ACCESS TO MEDICAL PRODUCTS IN THE SOUTH-EAST ASIA REGION

2023
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The WHO South-East Asia Region is committed to ensuring access for all to safe, effective, affordable and quality medical products, in alignment with the 2018 Delhi Declaration on Improving Access to Essential Medical Products, as well as the Region’s Flagship Priority on achieving universal health coverage (UHC). Access to essential medicines directly translates into improved health outcomes, reduced mortality and morbidity, and an enhanced quality of life. It addresses broader health disparities, promotes health equity, and serves as a vital means to reduce socioeconomic and geographical inequalities in care.

To monitor access to safe, effective, affordable and quality medicines in the Region, this bi-annual progress report documents progress on strengthening pharmaceutical systems across nine key indicators: spending on health and pharmaceuticals, pharmaceutical legislation, regulation, national medicines policies, rational selection, purchasing, pricing policies, rational use and antimicrobial resistance, and pharmacy workforce. In addition, the report contains detailed historical information on country policies in each of these areas, highlighting the Region’s multidecade trajectory. The report finds that gaps and challenges remain, especially on out-of-pocket expenditure on medicines, which is above 50% in five countries of the Region.

The report concludes by outlining a clear and actionable way forward, with a focus on five priorities: first, allocating resources effectively based on evidence; second, improving data collection and information for decision-making; third, enhancing rational selection and adherence to guidelines and essential lists; fourth, strengthening regulation and supply chain resilience; and fifth, fostering the active participation of pharmacists and related professionals in strengthening medical products management.

I urge all stakeholders to appropriately leverage this report for a South-East Asia Region in which everyone, everywhere in the Region can access safe, effective, affordable and quality medical products, leaving no one behind.

Dr Poonam Khetrapal Singh
Regional Director
WHO South-East Asia
## Acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMC</td>
<td>antimicrobial consumption</td>
</tr>
<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
</tr>
<tr>
<td>AWaRe</td>
<td>Access, Watch, Reserve classification</td>
</tr>
<tr>
<td>CHE</td>
<td>current health expenditure</td>
</tr>
<tr>
<td>GLASS</td>
<td>Global Antimicrobial resistance Surveillance System</td>
</tr>
<tr>
<td>HTA</td>
<td>health technology assessment</td>
</tr>
<tr>
<td>INN</td>
<td>International Nonproprietary Name</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>NEML</td>
<td>national essential medicines list</td>
</tr>
<tr>
<td>NHA</td>
<td>national health accounts</td>
</tr>
<tr>
<td>OOPE</td>
<td>out-of-pocket expenditure</td>
</tr>
<tr>
<td>SHI</td>
<td>social health insurance</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organization</td>
</tr>
</tbody>
</table>
PART I

Access to medical products
Improving access to essential medicines is important, with far-reaching implications for individuals and societies at large. At its core, this endeavour represents a fundamental human right – a commitment to ensure that every person, regardless of their background or circumstances, can obtain the medications they need to maintain and restore their health.

Access to essential medicines directly translates into improved health outcomes, reduced mortality and morbidity, and an enhanced quality of life. It also addresses broader health disparities and promotes health equity. It serves as a vital means to reduce socioeconomic and geographical inequalities in health care. From an economic standpoint, a healthier population is more productive and incurs fewer health-care-related costs, alleviating economic burdens on individuals and governments alike.

At the Seventy-first session of the WHO Regional Committee in September 2018, intercountry technical consultations following Decision SEA/RC70(3) that was adopted by the Seventieth session of the Regional Committee led to the adoption of the ministerial “Delhi Declaration on Improving Access to Essential Medical Products in the Region and Beyond”. The Delhi Declaration was significant as it provided a concrete set of actions for Member States and reinforced regional collaboration in procurement, regulation and price transparency. Since then, progress reports have been shared with Member States every 2 years.

Pharmaceutical systems are the complex networks and structures in place to ensure the effective and efficient delivery of pharmaceutical products and services within a health-care system. These systems encompass the entire lifecycle of pharmaceuticals, from research and development to regulation, policies, procurement, distribution, prescribing, dispensing, pharmaceutical workforce and rational use.

The Region has the opportunity to harness its existing strengths within its pharmaceutical systems to enhance access to essential medical products. These encompass the following:

• The Region’s strong pharmaceutical legislative environment forms a solid foundation for the oversight and governance of the pharmaceutical sector, ensuring safety and quality of medical products, and promoting transparent and ethical practices. The historical leadership of some Member States and their continued commitment to legal evolution position the Region well in addressing the evolving needs of health care and pharmaceuticals.

• The regulatory framework for medical products is evolving, and responsive to specific country contexts. Licensing provisions and the inclusion of various entities in the regulatory process demonstrate commitment. A focus on essential medicines and the regular updating of the national essential medicines list (NEML) demonstrates a strong commitment to improving access to lifesaving medical products, efficient purchasing and promoting rational use.
However, critical challenges and barriers persist on the path to improved access, including:

- the relatively high out-of-pocket expenditure (OOPE) on health and medicines. This financial burden on individuals and households can pose barriers to accessing essential health-care services and life-saving medicines. Despite improvements in the availability of essential medical products, spending on medicines accounts for the major share of out-of-pocket (OOP) payment in several countries of the Region;

- availability of key pharmacy workforce. This plays a critical role in enhancing medication safety, rational use and improving health outcomes. While some countries in the Region have a robust presence of pharmacists, others face challenges, with a limited pharmacy workforce. These variations necessitate targeted efforts to bolster health-care resources and optimize good pharmacy practices.

Strengthening pharmaceutical systems is pivotal to improving access to medicines. Robust pharmaceutical systems in the Region are necessary to provide a well-regulated and transparent framework for the procurement, distribution and management of medicines. Measures to reduce OOPE through pricing policies and national health insurance schemes make medicines more affordable, addressing a critical barrier to access. Hence, a well-functioning pharmaceutical system is the cornerstone of equitable access to medicines.
While the availability of comprehensive data is limited, estimates suggest that India has the most substantial private pharmaceutical market in the Region, with a market size of US$ 23 billion. Thailand and Bangladesh follow, with respective market sizes of US$ 7.9 billion and US$ 2.1 billion. Sri Lanka, in comparison, maintains a pharmaceutical market size of US$ 599.9 million.

The South-East Asia Region also comprises Member States with significant pharmaceutical manufacturing capacity, with India leading with over 3000 manufacturers. Bangladesh and Indonesia, while smaller in scale, exhibit a similar number of pharmaceutical manufacturers. Following closely are Thailand and Nepal. On the other hand, DPR Korea, Myanmar and Sri Lanka house a limited number of local pharmaceutical manufacturers. Notably, Bhutan, Maldives and Timor-Leste do not engage in local production of allopathic medicines and rely solely on the importation of pharmaceutical products.

Table 1. Pharmaceuticals manufacturing capacities among countries in the South-East Asia Region (2023)

<table>
<thead>
<tr>
<th>Large industry (&gt;100 manufacturers)</th>
<th>Small industry (10–50 manufacturers)</th>
<th>No manufacturing capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh(^3)</td>
<td>DPR Korea(^9)</td>
<td>Bhutan(^{12})</td>
</tr>
<tr>
<td>India(^5)</td>
<td>Myanmar(^{10})</td>
<td>Maldives(^{13})</td>
</tr>
<tr>
<td>Indonesia(^6)</td>
<td>Sri Lanka(^{11})</td>
<td>Timor-Leste(^{14t})</td>
</tr>
<tr>
<td>Nepal(^7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thailand(^8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Countries with higher per capita gross domestic product (GDP) tend to exhibit higher levels of health spending per capita with a few exceptions (Fig. 1). In terms of per capita expenditure, Maldives leads with the highest current health expenditure (CHE) at US$ 826, followed by Thailand at US$ 305. Sri Lanka spends US$ 151 per capita on health, while Bhutan and Indonesia spend US$ 134 and US$ 133 per capita, respectively. Timor-Leste’s per capita health expenditure stands at US$ 121. In contrast, India and Bangladesh spend US$ 57 and US$ 51 per capita on health, respectively. Myanmar and Nepal, despite having lower per capita GDP than India and Bangladesh, spend US$ 72 and US$ 58 per capita, respectively. These variations underscore the complex relationship between economic growth and health-care investment.

Fig. 1. Per capita CHE in South-East Asia Region
CHE as a percentage of GDP varies significantly and ranges from some 3% each for Bangladesh, India and Indonesia to 11% for Maldives. OOPE as a percentage of CHE is notably higher for countries with lower per capita health expenditure. Myanmar has the highest OOPE, accounting for a substantial 78% of its CHE. The country spends some 5% of its GDP on health. Bangladesh has the second highest OOPE representing 73% of its CHE, while Nepal stands at 54% while spending about 5% of its GDP on health. India and Sri Lanka have 52% and 47% OOPE as a percentage of CHE, respectively. Indonesia (31%), Maldives (17%), Bhutan (15%), Thailand (11%) and Timor-Leste (7%) exhibit lower OOPE, as depicted in Fig. 2. These figures underscore the financial burden placed on individuals in countries with limited per capita health expenditure, emphasizing the need for measures to reduce OOP health costs and enhance affordability.

![Fig. 2. CHE as a percentage of GDP and OOPE as a percentage of CHE in the South-East Asia Region](image-url)
The high level of OOPE spending on health in many countries of the South-East Asia Region is a matter of concern. Despite improvements in the availability of essential medical products, spending on medicines accounts for the major share of OOP payment in several countries of the Region. The proportion of pharmaceutical expenditure in relation to CHE is noticeably higher in countries with lower per capita CHE, as illustrated in Fig. 3. The highest share of pharmaceuticals in CHE was in Bangladesh (47%), followed by Nepal (38%), India (35%), Myanmar (30%), Maldives (30%), Bhutan and Indonesia (26%), Thailand (20%) and Timor-Leste (2%).

Fig. 3. Pharmaceutical expenditure as a percentage of CHE in South-East Asia Region

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1 Disclaimer: Please note that the estimates of total pharmaceutical expenditure (TPE) as a percentage of CHE may not be strictly comparable across countries for which they have been reported due to different methodologies. The Indonesian figure taken from its NHA is reported as a percentage of total health expenditure (THE) instead of CHE.
The share of OOPE on pharmaceuticals was the highest in Timor-Leste (82%), followed by Bhutan (76%), Nepal (66%), Bangladesh (65%), Maldives (62%), Myanmar (44%), India (42%), and Sri Lanka (34%) (Fig. 4).

Fig. 4. Share of OOPE on medicines in the South-East Asia Region
In terms of government expenditure on pharmaceuticals, Maldives[^13] spent US$ 185 per person on pharmaceuticals. Myanmar[^25] follows with a substantially lower per capita government spending amounting to US$ 9. Sri Lanka[^26] and Timor-Leste[^14] allocate US$ 8 each per capita for pharmaceuticals. In contrast, the Government of Nepal[^17] spent US$ 3 per capita on pharmaceuticals as depicted in Fig. 5. These figures reflect the variation in government investment in health care and pharmaceuticals across these countries, emphasizing differences in health-care priorities and resource allocation.

**Fig. 5. Per capita government pharmaceutical expenditure in the South-East Asia Region (in US$)**

![Graph showing per capita government pharmaceutical expenditure in the South-East Asia Region (in US$)](image-url)
Pharmaceutical legislation plays a pivotal role in establishing a robust regulatory framework to ensure the safety, efficacy and quality of medical products. These laws govern various aspects of the pharmaceutical industry, including research and development, manufacturing, distribution and marketing, holding pharmaceutical companies accountable to rigorous standards of compliance. Moreover, pharmaceutical legislation serves as a crucial safeguard against the proliferation of substandard and falsified products, thus safeguarding public health. Additionally, these laws promote transparency, ethical conduct, and fair competition within the industry, bolstering trust and confidence among both the general public and health-care professionals.

Furthermore, historical milestones underscore the commitment of Member States in the South-East Asia Region to pharmaceutical regulation. Bangladesh and India were trailblazers in this regard, developing their respective drugs acts in 1940. Subsequently, Thailand enacted its initial Drugs Act in 1976, while Nepal and Sri Lanka followed suit with their drugs acts in 1978 and 1980, respectively. Myanmar established its National Drug Law in 1992, and Maldives introduced its Medicines Act in 1994. Bhutan and Timor-Leste passed the Bhutanese Medicines Act in 2003 and the Law on Pharmaceutical Activities in 2004, respectively. Notably, DPR Korea reinvigorated its national legislation in 2016, showcasing a collective commitment to continuously adapt and enhance pharmaceutical legislation to address emerging challenges in the sector. All Member States have subsequently enacted multiple laws and acts to strengthen their pharmaceutical regulatory frameworks (see Table 2).

