set a maximum price for unbranded generic medicines in the public sector and Anggriani (2013)\textsuperscript{liii} noted the absence of any policy regulating the price of innovator brands. Low prices for generic medicines lead to a lower private sector profit margin, so these private sector facilities sold unbranded (INN) medicines at a price higher than the public sector maximum retail price. The government did not regulate these private sector outlets. Some pharmaceutical companies ceased making low-price medicines and, in turn, the availability of some INN generic medicines declined and use of unbranded generics did not increase. This problem may have been caused by stakeholders’ perceptions of the quality of unbranded generic INN medicines.

In Nepal, the National Health Policy 2019 and the Public Health Service Act 2018 state the provisions of promoting generic prescribing but the practices of prescribing generics has not been implemented in general.\textsuperscript{6b} As a result, the bulk of the sales of pharmaceuticals in the country are for “branded generics”, that is, off-patent formulations marketed and sold as brands that are not proven to be bioequivalent. In one survey, it was noted that the main teaching hospital in Nepal teaches graduates to prescribe the brand names they trust and know rather than the INN names.\textsuperscript{6b} In India as well, generic drugs are sold as brand names, which push up the cost of treatment as doctors prescribe branded generics. Instead, if drugs are sold as unbranded generic (INN) names, the cost could be contained.\textsuperscript{8}
Moreover, also in Nepal (as in India) the pharmaceutical companies provide a variety of incentives to prescribers. Heavy incentives, bonuses and profit margins offered to the private retail pharmacies for a given brand of medicines results in unwarranted substitution by dispensing staff. Giving bonuses is the company practice of handing over additional free products with each purchase. The government regulations state that only a 16% margin can be applied to the wholesale price, and one survey noted that “it is only with incentives — particularly bonuses — that retailers can make a decent profit”. Several retailers interviewed admitted that pharmaceutical representatives do try to incentivize them with gifts and bonuses lv.

In Indonesia, the structure of the pharmaceutical market is distorted by the actions of doctors who have a dominant role in determining the choice of drugs, both to be obtained by patients and to be provided at the hospital. It is suspected – but not proven – that there is a transactional relation between doctors and pharmaceutical companies in the making of prescriptions. A regulation of the Minister of Health obliges doctors to prescribe generic drugs, but it is only limited at the government-owned health facilities xv.

Generic substitution is not legally permitted in India. Hence, patients’ awareness about generics and price variation is very limited. As per the provisions under Rule 65 of the Drugs and Cosmetics Act 1940, and the related Rules of 1945, a dispensing pharmacist is not authorized to substitute a branded medicine with a branded-generic (or generic), which also adds to the patient’s burden lvii. Moreover, doctors are not prescribing generics because, among other factors, the pharmaceutical companies sponsor conferences and offer personal gifts (in lieu of prescribing branded versions) xxxi.

**Value-based pricing**

Value-based pricing can potentially delay product launch due to technical and process complexities and result in unaffordable prices. This policy also includes health technology assessments that makes use of metrics such as quality- or disability-adjusted life years (i.e. QALY or DALY) as the measures for quantifying the comparative value of a product. This is known to cause age discrimination and discrimination by type of illness severity as QALYs are used to determine whether or not to offer any treatment at all to some patients, or whether to offer a particular treatment to some patients even when no alternatives are preferred lviii.

The use of economic evaluation to inform policy in India is currently in its initial stages and there is not enough understanding about the issue. The dual source of policy-making – at the federal or Union level and the states – makes the situation more complex. Similar to the Federal government, economic evaluation is not used by many state governments because decision-makers currently do not demand it or lack the capacity to supply economic evidence. Moreover, there is no official mechanism to include cost-effectiveness evidence in the decision-making process lvii.

Indonesia has also initiated the early stages of such an effortlix as has Sri Lanka lx.

**Free essential medicines in the public sector**

The provision of free essential medicines is seen as a cornerstone of universal health coverage. However, even though on paper all Member States of the WHO SEA Region have policies that ensure free essential medicines for at least some population groups (e.g. children, pregnant women, TB patients, etc.), in reality these policies often fail to achieve their goal of securing access to affordable essential medicines since the public sector facilities which are supposed to provide these medicines do not have them available.
Apart from supply chain challenges, there are also other barriers, such as those reported from Nepal. The few published studies evaluating the Free Drug List (FDL) noted several issues such as lack of appropriate process, obvious gaps in the listed drugs and Nepal's burden of disease, and also lack of consideration for unit costs or cost-effectiveness of drugs included in the FDL.

**Price transparency**

Although the WHO Pricing Guideline conditionally recommends countries to consider price transparency as one of the policies to promote affordable medicines, it states that the promotion of price transparency of medicines could restrict the practice of offering confidential discounts. Although there is no rigorous evidence, in theory this could slow down the diffusion of innovative products to low-income countries and negatively impact patient access to innovative medicines therein.

