Access to medical products in the South-East Asia Region, 2019: Review of progress
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Expanding access to essential medical products

FOREWORD BY THE REGIONAL DIRECTOR

Improving access to medical products is key to achieving universal health coverage (UHC) and the health-related Sustainable Development Goals. SDG 3.8 specifically mentions that “access to safe, effective, quality and affordable essential medicines and vaccines for all” is a central component of UHC.

This 2019 report provides an update to the 2017 publication “Improving access to medicines in the South-East Asia Region”. The scope is broader than the previous report: while the main focus is still on medicines, information on access to vaccines, medical devices and diagnostics is included where possible, in keeping with recent regional and global developments.

Improving access to essential medicines has been a focus of the Region’s Flagship Priority on universal health coverage, which was launched in 2014. There has been welcome progress. Current data, although limited, does show the overall availability of medicines has improved over the past ten years, and is on the whole better for communicable diseases than noncommunicable diseases. By contrast, data on the availability of basic medical diagnostics and devices show more significant gaps. In addition, the latest analysis reconfirm that the main driver of out-of-pocket spending and impoverishment due to health spending continues to be medicines.

The “Delhi Declaration: improving access to essential medical products in the South-East Asia Region and beyond” was signed by all Member States in 2018. It encapsulates a set of commitments to address remaining challenges in procurement and pricing, regulation, financing, use of intellectual property and trade rules, supply chain management, rational use and generation of better data.

Some actions lie with individual national authorities. There are also growing opportunities for collaboration between countries in multiple areas, and for innovation. Progress in the different areas is reviewed in this publication. I highlight a few major developments here, with a particular focus on inter-country collaboration and innovation.

Collaboration in procurement

The Initiative for Coordinated Antidotes Procurement in the South-East Asia Region (iCAPS) was launched in 2017. It helps South-East Asia Region Member States procure antidotes for a range of common poisonings. There is increasing interest in strengthening intercountry and sub-regional collaboration on procurement and pricing, and there is now an opportunity to develop tailored regional procurement models for medicines and vaccines.
Collaboration for smarter regulation

The South East Asia Regulatory Network (SEARN) has facilitated collaboration and reliance between national regulatory authorities in the Region since 2016. SEARN also plays a major role in improving the technical capacity of national regulators, inspectors and medicines quality control laboratories to ensure the quality of medicines and other medical products.

SEARN’s working groups are promoting collaboration in quality assurance, vigilance and good regulatory practice. I want to highlight three useful products here. First, accelerated product registration is being actively explored using antiviral medicines for HIV/AIDS and hepatitis C as a test case. Second, SEARN is facilitating access to medicine quality control testing for countries with limited capacity through a quality control laboratory network. And third, the SEARN Information Sharing Platform (ISP), launched in 2018, is now a key tool for closer information exchange between regulators.

Greater capacity to work within intellectual property and competition rules and use TRIPS flexibilities

The World Trade Organization’s Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) allows Member States to take measures to ensure early access to medicines even when patents are still in force. In practice, there is flexibility within TRIPS that gives countries several options for action, and there is experience within this Region that can be shared. This is important and to be encouraged.

Appropriate use of medical products

Medicines, diagnostics and devices need to be used correctly to be effective. Clinical guidelines and essential lists for medicines and for different medical products can help. It is encouraging to see the emerging development of national essential diagnostics lists. However, adherence to guidelines by health professionals is still variable, and an area worthy of more attention.

...with more attention to antimicrobial stewardship

Effective antimicrobial stewardship includes the monitoring of trends in consumption, national policies and guidance, and education and advocacy on antimicrobial use for consumers and health professionals. WHO is supporting the development of national systems to monitor antimicrobial consumption, with some countries already developing robust systems and initiated reporting.

A new tool classifies antibiotics into three groups – Access, Watch, Reserve (AWaRe) to help prescribers prescribe more appropriately. It is encouraging to see almost half of the South-East Asia Region’s Member States have already adopted the AWaRe classification as a tool to maintain effective use of antibiotics.
Innovations to improve monitoring of access to medical products

The lack of robust information on availability, access to and affordability of medical products means that it is difficult for policymakers to know how their policies are working. MedMon is a new smartphone application that can facilitate the rapid collection of data on availability and price of medical products. It is now being used in the field by several South-East Asia Region countries.

At the regional level, a set of practical key performance indicators for monitoring access and the performance of pharmaceutical systems were identified in 2019 at a regional expert consultation and will be tested in countries for regular monitoring.

Overall, I am encouraged by the Region’s progress, though emphasize the need to accelerate it. I have confidence that Member States are well-positioned to do that, and take innovative approaches to increase access to essential medical products. We will continue to report on progress in the Region every two years.

Dr Poonam Khetrapal Singh
Regional Director
PART I
Improving access to medical products: where are we now?
Universal coverage means all people get the health care they need, without suffering financial hardship. The Regional Flagship on Universal Health Coverage (UHC) has had a focus on improving access to essential medicines, together with strengthening the health workforce, since 2014. The Region was therefore well-positioned when a similar commitment was made with the adoption of the 2030 Agenda for Sustainable Development in 2016. That agenda explicitly recognized the importance of access to medicines to make progress on UHC. Within the Sustainable Development Goal (SDG) for health, target 3.8 is to “Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”.¹

Last year, Member States of the South-East Asia Region reaffirmed and extended their commitment by endorsing the Delhi Declaration on Improving Access to Essential Medical Products in the South-East Asia Region and Beyond². The Declaration goes beyond medicines to include vaccines, diagnostics and medical devices, it covers actions on pricing, procurement, intellectual property, regulation, appropriate use, data and financing to accelerate progress. In addition, following the Astana Declaration on Primary Health Care³ in 2018, there is increasing attention to improving the availability of essential medical products in frontline health facilities.

| Box 1. The Sustainable Development Goals (SDG) access to medicines target and indicator |
| SDG Target 3.b: | SDG Target 3.b. indicators for access |
| Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all. | 3.b.1 Proportion of the target population covered by all vaccines included in their national programme ¹ |
| 3.b.3 Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis ¹ |

Increased attention is also being given to monitoring access. The approval of the Sustainable Development Goals’ (SDGs) indicator 3.b. on access to medicines and vaccines⁴, is part of formal reporting on progress towards SDGs. The SDG Target 3.b. has two indicators relevant to access to medicines and other health products.
What is the status of these indicators in the South-East Asia Region?