Table 2. A historical overview of pharmaceutical legislation among countries in the South-East Asia Region (1940–2022)

<table>
<thead>
<tr>
<th>Countries</th>
<th>Pharmaceutical legislation(s)</th>
<th>Year(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Drugs Act; Bengali Drug Rule; Drug (Control) Ordinance</td>
<td>1940; 1946; 1982</td>
</tr>
<tr>
<td>Bhutan</td>
<td>The Medicines Act of the Kingdom of Bhutan; Bhutan Medicines Rules and Regulation</td>
<td>2003; 2012; 2019</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>National legislation, Rule and Regulations for Narcotic Control (revived); National legislation, Rule and Regulations for Drug Management</td>
<td>2016 (revived); 2018; 2019</td>
</tr>
<tr>
<td>Countries</td>
<td>Pharmaceutical legislation(s)</td>
<td>Year(s)</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>India</td>
<td>Drugs and Cosmetics Act; Drugs and Cosmetics Rules; Pharmacy Act; Drugs and Magic Remedies Act; Essential Commodities Act; Medicinal &amp; Toilet Preparations Act; Drugs Order; Indian Patent Act; Narcotic Drugs and Psychotropic Substances Act; New Drugs, Medical Devices and Cosmetics Bill (draft)</td>
<td>1940; 1945; 1948; 1954; 1955; 1956; 1962; 1970; 1985; 2022</td>
</tr>
<tr>
<td>Indonesia</td>
<td>NEML, Ministry of Health Decree HK.01.07/Menkes/6477/2021</td>
<td>2021</td>
</tr>
<tr>
<td>Maldives</td>
<td>Medicines Act</td>
<td>1994</td>
</tr>
<tr>
<td>Nepal</td>
<td>Drugs Act; Drug Registration Regulation; Interrogation and Inspection Regulation; Codes on Drug Manufacturing; Drug Standard Regulation; Codes on Sales and Distribution; Health Technology Product and Equipment Directive</td>
<td>1978; 1981; 1983; 1984 (updated 2015); 1986; 2014; 2017</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Regulations of Cosmetics, Devices and Drugs Act No. 27; National Medicines Regulatory Authority Act, No. 5</td>
<td>1980; 2015</td>
</tr>
<tr>
<td>Thailand</td>
<td>Drug Act of B.E. 2510; Drug Act of (No.2) B.E. 2518; Drug Act of No.3 2522 and Narcotic Act B.E 2522; Drug Act of (No.4) B.E. 2528 and Narcotic Act (No.2) B.E 2528; Drug Act of (No.5) B.E. 2530 and Narcotic Act (No.3) B.E. 2530; Narcotic Act (No.5) B.E.2545; Psychotropic Substance Act,B.E. 2559; Narcotic Act (No.6) B.E. 2560; Drug Act (No.6), B.E. 2562,Narcotic Act (No.7) B.E.2562 and Herbal Product Act, BE 2562</td>
<td>1967; 1975; 1979; 1985; 1987; 2002; 2016; 2017; 2019</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>Decree Law No. 12/2004, Pharmaceutical Activities</td>
<td>2004</td>
</tr>
</tbody>
</table>
In the Region, all countries are members of the World Trade Organization (WTO), with the exceptions being Bhutan, DPR Korea and Timor-Leste. Notably, Bangladesh, Myanmar and Nepal maintain exemptions from enforcing and granting patents related to pharmaceuticals, in alignment with the provisions outlined in the Agreement on Trade-Related Intellectual Property Rights (TRIPS). In contrast, India, Indonesia and Thailand have aligned their intellectual property legislations with the TRIPS Agreement, incorporating its provisions into their national laws. Furthermore, these countries have also exercised certain flexibilities allowed under the TRIPS Agreement (Table 3).

<table>
<thead>
<tr>
<th>Country</th>
<th>TRIPS flexibilities incorporated into the laws$</th>
<th>TRIPS flexibilities utilized$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh*</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Bhutan**</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>DPR Korea**</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>India</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Maldives</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Myanmar*</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Nepal*</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Sri Lanka*</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Thailand</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Timor-Leste**</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

* Exempted from enforcing TRIPS
** Currently not members of WTO

Table 3. Incorporation and utilization of TRIPS flexibilities among countries in the South-East Asia Region (2023)
In the Region, all Member States regulate various categories of medical products, including medicines, biologicals, medical devices and traditional medicines, with a notable exception being Bhutan, which currently lacks specific provisions for the regulation of medical devices.

Among countries in the Region, Bangladesh, Bhutan, India, Indonesia, Myanmar, Nepal and Thailand have comprehensive provisions in place for the licensing of entities engaged in the pharmaceutical sector. These provisions encompass licensing requirements for pharmaceutical manufacturers, importers, exporters, wholesalers, distributors and retailers, ensuring robust oversight across the entire pharmaceutical supply chain.

Sri Lanka also maintains licensing provisions for all entities involved in the pharmaceutical sector, except for exporters. Timor-Leste, due to the absence of domestic pharmaceutical manufacturing, does not have specific provisions for licensing manufacturers or exporters.

Maldives, on the other hand, has tailored licensing regulations that exclusively apply to importers and retailers within its regulatory system, reflecting the country’s unique import-dependent health-care infrastructure (Table 4). These varied approaches to licensing demonstrate a commitment to regulating the pharmaceutical sector while adapting licensing to each country’s specific needs and circumstances.
Table 4. The status of the licensing of establishments[^22] among countries of the South-East Asia Region (2023)

<table>
<thead>
<tr>
<th>Country</th>
<th>Manufacturers</th>
<th>Importers</th>
<th>Exporters</th>
<th>Wholesalers</th>
<th>Distributors</th>
<th>Retailers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>DPR Korea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>India[^28]</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Maldives</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Myanmar[^29,^30]</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Nepal</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sri Lanka[^31]</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Thailand</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Every Member State within the Region maintains at least one national quality control laboratory, underscoring the collective commitment to ensuring the quality and safety of medicines. Notably, Bangladesh, India, Indonesia, Myanmar and Thailand have achieved ISO certification for their national quality control laboratories.

It is worth mentioning that, with the exception of Myanmar, all countries with ISO-certified national laboratories have additionally obtained the WHO prequalification for their laboratories. This dual certification signifies a robust commitment to upholding stringent global quality standards in the evaluation and monitoring of medicines (Table 5). This alignment with international quality benchmarks reinforces the Region's capacity to assure the quality and safety of medicines for its populations.
Table 5. The status of certification of national medicines quality control laboratories among countries in the South-East Asia Region (2023)

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of laboratories</th>
<th>ISO 17025 certified</th>
<th>WHO prequalified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>2</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Bhutan</td>
<td>1</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>1</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>India*</td>
<td>7</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indonesia**</td>
<td>34</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Maldives*</td>
<td>1</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Myanmar*</td>
<td>3</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Nepal*</td>
<td>1</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sri Lanka*</td>
<td>1</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Thailand</td>
<td>319</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Timor-Leste**</td>
<td>1</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

* 5 central drug testing laboratories; 2 regional drug testing laboratories
** 1 national quality control laboratory; 33 provincial laboratories

All Member States have provisions for cancellation of licenses of pharmaceutical establishments and market authorization of products, as well as for initiating product recalls and withdrawals.
National medicines policies serve as the foundational framework for a country's strategic approach to organizing, financing and regulating the pharmaceutical sector, with the overarching goal of ensuring equitable access to high-quality medicines and health products that align with health care needs. To maintain relevance and effectiveness, WHO recommends that these national policies undergo updates every five years.

Thailand led the way in the Region as the first Member State to establish a national medicines policy back in 1981. Thailand has since demonstrated its commitment by actively updating its policy, with the latest iteration currently in the drafting phase for the period 2023–2027. Following suit, Bangladesh formulated its policy in 1982 and subsequently revised it in 2005, followed by another update in 2016.

Sri Lanka and Timor-Leste have recently embarked on drafting new policies to align with evolving health needs, while Maldives is currently engaged in the process of updating its existing policy (Table 6). These initiatives underscore the Region's dedication to adapting and optimizing national medicines policies to meet the dynamic health-care landscape and to ensure equitable access to essential medical products.

### Table 6. National medicines policies among countries in the South-East Asia Region (1982–2023)

<table>
<thead>
<tr>
<th>Countries</th>
<th>National medicines policy available</th>
<th>Year(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Yes</td>
<td>1982; 2005; 2016</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Yes</td>
<td>2007</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>Yes</td>
<td>2019</td>
</tr>
<tr>
<td>India</td>
<td>Yes</td>
<td>2002</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>2006</td>
</tr>
<tr>
<td>Maldives</td>
<td>Yes</td>
<td>2007; 2018–2023</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Yes</td>
<td>2019</td>
</tr>
<tr>
<td>Nepal</td>
<td>Yes</td>
<td>1995; 2007</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Yes</td>
<td>2006; 2020 (draft)</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>Yes</td>
<td>2018, 2023 (draft)</td>
</tr>
</tbody>
</table>
The concept of essential medicines is a long-established approach to enhancing access to critical lifesaving medicines. The inaugural edition of WHO’s Model List of Essential Medicines was introduced in 1977 and, since then, WHO has updated this list every two years. In parallel, WHO strongly advocates for Member States to regularly update their national essential medicines lists (NEML) in alignment with evolving health needs.

These lists serve a dual purpose, aiming to optimize the efficiency of public sector procurement and promote the rational use of medicines. The criteria guiding the selection of medicines for inclusion in these lists encompass prevalent health conditions, evidence of cost–effectiveness, and affordability for government health-care systems or health insurance schemes.

Notably, the majority of Member States have developed multiple editions of their NEMLs, reflecting their commitment to keeping these lists current and aligned with emerging health-care priorities. Myanmar took pioneering steps in the Region by establishing its NEML in 1978, followed by Indonesia in 1980, Thailand in 1981, Sri Lanka in 1985, and Nepal in 1986. Bhutan and India followed suit by formulating their initial NEMLs in 1994 and 1996, respectively, with subsequent entries by Bangladesh in 2008 and Maldives in 2009.

Thailand distinguishes itself by consistently updating its NEML with revisions every few years, signifying a proactive approach to maintaining a relevant list. Furthermore, it is worth noting that the most recent edition of the NEML for Maldives was developed in 2023 (Table 7). These efforts collectively reflect the Region’s unwavering dedication to ensuring access to essential medicines that align with evolving health-care landscapes.
Table 7. National essential medicines lists among countries in the South-East Asia Region

<table>
<thead>
<tr>
<th>Country</th>
<th>First edition</th>
<th>Latest edition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>2008</td>
<td>2016</td>
</tr>
<tr>
<td>Bhutan</td>
<td>1994</td>
<td>2021</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>No data</td>
<td>2019</td>
</tr>
<tr>
<td>India</td>
<td>1996</td>
<td>2022</td>
</tr>
<tr>
<td>Indonesia</td>
<td>1980</td>
<td>2021</td>
</tr>
<tr>
<td>Maldives</td>
<td>2009</td>
<td>2023</td>
</tr>
<tr>
<td>Myanmar</td>
<td>1978</td>
<td>2016</td>
</tr>
<tr>
<td>Nepal</td>
<td>1986</td>
<td>2021</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>1985</td>
<td>2013/2014</td>
</tr>
<tr>
<td>Thailand</td>
<td>1981</td>
<td>2022</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>No data</td>
<td>2015</td>
</tr>
</tbody>
</table>

Health technology assessment (HTA) plays a pivotal role in the selection of essential medicines in Bhutan, Indonesia and Thailand. India, Indonesia and Thailand have taken a significant step by institutionalizing HTA through dedicated agencies although India does not yet use HTA for essential medicines selection.

The NEML of Bhutan, DPR Korea, Indonesia, Maldives, Nepal, Thailand and Timor-Leste have successfully incorporated the WHO AWaRe (Access, Watch, Reserve) classification, reflecting a commitment to aligning their essential medicines lists with global standards.

With the exception of Myanmar and Nepal, all countries have listed their medicines by levels of care. Additionally, several Member States (Bangladesh, Bhutan, DPR Korea, Indonesia, Myanmar, Nepal, Sri Lanka, and Thailand) have inclusively integrated traditional medicines into their NEMLs. India stands out by maintaining a separate list of essential traditional medicines.

Furthermore, almost all Member States of the Region, with the exception of Maldives and Timor-Leste, have established a national formulary to guide health-care professionals in their prescribing practices.