However, there is evidence that price transparency in procurement has resulted in price reduction. The World Health Organization together with many other international partners introduce price transparency of antiretroviral medicines via the Global Price Reporting Mechanism (GPRM) which was instrumental to benchmark prices of antiretrovirals in the 2000s. In South-East Asia, procurement price transparency in the Indian states of Tamil Nadu and Rajasthan and in Sri Lanka are good examples of how transparent prices and processes can achieve lower prices.

Evidence suggests that the disclosure of price information to prescribers does not seem likely to produce sustained effects on more efficient use of medicines. In India, the National List of Essential Medicines forms a sort of reference list from which the list of drugs to be placed under price control can be drawn. Unfortunately, at present, it is only a guideline and a prescriptive tool and does not accurately reflect the reality of the pattern of drug production, prescription, and drug availability in the country. The reality of the pattern of prescriptions is that most of the drugs prescribed lie outside the NLEM.

Currently, in India, if a company is caught overcharging medicine prices, it is not required to pay any penalty but only pay the overcharged amount along with interest for the period during which the overcharging took place. Consumers essentially depend on doctors’ prescriptions and are not equipped to make an informed decision while purchasing medicines.

**Cross-cutting theme: Small pharmaceutical markets**

In this subsection we describe some challenges that countries with small pharmaceutical markets face in implementing pricing policies. One third of all WHO SEA Region countries, namely Bhutan, Maldives, Nepal and Timor-Leste, are small pharmaceutical markets compared with India, Bangladesh and Indonesia, making the discussion of challenges of these types of markets relevant. A review of the literature on challenges of pricing policies in countries with a small pharmaceutical market size showed that there is evidence, particularly from countries in Europe. For example, Lithuania faced a 34% reduction in the number of authorized medicines when it joined the European Union (EU) due to its small market size of only 3.2 million inhabitants. In Latvia, weak competitiveness in some therapeutic areas in addition to the low purchasing power/small market size is considered to be one of the reasons for high medicine prices. Similarly, in Estonia, several medicines are unavailable despite existing market authorizations.
There is a lack of interest on the part of manufacturers to introduce their products in small markets and this is not only attributed to the low profitability of these markets but also to the lower-than-average GDP per capita of these countries. Other barriers include inadequate financing, inadequate incentives for maintaining stocks, inefficiencies in processes, local language requirements and price spillovers through international reference pricing. In principle, these barriers are also likely to be issues with respect to pharmaceutical pricing policies in smaller markets in the SEA Region.

**External reference pricing**

Many European countries use international reference pricing as one of the price-setting criteria for medicines. However, this can be detrimental to small markets. If richer countries include low-income countries in the same basket of reference pricing it can lead to physical arbitrage of medicines from one country to another, i.e. lower-priced products flowing back to the higher price market. Contrastingly, in Norway, the international reference pricing, introduced in 2000, was regarded as the most successful policy because it led to considerable and predictable price reductions.

The effects of the indirect pricing strategies, e.g. reference-based pricing (1993–2000), generic substitution (2001 onwards), and index pricing (2003–2004), have been more limited in Norway because of unpredictable market mechanisms such as delivery failure, asymmetric information and counteractive behaviour. With regard to the SEA Region, the smaller markets of Bhutan, Maldives and Nepal do not use this policy in the sense of using other countries as a price “benchmark”. The issue of arbitrage mentioned here would seem to be more apparent than real with respect to small markets as the “leakage” of medicines into richer countries from Bhutan, Maldives and/or Nepal may well be minimal when viewed in the larger context.

**Pooled procurement**

With respect to pooled procurement, in Europe, collaborative approaches such as joint negotiations and procurements were sought to address high medicines prices in small markets. Member States of the EU wanted to increase their negotiation powers in order to achieve lower prices and improve access to lower-priced medicines in smaller markets.

The WHO SEA Region had plans to implement pooled procurement in the Region benefiting in particular countries with a small pharmaceutical market. However, plans were not developed further after a time because critical enabling factors were not, and still are not, in place across the Region. These include harmonized medicines registration/quality assurance requirements, accurate demand forecasting and financing commitments in advance by Member countries.

**Promotion of generics**

Following the 2008 financial crisis emanating from Greece, the price cap for generics was reduced from 70% to 63% and later to 40% below the originator price. In the hospital market, priority has been given to generics over originators by means of tendering. It is expected that generic prescribing would increase the use of less costly generics and thereby increase efficiency. The public pharmaceutical expenditure in Greece was thus found to have decreased due to significant price cuts for originators and generics, higher generic market penetration and lower wholesaler mark-ups.

Generic medicines can help governments to contain pharmaceutical expenditures. Generics are generally 10%–80% lower in price than brand medicines. European countries with smaller populations can obtain substantial reductions in prices of generics versus originators as is the case in Lithuania. In Lithuania, the first generic launched must
be priced at least 30% below the originator, setting the reimbursement rate for the molecule. The reference price groups (internal reference pricing) are just based on International Non-Proprietary Name (INN) name and method of administration. Physicians must write prescriptions by INN name except for biological products, provide pricing information to patients on a computer screen and dispense the cheapest generic.