This publication provides an update to the 2017 report on improving access to medicines and includes information for the first time on selected other medical products.

Proportion of target population covered by vaccines

Regional immunization coverage with three doses of diphtheria, tetanus, and pertussis (DTP3) has been maintained above 90% since 2012, with DPT coverage ranging between 76% - 99% in 2017. In the last five years five countries sustained high (>95%) coverage.

Figure 1: Regional Immunization coverage with three doses of diphtheria, tetanus, and pertussis (DTP3) containing vaccines, 2008 – 2017

Availability of essential medicines in health facilities

The availability and affordability of medicines, as per the standard method for reporting SDG 3. b.3. indicator of medicines availability, is not yet regularly monitored globally or in the South-East Asia Region. The last section of this publication will discuss approaches to strengthening monitoring in more detail.

Table 1 summarizes recent health facility surveys in the Region which collect information on medicines availability and price.

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Reference</th>
<th>Study reporting on availability</th>
<th>Study reporting on prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>2018</td>
<td>Service Availability and Readiness Assessment (SARA) survey for NCDs and Disability Service Delivery System in Bangladesh. 2018; (Internal Communication)</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Myanmar</td>
<td>2015</td>
<td>Nation-wide Service Availability and Readiness Assessment (SARA) Myanmar 2015 (Internal Communication)</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Country</td>
<td>Year</td>
<td>Reference</td>
<td>Study reporting on Availability</td>
<td>Prices</td>
</tr>
<tr>
<td>---------</td>
<td>------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------</td>
<td>--------</td>
</tr>
</tbody>
</table>

Figure 2 reports the overall availability of a nationally defined basket of essential medicines from recent national surveys in four countries. It ranges from 51% to 79% and is on average higher in private than public facilities, as was reported in the 2017 publication.5

*Figure 2: Average availability (%) of essential medicines in four countries of the WHO South-East Asia Region*

![Figure 2: Average availability (%) of essential medicines in four countries of the WHO South-East Asia Region](image)

n = number of medicines in the basket

Source: Service Availability and Readiness Assessments (SARA) survey Myanmar, 2015, Sri Lanka, 2017; Service Provision Assessments (SPA) survey Bangladesh, 2017, Nepal, 2015 (Table 1)

When disaggregated by level of care medicines availability is higher in hospitals compared to primary care facilities in public sector (Figure 3).
Figure 3: Availability of essential medicines in public and private health facilities by level of care

Altogether, the availability of a basket of essential medicines in public and private health facilities appears to be improving, based on information from these surveys.

Availability of essential diagnostics in health facilities

Availability of essential diagnostic tests in the same four countries shows that these were less available compared with medicines. Again, availability tends to be higher in the private sector. Low availability of blood glucose and urine dipsticks is a concern given the rising burden of diabetes in the Region.

Figure 4: Average availability of three essential diagnostic tests in public and private health facilities

Notes * ANC Haemoglobin shows availability in facilities providing antenatal services; # Blood glucose tests indicate using glucometer. + Urine protein indicates using urine dipsticks.
Treatment for noncommunicable diseases

Noncommunicable diseases (NCDs) – cardiovascular diseases, cancers, chronic respiratory diseases and diabetes – contributed to over 9 million deaths in the South-East Asia Region in 2016.\(^1\) Medicines are needed for effective control.

Access to NCD medicines is variable across South-East Asia Region countries but with signs of progress.\(^8\) Importantly, better data, now provides a more accurate picture of the situation. A survey in Bangladesh in 2018 found the availability of essential medicines in 541 health facilities was 17% for diabetes; 32% for cardiovascular diseases and 21% for asthma. The capacity of frontline health facilities to conduct necessary diagnostics test for these conditions were similarly low. Encouragingly, trend data from Sri Lanka shows that since 2014 (Figure 5) the availability of medicines for cardiovascular diseases has improved, with over 90% of facilities (Table 1) stocking ACE inhibitors, beta blockers, loop diuretics, statins and thiazide.

*Figure 5: Improvement in availability of cardiovascular medicines in Sri Lanka (2014 vs 2017)*

![Figure 5: Improvement in availability of cardiovascular medicines in Sri Lanka (2014 vs 2017)](image)

Source: WHO/HAI medicines price and availability survey 2014 and SARA survey 2017 (Table 1)

Altogether, data from the latest WHO STEPS surveys in nine Member States show that the percentage of people with hypertension whose condition is controlled ranges from under 2% to 30%. The range is similar for diabetes. At best this means less than a third of patients with hypertension and diabetes are controlled in the Region. This is a large and urgent problem.
Figure 6: Diagnosis and treatment gap for hypertension in the Member States of WHO South-East Asia Region

![Graph showing diagnosis and treatment gap for hypertension](image)

Source: Calculations from different STEP or Equivalent population-based Surveys. India for selected 15 states. *among people who were measured to be hypertensive at the time of the survey.

Access to pain medication

Improving access to pain relief and palliative care has received an increased attention in the last five years. WHO Member States passed the first global resolution on palliative care in 2014, WHO has included an indicator in its 13th General Programme of Work (2019-2023) Impact Framework, with a target to increase the availability of oral morphine in facilities providing palliative care, from 25% to 50%.