Bhutan and India have extended their efforts to developing national essential diagnostics lists, while Nepal is currently in the process of drafting a similar list. In contrast, Maldives and Timor-Leste are actively engaged in the initial stages of creating their first edition of the essential diagnostics list (Table 8).
Table 8. Key attributes of the National Essential Medicines List and National Essential Diagnostic List (2023) among countries in the South-East Asia Region

<table>
<thead>
<tr>
<th>Country</th>
<th>HTA used in the selection process</th>
<th>NEML incorporated the AWaRE list</th>
<th>Medicines listed by level of care</th>
<th>Traditional medicines included</th>
<th>National formulary</th>
<th>National Essential Diagnostics List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes(^{3,35})</td>
<td>No</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes(^{12})</td>
<td>Yes(^{12})</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes(^{9})</td>
<td>No</td>
</tr>
<tr>
<td>India</td>
<td>No</td>
<td>No(^{36})</td>
<td>Yes</td>
<td>Yes(^{*,37})</td>
<td>Yes(^{38})</td>
<td>Yes(^{39})</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes(^{32})</td>
<td>No</td>
</tr>
<tr>
<td>Maldives</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No(^{13})</td>
<td>(under development)(^{13})</td>
</tr>
<tr>
<td>Myanmar</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes(^{40})</td>
<td>No</td>
</tr>
<tr>
<td>Nepal</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes(^{41})</td>
<td>Yes (in draft)(^{17})</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes(^{42})</td>
<td>No</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes(^{4})</td>
<td>No</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No(^{9})</td>
<td>(under development)(^{14})</td>
</tr>
</tbody>
</table>

Note: *separate list
Essential medicines are financed by national governments either through public procurement, social health insurance (SHI) schemes or both. Public procurement involves the government directly purchasing medicines in bulk, often through competitive bidding, negotiation or centralized purchasing agencies. This approach can lead to cost savings, as it leverages the government's monopsony power. On the other hand, SHI schemes use contributions from both individuals and employers to establish prepaid funds for purchasing medicines and health-care services. These schemes help beneficiaries to access a predetermined list of essential medicines.

In the Region, all Member States have public procurement functions with varying types of SHI schemes for medicines.

Specifically, Bangladesh, India, Myanmar and Thailand have implemented systems that incorporate both centralized and decentralized procurement strategies for essential medicines. Conversely, Bhutan, Maldives, Myanmar, Sri Lanka and Timor-Leste rely on centralized systems for public procurement. Indonesia, in contrast, follows a decentralized approach to procurement. Additionally, there is considerable variation in the frequency of tender processes across these Member States.

To enhance efficiency and accountability, several countries – Bangladesh, Bhutan, India, Maldives, Nepal, Sri Lanka, Thailand and Timor-Leste – have deployed a logistics management information system (LMIS) to streamline the management of medical products supply chains.
<table>
<thead>
<tr>
<th>Country</th>
<th>Procurement</th>
<th>Centralized/ decentralized</th>
<th>Agency responsible for procurement</th>
<th>LMIS</th>
<th>Frequency of tender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Yes</td>
<td>A mix of centralized and decentralized&lt;sup&gt;6&lt;/sup&gt;</td>
<td>Essential Drugs Company Ltd (EDCL), Central Medical Stores Depot (CMSD) &amp; Directorate General of Health Services (DGHS)&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Annual or biannual&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Yes</td>
<td>Centralized&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Department of Medical Supplies and Health Infrastructure (DoMSHI)&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;12&lt;/sup&gt;</td>
<td>Annual&lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>Yes</td>
<td>Centralized&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Medicines Management Department, Ministry of Public Health&lt;sup&gt;9&lt;/sup&gt;</td>
<td>No data</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>Yes</td>
<td>A mix of centralized and decentralized&lt;sup&gt;9&lt;/sup&gt;</td>
<td>State procurement agencies and central procurement agency&lt;sup&gt;44,45&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;46&lt;/sup&gt;</td>
<td>Annual&lt;sup&gt;24&lt;/sup&gt;</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>Decentralized&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Procurement carried out by facilities and provincial government, regulated by MoH&lt;sup&gt;32&lt;/sup&gt;</td>
<td>Not fully implemented&lt;sup&gt;32&lt;/sup&gt;</td>
<td>Ad hoc&lt;sup&gt;32&lt;/sup&gt;</td>
</tr>
<tr>
<td>Maldives</td>
<td>Yes</td>
<td>Centralized&lt;sup&gt;13&lt;/sup&gt;</td>
<td>State Trading Organization (for public sector pharmacies); Ministry of Hospitals (for government health facilities)&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Biannual&lt;sup&gt;13&lt;/sup&gt;</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Yes</td>
<td>Centralized&lt;sup&gt;47&lt;/sup&gt;</td>
<td>Procurement and Distribution Division, Department of Public Health, Department of Medical Services&lt;sup&gt;30&lt;/sup&gt;</td>
<td>No&lt;sup&gt;30&lt;/sup&gt;</td>
<td>Ad hoc&lt;sup&gt;30&lt;/sup&gt;</td>
</tr>
<tr>
<td>Country</td>
<td>Procurement</td>
<td>Centralized/decentralized</td>
<td>Agency responsible for procurement</td>
<td>LMIS</td>
<td>Frequency of tender</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
<td>----------------------------</td>
<td>----------------------------------------------------------------------------------------------------</td>
<td>------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Nepal</td>
<td>Yes</td>
<td>A mix of centralized and decentralized&lt;sup&gt;9&lt;/sup&gt;</td>
<td>At federal level: Logistic Management Section, Management Division, Department of Health Service; Federal level Hospital; At province level: Province Health Logistics Management Centre; At local level: Local level body, Basic Hospital&lt;sup&gt;17&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;17&lt;/sup&gt;</td>
<td>Annual&lt;sup&gt;17&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Yes</td>
<td>Centralized&lt;sup&gt;4&lt;/sup&gt;</td>
<td>State Pharmaceutical Corporation (SPC)&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Annual plus emergency tenders, if necessary&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>Thailand</td>
<td>Yes</td>
<td>A mix of centralized and decentralized&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Decentralized – each hospital; Centralized – National Health Security Office (NHSO), Social Security Office (SSO), Department of Disease Control&lt;sup&gt;18&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Ad hoc&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>Yes</td>
<td>Centralized&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Central Medical Stores – SAMES I.P&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;14&lt;/sup&gt;</td>
<td>Annual plus emergency tenders, if necessary&lt;sup&gt;14&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Among Member States of the Region, Bangladesh, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka and Thailand have implemented SHI schemes, each with distinct levels of coverage (Table 10). Both India and Thailand feature multiple SHI schemes tailored to specific population segments.

Remarkably, Maldives and Thailand have extended SHI coverage to encompass their entire populations, demonstrating a comprehensive approach to health-care access. Thailand further distinguishes itself by covering all medicines listed in the NEML, underscoring its commitment to ensuring broad access to essential medications. Additionally, it is noteworthy that Maldives boasts the highest number of medicines included in its insurance scheme, further enhancing the comprehensiveness of health-care coverage for its citizens.
Table 10. Social health insurance (SHI) schemes among countries of the WHO South-East Asia Region (2023)

<table>
<thead>
<tr>
<th>Country</th>
<th>Existence of the SHI scheme</th>
<th>Name</th>
<th>Population coverage</th>
<th>Medical products covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh3</td>
<td>Yes</td>
<td>Shasthyo Surokkha Karmasuchi (SSK) (pilot since 2016)</td>
<td>Population below the poverty line in 7 districts</td>
<td>No data</td>
</tr>
<tr>
<td>Bhutan</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPR Korea</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>India49</td>
<td>Yes</td>
<td>Ayushman Bharat – Pradhan Mantri Arogya Yojana (PM-JAY) and other state health insurance schemes</td>
<td>500 million beneficiaries under PM-JAY</td>
<td>All medicines and medical consumables used for inpatient care</td>
</tr>
<tr>
<td>Indonesia32,50</td>
<td>Yes</td>
<td>Jaminan Kesehatan Nasional (JKN)</td>
<td>91.5% of the population</td>
<td>623 APIs and 1059 SKUs</td>
</tr>
<tr>
<td>Maldives33,51</td>
<td>Yes</td>
<td>Aasandha</td>
<td>Entire population</td>
<td>3428 products</td>
</tr>
<tr>
<td>Myanmar23</td>
<td>Yes</td>
<td>Social Security Service</td>
<td>706 750 employees (government and private)</td>
<td>No data</td>
</tr>
<tr>
<td>Nepal52,53</td>
<td>Yes</td>
<td>National Health Insurance Program (NHIP)</td>
<td>15.19% of the population</td>
<td>1133</td>
</tr>
<tr>
<td>Sri Lanka4,54</td>
<td>Yes</td>
<td>Agrahara</td>
<td>13% of the total population (only civil servants and their families)</td>
<td>None</td>
</tr>
<tr>
<td>Thailand2</td>
<td>Yes</td>
<td>Universal Coverage Scheme (UCS); 2. Social Security Scheme (SSS); 3. Civil Servant Medical Benefit Scheme (CSMBS)</td>
<td>UCS: 71%; SSS: 19%; CSMBS: 10%</td>
<td>All products included in NEML</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
While lowering medicines prices alone is unlikely to be sufficient to increase financial protection or reduce OOPE, it decreases the economic burden on patients and increases value for money for purchasing organizations as prices are a significant barrier to access.

To improve the affordability of medicines, Member States of the Region employ at least one or several sets of measures to limit the price of medicines in the market to control pharmaceutical expenditure (Table 11).

The most widely used pricing policy is tendering. Member States use international and/or local competitive bidding through manufacturers and wholesalers, depending on factors such as centralized/decentralized procurement system, local production capacity and volume requirements. Almost all Member States promote the use of generic medicines through a variety of strategies. The most common is mandatory prescription by International Nonproprietary Name (INN) and either voluntary or mandatory generic substitution.

Some policies such as value-based pricing and price negotiation or special price agreements are used in only a few countries as these policies require technical capacity and continuous investment.
Table 11. Summary of pharmaceutical pricing policies among countries of the WHO South-East Asia Region (2022)

<table>
<thead>
<tr>
<th>Bangladesh</th>
<th>Bhutan</th>
<th>DPR Korea</th>
<th>India</th>
<th>Indonesia</th>
<th>Maldives</th>
<th>Myanmar</th>
<th>Nepal</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Timor-Leste</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External reference</strong></td>
<td>✓</td>
<td>(✓) ²</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>(✓) ²</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Internal reference</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Value-based pricing</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Mark-up regulations</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Price transparency</strong></td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
<td>✓ (Retail)</td>
</tr>
<tr>
<td><strong>Tendering</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Negotiation/Special price arrangements</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Generic medicines</strong></td>
<td>✓ (MS, MPINN, Visual)</td>
<td>✓ (MPINN)</td>
<td>✓ (Visual)</td>
<td>✓ (MPINN)</td>
<td>✓ (VS)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Pooled procurement</strong></td>
<td>✓ (MS, MPINN, Visual)</td>
<td>(✓) ³</td>
<td>✓ (Visual)</td>
<td>✓ (MPINN)</td>
<td>✓ (VS)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Cost-plus pricing</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Tax exemptions</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

¹ FP: ex-factory price; MEA: Managed Entry Agreement; MPINN: mandatory prescription by International Nonproprietary Names (INN); MRP: maximum retail price; MS: mandatory substitution; PVA: price–volume agreement; RSA: risk-sharing agreement; retail price: price transparency regarding the retail price as it is displayed in the product; visual = visuals on the product package to indicate that it is generic; VS = voluntary substitution.
² According to the interviewee, Bhutan is not using an external reference price but the manufacturer has to register the maximum retail price with the medicine regulatory authority.
³ Nepal does not allow marketing of products with prices exceeding the exporting country’s price. While submitting the dossier for market authorization, the applicant of a new pharmaceutical product is required to list reference product prices and its proposed MRP.
⁵ Myanmar Pharmaceutical Factory and the Ministry of Industry are the purchasing authorities that form a single entity for purchasing health products in the country.
⁶ Although there is no policy such as “external” pooled procurement where, for example, different countries pool their purchasing power, interviewees reported that the Department of Health Service purchases all medicines for the country’s public sector health institutions.
⁷ Union Tax Law
⁸ The tax exemption is declared in the budget speech of every fiscal year.
Antimicrobial resistance (AMR) is a significant threat to health and human development, affecting our ability to treat a range of infections. Consumption and use of antimicrobials are the main drivers for the development of AMR. To obtain a thorough and comprehensive picture of AMR and identify areas in which actions are needed, data from surveillance of antimicrobial consumption (AMC) are essential. These data should be easily compared and exchanged and should be used locally, nationally, regionally and globally.

WHO developed a methodology for the global programme on surveillance of AMC that was extended as a component of the Global Antimicrobial Resistance and Use Surveillance System (GLASS) in 2020. GLASS-AMC provides a common technical basis for setting up national surveillance systems on AMC that can produce reliable and comparable data at national and global levels.