In Sweden, with its population of 9.18 million, the introduction of compulsory generic substitution was instrumental in successfully lowering generic prices. There was an 87%–96% reduction in expenditure/Defined Daily Dose (DDD) for six high-volume generics in 2008 versus pre-patent loss prices (i.e. generic prices were between 4% and 13% of pre-patent loss originator prices). In Norway, an index price was set for each included substance and updated every third month. The price was equal to the average of the three lowest reported producer prices of that substance plus a fixed wholesale and retail margin. Generic substitution and price regulation of generic products in relation to the originator product are important policy options that the SEA Region should consider.

**Internal reference pricing**

Reference pricing can also help governments contain public pharmaceutical expenditure as it controls the reimbursement level of medicines. A reference pricing system may also promote generic medicine use because originator medicines priced above the level of the reference price are likely to lose their market share as a result of the additional patient co-payment.

Many European countries have already installed a reference pricing system. In Norway, reference pricing was applied from 1993 until the end of 2000. In 2003, the Norwegian government installed a similar system called “index pricing” to a set of off-patent medicines. Reference pricing is in many European countries combined with other policies such as prescribing by international non-proprietary name or generics substitution, as this combination of policies seems to positively influence each other. In Belgium, the reference price is set at 69% of the price of the originator medicine on the patent expiration date. This method has the benefit of guaranteeing savings to health insurance funds but has in general not generated price reductions of generic medicines below the reference price.

It would appear that none of the smaller SEA Region markets use this form of reference pricing (See Table 1). It is critical, however, how policy-makers of reference pricing take into account evidence-based medicine, particularly in markets with multiple versions of the same therapeutic product (e.g. multiple statins). Products with greater effectiveness may be expected to have higher economic value. Similarly, improved safety characteristics, or even more registered indications may also justify price differentials for products even in the same therapeutic class. If efficacy differences are not carefully taken into account then only cost considerations will drive prescription practice.

### 3.4 Medicines’ pricing surveys conducted in WHO SEA Region countries

The WHO/Health Action International (HAI) analysis of consumer medicines prices in Table 4 summarizes the relevant information extracted from the WHO/HAI SEA Region surveys. The results are difficult to generalize given the diversity in medicine supply, financing and price controls in different SEA Region countries but it would appear that: a) affordability of the lowest generic priced medicines in the public sector in Indonesia, and both public and private sector in Sri Lanka are generally considered acceptable by WHO/HAI standards; and b) public sector prices for most medicines are generally less expensive than their private sector counterparts but are often less widely available than their counterparts in the private sector.
Sri Lanka’s medicine financing policies (see also Fig. 5 and 6) tend to indicate that they substantially lower out-of-pocket expenditure on medicines because public funding is relatively high compared with other countries in the Region. Survey findings from other countries suggest that unaffordability of medicines purchased in the private sector is a critical access challenge, particularly for the elderly who often have multiple comorbidities with concomitant polypharmacy. It is also significant that the few WHO/HAI surveys dealing with pediatric medicine all suggest that many such medicines are unaffordable.