Over 15 million people in South-East Asia Region are estimated to experience serious health-related suffering, with a significant gap in access to adequate pain relief. The medical use of opioids for pain relief is low in South East Asia compared to other Regions and significantly below the globally accepted adequate level of 200 S-DDD level.

Figure 7: Total opioid consumption, excluding methadone*, (Defined Daily Dose/million population/day (S-DDD))

![Graph showing total opioid consumption excluding methadone](image)

*Methadone is mainly used as part of treatment for addiction to narcotics, hence it is excluded from this analysis. 200 S-DDD threshold below consumption considered inadequate according to INCB.

With the growing prevalence of chronic diseases, cancer and other disorders associated with severe pain, it is timely to consider how to improve access to medicines to relieve severe pain in this Region. Commonly reported barriers to the availability of narcotic medicines for pain management globally are shown in Figure 8.
Figure 8: Top five most commonly reported factors limiting the availability of narcotic drugs

![Chart showing the top five factors limiting the availability of narcotic drugs: Lack of training/awareness, Fear of addiction, Fear of diversion, Problems in sourcing, Trade control measures.]


Out-of-pocket expenditure on medicines

Universal health coverage is about two things: access to needed quality care and financial protection. Despite the improvements noted earlier, availability of essential medicines and other essential medical products remains a challenge. The result is that people then pay for their medicine out-of-pocket from private outlets. The high level of out-of-pocket spending on health care in many South-East Asia Region countries is well-known. Evidence from seven South-East Asia Region countries show that spending on medicines accounts for the main share of out-of-pocket payment, in all but one of these countries (Figure 9). Medicines continue to be the main driver of impoverishment due to health care costs.

Figure 9: Share of medicines expenditures as % of total households’ out-of-pocket (OOP) spending on health

![Bar chart showing the share of medicines expenditures as % of total households’ OOP spending on health for different countries.]

Out-of-pocket spending on medicines is also inequitable. Figure 10 shows that poorer households spend up to 18% more on medicines than their richer counterparts.
Spending on both low cost and high cost medicines and other medical products may lead to catastrophic spending and impoverishment. There is growing awareness of a problem with high cost cancer medicines. A recent study in the Association of Southeast Asian Nations (ASEAN) countries found that 75% of patients had either died or suffered financial catastrophe a year after cancer diagnosis. People from low-income groups were hardest hit and had higher odds of financial catastrophe or death compared to those from high-income groups.
PART 2
Improving access to essential medical products: what interventions are being used?
**National medicines policies**

National medicines policies provide the framework for how a country intends to organize, finance and regulate the pharmaceutical sector, to ensure equitable access to quality medicines and other health technologies to meet health care needs.

WHO recommends national policies are updated every five years. National medicines policies have been updated in four South-East Asia Region countries in the last five years.

*Table 2: Latest year of updating National Medicines Policies*

<table>
<thead>
<tr>
<th>BAN</th>
<th>BHU</th>
<th>DPRK</th>
<th>IND</th>
<th>INO</th>
<th>MAV</th>
<th>MMR</th>
<th>NEP</th>
<th>SRL</th>
<th>THA</th>
<th>TLS</th>
</tr>
</thead>
</table>

** National legislature, rule and regulation for drug management

Source: Country pharmaceutical profile information (Part 4)

**Product selection, pricing and procurement**

**Essential medicines lists are adapting to changing health needs**

The concept of Essential Medicines is a long-established approach to improve access. The 1st edition of WHO’s Model List of Essential Medicines was published in 1977. Since then, all countries have developed their own National EMLs in the Region. National Essential Medicines Lists (EMLs) are used both to improve efficiency of public sector procurement and promote rationale use. Criteria for the selection of medicines in national EMLs include common morbidities, evidence of cost–effectiveness, and affordability for government or health insurance schemes.

WHO suggests countries update their EMLs every two years. Since 2017, seven countries have updated their national EMLs (Table 3).

*Table 3: National essential medicines lists: dates of most recent revision*

<table>
<thead>
<tr>
<th>BAN</th>
<th>BHU</th>
<th>DPRK</th>
<th>IND</th>
<th>INO</th>
<th>MAV</th>
<th>MMR</th>
<th>NEP</th>
<th>SRL</th>
<th>THA</th>
<th>TLS</th>
</tr>
</thead>
</table>

EML updates in South-East Asia Region countries are now incorporating WHO’s Access/Watch/Reserve “AWaRe” classification for antibiotics, introduced in 2017 (Box 2).

Antibiotics have been grouped into the three categories, with recommendations on when each category should be used. The change aims to ensure that antibiotics are available when needed, and that the right antibiotics are prescribed for the right infections.
Access to medical products in the South-East Asia Region, 2019: Review of progress

Box 2. The WHO AWaRe categorization

The overall goal is to reduce the use of Watch Group and Reserve Group antibiotics and to increase the use of Access antibiotics where availability is low.

Access to treatment for cancer

The second EML-related development concerns cancer medicines. The most recent WHO Model Essential Medicines List includes an increasing range of cancer medicines.

All South-East Asian Region countries include some cancer treatment in their national EMLs, though there is a wide variation between countries (Figure 11) in the WHO recommended cancer treatments that are included in EMLs. India and Thailand have over half of the WHO recommended cancer medicines in their EMLs, while Bangladesh includes less than one-third. It is usual for countries to take a gradual approach to adding new drugs into EMLs, but low rate of selection of effective cancer medicines limits access to life-saving treatment prices of these high cost medicines.

Figure 11. Selection of 38 essential cancer medicines in national lists of essential medicines in the WHO South-East Asia Region

Bangladesh, Bhutan, Indonesia, Maldives and Nepal, have already included or are in the process of adopting the AWaRe categorization in their national EML and/or national formulary, and other countries are also planning to use this strategy. This is an important part of the campaign against antimicrobial resistance.
Even if cancer medicines are included in national EMLs, patients may still bear the cost of treatment out-of-pocket: of five South-East Asian Region countries with data on this, Indonesia and Thailand are the only ones where both regular availability and free access is reported for cancer medicines listed in the national EML. 16,17

**Essential diagnostic lists are beginning to be introduced, using the same concept**

The concept of essential medicines lists is now being also applied to diagnostics and medical devices to improve access to these health products.