In the Region, Bangladesh, Bhutan, Indonesia, Maldives, Nepal and Timor-Leste have enrolled in WHO’s GLASS-AMC. It must be noted that all countries in the Region are enrolled on GLASS-AMR, antimicrobial resistance surveillance (Table 12).
Table 12. The status of WHO GLASS-AMC enrolment among countries in the WHO South-East Asia Region (2023)

<table>
<thead>
<tr>
<th>Country</th>
<th>WHO GLASS-AMC enrolment</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Yes</td>
<td>2022</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Yes</td>
<td>2020</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes</td>
<td>2020</td>
</tr>
<tr>
<td>Maldives</td>
<td>Yes</td>
<td>2020</td>
</tr>
<tr>
<td>Myanmar</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Nepal</td>
<td>Yes</td>
<td>2020</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Thailand</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>Yes</td>
<td>2020</td>
</tr>
</tbody>
</table>
The pharmacy workforce plays an instrumental multifaceted role in ensuring the safe, effective and rational use of medical products. Pharmacists, pharmacy technicians, and other professionals in this field are on the frontline of health care, serving as medication experts who collaborate with patients and other health-care providers to optimize treatment outcomes. They contribute to medication safety by verifying prescription accuracy, counselling patients on medication use and adherence to dosage, and identifying and preventing potential drug interactions or adverse events.

In the Region, India leads with the highest number of pharmacists, boasting 9 pharmacists per 10 000 population. Maldives closely follows with 7 pharmacists per 10 000 population, while Thailand maintains 6 pharmacists per 10 000 population. DPR Korea and Indonesia feature 4 and 3 pharmacists per 10 000 population, respectively, while Timor-Leste has 2 pharmacists per 10 000 population.

Bangladesh, Bhutan, Myanmar and Sri Lanka report lower numbers of pharmacists, with figures falling below or equal to 1 pharmacist per 10 000 population in these countries. These variations underscore the diversity in health-care workforce distribution across the Region (Fig. 6).

**Fig. 6. The number of pharmacists per 10 000 population among countries in the WHO South-East Asia Region\textsuperscript{57} (2023)**
Table 13. Pharmacy education accreditation and continuing professional development in countries of the South-East Asia Region

<table>
<thead>
<tr>
<th>Countries</th>
<th>Pharmacy education accreditation</th>
<th>Continuing professional development for pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Bhutan&lt;sup&gt;12&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>DPR Korea&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>India&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes</td>
<td>Partly</td>
</tr>
<tr>
<td>Indonesia&lt;sup&gt;32&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Maldives&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes</td>
<td>Partly</td>
</tr>
<tr>
<td>Myanmar&lt;sup&gt;30&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Nepal&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes</td>
<td>Partly</td>
</tr>
<tr>
<td>Sri Lanka&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Thailand&lt;sup&gt;58&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Timor-Leste&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
The way forward

Regulation and policy

⇒ Establish and enforce a comprehensive legal framework that governs medical products from market entry to exit.
⇒ Strengthen the capacity of national regulatory authorities.
⇒ Implement intellectual property rights that balance incentives for innovation with ensuring generic entry into the market for affordable access.

Rational selection and use

⇒ Develop and regularly update the NEML based on disease prevalence, therapeutic safety, efficacy, cost–effectiveness and quality.
⇒ Build capacity in HTA to provide critical evidence for decision-making on the inclusion of new medical products for resource allocation.

Purchasing

⇒ Enhance procurement efficiency through centralized purchasing, bulk procurement and competitive bidding.
⇒ Strengthen the capacity of public procurement agencies.
⇒ Expand the coverage of health insurance schemes for medical products to reduce OOPE.

Price control

⇒ Develop and implement comprehensive pricing control mechanisms.
⇒ Promote price transparency through price information-sharing.

Workforce

⇒ Foster active participation of pharmacists and align pharmacy education with evolving health-care needs.
⇒ Continuously educate and train health-care professionals on rational prescribing and use of medicines and promote compliance with national protocols and essential medicines list.

Monitoring and evaluation

⇒ Establish robust data collection systems to monitor medicine availability, affordability, quality and use these to measure progress on equitable access.
References

2. Reported by the Ministry of Public Health, Thailand (internal communication)
3. Reported by the Ministry of Health and Family Welfare, Bangladesh (internal communication)
4. Reported by the Ministry of Health, Sri Lanka (internal communication)
7. Reported by the Ministry of Health, Bhutan, 2023 (internal communication)
8. Reported by the Ministry of Health, Maldives, 2023 (internal communication)
9. Reported by the Ministry of Health, Timor-Leste, 2023 (internal communication)
17. Reported by the Ministry of Health and Family Welfare, India (internal communication)
20. Reported by the respective ministries of health (internal communication) unless otherwise specified
23. Reported by the Ministry of Health and Sports, Myanmar, 2023 (internal communication)
26. Reported by the Ministry of Health, Indonesia, 2023 (internal communication)


Pharmaceutical country profile

**BANGLADESH**

### Socioeconomic

- **Population**
  - 171,186,372 (2022)

- **Life expectancy at birth**
  - 72 years (2021)

- **GDP/capita (current US$)**
  - US$ 2688 (2022)

### Spending on health

- **Current health expenditure (CHE)/capita (current US$)**
  - US$ 51 (2020)

- **Government health expenditure (% of CHE)**
  - 18% (2020)

- **Out-of-pocket expenditure (% of CHE)**
  - 73% (2020)

### Spending on pharmaceuticals

- **Government pharmaceutical expenditure**
  - No data

- **Government pharmaceutical expenditure/capita**
  - No data

- **Pharmaceutical expenditure (% of CHE)**
  - 47%

- **Share of out-of-pocket expenditure on pharmaceuticals**
  - 65%

### Medical and pharmacy workforce

- **Medical doctors/10,000 population**
  - 6.7 (2021)

- **Pharmacists/10,000 population**
  - 1.01 (2021)

- **Pharmacy education accreditation**
  - Yes

- **Continuing professional development for pharmacists**
  - No

### Pharmaceutical legislation and policy

- **1940**
  - Drugs Act

- **1946**
  - Bengali Drug Rule

- **1982**
  - National Drug Policy; Drug (Control) Ordinance

- **2005**
  - National Drug Policy

- **2013**
  - National Immunization Policy

- **2016**
  - National Drug Policy

- **2017–2022**
  - National Action Plan on AMR Containment
Pharmaceutical country profile

Bangladesh

**Intellectual property rights**
- TRIPS flexibilities incorporated into the law
- TRIPS flexibilities utilized

**Rational use and antimicrobial resistance**

<table>
<thead>
<tr>
<th>% of market share of non-EML products</th>
<th>FDC sales in the private market</th>
<th>Number of antibiotics on the private market</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data</td>
<td>No data</td>
<td>Total Access Watch Reserve Others Not recommended</td>
</tr>
<tr>
<td>WHO GLASS-AMC enrollment*: Yes, 2022</td>
<td></td>
<td>Single drugs: 60 21 34 0 5 No data</td>
</tr>
<tr>
<td>Total consumption of antibiotics*: 1 526 232 088.00 DDD</td>
<td></td>
<td>FDCs: 13 2 2 6 3 No data</td>
</tr>
<tr>
<td>DID = 25.64</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Market entry**

- **National Regulatory Authority**
  - Directorate-General of Drug Administration
  - Website: https://dgda.portal.gov.bd/
  - Staff*: 378
  - Annual budget*: US$ 8.33 million

- **Products regulated**
  - Medicines
  - Biologicals
  - Medical devices
  - Traditional medicines

- **Licensing of establishments**
  - Manufacturers
  - Importers
  - Exporters
  - Wholesalers
  - Distributors
  - Retailers

- **National Medicines Quality Control Laboratory**
  - 2
  - ISO 17025 certified
  - WHO prequalified

- **Body responsible for selection of medical products**
  - Directorate General of Drug Administration (DGDA)

- **National Essential Medicines List (number of active ingredient)**
  - 2008: 209 medicines
  - 2016: Allopathic: 285; ayurvedic: 100; unani: 223

- **National Medicines Formulary**
  - 2015
  - 2019

- **National Essential Diagnostics List**: No

---

* Data as of 2022

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* Data as of 2020
Bangladesh

Pharmaceutical country profile

Pricing regulatory authority

Directorate General of Drug Administration (DGDA)

Public sector

Tendering

Yes

Private sector

Maximum retail price

Yes

Number of price controlled products

117 medicines

Pricing

regulation

Procurement

Centralised and Decentralised
Agency responsible for procurement

Essential Drugs Company Ltd (EDCL); Central Medical Stores Depot (CMSD); Directorate General of Health Services (DGHS)

LMIS used

eLMIS

Frequency of tender

Annual or bi-annual

Market exit

Legal provision for

Cancellation of licences of pharmaceutical establishments

Cancellation of marketing authorization of products

Initiating product recalls and withdrawals

Market distribution

Estimated pharmaceutical market value

US$ 2.1 billion

Public

Tertiary hospitals

59

Secondary hospitals

126

PHC facilities

19 352

Private

Manufacturers

295

Importers

351

Wholesalers/distributors

2800

Retail pharmacies

Total retail pharmacy: 205 589 (allopathic: 199 257; unani: 1250; ayurvedic: 1505; homeo: 3548; herbal: 30)

1982

National Drug Policy

2005

National Drug Policy

2016

National Drug Policy

Social Health Insurance

Name of SHI scheme

Shasthyo Surokkha Karmasuchi (SSK) (pilot since 2016)

Population coverage

Population below the poverty line in 7 districts

Number of products covered

No data
Pharmaceutical country profile

Bangladesh

References

5. Reported by the Ministry of Health and Family Welfare, Bangladesh, 2023 (internal communication)
9. The Directorate General of Drug Administration (DGDA) [website]. Bangladesh (https://dgdagov.info/)
11. DGHS-ELMIS [online database]. Bangladesh (https://scmpbd.org/dghs-elmis/)
13. University of Boston, United States of America, "Medicines' price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research ", WHO 2021
**Socioeconomic**

- Population: 782,455 (2022)
- Life expectancy at birth: 72 years (2021)

**Spending on health**

- Current health expenditure (CHE)/capita (current US$): 134 (2020)
- Government health expenditure (% of CHE): 4% (2020)
- Out-of-pocket expenditure (% of CHE): 78% (2020)
- Government pharmaceutical expenditure: No data
- Government pharmaceutical expenditure/capita: No data

**Spending on pharmaceuticals**

- Government pharmaceutical expenditure: No data
- Government pharmaceutical expenditure/capita: No data
- Pharmaceutical expenditure (% of CHE): 26% (2019–2020)
- Share of out-of-pocket expenditure on pharmaceuticals: 76% (2012)

**Medical and pharmacy workforce**

- Medical doctors/10,000 population: 5.6 (2021)
- Pharmacists/10,000 population: 0.63 (2021)
- Pharmacy education accreditation: Yes
- Continuing professional development for pharmacists: Yes

**Pharmaceutical legislation and policy**

- 2003: The Medicines Act of the Kingdom of Bhutan
- 2007: National Drug Policy
- 2011: National Immunization Policy and Strategic Guidelines
- 2012: Bhutan Medicines Rules and Regulation
- 2019: Bhutan Medicines Rules and Regulation; National Medicines Policy
**Intellectual property rights**

- TRIPS flexibilities incorporated into the law: Not applicable
- TRIPS flexibilities utilized: Not applicable

**Rational use and antimicrobial resistance**

- % of market share of non-EML products: No data
- WHO GLASS-AMC enrollment*: Yes, 2020
- Total consumption of antibiotics: No data
- FDC sales in the private market: No data
- Number of antibiotics on the private market

<table>
<thead>
<tr>
<th>Total</th>
<th>AWARe</th>
<th>Not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single drugs</td>
<td>No data</td>
<td></td>
</tr>
<tr>
<td>FDCs</td>
<td>No data</td>
<td></td>
</tr>
</tbody>
</table>

**Market entry**

**National Regulatory Authority**

- Bhutan Food and Drug Authority (BFDA)
- Website: [https://dra.gov.bt/](https://dra.gov.bt/)
- Staff*: 24
- Annual budget*: US$ 23,570.65

**Products regulated**

- ✓ Medicines
- ✓ Biologics
- ❌ Medical devices
- ✓ Traditional medicines

**Licensing of establishments**

- ✓ Manufacturers
- ✓ Importers
- ✓ Exporters
- ✓ Wholesalers
- ✓ Distributors
- ✓ Retailers

**National Medicines Quality Control Laboratory**

- 1
- ✓ ISO 17025 certified
- ❌ WHO prequalified

**Rational selection**

**Body responsible for selection of medical products**

- Health Intervention and Technology Assessment Division, Department of Health Service
- HTA used in the selection process
- NEML incorporated AWARe list
- Medicines listed by level of care
- Traditional medicines included

**National Essential Medicines List (number of active ingredient)**

- 1994
- 2016
- 2021

**National Medicines Formulary**

- 2015
- 2017

**National Essential Diagnostics List**: Yes
Pricing regulatory authority
Bhutan Food and Drug Authority

Public sector
Tendering: Yes

Private sector
Maximum retail price: Yes
Number of price controlled products: 2112 (all registered products)

Legal provision for
- Cancellation of licences of pharmaceutical establishments
- Cancellation of marketing authorization of products
- Initiating product recalls and withdrawals

Estimated pharmaceutical market value
No data

Purchasing
Agency responsible for procurement: Department of Medical Supplies and Health Infrastructure (DoMSHI)
LMIS used: Yes
Frequency of tender: Annual

Pricing
Pricing regulatory authority
Bhutan Food and Drug Authority

Public sector
Tendering: Yes

Private sector
Maximum retail price: Yes
Number of price controlled products: 2112 (all registered products)

Market distribution

Public
Tertiary hospitals: 3
Secondary hospitals: 50
PHC facilities: 179 primary health centers; 53 subposts; 555 outreach clinics.