### Table 4. Data extraction from pricing surveys in WHO SEA Region countries between 2011–2020

<table>
<thead>
<tr>
<th>Country and year</th>
<th>Authors</th>
<th>Public sector IRF</th>
<th>Private sector IRF</th>
<th>Affordability</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh 2019</td>
<td>Kasonde et al.</td>
<td>0.977</td>
<td>1.700</td>
<td>Least affordable in the private sector are bisoprolol (hypertension), metformin (diabetes) and atorvastatin (hypercholesterolemia). The issue of affordability in the private sector is particularly important given the low availability of medicines in the public sector.</td>
<td>A small number of medicines are consistently expensive across sectors in Bangladesh. Catastrophic expenditure in Bangladesh may be easily encountered by patients, particularly those suffering from multiple NCDs.</td>
</tr>
<tr>
<td>India Odisha state 2015</td>
<td>Swain et al.</td>
<td>0.52</td>
<td>1.46–1.83 (retail) 2.08 (faith-based)</td>
<td>Substantial price variation was observed for some children's medicines, primarily antimicrobials across individual outlets.</td>
<td>Cost of children’s medicine is relatively high in both private and NGO sectors compared with the international reference price.</td>
</tr>
<tr>
<td>India Odisha state 2017 c</td>
<td>Samal et al.</td>
<td>Add-on costs such as taxes, wholesale and retail markups contribute substantially to the final price of medicines in the private sector, particularly for branded-generic products. The largest contributor to add-on costs is at the level of the retailer shop.</td>
<td>Policy should be framed to achieve greater transparency and uniformity in the pricing of medicines at different health sectors of Odisha.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>India New Delhi 2019</td>
<td>Faruqui et al.</td>
<td>0.71</td>
<td>The estimated cost of chemotherapy medicines needed for treating a 30-kg-weight child with standard-risk leukaemia was INR 27 850 (US$ 442) and INR 17 500 (US$ 276) for Hodgkin’s lymphoma, requiring 88 and 55 days’ wages, respectively, for the lowest paid government worker.</td>
<td>Cost of chemotherapy medicines seems unaffordable in the local context. Total out-of-pocket spending for cancer care in both outpatient and inpatient departments was higher than for other diseases in India.</td>
<td></td>
</tr>
<tr>
<td>Indonesia 2013</td>
<td>Anggriani et al.</td>
<td>Wide variations were observed in excess of the unbranded generic medicine price paid by patients compared with the maximum retail price from the Ministry of Health, exceeding the maximum price by approximately 2% to 600%.</td>
<td>The prices paid by patients for unbranded generic medicines are more expensive than the maximum prices set by government policy. Generic medicine pricing policies have succeeded in lowering the price of unbranded generic medicines. The price of 18 medicines has declined but remains high compared with the international reference price.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country and year</td>
<td>Authors</td>
<td>Public sector IRF</td>
<td>Private sector IRF</td>
<td>Affordability</td>
<td>Conclusion</td>
</tr>
<tr>
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<td>------------</td>
</tr>
<tr>
<td>Indonesia 2015</td>
<td>Siahaan et al. (^{lxxvii})</td>
<td></td>
<td></td>
<td>Medicines prices are higher than their international reference price, sometimes by 100 times.</td>
<td>The government needs to make drug prices more affordable.</td>
</tr>
<tr>
<td>Indonesia 2020</td>
<td>Kristina et al. (^{lxxviii})</td>
<td>0.98</td>
<td>2.46</td>
<td>Findings of median MPR of lowest-priced generic (LPG) in the private sector for ceftriaxone was 5.64, ranitidine was 4.35, and salbutamol was 4.19 times higher than international price. In public health facilities, ceftriaxone injection was 2.19 times higher compared with the international price.</td>
<td>Procurement prices of surveyed medicines were considered efficient, especially in the public sector; yet in the private sector, the prices tend to be high since there is no price control in private hospitals. Cost containment is concentrated in government health and primary health centres and only on medicines listed in the national formulary.</td>
</tr>
<tr>
<td>Nepal 2019</td>
<td>Khanal et al. (^{lxxix})</td>
<td>0.6–2200</td>
<td></td>
<td>No price variation between the regions. Most cancer medicines are not sold in most private pharmacies and are not available at the primary care-level public health-care organizations.</td>
<td>Treating selected NCD conditions with medicines was generally affordable, with 1 month of treatment costing no more than a day's wage of the lowest paid unskilled government worker. However, multiple morbidities may lead a patient to spend several days' wages for treatment.</td>
</tr>
<tr>
<td>Sri Lanka 2011</td>
<td>Senarathna et al. (^{lxxx})</td>
<td>IB: 4–7 G: &lt;1</td>
<td>IB: 5–6 G: &lt;1</td>
<td>Innovators cost more than a day’s wage of the lowest-paid government worker; in contrast, generics were always priced at less than a day’s wage. There seems to be no difference in affordability between privately owned or semi-government pharmacies.</td>
<td>Generic medicines have effective pricing and are available and affordable. The reason for the lower pricing of generic medicines is not very clear; however, this may be due to the State Pharmaceuticals Corporation's dominance in the market and their procurement system.</td>
</tr>
<tr>
<td>Sri Lanka 2014</td>
<td>Dabare et al. (^{lxxxi})</td>
<td>About 50% of med.</td>
<td>IB: &gt;5</td>
<td>Less than a single day’s wage was adequate to purchase a month’s supply of the lowest priced generic of more than 67% of the surveyed NCD medicines.</td>
<td>Most NCD medicines are affordable for the lowest income earners in the community.</td>
</tr>
<tr>
<td>Sri Lanka 2014 c</td>
<td>Balasubramaniam et al. (^{lxxxii})</td>
<td>IB: 3.7 G: 1.35</td>
<td></td>
<td>National data on price and affordability of key essential medicines for children show that prices of LPGs are reasonable, but their affordability depends on factors such as income, cost of living, and prescribing practices.</td>
<td>Treatment for chronic childhood illnesses requiring liquid or inhaled dosage forms of medicines were largely unaffordable.</td>
</tr>
<tr>
<td>Thailand</td>
<td>Ngorsuraches et al. (^{lxxxiii})</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Most single-source drug prices in Thailand were higher than their equitable prices and were likely to be unaffordable for Thai citizens.</td>
</tr>
</tbody>
</table>
Medicines’ price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research