India has been the first country in the Region to draft a National Essential Diagnostic List (NEDL) in 2018, aiming to improve the availability of quality diagnostics at all levels of healthcare facilities in the country. This effort, coupled with the recent “Free Diagnostics Initiative” of the National Health Mission, is contributing to improved availability of free diagnostics in India, as shown in Box 3. 18

**Box 3. Andhra Pradesh – free diagnostics scheme**

There has been significant improvement in access to laboratory services and a reduction in out-of-pocket expenditure for diagnostic services because of the implementation of NTR Vaidya Pariksha scheme or free diagnostic scheme.

The expanded basket of tests available through the service meant that compared to the period in 2015-16 before the implementation of the scheme when the total number of patients tested increased by 15%, during to 2016-17 there was an increase of 29%.

A survey commissioned by the state government revealed that per capita out-of-pocket expenditure on diagnostics across public and private sectors reduced by 55%.

Average out-of-pocket expenditure per patient on diagnostics for chronic diseases in the public sector decreased by 40% in this period.

**Improving access by strengthening national procurement capacity**

Timor-Leste began Saúde na Família, its primary health care programme in 2015. There have been challenges in ensuring uninterrupted access to essential medicines, particularly in primary care centres. This is partly to do with national procurement capacity.

In the last two years, action has been taken to strengthen capacity of the national procurement agency, Serviço Autônomo de Medicamentos e Equipamentos de Saúde (SAMÉS), which has improved its quantification and forecasting methods to reduce stockouts. It has enhanced pharmaceutical quality assurance and its logistics management information systems with more sophisticated reporting on performance. Timor-Leste’s investments in capacity building for procurement have already resulted in savings of over US$2 million and fewer stock-outs.
Improving access through inter-country collaboration in procurement

Cost-effective procurement is a well-recognized challenge for small countries who have small markets and therefore less price-negotiation power. The challenge of “small markets” can also apply to entire product groups for which only small volumes are needed. Antidotes are one example of such “orphan drugs”, which are difficult to procure either because of global shortages or because of the small volumes needed at any one time.

In the WHO South-East Asia Region, public procurement agencies have been experiencing unfulfilled tenders for essential antidotes due to low prices and small volumes, resulting in facility stockouts.

The Initiative for Coordinated Antidotes Procurement in the South-East Asia Region (iCAPS) was launched in early 2018. Through iCAPS, South-East Asia Region Member States can utilize Thailand’s Ramathibodi Poison Centre as a regional hub to procure antidotes for a wide range of common poisonings: non-specific poisoning, heavy-metal poisoning, cyanide poisoning, lead poisoning, and methemoglobinemia. They can do this on a regular or emergency basis (see Box 4). This systematic approach for antidote procurement is expected to improve procurement efficiency by aggregating demand, reducing costs, and coordinating quality assurance. Six countries are now active in the initiative, and four have placed orders in 2019.

| Box 4. Pathways for coordinated antidotes procurement through iCAPS |
|--------------------------|---------------------------------|------------------|------------------|------------------|
| **EMERGENCY RESPONSE PATHWAY** | **CALL** Call by authorized country representative (identified by WHO) to Ramathibodi Poison Centre in Bangkok, Thailand followed by submission | **DELIVER** Rapid delivery of antidote for individual case via fast-tracked process | **TRACK CASE** Evaluation form completed by country and sent back to Ramathibodi Poison Centre |
| **PLANNED JOINT ANNUAL PROCUREMENT PATHWAY** | **FORECAST/ORDER** Annual quantities of selected antidotes forecasted by requesting countries. Order submitted to National Health Security Office, Thailand. | **PROCURE/DELIVER** Order delivered to countries and payments transferred per schedule of purchasing contract. | **MONITOR & EVALUATE** Periodic review of initiative |
Two pathways for coordinated antidotes procurement through iCAPS

The initiative for coordinated antidotes procurement in the South-East Asia Region (iCAPS) aims to improve access to essential antidotes and help to prevent premature deaths due to poisoning. iCAPS does this by supporting public health systems to secure the supply of essential antidotes both in emergencies and on a regular basis through multi-country collaborative procurement.19

Pricing policies

Pricing policies can be applied to public procurement agencies and to private sales to consumers. In a region where so many people buy from private outlets, price variation of the same medicine in different pharmacies is a major challenge. One study found a 1500% variation in the price of furosemide, a commonly prescribed essential medicine for congestive heart failure.20

In order to improve affordability of medicines, India and Sri Lanka have set ceiling prices on selected essential medicines and devices. Showing the impact of these policies on financial access and out-of-pocket payment will take time, but there are some early findings, shown in Box 5.