Private
Manufacturer: 6
Importers: 29, plus 3 institutional importers
Wholesalers/distributors: 29
Retail pharmacies: 75

Market exit

Social Health Insurance
Name of SHI scheme: Not applicable
Population coverage: Not applicable
Number of products covered: Not applicable
References

8. Reported by the Ministry of Health, Bhutan, 2023 (internal communication)
14. University of Boston, United States of America, "Medicines' price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research ", WHO 2021
### Pharmaceutical country profile

#### Demographic

| Population | 26 069 416 (2022) |
| Life expectancy at birth | 73 years (2021) |
| GDP/capita (current US$) | No data |

#### Spending on health

- Current health expenditure (CHE)/capita (current US$): No data
- Current health expenditure as share of GDP: No data
- Government health expenditure (% of CHE): No data
- Out-of-pocket expenditure (% of CHE): No data

#### Spending on pharmaceuticals

- Government pharmaceutical expenditure: No data
- Government pharmaceutical expenditure/capita: No data
- Pharmaceutical expenditure (% of CHE): No data
- Share of out-of-pocket expenditure on pharmaceuticals: No data

#### Medical and pharmacy workforce

| Medical doctors/10 000 population | 37 (2017) |
| Pharmacists/10 000 population | 4 (2017) |
| Pharmacy education accreditation | Yes |
| Continuing professional development for pharmacists | Yes |

#### Pharmaceutical legislation and policy

<table>
<thead>
<tr>
<th>Year</th>
<th>Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>National legislation, Rule and Regulations for Narcotic Control (revived); National Action Plan on AMR</td>
</tr>
<tr>
<td>2019</td>
<td>National legislation, Rule and Regulations for Drug Management</td>
</tr>
<tr>
<td>2021–2025</td>
<td>National Action Plan on AMR</td>
</tr>
</tbody>
</table>
Pharmaceutical country profile

Democratic People's Republic of Korea

Intellectual property rights

TRIPS flexibilities incorporated into the law

TRIPS flexibilities utilized

Not applicable

Rational use and antimicrobial resistance

% of market share of non-EML products
No data

WHO GLASS-AMC enrollment*: Yes, 2020

Total consumption of antibiotics:
No data

FDC sales in the private market
No data

Number of antibiotics on the private market

<table>
<thead>
<tr>
<th>Total</th>
<th>AWARe</th>
<th>Not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Access</td>
<td>Watch</td>
</tr>
<tr>
<td>Single drugs</td>
<td>No data</td>
<td></td>
</tr>
<tr>
<td>FDCs</td>
<td>No data</td>
<td></td>
</tr>
</tbody>
</table>

National Regulatory Authority*

National Drug Regulatory Authority (NDRA)

Website: No data

Staff*: 713 (2012)

Annual budget: No data

Products regulated

- [x] Medicines*
- [x] Biologicals*
- [x] Medical devices*
- [x] Traditional medicines*

Number of registered products*: 3000-4000, 671 traditional medicines registered as of 2010

Licensing of establishments

- [x] Manufacturers
- [x] Importers
- [x] Exporters
- [x] Wholesellers
- [x] Distributors
- [x] Retailers

National Medicines Quality Control Laboratory*

1 central laboratory under NDRA and one per province

- ISO 17025 certified*
- WHO prequalified*

Body responsible for selection of medical products*

National Drug Regulatory Authority, Ministry of Public Health

- HTA used in the selection process
- NEML incorporated AWaRE list
- Medicines listed by level of care*
- Traditional medicines included*

National Essential Medicines List (number of active ingredient)*

National List of Essential Medicines, 2019
343 medicines

National Medicines Formulary*

2016

National Essential Diagnostics List: No
Democratic People’s Republic of Korea

Pricing regulatory authority
National Price Control Committee

Public sector
Tendering*: Yes

Private sector
Maximum retail price: No data
Number of price controlled products: No data

Legal provision for
- Cancellation of licences of pharmaceutical establishments
- Cancellation of marketing authorization of products
- Initiating product recalls and withdrawals

Social Health Insurance
Name of SHI scheme: Not applicable
Population coverage: Not applicable
Number of products covered: Not applicable

Procurement*: Centralised
Agency responsible for procurement*: Medicines Management Department, Ministry of Public Health
LMIS used: No data
Frequency of tender: No data

Purchasing

Market distribution

Market exit

Estimated pharmaceutical market value
No data

Public
Tertiary hospitals*: 1608
Secondary hospitals*: 133
PHC facilities*: 6263 Ri clinics

Private
Manufacturers*: 210 manufactures for traditional medicinal products
Importers: No data
Wholesellers/distributors: No data
Retail pharmacies*: 260 government owned people’s drug stores in Pyongyang city

No data
Democratic People’s Republic of Korea

References


7. MoH (2018), Essential packages of Health Services in DPR Korea, Ministry of Health Korea
**Pharmaceutical country profile**

**INDIA**

### Socioeconomic
- **Population**
  - 1,417,173,170 (2022)
- **Life expectancy at birth**
  - 67 years (2021)
- **GDP/capita (current US$)**
  - US$ 2,389 (2022)

### Spending on health
- **Current health expenditure (CHE) / capita (current US$)**
  - US$ 57 (2020)
- **Government health expenditure (% of CHE)**
  - 35% (2019–20)
- **Out-of-pocket expenditure (% of CHE)**
  - 52% (2019–20)

### Spending on pharmaceuticals
- **Government pharmaceutical expenditure / capita**
  - No data
- **Government pharmaceutical expenditure / capita**
  - No data

### Medical and pharmacy workforce
- **Medical doctors / 10,000 population**
  - 7.27 (2020)
- **Pharmacists / 10,000 population**
  - 8.6 (2020)
- **Pharmacy education accreditation**
  - Yes
- **Continuing professional development for pharmacists**
  - Partly

### Pharmaceutical legislation and policy
- **1940**: Drugs & Cosmetics Act
- **1945**: Drugs & Cosmetics Rules
- **1948**: Pharmacy Act
- **1954**: Drugs & Magic Remedies (Objectionable Advertisements) Act
- **1955**: Essential Commodities Act
- **1956**: Medicinal and Toilet Preparations (Excise Duties) Act
- **1962**: Drugs (Display of Price) Order
- **1970**: Indian Patent Act
- **1985**: Narcotic Drugs & Psychotropic Substances Act
- **2002**: Pharmaceutical Policy
- **2011**: National Vaccine Policy
- **2012**: National Pharmaceutical Pricing Policy
- **2017**: National Health Policy; National Action Plan for AMR
- **2022**: New Drugs, Medical Devices and Cosmetics Bill (draft)
- **2023**: National Medical Devices Policy
Pharmaceutical country profile

India

**Intellectual property rights**

- **TRIPS flexibilities incorporated into the law**
  - Process patent regime: TRIPS signatory 1995
  - Product patent regime: amended 2005 Indian Patent Act

- **TRIPS flexibilities utilized**

**Rational use and antimicrobial resistance**

- **% of market share of non-EML products**: No data
- **WHO GLASS-AMC enrollment**: No
- **Total consumption of antibiotics**: No data

| FDC sales in the private market | 48% | 52% |

<table>
<thead>
<tr>
<th>Number of antibiotics on the private market</th>
<th>Total</th>
<th>Access</th>
<th>Watch</th>
<th>Reserve</th>
<th>Not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single drugs</td>
<td>78</td>
<td>21</td>
<td>50</td>
<td>9</td>
<td>Not applicable</td>
</tr>
<tr>
<td>FDCs</td>
<td>112</td>
<td>39</td>
<td>70</td>
<td>3</td>
<td>57</td>
</tr>
</tbody>
</table>

**Market entry**

- **National regulatory authority**
  - Central Drugs Standard Control Organization, Ministry of Health and Family Welfare
  - Website: https://cdsco.gov.in/opencms/opencms/en/Home/
  - Staff: No data
  - Annual budget: approx. US$ 17.13 Million

- **Products regulated**
  - Medicines
  - Biologicals
  - Medical devices
  - Traditional medicines

- **Licensing of establishments**
  - Manufacturers
  - Importers
  - Exporters
  - Wholesalers
  - Distributors
  - Retailers

- **National medicines quality control laboratory**
  - 5 central drug testing laboratories; 2 regional drug testing laboratories
  - ISO 17025 certified
  - WHO prequalified

**Rational selection**

- **Body responsible for selection of medical products**
  - Committee set up by the Ministry of Health and Family Welfare

- **National essential medicines list (number of active ingredient)**
  - 1996: 348 medicines
  - 2003: 376 medicines
  - 2011: 384 medicines

- **National medicines formulary**
  - 1960
  - 1966
  - 1979
  - 2011
  - 2016
  - 2021

- **National essential diagnostics list**: Yes, 2019
Pricing regulatory authority
National Pharmaceutical Pricing Authority; Department of Pharmaceuticals; Ministry of Chemicals and Fertilizers

Public sector
Tendering: Yes

Private sector
Maximum retail price: Yes
Number of price controlled products: 384 (limited formulations)

Cost-based pricing

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1963</td>
<td>Drugs (Control of Prices) Order</td>
</tr>
<tr>
<td>1966</td>
<td>Drugs Price Control Order</td>
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<td>1970</td>
<td>Drugs Price Control Order</td>
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<td>1995</td>
<td>Drugs Price Control Order</td>
</tr>
<tr>
<td>1997</td>
<td>National Pharmaceutical Pricing Authority established</td>
</tr>
<tr>
<td>2012</td>
<td>National Pharmaceutical Pricing Policy</td>
</tr>
<tr>
<td>2013</td>
<td>Trade Margin Regulation of Cancer Medicines</td>
</tr>
</tbody>
</table>

Market-based pricing

Estimated pharmaceutical market value
US$ 23 billion (2022–2023)

Public
Tertiary hospitals: 307
Secondary hospitals: 1224 subdivisional hospitals; 764 district hospitals
PHC facilities: 157 819 sub centres; 30 579 primary health centres; 5951 community health centres

Private
Manufacturers: >3000 companies; 10 500 manufacturing facilities
Importers: No data
Wholesalers/distributors: No data
Retail pharmacies: No data

Legal provision for
- Cancellation of licences of pharmaceutical establishments
- Cancellation of marketing authorization of products
- Initiating product recalls and withdrawals
References

6. Reported by the Ministry of Health and Family Welfare, India, 2023 (internal communication)
9. PharmaTrac data, AIOCD AWACS (2020)
26. PharmaTrac data from AIOCD AWACS (June 23 MAT)
28. Invest India [website]. India (https://www.investindia.gov.in/sectors/pharmaceuticals#:~:text=India%20also%20has%20the%20highest%20highly%20skilled%20resource%20pool.)
Pharmaceutical country profile

INDONESIA

Socioeconomic

Population
275,501,339 (2022)

Life expectancy at birth
72 years (2022)

GDP/capita (current US$)
US$ 4788 (2022)

Spending on health

Current health expenditure (CHE)/capita (current US$)
US$ 133 (2020)

3% (2020) Current health expenditure as share of GDP

55% (2020) Government health expenditure (% of CHE)

31% (2020) Out-of-pocket expenditure (% of CHE)

Spending on pharmaceuticals

Government pharmaceutical expenditure
No data

Government pharmaceutical expenditure/capita
No data

Medical and pharmacy workforce

Medical doctors/10,000 population
6.95 (2021)

Pharmacists/10,000 population
3.11 (2021)

Pharmacy education accreditation
Yes

Continuing professional development for pharmacists
Yes

Pharmaceutical legislation and policy

2006
National Medicines Policy

2017–2019
National Action Plan for AMR

2021
NEML, Ministry of Health Decree HK.01.07/Menkes/6477/2021; National Formulary, KMK HK.01.07/Menkes/6485/2021

2022
National Formulary, KMK HK.01.07/Menkes/1970/2022
### Intellectual property rights

- **TRIPS flexibilities incorporated into the law**: Yes
- **TRIPS flexibilities utilized**: Yes