<table>
<thead>
<tr>
<th>Country and year</th>
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<th>Private sector IRF</th>
<th>Affordability</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO SEA Region (India, Sri Lanka, Thailand: 2017)</td>
<td>Wang et al.</td>
<td>Access to affordable essential medicines for noncommunicable, chronic diseases in India, Sri Lanka and Thailand is such that less than one day’s wage is required to purchase one month’s treatment of a chronic disease, in the public and private sectors.</td>
<td>Patient prices in the private sector were generally higher than in the public sector in most countries. Older people often have multiple chronic conditions, and each condition is often treated using more than one medicine.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global LMIC (2020)</td>
<td>Husain et al.</td>
<td>The cost of 1 month’s antihypertensive medications was, on average, equivalent to 6 days’ wages for branded medicines and 1.8 days’ wages for generics across all countries.</td>
<td>Patients in lower-income countries faced higher prices and lower affordability compared with higher-income countries for both branded and generic medicines, though generic medicines were more affordable than branded drugs in all countries evaluated.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N/A = article not available; C = children; IB = innovator brand; IRF = international reference price; LPG = least-priced generic

*The data for this study came from 84 surveys in 59 countries that used the WHO/HAI methodology. SEA Region data is from India, Indonesia and Thailand (see above).

4. Discussions

The objective of this report is two-fold: (1) to summarize the current evidence on the impact of key price regulatory interventions in the WHO South East Asia Region on access to essential medicines; and (2) to identify gaps in knowledge and/or policy implementation practices in the Region.

The results described allow for assessing the current status of pricing policy development and implementation in Member countries of the Region and place them in the context of their medicines financing and progress towards UHC.

The findings show that there is room for further pricing policy development and adjustments. Hereinafter are narrated seven key findings from our analysis:

(1) Our analysis of financing medicines demonstrates that there are several countries in the Region where prepaid, public and/or private financing of medicines is very low, hindering access to essential medicines for the population and progress towards UHC. Pricing policies will not achieve the goal of improving population access to essential medicines without adequate public financing of essential medicines for those who cannot afford them.

(2) Our findings show that in about a third of the Member countries of the WHO SEA Region a large proportion of households face catastrophic expenditures on medicines. This is a direct result of the lack of prepaid financing of medicines as well as possibly high prices in relation to household income. These catastrophic expenditures have devastating consequences for overall population wealth. It has been estimated that globally over 100 million individuals slide into poverty each year due to high out-of-pocket expenditure on health, many of them a result of purchase of necessary medicines. A recent report confirmed that this global estimation is significantly driven by countries with low prepaid health financing. More importantly, many households may forgo the expenses of buying needed medicines.
medicines but face adverse health outcomes as a consequence, which also has a long-term social and economic impact on the country.

(3) Our summary of the literature on pricing surveys in the public and private sector demonstrates that in those countries with a lack of prepaid medicines, financing prices are often unaffordable in the private sector. Since the availability of medicines in the public sector is often low, there is no choice for individuals but to purchase medicines from the private sector or forgo the purchase altogether. Hence, the pricing policies that affect medicines in the private sector are particularly relevant in countries where large segments of the population rely on the private sector as their main point of access.

(4) This report brings together the findings of an expert survey in all 11 Member States of the WHO SEA Region. Ten experts from nine countries responded. The findings highlight that some pricing policies are very commonly used in all countries, such as promotion of generic medicines, tendering and supply of free essential medicines in the public sector. All of these policies are recommended by the WHO Pricing Guideline. At the same time it is noteworthy that some pricing policies are only used in a few countries, such as value-based pricing and price negotiation or special price agreements. These particular policies require technical capacity and continuous investment. Evidence of the impact of these policies largely exists from upper-middle-income and high-income countries where a large proportion of the population enjoys a pharmaceutical benefit package (e.g. medicines prepaid without substantial out-of-pocket payments).

(5) Our report shows that there is evidence of unintended and harmful consequences of several SEA Region pricing policies such as cost-plus policies, several mark-up policies and some external reference pricing policies. Countries are encouraged to review these policies and adjust them to avoid further negative consequences in terms of health or economic well-being of their population. Some evidence also shows that there was an absence of the intended policy effect. This could be due to a flawed evaluation design or because the policies indeed did not make any difference. Countries are encouraged to invest in studying the effects of their pricing policies. One critical input in such analysis of pricing policies is a pricing survey covering both public and private sectors as well as different levels of care (e.g. primary, secondary and tertiary). The newly developed app “WHO MedMon” can support countries in their regular pricing surveys. Pricing surveys should be complemented with a variety of other pricing studies such as the evaluation of procurement performance, price negotiation, as well as linking pricing studies with assessments of medicine quality and medicine utilization analysis.

(6) With respect to existing WHO/HAI pricing surveys, attention must be paid to understanding the impact of pricing policies on the actual, household-level affordability of NCD medicines given that persons with NCDs, particularly the elderly, may have multiple comorbidities. Further, as these surveys revealed that some pediatric formulations are largely unaffordable, attention should also be paid to further understand which pricing policies are most appropriate for pediatric formulations.