<table>
<thead>
<tr>
<th>Box 5. Impact of price reductions in India and Sri Lanka</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INDIA Ayushman Bharat and improving access to reduced price generic products</strong></td>
</tr>
<tr>
<td>A centrally sponsored scheme launched in 2018, under the Ayushman Bharat reform of Ministry of Health and Family Welfare aims at improving access to quality health care in India.</td>
</tr>
<tr>
<td>India’s Pradhan Mantri Bhartiya Jan Aushadhi Yojana Kendra campaign launched by the Department of Pharmaceuticals, aims to provide quality medicines at affordable prices.</td>
</tr>
<tr>
<td>Affordable quality generics are sold at much lower (50%–90% less) prices than in private pharmacies, through Jan Aushadhi Kendra outlets. This is contributing to improved access and lowering of out-of-pocket payments.</td>
</tr>
<tr>
<td><strong>Sri Lanka medicines prices controls</strong></td>
</tr>
<tr>
<td>Price caps on retail prices of 48 essential medicines were introduced in October 2016.</td>
</tr>
<tr>
<td>Subsequently, the National Medicines Regulatory Authority (NMRA) expanded price controls to more medicines and medical devices and introduced maximum price controls on tender prices for high-cost cancer medicines.</td>
</tr>
<tr>
<td>There is some preliminary evidence of benefits to patients in terms of increased sales of price-controlled products.</td>
</tr>
<tr>
<td>The NMRA is evaluating the effect of these pricing regulations. They are also continuing with further development of other approaches such as external reference pricing, mark-up regulation and index pricing.</td>
</tr>
</tbody>
</table>
Regional information sharing on pricing

The WHO Price Information Exchange for Medicines (PIEMEDS)\(^2\) is a web-based platform enabling procurement groups, policy makers, price negotiators, and regulators to: negotiate fair prices, strengthen collaboration between agencies for joint procurement, compare medicine expenditures with other countries at similar stages of development, track trends and impact of interventions, use price information as evidence to design and update pricing policies, and understand reasons for regional price variations.

**Working within intellectual property and competition rules, using TRIPS flexibilities**

The Delhi Declaration includes reference to “encourage management of intellectual property and trade rules and using TRIPS flexibilities”. The World Trade Organization’s 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was designed to provide product patent protection. Countries with Least Developed Country (LDC) status (there are five in South-East Asia Region) are not obliged to observe WTO requirements on patent protection of pharmaceuticals (Table 4). The TRIPS Agreement acknowledged LDCs’ need for maximum flexibility in implementing laws and regulations domestically to advance in their national development. Box 6 provides an example. However, once countries graduate from LDC status they would need to become TRIPS compliant, that is, be able to enforce and protect patents and intellectual property.

In the 2001 Doha Declaration, the use of TRIPS flexibilities to promote access to treatment of public health importance were reaffirmed. In practice, this means using a product without the patent holders’ permission – by issuing compulsory licenses or permitting parallel imports.

**Table 4:** The use of compulsory licenses by South-East Asia countries in the last 5 years\(^22,23\)

<table>
<thead>
<tr>
<th>Country</th>
<th>WTO membership since</th>
<th>Least developed country (LDC) status</th>
<th>TRIPS flexibilities utilized in last 5 years (or most recent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>1-Jan-95</td>
<td>LDC</td>
<td>NO</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Observer (1999)</td>
<td>LDC</td>
<td>NO</td>
</tr>
<tr>
<td>DPRK</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>India</td>
<td>1-Jan-95</td>
<td>NO</td>
<td>2015 (Saxagliptin – flexibility not executed)</td>
</tr>
<tr>
<td>Indonesia</td>
<td>1-Jan-95</td>
<td>NO</td>
<td>2012 (ABC, DDI, EFV, EFV/FTC/TDF, LPV/r, TDF, FTC/TDF)</td>
</tr>
<tr>
<td>Maldives</td>
<td>31-May-95</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Myanmar</td>
<td>LDC</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Nepal</td>
<td>23-Apr-04</td>
<td>LDC</td>
<td>2008 – ARVs</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>1-Jan-95</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Thailand</td>
<td>1-Jan-95</td>
<td>NO</td>
<td>2012 (EFV/FTC/TDF, 3TC/AZT/EFV)</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>Observer (2015)</td>
<td>LDC</td>
<td>NO</td>
</tr>
</tbody>
</table>
Box 6. Bangladesh: Developing national medicines production capacity

As an LDC member of WTO, Bangladesh is exempted from patentability and is under no obligation to grant patent protection to pharmaceutical products while on the LDC list. This partially helped the rapid development and expansion of national pharmaceutical production capacity, including the recent production of generic version of innovative medicines for treatment of Hepatitis C.

Patients may benefit by early access to new treatments due to this national production capacity and LDC status of Bangladesh.

Once Bangladesh graduates from LDC status the country will need to frame modern intellectual property laws; fully incorporating in national law the TRIPS flexibilities. Intellectual property provisions should assist in strengthening innovative capacity, in a way that is consistent with affordable access to medicines, while providing benefits in terms of investment, employment and technology transfer.

Enhancing regulatory capacity for quality and safety of health products

Strengthening National Regulatory Authorities (NRAs)

There has been significant progress in NRA capacity development in recent years in the Region. Currently, National Regulatory Authorities (NRAs) in three countries – India, Indonesia and Thailand – have been judged to have adequate regulatory capacity (“functional NRA”) for vaccines, based on WHO’s assessment.

There is also progress on medicines regulation. The Bangladesh National Regulatory Authority has completed the WHO interim assessment for both their medicines and vaccines regulatory capacity and are aiming to achieve Maturity Level 3 in the near future. Bangladesh has also successfully implemented a technical/ donor partner coordination mechanism to support implementation of their Institutional Development Plan to improve regulatory performance and increase efficiency of technical support received from WHO, Management Sciences for Health (MSH), United States Pharmacopeia (USP) and United States Agency for International Development (USAID).

Other regulatory agencies are at different stages of self-assessment using the WHO Global Benchmarking tool. Nepal and Sri Lanka are moving towards formal WHO assessment in 2019.

Greater regional cooperation for regulation through SEARN

The South-East Asia Regulatory Network (SEARN) was established in 2016 to enhance information-sharing, collaboration and convergence of regulatory practices for medical products across the Region to guarantee access to high-quality medical products. \(^{24,25}\)

Three annual meetings that SEARN convened have been of critical importance in taking this collaborative agenda forward. To support its overall objectives SEARN has set-up five working groups:
- **SEARN Information Sharing Platform**: has been launched, with support from India, as the main gateway to share regulatory information between SEARN NRAs and support all communication/data/information sharing needs of all SEARN working groups.