**2016 Law Number 13/2016**

### Rational use and antimicrobial resistance

% of market share of non-EML products: No data

WHO GLASS-AMC enrollment**: Yes, 2020

Total consumption of antibiotics: No data

#### FDC sales in the private market: No data

#### Number of antibiotics on the private market

<table>
<thead>
<tr>
<th>Total</th>
<th>AWARe</th>
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</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>FDCs</td>
<td>No data</td>
<td></td>
</tr>
</tbody>
</table>

### Market entry

#### Products regulated
- **Medicines**: Yes
- **Biologics**: Yes
- **Medical devices**: Yes
- **Traditional medicines**: Yes

#### Licensing of establishments
- **Manufacturers**: Yes
- **Importers**: Yes
- **Exporters**: Yes
- **Wholesalers**: Yes
- **Distributors**: Yes
- **Retailers**: Yes

#### National Medicines Quality Control Laboratory
1 national quality control laboratory and 33 provincial laboratories

#### Body responsible for selection of medical products
Ministry of Health

### National Regulatory Authority
1. National Agency for Drug and Food Control (NADFC), Republic of Indonesia (BADAN-POM)
2. Ministry of Health for medical devices

Website: [https://www.pom.go.id/new/view/direct/background; https://kemkes.go.id/](https://www.pom.go.id/new/view/direct/background; https://kemkes.go.id/)

Staff: No data
Annual budget: No data

### National Essential Medicines List (number of active ingredient)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>323</td>
<td>331 medicines in 2008</td>
<td>324</td>
<td>319</td>
<td>324</td>
<td>318</td>
<td>320</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### National Medicines Formulary

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2015</th>
<th>2017</th>
<th>2019</th>
<th>2021</th>
<th>2022</th>
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</thead>
<tbody>
<tr>
<td>320</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### National Essential Diagnostics List: No
## Indonesia

### Pharmaceutical country profile

#### Purchasing
- **Procurement**: Decentralised
  - Agency responsible for procurement: Procurement carried out by facilities and provincial government, regulated by MoH
  - LMIS used: Not fully implemented
  - Frequency of tender: Ad hoc

#### Pricing regulation
- **Pricing regulatory authority**: Ministry of Health
- **Public sector**
  - Tendering: Yes
- **Private sector**
  - Maximum retail price: Yes
  - Number of price controlled products: No data

#### Market distribution
- **Estimated pharmaceutical market value**: No data
  - **Public**
    - Tertiary hospitals: 69
    - Secondary hospitals: 2998
    - PHC facilities: 10,230
  - **Private**
    - Manufacturers: 241
    - Importers: No data
    - Wholesalers/distributors: 2994
    - Retail pharmacies: 30,200

#### Market exit
- **Legal provision for**
  - Cancellation of licences of pharmaceutical establishments
  - Cancellation of marketing authorization of products
  - Initiating product recalls and withdrawals

#### Social Health Insurance
- **Name of SHI scheme**: Jaminan Kesehatan Nasional (JKN)
- **Population coverage**: 91.5%
- **Number of products covered**: Benefit package in JKN is based on National Formulary; 623 APIs and 1059 SKUs

---

Maxim margin for retailer price

No year

**Maximum margin for retailer price**

---

No data

---

**No year**

**Maximum margin for retailer price**
References

2. Indonesia Bureau of statistic (Badan Pusat Statistik (bps.id)) (2022)
7. Reported by the Ministry of Health, Indonesia, 2023 (internal communication)
**Socioeconomic**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>515,132 (2022)</td>
</tr>
<tr>
<td>Life expectancy at birth</td>
<td>82 years (2020)</td>
</tr>
<tr>
<td>GDP/capita (current US$)</td>
<td>US$ 11,818 (2022)</td>
</tr>
</tbody>
</table>

**Spending on health**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current health expenditure (CHE)/ capita</td>
<td>US$ 826 (2020)</td>
</tr>
<tr>
<td>Government health expenditure (% of CHE)</td>
<td>11% (2020)</td>
</tr>
<tr>
<td>Out-of-pocket expenditure (% of CHE)</td>
<td>80% (2020)</td>
</tr>
<tr>
<td>Share of out-of-pocket expenditure on pharmaceuticals</td>
<td>62% (2009)</td>
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</table>

**Spending on pharmaceuticals**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government pharmaceutical expenditure</td>
<td>US$ 89 million</td>
</tr>
<tr>
<td>Government pharmaceutical expenditure/capita</td>
<td>US$ 185</td>
</tr>
</tbody>
</table>

**Medical and pharmacy workforce**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical doctors/ 10,000 population</td>
<td>22 (2020)</td>
</tr>
<tr>
<td>Pharmacists/ 10,000 population</td>
<td>6.84 (2020)</td>
</tr>
<tr>
<td>Pharmacy education accreditation</td>
<td>Yes</td>
</tr>
<tr>
<td>Continuing professional development for pharmacists</td>
<td>Partly</td>
</tr>
</tbody>
</table>

**Pharmaceutical legislation and policy**

- **1994**: Medicines Act
- **2007**: National Medicines Policy
- **2009**: National Medication Practice standards
- **2014**: Medicine Regulation No: 2014/R-46
- **2015**: Health Services Act
- **2016**: Medicine Regulation No: 2016/R-49
- **2017–2021**: National Action Plan for containment of AMR
- **2018–2023**: National Medicine Policy
- **2021**: Guidelines on Product Registration and Approval for Medicines
Pharmaceutical country profile

Maldives

Intellectual property rights

- TRIPS flexibilities incorporated into the law: Yes
- TRIPS flexibilities utilized: No data

Rational use and antimicrobial resistance

% of market share of non-EML products: 20

WHO GLASS-AMC enrollment: Yes, 2020

Total consumption of antibiotics: 15.47 DID

FDC sales in the private market: No data

Number of antibiotics on the private market

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>AWARe</th>
<th>Not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single drugs</td>
<td>No data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDCs</td>
<td>No data</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Market entry

Maldives Food and Drug Authority


Staff: 22

Annual budget: US$ 51,840

Products regulated

- Medicines
- Biologics
- Medical devices
- Traditional medicines

Licensing of establishments

- Manufacturers
- Importers
- Exporters
- Wholesalers
- Distributors
- Retailers

National Medicines Quality Control Laboratory

1 (National Health Laboratory)

ISO 17025 certified

WHO prequalified

Body responsible for selection of medical products

Maldives Food and Drug Authority

National Regulatory Authority

National Essential Medicines List (number of active ingredient)

<table>
<thead>
<tr>
<th>Year</th>
<th>Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>428</td>
</tr>
<tr>
<td>2013</td>
<td>428</td>
</tr>
<tr>
<td>2016</td>
<td>428</td>
</tr>
<tr>
<td>2018</td>
<td>428</td>
</tr>
<tr>
<td>2021</td>
<td>425</td>
</tr>
<tr>
<td>2023</td>
<td>425</td>
</tr>
</tbody>
</table>

National Essential Diagnostics List: No (under development)
Maldives

Pharmaceutical country profile

Pricing regulation

Pricing regulatory authority
Maldives Food and Drug Authority

Public sector
Tendering: Yes

Private sector
Maximum retail price: No
Number of price controlled products: Not applicable

Legal provision for
- Cancellation of licences of pharmaceutical establishments
- Cancellation of marketing authorization of products
- Initiating product recalls and withdrawals

Market distribution

Estimated pharmaceutical market value
No data

Public
Tertiary hospitals: 4
Secondary hospitals: 14
PHC facilities: 165

Private
Manufacturers: None
Importers: 73
Wholesellers/distributors: 76
Retail pharmacies: 453

Purchasing

☑ Procurement: Centralised
Agency responsible for procurement: State Trading Organization (for public sector pharmacies); Ministry of Hospitals (for government health facilities)
LMIS used: Yes
Frequency of tender: Biannual

☑ Social Health Insurance
Name of SHI scheme: Aasandha
Population coverage: Total population
Number of products covered: 3428 (including different brands of generic medicines)
References


5. Reported by the Ministry of Health, Maldives, 2023 (internal communication)


15. University of Boston, United States of America, "Medicines' price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research", WHO 2021

Pharmaceutical country profile

**Socioeconomic**
- **Population**¹: 54,179,306 (2022)
- **Life expectancy at birth**²: 66 years (2021)
- **GDP/capita (current US$)**³: US$ 1,096 (2022)

**Spending on health**
- **Current health expenditure (CHE)/ capita (current US$)**⁴: $72 (2020)
- **Government health expenditure (% of CHE)**⁴: 16% (2020)
- **Out-of-pocket expenditure (% of CHE)**⁴: 78% (2020)

**Spending on pharmaceuticals**
- **Pharmaceutical expenditure (% of CHE)**⁵: 30% (2020)
- **Share of out-of-pocket expenditure on pharmaceuticals**⁷: 44% (2013)

**Medical and pharmacy workforce**
- **Medical doctors/10,000 population**⁸: 7.51 (2019)
- **Pharmacists/10,000 population**⁸: 0.79 (2019)
- **Pharmacy education accreditation**⁹: No
- **Continuing professional development for pharmacists**⁹: No

**Pharmaceutical legislation and policy**
- **1992**: National Drug Law
- **2014**: Amendment of National Drug Law
- **2017**: National Action Plan for containment of AMR
- **2019**: National Medicines Policy
Pharmaceutical country profile

Myanmar

**Intellectual property rights**

- TRIPS flexibilities incorporated into the law: Not applicable
- TRIPS flexibilities utilized: Not applicable

**Rational use and antimicrobial resistance**

% of market share of non-EML products: 15–25% in public; 46% in private

WHO GLASS-AMC enrollment: No

Total consumption of antibiotics: 5,794,904 DDD (2017)

FDC sales in the private market: No data

Number of antibiotics on the private market

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>AWARe</th>
<th>Not recommended</th>
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</thead>
<tbody>
<tr>
<td>Single drugs</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>FDCs</td>
<td>No data</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**National Regulatory Authority**

1. Department of Food and Drug Administration (DFDA);
2. Department of Traditional Medicine (DTM)

Website: http://www.fdamyanmar.gov.mm/
https://www.dtm.gov.mm/

Staff*: 2875 (sanctioned)

Annual budget: No data

**Products regulated**

- Medicine* 
- Biologicals* 
- Medical devices* 
- Traditional medicines* 

Number of registered products: 21,000 allopathic (January 2019); 14,529 registered drugs in the National Traditional Medicine Formulary

**Licensing of establishments**

- Manufacturers* 
- Importers* 
- Exporters* 
- Wholesalers* 
- Distributors* 
- Retailers*

**National Medicines Quality Control Laboratory**

1 Drug Microbiological Laboratory; 1 Bio standardized Laboratory; 1 Drug Chemical Quality Control Laboratory of DFDA

- ISO 17025 certified* 
- WHO prequalified*

**Body responsible for selection of medical products**

Essential Drug Program, Medical Care Division, Department of Medical Services

**National Essential Medicines List (number of active ingredient)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>1978</td>
<td>254 medicines</td>
</tr>
<tr>
<td>1984</td>
<td>240 medicines</td>
</tr>
<tr>
<td>1987</td>
<td>211 medicines</td>
</tr>
<tr>
<td>1998</td>
<td>184 medicines</td>
</tr>
<tr>
<td>2001</td>
<td>319 medicines</td>
</tr>
<tr>
<td>2009</td>
<td>341 medicines</td>
</tr>
<tr>
<td>2016</td>
<td>486 medicines</td>
</tr>
</tbody>
</table>

**National Medicines Formulary**: 1998

**National Essential Diagnostics List**: No
Myanmar Pharmaceutical country profile

Pricing regulatory authority
Myanmar Pharmaceutical and Medical Equipment & Entrepreneur Association in collaboration with Ministry of Commerce

Public sector
Tendering: Yes

Private sector
Maximum retail price: No
Number of price controlled products: Not applicable

Purchasing

☑ Centralised
Agency responsible for procurement: Procurement and Distribution Division, Department of Public Health, Department of Medical Services
LMIS used: No
Frequency of tender: Ad hoc

☑ Social Health Insurance
Name of SHI scheme: Social Security Service
Population coverage: 706,750 employees (government and private)
Number of products covered: No data

Market exit

Legal provision for
☑ Cancellation of licences of pharmaceutical establishments
☑ Cancellation of marketing authorization of products
☑ Initiating product recalls and withdrawals

Market distribution

Estimated pharmaceutical market value
No data

Public
Tertiary hospitals: 36
Secondary hospitals: 81
PHC facilities: 827

Private
Manufacturers: 16 (March 2017)
Importers: ~170
Wholesalers/distributors: >100
Retail pharmacies: >10,000
Pharmaceutical country profile: NEPAL