(7) Our work indicates that the large differences in country characteristics (the WHO SEA Region has some of the most populous and some of the smallest countries in the world) make it challenging to consolidate support for pricing policies within the Region. In addition, countries are at very different stages in the roll-out of
UHC, which means that the need for pricing policies will vary depending on the maturity of the pharmaceutical benefit schemes. Five of the 11 WHO SEA Region countries are “least developed countries” that are currently exempt from WTO patent regulations on medicines, allowing at least one of them, Bangladesh, to continue to produce generic versions of otherwise patented medicines. Nonetheless, one challenge that stood out is that of small markets. One third of all countries in the Region are small pharmaceutical markets where traditional pricing policies such as price negotiation are less effective due to their small purchase volumes. Other regions, such as the WHO European Region, could provide some useful lessons going forward as European countries with small markets have documented the results of their pricing policies, including some positive outcomes. For instance, some European countries have introduced pooled procurement and a price index for generic medicines, which is regularly updated.

The present report can serve as a basis for discussion in the Region on medicines pricing policies. Regular medicines pricing studies in combination with household health expenditure surveys are necessary to track the effect of policies aiming to promote affordability of medicines. The expansion of universal health coverage in several countries in the South-East Asia Region is critical to protect households against financial hardship from medicines-related health expenditure. Additionally, the effective regulation of prices in the private sector was identified as one of the biggest challenges in the Region. Future projects should study the effects of policies aiming to effectively regulate medicines prices in the private sector.
Annex 1

**Search strategy**

Title and abstract “pharmaceutical” OR “drug” OR “medicine” AND Title and abstract “price” OR “pricing” AND Title and abstract “policy” OR “strategy”

Using PubMed MeSH terms, one may use:


or

Dear colleagues,

The WHO SEA Region is reviewing the current evidence of the impact of price regulatory interventions on access, availability, affordability and quality of essential medicines. We wish to identify gaps in knowledge and/or policy implementation practices in the South-East Asia Region to be discussed in a regional consultation of experts. The outputs from this expert consultation will lead to the development of a policy brief and other practical documents to be used in future regional consultations on access to medicines.

To collect up-to-date information we request you to respond to the questionnaire below by September 30 2020.

In case you have questions please email wak@bu.edu or vwirtz@bu.edu

Thank you for your support!

1. Is cost-plus pricing implemented in your country?

Definition: “Cost plus pricing is a cost-based method for setting prices of medicines, whereby the production costs, research and development (R&D), administrative costs, overheads and profit, and promotional expenses are summed to determine a price.”

Yes ☐
No ☐
I do not know ☐

a. If yes, are there peer-reviewed journal articles or reports from your country on the effects of cost-plus pricing on access including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL:____________________________________________
b. If yes, besides the evidence on the effects of the policy, is there any other published information of which you are aware from your country about cost-plus pricing?

Web URL: ________________________________

2. Is internal reference pricing implemented in your country?

Definition: “Internal pricing policy refers to the practice of setting or negotiating reimbursed medicine prices by referencing prices of medicines within the country that are identical, similar, or therapeutically equivalent.”

Yes ☐

No ☐

I do not know ☐

a) If yes, are there peer-reviewed journal articles or reports on the effect of internal reference pricing on access including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: ________________________________

b) If yes, besides the evidence on the effects of the policy, is there any other information about which you are aware from your country about internal reference pricing?

Web URL: ________________________________

3. Is external reference pricing implemented in your country?

Definition: “External reference pricing is commonly known as international reference pricing, and is a price-control mechanism whereby a government considers the price of a medicine in other countries to inform or establish a price in its own country.”

Yes ☐

No ☐

I do not know ☐

If yes, are there peer-reviewed journal articles or reports on the effects of external reference pricing on access including availability, affordability and quality of essential medicines?
medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: __________________________________________

If yes, besides the evidence on the effects of the policy, is there any other information of which you are aware from your country about the External Reference Pricing?

Web URL: __________________________________________

4. Is value-based pricing implemented in your country?

Definition: “Value-based pricing (VBP) is an approach that aims to set prices for pharmaceutical products based on the measured and quantified ‘value’ attributed to the pharmaceutical products. It often involves a cost-effectiveness analysis (CEA) to examine the value of medicines, usually defined in terms of its consequences (e.g. quality-adjusted life years (QALYs) gained) relative to its cost.”

Yes ☐

No ☐

I do not know ☐

If yes, are there peer-reviewed journal articles or reports on the effects of value-based pricing on access including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: __________________________________________

If yes, besides the evidence on the effects of the policy, is there any other relevant published information of which you are aware from your country about value-based pricing?