- **Quality assurance and standards of medical products**: the working group has developed collaboration between National Medicines Quality Control laboratories to strengthen their capacity and design laboratory testing services across countries. A list of priority medicines for quality control testing has been agreed.

- **Good Regulatory Practices (GRP)**: the working group agreed to share information/experiences and support capacity building in GRPs and GXP*s (GCP, GLP, GMP, GDP, etc.). The working group is developing regional regulatory pathways that can accelerate market entry of medicines. This is starting with joint assessment of priority antiretroviral fixed-dose combination products.

- **Vigilance for medical products**: to improve medicines and health product safety in the Region the working group is setting up communication channels on medicines alerts and other medical product safety issues. Annual capacity development activities in pharmacovigilance and other vigilance related to health products are planned.

- **Medical devices and diagnostics**: the working group will share information/experiences and support capacity building on how to develop regulatory frameworks, safety monitoring systems for medical devices and *in vitro* diagnostics.

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*a GXPs is abbreviation for “good practices” quality guidelines and regulations, e.g. Good clinical practice (GCP); Good laboratory practice (GLP); Good manufacturing practice (GMP); Good Distribution Practice (GDP), etc.*
The SEARN Information Sharing Platform (ISP) gateway, is progressively expanding the data it stores across several key regulatory areas. As it matures, NRAs will share alerts and confidential information to ensure quality medical products reach all people, everywhere in the Region.

**Appropriate use of medicines: a focus on antibiotic stewardship**

Ensuring appropriate use of medicines is part of ensuring access. Antibiotic sales analysis shows worryingly high sales of many WATCH Group antibiotics. In the recent WHO analysis of IQVIA antibiotics sales data in South-East Asia Region, WHO WATCH Group antibiotics were consistently among the top 10 antibiotics sold (unpublished results). (Table 5)

Similar results were noted in Thailand’s human and veterinary analysis of antimicrobial consumption – highest priority critically important antimicrobials (i.e. last resort antibiotics) made up 58% of human consumption and 43% of veterinary consumption. High irrational consumption of these products may lead to antibiotic resistance.

*Table 5.* Top 10 WHO WATCH category oral antibiotics sold in 2016

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of WHO WATCH category antibiotics in the top 10 oral antibiotics sold in 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>4/10: ciprofloxacin, levofloxacin, cefixime, azithromycin</td>
</tr>
<tr>
<td>India</td>
<td>4/10 – 7/10 (depending on State): ciprofloxacin, ofloxacin and levofloxacin, cefixime, cefpodoxime, azithromycin</td>
</tr>
<tr>
<td>Indonesia</td>
<td>4/10: ciprofloxacin, levofloxacin, cefixime, azithromycin</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>4/10: ciprofloxacin, azithromycin, clarithromycin, erythromycin</td>
</tr>
<tr>
<td>Thailand</td>
<td>4/10: ciprofloxacin, norfloxacin, roxithromycin, clarithromycin</td>
</tr>
</tbody>
</table>

A dispensing audit in Bangladesh had similar findings. These findings indicate that patient and health worker education around antimicrobial resistance and antibiotic stewardship in South-East Asia Region is a priority.

**Actions being taken to strengthen antimicrobial stewardship**

Most countries in South-East Asia Region have developed a national policy or plan to optimize use of antimicrobials and reduce the risk of antimicrobial resistance, that includes actions to strengthen antimicrobial stewardship.

- Bangladesh and India have removed irrational fixed dose combinations of antimicrobials.
- Bhutan has established an antimicrobial stewardship unit in the central referral hospital that conducts daily reviews of prescription of restricted antibiotics and provides prescribers with advice on how to optimize their use. The unit also conducts regular point prevalence surveys to understand prescribing patterns and clinical protocols to improve prescribing.
Indonesia has mandated antimicrobial stewardship as a criterion for hospital accreditation and introduced GeMa CerMat, a program to increase public understanding and awareness of rational and appropriate antibiotic use.

Nepal has introduced a Physician Stewardship Champion programme in conjunction with their post-prescription review and feedback programmes and found that 95% of antibiotic recommendations were followed.

Thailand has introduced several antibiotic audit initiatives including use evaluations, feedback within certain time intervals to assess knowledge and awareness on antibiotic use, and guidelines for de-escalation of antibiotic therapy (switching from broad to narrower spectrum antibiotics), as well as monitoring of the impact of AMR on morbidity, mortality, and the economy.

Box 8. Removal of irrational fixed dose combinations of antimicrobials: Bangladesh and India

Regulatory action to stop sales of irrational fixed dose combinations of antimicrobials

- Bangladesh initiated regulatory actions and stopped registration of irrational fixed-dose combination antimicrobials in 2018.
- The Government of India in September 2018 made the decision to ban 328 “irrational” and “unsafe” Fixed-Dose Combination drugs (FDCs); including 58 irrational antimicrobial combinations.
- The ban was imposed after years of a high-profile legal battle between the Ministry of Health and Family Welfare (MoHFW) and activist groups on one side, and the multinational and domestic pharmaceutical industry on the other.
- The irrational FDC antimicrobial, with potentially sub-optimal dosing can fail to deliver adequate therapeutic outcome and can promote the development of antimicrobial resistance.
- This historic step by regulatory agencies in Bangladesh and India is an important milestone, to demonstrate their capacity to optimize use of antimicrobials through stricter regulation.

Summary of strategies to improve access to medical products in the WHO South-East Asia Region

The countries of South-East Asia Region have been using a diverse set of strategies to improve access to medicines and medical products. However, actions and new innovative strategies are needed to meet evolving needs in the Region in an equitable way to ensure sustainable access to the relevant medicines and medical products or health technologies.