**Socioeconomic**

- **Population**
  - 30,547,580 (2022)

- **Life expectancy at birth**
  - 68 years (2021)

- **GDP/capita (current US$)**
  - US$ 1,337 (2022)

**Spending on health**

- **Current health expenditure (CHE)/ capita (current US$)**
  - $58 (2020)

- **Government health expenditure (% of CHE)**
  - 30% (2020)

- **Out-of-pocket expenditure (% of CHE)**
  - 54% (2020)

**Spending on pharmaceuticals**

- **Government pharmaceutical expenditure**
  - US$ 76 million (2019–20)

- **Government pharmaceutical expenditure/capita**
  - US$ 3 (2019–20)

- **Pharmaceutical expenditure (% of CHE)**
  - 38% (2019–20)

- **Share of out-of-pocket expenditure on pharmaceuticals**
  - 66%

**Medical and pharmacy workforce**

- **Medical doctors/10,000 population**
  - 8.67 (2021)

- **Pharmacists/10,000 population**
  - 1.71 (2021)

- **Pharmacy education accreditation**
  - Yes

- **Continuing professional development for pharmacists**
  - Partly

**Pharmaceutical legislation and policy**

- **1978**
  - Drugs Act, 2035

- **1981**
  - Drug Registration Regulation, 2038

- **1983**
  - Interrogation and Inspection Regulation, 2040

- **1984**
  - Codes on Drug Manufacturing, 2041 (updated 2015)

- **1986**
  - Drug Standard Regulation, 2043

- **1995**
  - National Drug Policy

- **2014**
  - Codes on sales and Distribution

- **2015**
  - Hospital Pharmacy Guideline

- **2015–2020**
  - Nepal Health Sector Strategy

- **2016**
  - Medicine Registration Guidance

- **2017**
  - Special permission guideline; Health Technology Product and Equipment Directive, 2074

- **2019**
  - National Health Policy

**Additional data**

- **Life expectancy at birth**
  - 68 years (2021)

- **Current health expenditure (CHE)/ capita (current US$)**
  - $58 (2020)

- **Government health expenditure (% of CHE)**
  - 30% (2020)

- **Out-of-pocket expenditure (% of CHE)**
  - 54% (2020)

- **Pharmaceutical expenditure (% of CHE)**
  - 38% (2019–20)

- **Share of out-of-pocket expenditure on pharmaceuticals**
  - 66%

- **Medical doctors/10,000 population**
  - 8.67 (2021)

- **Pharmacists/10,000 population**
  - 1.71 (2021)

- **Pharmacy education accreditation**
  - Yes

- **Continuing professional development for pharmacists**
  - Partly

- **Population**
  - 30,547,580 (2022)

- **Life expectancy at birth**
  - 68 years (2021)

- **GDP/capita (current US$)**
  - US$ 1,337 (2022)

- **Current health expenditure (CHE)/ capita (current US$)**
  - $58 (2020)

- **Government health expenditure (% of CHE)**
  - 30% (2020)

- **Out-of-pocket expenditure (% of CHE)**
  - 54% (2020)

- **Pharmaceutical expenditure (% of CHE)**
  - 38% (2019–20)

- **Share of out-of-pocket expenditure on pharmaceuticals**
  - 66%

- **Medical doctors/10,000 population**
  - 8.67 (2021)

- **Pharmacists/10,000 population**
  - 1.71 (2021)

- **Pharmacy education accreditation**
  - Yes

- **Continuing professional development for pharmacists**
  - Partly
Pharmaceutical country profile

**Nepal**

**Pharmaceutical legislation and policy**

Drug Registration Regulation, 2038

Medicine Registration Guidance, 2016

National Health Policy, 2019

Special permission guideline; Health Technology Product and Equipment Directive, 2074

Interrogation and Inspection Regulation, 2040

Drug Standard Regulation, 2043

National Drug Policy, 1995

Codes on sales and Distribution, 2014

Hospital Pharmacy Guideline, 2015

Codes on Drug Manufacturing, 2041 (updated 2015)

Drugs Act, 2035

**Medical and pharmacy workforce**

Medical doctors/10 000 population: 8.67 (2021)

Pharmacists/10 000 population: 1.71 (2021)

Pharmacy education accreditation: Yes

Continuing professional development for pharmacists: Partially

**Spending on pharmaceuticals**

% of market share of non-EML products: No data

WHO GLASS-AMC enrollment*: Yes, 2020

Total consumption of antibiotics: 891 911 859.47 DDD

**Spending on health**

Current health expenditure as share of GDP: 5% (2020)

Government health expenditure (% of CHE): 30% (2020)

Out-of-pocket expenditure (% of CHE): 54% (2020)

**Socioeconomic**

Life expectancy at birth: 68 years (2021)

GDP/capita (current US$): US$ 1337 (2022)

Population: 30 547 580 (2022)

**Intellectual property rights**

TRIPS flexibilities incorporated into the law

TRIPS flexibilities utilized: Not applicable

**Rational use and antimicrobial resistance**

% of market share of non-EML products: No data

WHO GLASS-AMC enrollment*: Yes, 2020

Total consumption of antibiotics: 891 911 859.47 DDD

**FDC sales in the private market**

No data

**Number of antibiotics on the private market**

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>AWARe</th>
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<tr>
<td>FDCs</td>
<td>4</td>
<td>No data</td>
<td></td>
</tr>
</tbody>
</table>

**National Regulatory Authority**

Department of Drug Administration (DDA)

Website: https://www.dda.gov.np/

Staff*: 115 (Technical and non technical)

Annual budget*: approx. US$ 10 575 (last fiscal year)

**Products regulated**

- **Medicines**
- **Biologicals**
- **Medical devices**
- **Traditional medicines**

**Licensing of establishments**

- **Manufacturers**
- **Importers**
- **Exporters**
- **Wholesalers**
- **Distributors**
- **Retailers**

**National Medicines Quality Control Laboratory**

1 (National Medicine Laboratory)

- ISO 17025 certified
- WHO prequalified

**Body responsible for selection of medical products**

Department of Drug Administration

- HTA used in the selection process
- NEML incorporated AWARe list
- Medicines listed by level of care
- Traditional medicines included

**National Essential Medicines List (number of active ingredient)**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Number of medicines</td>
<td>357</td>
<td>398</td>
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</table>

**National Medicines Formulary**

<table>
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<tr>
<th></th>
<th>1997</th>
<th>2010</th>
<th>2018</th>
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</thead>
<tbody>
<tr>
<td>Number of medicines</td>
<td>398</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**National Essential Diagnostics List**: Yes (in draft)
Pricing regulatory authority
Department of Drug Administration; Drug Pricing Monitoring Committee

Public sector
Tendering*: Yes

Private sector
Maximum retail price*: Yes
Number of price controlled products*: 117

1978
Article 26 of Drugs Act 1978

Estimated pharmaceutical market value
No data

Public
Tertiary hospitals*: 24
Secondary hospitals*: 92
PHC facilities*: 3911

Private
Manufacturers*: 128 (Allopathic + Vet); 80 Ayurveda
Importers*: 169
Wholesellers/distributors*: 3622
Retail pharmacies*: 27,903

Legal provision for
- Cancellation of licences of pharmaceutical establishments*
- Cancellation of marketing authorization of products*
- Initiating product recalls and withdrawals*
References

5. Reported by the Ministry of Health and Population, Nepal, 2023 (internal communication) based on NHA 2019-20
6. Reported by the Ministry of Health and Population, Nepal, 2023 (internal communication)
13. University of Boston, United States of America, "Medicines' price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research ", WHO 2021
SRI LANKA

Pharmaceutical country profile

**Socioeconomic**
- Population: 22,181,000 (2022)
- Life expectancy at birth: 76 years (2021)

**Spending on health**
- Current health expenditure (CHE)/capita: US$ 151 (2020)
- Government health expenditure (% of CHE): 47% (2020)
- Out-of-pocket expenditure (% of CHE): 4% (2020)
- Current health expenditure as share of GDP: 4% (2020)

**Spending on pharmaceuticals**
- Government pharmaceutical expenditure: US$ 176 million

**Medical and pharmacy workforce**
- Medical doctors/10,000 population: 12 (2021)
- Pharmacists/10,000 population: 1 (2021)
- Pharmacy education accreditation: Yes
- Continuing professional development for pharmacists: Yes

**Pharmaceutical legislation and policy**
- 1980: Regulations of Cosmetics, Devices and Drugs Act No. 27
- 1961: Ayurveda Act No. 31 of 1961
- 2006: National Medicinal Drug Policy
- 2014: National Immunization Policy
- 2015: National Medicines Regulatory Authority Act, No. 5
- 2017–2022: National Strategic Plan for Combating AMR

**Miscellaneous**
- Life expectancy at birth: 76 years (2021)
- Population: 22,181,000 (2022)
**Pharmaceutical country profile**

**Sri Lanka**

### Intellectual property rights

- TRIPS flexibilities incorporated into the law\(^6\)
- TRIPS flexibilities utilized\(^5\)

2003

Intellectual Property Act, No. 36 of 2003

### Rational use and antimicrobial resistance

#### % of market share of non-EML products

No data

WHO GLASS-AMC enrollment\(^9\): No

Total consumption of antibiotics\(^11\): 344.72 million DDD

#### FDC sales in the private market

No data

#### Number of antibiotics on the private market

<table>
<thead>
<tr>
<th>Total</th>
<th>AWARe</th>
<th>Not recommended</th>
</tr>
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<tbody>
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<td>Single drugs</td>
<td>No data</td>
<td></td>
</tr>
<tr>
<td>FDCs</td>
<td>No data</td>
<td></td>
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</tbody>
</table>

### Market entry

**National Regulatory Authority\(^12\)**

National Medicines Regulatory Authority (NMRA); Department of Ayurveda

Website: http://nmra.gov.lk; http://ayurveda.gov.lk

**Staff\(^9\):** NMRA: 141; Department of Ayurveda: 14

**Annual budget:** US$ 7,610,360

#### Products regulated

- ☑️ Medicines\(^9\)
- ☑️ Biologicals\(^9\)
- ☑️ Medical devices\(^9\)
- ☑️ Traditional medicines\(^9\)

**Number of registered products\(^9\):** approx. 6000 medicines and 960 traditional medicines (until 2018)

#### Licensing of establishments

- ☑️ Manufacturers\(^13\)
- ☑️ Importers\(^13\)
- ☑️ Wholesalers\(^13\)
- ☑️ Distributors\(^13\)
- ☑️ Retailers\(^13\)

#### National Medicines Quality Control Laboratory\(^9\)

1 laboratory

- ☑️ ISO 17025 certified\(^9\)
- ☑️ WHO prequalified\(^9\)

**Body responsible for selection of medical products\(^14\)**

Medical Supplies Division, Ministry of Health

**National Essential Medicines List (number of active ingredient)\(^15\)**

<table>
<thead>
<tr>
<th>1985</th>
<th>1988</th>
</tr>
</thead>
<tbody>
<tr>
<td>203 medicines</td>
<td></td>
</tr>
</tbody>
</table>

**National Medicines Formulary\(^16\):**

2016/2017

**National Essential Diagnostics List\(^5\):** No
Pricing regulatory authority
Medical Supplies Division; Ministry of Health; National Medicines Regulatory Authority

Public sector
Tendering: Yes

Private sector
Maximum retail price: Yes
Number of price controlled products: 60

2016
The National Medicines Regulatory Authority (Ceiling on Prices) Regulations No. 2 of 2016

2017
The National Medicines Regulatory Authority (Ceiling on Prices) Regulations No. 2 of 2017

2018
The National Medicines Regulatory Authority (Ceiling on Prices) Regulations No. 6 of 2018

2019
The National Medicines Regulatory Authority (Ceiling on Prices) Regulations 2019
The National Medicines Regulatory Authority Pricing Regulations 2019

Estimated pharmaceutical market value
US$ 599.5 million

Public
Tertiary hospitals: 49
Secondary hospitals: 71
PHC facilities: 973

Private
Manufacturers: 20
Importers: 200+
Wholesalers/distributors: 760+
Retail pharmacies: 2000+

Legal provision for
Cancellation of licences of pharmaceutical establishments
Cancellation of marketing authorization of products
Initiating product recalls and withdrawals

Social Health Insurance
Name of SHI scheme: Agrahara
Population coverage: 13% of the total population (only civil servants and their families)
Number of products covered: No (Agrahara only covers impatient care at private hospitals)
References

5. Reported by the Ministry of Health, Sri Lanka, 2023 (internal communication)
18. University of Boston, United States of America. "Medicines’ price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research ", WHO 2021
### Pharmaceutical Legislation and Policy