Web URL: __________________________________________

5. Is tendering and negotiation implemented in your country?

Definition: “Tendering and negotiation is understood as the government engages manufacturers to submit quotations for a particular contract. It simultaneously works as a procurement strategy to aid supplier and volume decisions for certain medicines and typically
relies on some form of negotiation. Negotiation refers to discussions aimed at reaching an agreement with potential suppliers. In addition to acceptable general terms and conditions, the outcome of tendering and negotiation might include specific price reductions through discounts and rebates.”

Yes ☐

No ☐

I do not know ☐

If yes, are there peer-reviewed journal articles or reports on the effects of tendering and negotiation on access including availability, affordability and quality of essential medicines?

Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL:____________________________________________

If yes, besides the evidence on the effects of the policy, is there any other relevant published information from your country of which you are aware about the tendering and negotiation?

Web URL:_____________________________________________________________

6. Are special pricing agreements implemented in your country?

Definition: “A type of innovative agreement for payers and pharmaceutical companies to align on value, speed to market, and/or risk, and are legal contracts between the government and the manufacturer.”

Yes ☐

No ☐

I do not know ☐

If yes, are there peer-reviewed journal articles or reports on the effects of special pricing agreements on access including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL:_____________________________________________________________
If yes, besides the evidence on the effects of the policy, is there any other relevant published information from your country of which you are aware about the special pricing agreements?

Web URL: ____________________________________________________________

If yes, what type of special pricing agreements are implemented in your country? Please check all that apply

Managed entry agreements □
Risk-sharing agreements □
Price volume agreements □
Other □ Please specify: ______________________________________________

I do not know □

7. Are there any mark-up regulations implemented in your country?

Definition: “A mark-up represents the additional charges and costs that are applied to the price of a commodity to cover overhead costs, distribution charges and profits or surplus. In the context of the pharmaceutical supply chain, policies may involve regulation of wholesale and retail mark-ups as well as pharmaceutical remuneration. Mark-up regulation is intended to reduce the variability of prices along the supply and distribution chain through clear pricing rules.”

Yes □

No □

I do not know □

If yes, are there peer-reviewed journal articles or reports on the effects of mark-up regulations on access including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: __________________________

If yes, besides the evidence on the effects of the policy, is there any other relevant published information from your country of which you are aware about the mark-up regulations?

Web URL: __________________________
8. Are there any tax exemptions or tax reductions for pharmaceutical products implemented in your country?

**Definition:** “Tax is a compulsory transfer of money from private individuals, institutions or groups to the government. Tariffs and taxes could present trade barriers, thereby potentially hindering access and market competition. Tax burden (i.e. tax incidence) could also potentially fall disproportionally on the patients, resulting in reduced affordability.”

- Yes □
- No □
- I do not know □

If yes, are there peer-reviewed journal articles or reports on the effects of the tax exemption or tax reduction on access, including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: ____________________________________________

If yes, besides the evidence on the effects of the policy, is there any other relevant published information from your country of which you are aware about tax exemption and tax reduction?

Web URL: ____________________________________________

9. Is pooled procurement implemented in your country?

**Definition:** “Pooled procurement refers to the formal arrangement where financial and non-financial resources are combined across various purchasing authorities to create a single entity for purchasing health products (e.g. medicines) on behalf of the individual purchasing authorities.”

- Yes □
- No □
- I do not know □

If yes, are there peer-reviewed journal articles or reports on the effects of the pooled procurement on access, including availability, affordability and quality of essential
medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: ________________________________

If yes, besides the evidence on the effects of the policy, is there any other relevant published information from your country of which you are aware about the pooled procurement?

Web URL: ________________________________

If yes, which purchasing authorities create a single entity for purchasing health products in the country?

_________________________________________________________________________

10. Are strategies in place to promote generic medicines in your country?

**Definition:** “This policy refers to strategies directed at patients, prescribers or pharmacists to encourage the use of quality-assured generic medicines or similar biological medicines (i.e. biosimilar medicines).”

Yes ☐  
No ☐  
I do not know ☐

If yes, are there peer-reviewed journal articles or reports on the effects of the promotion of generic medicines in your country on access including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: ________________________________

If yes, besides the evidence on the effects of the policy, is there any other relevant published information of which you are aware from your country about the promotion of generic medicines in your country?

Web ________________________________

If yes, which strategies are used to promote generic medicines? Please check all that apply

Mandatory substitution when dispensing ☐
Voluntary substitution when dispensing ☐
Mandatory prescribing by international non-proprietary name (INN) □

Visuals on product package to indicate that it is generic □

Others □ please specify___________________________________

11. **Is medicine product price transparency implemented in your country?**

Definition: “Price transparency refers to the sharing, disclosure and dissemination of information related to prices of pharmaceutical products to relevant parties and the general public to ensure accountability. Full price transparency includes the publication of prices at all price types (e.g. ex-factory prices, pharmacy retail prices), the disclosure of the net transaction prices between the suppliers (e.g. manufacturers, service providers) and the payers/purchasers (governments, consumers).”