Table 6 summarizes potential action where national medicines and medical product policies need to be reviewed and new innovative approaches implemented.
Table 6. Areas for improvement of both affordability and accessibility

<table>
<thead>
<tr>
<th>Efficiency of selection and procurement</th>
<th>Strengthening regulatory system</th>
</tr>
</thead>
<tbody>
<tr>
<td>⊗ Improve policies and processes used for selection of medicines in national EML.</td>
<td>⊗ Improve national regulatory capacity for timely processing of marketing authorization applications.</td>
</tr>
<tr>
<td>⊗ Develop similar essential lists for medical devices and diagnostics based on clear criteria.</td>
<td>⊗ Using SEARN as a regional regulatory network:</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
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<tr>
<td>⊗ Use economic evaluations (health technology assessment with budget impact analysis) to determine best value for high cost health products.</td>
<td></td>
</tr>
<tr>
<td>⊗ Innovate for more efficient national procurement procedures.</td>
<td></td>
</tr>
<tr>
<td>⊗ Use joint negotiations &amp; joint procurement across facilities; or subnational level.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Financing &amp; pricing policies</th>
<th>Transparency in pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>⊗ Increase investments and improve financial coverage policies for equitable and sustained access.</td>
<td>⊗ Share information on net transaction prices e.g. public procurement prices, mark-ups in the supply chain within and across countries.</td>
</tr>
<tr>
<td>⊗ Develop comprehensive pricing policies; including price control regulation where needed.</td>
<td>⊗ Publicly share reimbursement prices.</td>
</tr>
<tr>
<td>⊗ Increase competition where possible (generic pharmaceuticals, biosimilars, vaccines).</td>
<td>⊗ Report the costs of R&amp;D and production, including public sources of funding.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Access-oriented approaches to Intellectual Property rules</th>
<th>Inter-country collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td>⊗ Re-examine and update national laws to effectively use TRIPS – flexibilities and other trade-related rules to improve access.</td>
<td>⊗ Share information on technical assessments (regulatory &amp; pharmacoeconomic, cost-effectiveness evaluations).</td>
</tr>
<tr>
<td>⊗ Negotiate health system sensitive differential pricing for single source (patented) products.</td>
<td>⊗ Use joint negotiations &amp; joint procurement across countries to achieve affordable prices.</td>
</tr>
<tr>
<td>⊗ Use voluntary license agreements and actively implement WTO/TRIPS flexibilities supported approaches for essential medicines and medical products.</td>
<td>⊗ Agree on key indicators to monitor progress and regularly evaluate impact of different approaches.</td>
</tr>
<tr>
<td>⊗ Publicly share patent and marketing authorization status of medical products (SEARN information platform).</td>
<td>⊗ Share good practices, effective policies, supported by regional evidence and data.</td>
</tr>
<tr>
<td></td>
<td>⊗ Use opportunities for inter-country capacity building, knowledge and skill transfer.</td>
</tr>
<tr>
<td>Influence the demand</td>
<td>Realign incentives for R&amp;D</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>o  Restrict marketing/promotional activities of health products targeting clinicians and the public.</td>
<td>o  Incentivize research for diseases that affect populations in low-and-middle-income countries.</td>
</tr>
<tr>
<td>o  Promote generic policies to increase use of affordable generic medical products.</td>
<td>o  Focus on health service research to improve system efficiencies, rational use of medicines and development of cost-efficient packages of care.</td>
</tr>
<tr>
<td>o  Correct misperception about inferior quality of generic or biosimilar medicines.</td>
<td></td>
</tr>
<tr>
<td>o  Actively implement clinical guidelines to improve quality of prescribing and use.</td>
<td></td>
</tr>
</tbody>
</table>
Monitoring access to essential medicines is a high priority in the global development agenda.

WHO is in the process of developing indicators to monitor enablers of access. In February 2019, a Global and Regional Informal Expert Consultation on Monitoring the Enablers of Access to Medicines in New Delhi identified approximately 60 indicators to monitor the performance of the core functions of a national pharmaceutical system.

WHO-SEARO regional experts then met to select a sub-set for reporting in the South-East Asia Region. They selected:

- Eleven ‘core’ indicators: Financial protection (2), Pricing (1), Rational Use (1), Selection (1), Availability (2), Regulation (3), and Pharmacovigilance (1).
- Two “aspirational but important” indicators, given current information systems in low and middle-income countries (LMICs).
- One “complementary” indicator – an ABC analysis to determine the top medicines by expenditure and volume in each country – as a way to determine efficiency of selection as well as diagnose areas for pricing interventions. Experts also noted several complementary indicators that could be derived from core indicators on financial protection.

Core and complementary indicators are presented below in Table 7.

### Table 7. Recommended key performance indicators to monitor progress on access in the South East Asia Region

<table>
<thead>
<tr>
<th>Core indicators</th>
<th>Complementary indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability</td>
<td></td>
</tr>
<tr>
<td>SDG 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis.</td>
<td>% of medicines on the essential medicine list monitored through a tracking, traceability, or authentication system.</td>
</tr>
<tr>
<td>SDG 3.b.1 Proportion of the target population covered by all vaccines included in their national programme.</td>
<td></td>
</tr>
<tr>
<td>Financial protection</td>
<td></td>
</tr>
<tr>
<td>Total expenditure on medicines, US$ per capita.</td>
<td>Government expenditure on medicine as proportion of total government health expenditure.</td>
</tr>
<tr>
<td>Share of public and OPP spending on medicines (US$ and %).</td>
<td>Out-of-pocket expenditure on medicines as proportion of out-of-pocket expenditure on health.</td>
</tr>
<tr>
<td></td>
<td>Out-of-pocket expenditure on medicines as a proportion of total expenditure on medicines.</td>
</tr>
<tr>
<td>Core indicators</td>
<td>Complementary indicators</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td><strong>Pricing</strong></td>
<td></td>
</tr>
<tr>
<td>☐ Median price ratio (PPP$) per basket of medicines above reference price.</td>
<td></td>
</tr>
<tr>
<td><strong>Selection and rational use</strong></td>
<td></td>
</tr>
</tbody>
</table>
| ☐ % of public procurement based on EML. | ☐ Quality of prescribing / dispensing in public and private facilities:  
| ☐ Quality of prescribing / dispensing in public and private facilities:  
  A. % of medicines from EML,  
  B. % prescribed as generics  
  C. % antibiotics prescribed in Out-patient settings | D. % injectable (optional)  
  E. %poly-pharmacy (optional)  
  ☐ ABC analysis (top medicines by expenditure/volume) |
| **Regulation**  |                          |
| ☐ NRA Maturity Level according to Global Benchmarking Tool:  
  – based on self-assessment  
  – based on WHO-assessment  
  – with assessment information publicly available  
  – % of products at point of dispensing that have market authorization  
  – % of failed tests out of total sampled and tested medicines at point of dispensing (specifying whether risk-based sampling was used):  
    A. in total  
    B. with results publicly available | ☐ Pharmacovigilance  
  – % of ADRs reported, investigated, and acted upon.  
  ☐ Number of adverse events per million population |