<table>
<thead>
<tr>
<th>Year</th>
<th>Act/Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1967</td>
<td>Drug Act of B.E. 2510</td>
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<tr>
<td>1975</td>
<td>Drug Act of (No.2) B.E. 2518</td>
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<tr>
<td>1979</td>
<td>Drug Act of No.3 2522; Narcotic Act B.E. 2522</td>
</tr>
<tr>
<td>1981</td>
<td>National Drug Policy</td>
</tr>
<tr>
<td>1985</td>
<td>Drug Act of (No.4) B.E. 2528; Narcotic Act (No.2) B.E. 2528</td>
</tr>
<tr>
<td>1987</td>
<td>Drug Act of (No.5) B.E. 2530; Narcotic Act (No.3) B.E. 2530</td>
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<tr>
<td>1993</td>
<td>National Drug Policy</td>
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<tr>
<td>2002</td>
<td>Narcotic Act (No.5) B.E. 2545</td>
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<tr>
<td>2011</td>
<td>National Drug Policy</td>
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<tr>
<td>2016</td>
<td>Phychotropic Substance Act, B.E. 2559</td>
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<tr>
<td>2017</td>
<td>Narcotic Act (No.6) B.E. 2560</td>
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<td>2017–2021</td>
<td>National Drug Policy; National Policy and Strategic Plan for Herbal Medicine; National Strategic Plan on AMR; National Policy for Vaccine Security</td>
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<tr>
<td>2019</td>
<td>Drug Act (No.6), B.E. 2562; Narcotic Act (No.7) B.E.2562; Herbal Product Act, B.E. 2562</td>
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<tr>
<td>2021</td>
<td>Act Promulgating the Narcotics Code, B.E. 2564</td>
</tr>
<tr>
<td>2023–2027</td>
<td>National Drug Policy and Strategy (draft); National Policy and for Vaccine Security; National Policy and Strategic Plan for Herbal medicine; National Strategic Plan on AMR (draft)</td>
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</table>
### Intellectual property rights

<table>
<thead>
<tr>
<th>Year</th>
<th>Law/Act</th>
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<tbody>
<tr>
<td>1992</td>
<td>Patent Act (No.2) B.E. 2535</td>
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<td>1999</td>
<td>Patent Act (No.3) B.E. 2542</td>
</tr>
<tr>
<td>Draft</td>
<td>Patent Act B.E.</td>
</tr>
</tbody>
</table>

### Rational use and antimicrobial resistance

#### % of market share of non-EML products

- 48%

#### WHO GLASS-AMC enrollment

- No

#### Total consumption of antibiotics:

- Antimicrobial = 1 246 283 290.10 DDD
- Antimicrobial = 46.32 DID
- Antibacterials for systemic use = 27.18 DID

### FDC sales in the private market

- No data

### Number of antibiotics on the private market

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>AWARe</th>
<th>Not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Access</td>
<td>Watch</td>
<td>Reserve</td>
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<tr>
<td>Single drugs</td>
<td>3192</td>
<td>1835</td>
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<tr>
<td>FDCs</td>
<td>332</td>
<td>281</td>
<td>18</td>
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</tbody>
</table>

### National Regulatory Authority

- Thai Food and Drug Administration
  - Website: [https://en.fda.moph.go.th/](https://en.fda.moph.go.th/)
  - Staff: 940
  - Annual budget: US$ 30 million

#### Products regulated

- **Medicines**
- **Biologics**
- **Medical devices**
- **Traditional medicines**

#### Licensing of establishments

- Manufacturers
- Importers
- Exporters
- Wholesalers
- Distributors
- Retailers

#### National Medicines Quality Control Laboratory

- 319
  - ISO 17025 certified
  - WHO prequalified

### Body responsible for selection of medical products

- National Committee of Drug System Development
  - HTA used in the selection process
  - NEML incorporated AWaRE list
  - Medicines listed by level of care
  - Traditional medicines included

#### National Essential Medicines List (number of active ingredient)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1981</td>
<td></td>
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<tr>
<td>1987</td>
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<tr>
<td>1992</td>
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</tr>
<tr>
<td>2019</td>
<td></td>
</tr>
<tr>
<td>2022</td>
<td>823</td>
</tr>
</tbody>
</table>

#### National Medicines Formulary

- 2016/17 National Hospital Formulary and National Herbal Formulary

#### National Essential Diagnostics List

- No
Thailand

Pharmaceutical country profile

Pricing regulation

Pricing regulatory authority
Department of Internal Trade, under Ministry of Commerce

Public sector
Tendering: Yes

Private sector
Maximum Retail Price: Yes, Thailand uses sticker price
Number of price controlled products: All medicines on the market

Legal provision for
- Cancellation of licences of pharmaceutical establishments
- Cancellation of marketing authorization of products
- Initiating product recalls and withdrawals

Market Exit

1999
Prices of Goods and Services Act, B.E. 2542

Market Distribution

Estimated pharmaceutical market value
US$ 7928 million

Public
Tertiary hospitals: 324
Secondary hospitals: 682
PHC facilities: 9770

Private
Manufacturers: 164
Importers: 621
Wholesalers/distributors: 614
Retail pharmacists: 15,572

1. Prices of Goods and Services Act, B.E. 2542
References


9. Reported by the Ministry of Public Health, Thailand, 2023 (internal communication)


11. AMR Thailand [website]. Thailand (https://amrthailand.net/Home/Thailand)

12. Thai Food & Drug Administration [website]. Thailand (https://www.fda.moph.go.th/Pages/HomeP_D2.aspx)


15. https://script.google.com/macros/s/AKfycby3Vt7OktU8mBnWn51Gr6uhW3s7jaEYeqW8_rXuPXR9wabHTbKjSjHGnT-6I13jmgNDTjw/exec)


18. University of Boston, United States of America, "Medicines' price regulatory interventions in the WHO South-East Asia Region: Policy review and recommendations for further research ", WHO 2021


21. Shared by the country based on internal database of the Bureau of Drug Control


Pharmaceutical country profile

**Socioeconomic**

- **Population**
  - 1,341,296 (2022)

- **Life expectancy at birth**
  - 68 years (2021)

- **GDP/capita (current US$)**
  - US$ 2,358 (2022)

**Spending on health**

- **Current health expenditure (CHE)/capita (current US$)**
  - $121 (2020)

- **10% (2020) Current health expenditure as share of GDP**

- **55% (2020) Government health expenditure (% of CHE)**

- **7% (2020) Out-of-pocket expenditure (% of CHE)**

**Spending on pharmaceuticals**

- **Government pharmaceutical expenditure**
  - US$ 10 million

- **Government pharmaceutical expenditure/capita**
  - US$ 7.5

- **2% Pharmaceutical expenditure (% of CHE)**

- **82% (2014) Share of out-of-pocket expenditure on pharmaceuticals**

**Medical and pharmacy workforce**

- **Medical doctors/10,000 population**
  - 8 (2020)

- **Pharmacists/10,000 population**
  - 2 (2020)

- **Pharmacy education accreditation**
  - Yes

- **Continuing professional development for pharmacists**
  - No

**Pharmaceutical legislation and policy**

- **2004**
  - Decree Law No. 12/2004, Pharmaceutical Activities

- **2017–2020**
  - National Action Plan on AMR

- **2018**
  - National Drugs and Medicines Policy

- **2023**
  - National Medicines Policy (final draft); Law for Pharmacies (draft); Law for Medicines and Narcotics (draft); Law for Psychotropics and Precursors (draft)

**TIMOR LESTE**

- **Life expectancy at birth**
  - 68 years (2021)

- **GDP/capita (current US$)**
  - US$ 2,358 (2022)

- **Government health expenditure (% of CHE)**
  - 7% (2020)

- **Out-of-pocket expenditure (% of CHE)**
  - 82% (2014)

- **Government pharmaceutical expenditure**
  - US$ 10 million

- **Government pharmaceutical expenditure/capita**
  - US$ 7.5

- **Current health expenditure (CHE)/capita (current US$)**
  - $121 (2020)

- **Spending on pharmaceuticals**

- **Medical doctors/10,000 population**
  - 8 (2020)

- **Pharmacists/10,000 population**
  - 2 (2020)

- **Pharmacy education accreditation**
  - Yes

- **Continuing professional development for pharmacists**
  - No

- **National Action Plan on AMR**

- **National Drugs and Medicines Policy**

- **National Medicines Policy (final draft); Law for Pharmacies (draft); Law for Medicines and Narcotics (draft); Law for Psychotropics and Precursors (draft)**
**Pharmaceutical country profile**

**Timor Leste**

### Intellectual property rights

- TRIPS flexibilities incorporated into the law: Not applicable
- TRIPS flexibilities utilized: Not applicable

### Rational use and antimicrobial resistance

| % of market share of non-EML products | 68% |
| WHO GLASS-AMC enrollment: | Yes, 2020 |
| Total consumption of antibiotics: | No data |

#### FDC sales in the private market

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>AWARe</th>
<th>Not recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Access</td>
<td>Watch</td>
<td>Reserve</td>
</tr>
<tr>
<td>Single drugs</td>
<td>95</td>
<td>48</td>
<td>47</td>
</tr>
<tr>
<td>FDCs</td>
<td>25</td>
<td>25</td>
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</tr>
</tbody>
</table>

#### Number of antibiotics on the private market

- Total AWaRe Not recommended
- Total FDC sales in the private market
- Single drugs
- FDCs

### Market entry

**Products regulated**

- Medicines
- Biologics
- Medical devices
- Traditional medicines

**Licensing of establishments**

- Manufacturers
- Importers
- Exporters
- Wholesalers
- Distributors
- Retailers

**National Regulatory Authority**

1. National Directorate of Pharmacy and Medicines;
2. Cabinet of Licencing and Health Professional Registration;
3. Cabinet of Health Inspection and Audit;
4. National Health Laboratory

Website: [https://www.ms.gov.tl](https://www.ms.gov.tl)

Staff: 20

Annual budget: No data

**National Medicines Quality Control Laboratory**

1 (National Health Laboratory)

- ISO 17025 certified
- WHO prequalified

**Body responsible for selection of medical products**

Committee for Selection of Medicines; Products and Medical Equipment (CSMPEM sigla in Tetum) supervised by the National Directorate of Pharmacy and Medicines; Department of Pharmacovigilance and Medicine Control

**National Essential Medicines List (number of active ingredient)**

- 2015
- 274 medicines

**National Medicines Formulary**

- No data

**National Essential Diagnostics List**: No (under development)
### Procurement
- **Centralised**

**Agency responsible for procurement**: Central Medical Stores – SAMES I.P

**LMIS used**: mSupply

**Frequency of tender**: Annual plus emergency tenders, if necessary

### Pricing regulatory authority
1. National Regulatory Authority, National Directorate of Pharmacy and Medicines; 2. SAMES I.P

### Public sector
- **Tendering**: Yes

### Private sector
- **Maximum retail price**: No
- **Number of price controlled products**: No data

### Estimated pharmaceutical market value
- **Public**: No data
- **Private**: No data

### Market distribution
- **Public**
  - Tertiary hospitals: 1
  - Secondary hospitals: 5
  - PHC facilities: 9 municipal CHCs, 61 submunicipal CHCs, 321 health posts

### Market exit
- **Legal provision for**
  - Cancellation of licences of pharmaceutical establishments
  - Cancellation of marketing authorization of products
  - Initiating product recalls and withdrawals

### Social Health Insurance
- **Name of SHI scheme**: Not applicable
- **Population coverage**: Not applicable
- **Number of products covered**: Not applicable
### Timor Leste

#### Pharmaceutical Country Profile

**Pricing Regulation**

- **Market exit**: Cancellation of licences of pharmaceutical establishments, cancellation of marketing authorization of products, initiating product recalls and withdrawals.

**Purchasing**

- **Market distribution**: Centralised.
- **Agency responsible for procurement**: Central Medical Stores – SAMES I.P.
- **LMIS used**: mSupply.
- **Frequency of tender**: Annual plus emergency tenders, if necessary.

**Public Sector**

- **Tendering**: Yes.
- **Name of SHI scheme**: Not applicable.
- **Population coverage**: Not applicable.
- **Number of products covered**: Not applicable.

**Private Sector**

- **Manufacturers**: None.
- **Importers**: 25.
- **Wholesalers/distributors**: 25.
- **Retail pharmacies**: 60.

**Total Number of Public and Private Sector Establishments**

- **Tertiary hospitals**: 1.
- **Secondary hospitals**: 5.
- **PHC facilities**: 9 municipal CHCs, 61 submunicipal CHCs, 321 health posts.

**Estimated Pharmaceutical Market Value**

- No data.

**References**

5. Reported by the Ministry of Health, Timor-Leste, 2023 (internal communication)
6. Reported by the Ministry of Health, Timor-Leste, 2023 (internal communication) based on NHA 2021