**Yes, full price transparency** of disclosure of all price types, the net transaction prices and the payer purchasers □

**Yes, partial price transparency**, one or several of the components mentioned above are disclosed □

**No, none is disclosed** □

**I do not know** □

If yes, are there peer-reviewed journal articles or reports on the effects of medicine product price transparency on access including availability, affordability and quality of essential medicines? Please copy the web URL of the relevant documents. If the document is not available on the web, please email it to the contact details given above.

Web URL: ________________________________

If yes, besides the evidence on the effects of the policy, is there any other relevant published information from your country of which you are aware about medicine product price transparency?

Web __________________________________________________________

If yes, what prices are disclosed? Please check all that apply

Ex-factory prices □

Pharmacy retail prices □
Net transaction prices between manufacturers and service providers

Net transaction prices between government and consumers

I do not know

Is there anything you would like to comment on the issues mentioned above?

_____________________________________________________________
_____________________________________________________________

Thank you very much for your support.
Annex 3

Interview guide

1. Qualitative interview introduction

Length: 45–60 minutes

Opening the interview: Refer to earlier contacts with same person

– Indicate significance and potential benefits of study
– Explain interview process
– Explain publishing process
– Discuss the acknowledgement or option to be co-author of a report
– Acknowledge recording, if any
– Provide an opportunity to ask questions

Primary goal: To see what medicine pricing policies exist in your country and what their impact has been on access, including affordability, availability and quality of essential medicines. We want your opinion as to how well such policy/policies work in your country the way you see it. This is more like a conversation with a focus on your experience, your opinions and what you think or feel about the topics covered

2. Background Information

Overview:

Invite interviewee to briefly tell me about him/herself/themselves: General information about background (mostly about experiences and perspectives on issues surrounding pricing policies in country X)

Role in/as pharmaceutical management/R&D/procurement/distribution/provider/community member/both

Private sector/public sector/NGO/government

Region

3. Are/were you involved in formulating or evaluating pharmaceutical pricing policies?

If yes, in which policy (policies) are/were you involved?

How are/were you involved?
4. We have received the responses to a survey that describes the pricing policies in your country. We have shared the responses with you before this interview. Are there any responses about the presence or absence of pricing policies that you do not agree with? Which one? Why?

5. The results of the survey provide some information on the effects of these policies. However there are still many gaps. So we would like to ask about your views: in what ways do you think the policy/policies have made an impact on

access to medicines generally?

access to specific medicines?

availability of medicines generally?

availability of specific medicines?

affordability of medicines generally?

affordability of specific medicines

quality of medicines generally?

quality of specific medicines?

6a. What is your opinion as to the general impact of the medicines pricing policy on the public sector?

6b. What is your opinion as to the general impact of the medicines pricing policy on the private sector?
comes closest to how you feel/ think? • If you had to pick one answer, what would you choose?
FOR COMPLETENESS: • Anything else? • Tell me more. OTHER PROBING TECHNIQUES: • Repeat the question • Echo their response • Pause a second

7. Do you think that there are any unintended effects of the pricing policies?

7a. If yes, on which aspects of the pharmaceutical/health-care system?

FOR CLARITY/SPECIFICITY • Can you be more specific? • Can you tell me more about that? • What is your best estimate? • What do you think? • Which would be closer? • Which answer comes closest to how you feel/ think? • If you had to pick one answer, what would you choose?
FOR COMPLETENESS: • Anything else? • Tell me more. OTHER PROBING TECHNIQUES: • Repeat the question • Echo their response • Pause a second

8a. In your opinion, what conditions or barriers do you think exist that prevent the policy from having greater impact in your country?

8b. In your opinion, what factors or conditions exist that are helping to make the policy have an impact in your country?

FOR CLARITY/SPECIFICITY • Can you be more specific? • Can you tell me more about that? • What is your best estimate? • What do you think? • Which would be closer? • Which answer comes closest to how you feel/ think? • If you had to pick one answer, what would you choose?
FOR COMPLETENESS: • Anything else? • Tell me more. OTHER PROBING TECHNIQUES: • Repeat the question • Echo their response • Pause a second

9. Are you aware of any current evaluations of the impact of pricing policy in your country?

9a. If so, who is doing such evaluation(s)?

9b. Are these evaluations publicly available?

FOR CLARITY/SPECIFICITY • Can you be more specific? • Can you tell me more about that? • What is your best estimate? • What do you think? • Which would be closer? • Which answer comes closest to how you feel/ think? • If you had to pick one answer, what would you choose?
FOR COMPLETENESS: • Anything else? • Tell me more. OTHER PROBING TECHNIQUES: • Repeat the question • Echo their response • Pause a second

10. Closing the Interview

• Express appreciation – indicate how useful and productive the session has been

• Confirm the next steps
• Leave professional contact information

• Snowball sample?? Who do you recommend us to talk to in order to find out more on the evaluation of pricing policies in your country?

Thank you very much

11. Follow-up

Send notes back to participant for comments with a “thank you” note.
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