Member States in the South-East Asia Region are already monitoring some of these indicators.

☐ Several countries have used the WHO Global Benchmarking Tool to determine their NRA Maturity Level.

☐ Eight countries are full members of the WHO Programme for International Drug Monitoring and regularly report adverse events to the Uppsala Monitoring Centre.

☐ Proportion of public procurement based on national essential medicines list can be ascertained through analysis of public tenders.

☐ Financial protection is monitored through analysis of national health account data or household surveys.
The core SDG indicator 3.b.3 on medicines access – “Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis” - however, has often been complicated to report, both in South-East Asia Region and across the globe, due to the lack of routine monitoring systems in many countries.

This newly approved SDG indicator combines two dimensions of access - availability and affordability - for a core set of essential medicines as determined by country needs and priorities.

Tools such as the WHO/Health Action International (HAI) methodology on Measuring Medicine Prices, Availability and Affordability and Price Components and the WHO Service Availability and Readiness Assessment (SARA) and Service Provision Assessment (SPA) surveys have been the most common source of data for indicators on price and availability. However, countries are unable to use them for routine data collection due to the time and cost required for a single assessment. Assessments in the past were conducted on an ad-hoc basis; reliant on donor funding and often not repeated for many years or not at all.

To enable routine, sustainable monitoring of medicines’ price and availability, WHO has developed the WHO Essential Medicines and Health Products Price and Availability Monitoring Mobile Application (MedMon).

MedMon is an innovative multi-language electronic tool, building upon the SARA and WHO/HAI methodologies, allowing users to rapidly collect and analyse data on the price and availability of medicines in health facilities and pharmacies – regardless of sector or location.

Users can routinely monitor medicines’ access with MedMon in a sustainable, cost-effective, and timely manner. In 2019, WHO further developed MedMon to include an interactive data visualization and analysis platform enabling automated, real-time reporting. The tool has been piloted in 25 countries in four regions. Member States, such as Bangladesh, Bhutan, Nepal, Sri Lanka, and others will be using it as a way of integrating regular monitoring mechanism to generate data on availability and affordability of a basket of tracer medicines.

More complete and timely data on access to medicines will better enable to identify access disparities between population groups and understand the effects of interventions across their medicines’ supply and distribution chain.
References


PART 4
National medical products profiles
OVERALL SPENDING ON HEALTH

Current per capita spending on health care (current US$) 4

- 2006: $3
- 2008: $15
- 2010: $20
- 2012: $30
- 2014: $34
- 2016: $40

Share of government vs out-of-pocket spending on health 4

- 2006: 72%
- 2008: 72%
- 2010: 72%
- 2012: 72%
- 2014: 72%
- 2016: 28%

SPENDING ON MEDICINES

Spending on medicines as share of total health-care cost 5

- 2005: 44.6%
- 2008: 44.6%
- 2011: 44.6%
- 2014: 44.6%

Share of public and out-of-pocket spending on medicines

No data available

COUNTRY AT A GLANCE

163,046
Population (in 000s) 1

72.7
Life expectancy at birth (in years) 2

1,698.3
GDP (per capita in current US$) 3

MEDICAL AND PHARMACY WORKFORCE

5.3
Medical doctors/10,000 population 6A

1.6
Pharmacists/10,000 population 6A

Yes
Pharmacy education accreditation 6C

Unknown
Continuing professional development for pharmacists 6C
Key medicines policies and guidance

**Key pharmaceutical legislation**
- Drug Control Ordinance Amendment Act 2006

**National Medicine Policy**
- National Drug Policy 2016

**National Essential Medicines List**
- Essential Drug List - 2016

**National Standard Treatment Guidelines**
- Individual guidelines exist

**Intellectual property related policies & production**
- Number of local pharmaceutical manufacturers: 814
- Least developed country status: since 1975
- Member of World Trade Organization: since 1995
- TRIPS flexibilities used: Not applicable until graduation from least developed country status

Gaps in diagnosis and management of hypertension and diabetes

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated and controlled</td>
<td>80%</td>
<td>85%</td>
<td>75%</td>
<td>80%</td>
</tr>
<tr>
<td>Treated but uncontrolled</td>
<td>15%</td>
<td>10%</td>
<td>20%</td>
<td>15%</td>
</tr>
<tr>
<td>Diagnosed but untreated</td>
<td>5%</td>
<td>5%</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>Undiagnosed</td>
<td>0%</td>
<td>0%</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Levels of consumption of narcotic drugs

- Total
- Methadone
- Total methadone*
- Morphine

HIV/AIDS and tuberculosis treatment coverage

- 0% in 2008, 19% in 2012, 67% in 2018

Diphtheria-tetanus-pertussis (DTP3) and hepatitis B3 immunization coverage

- 97% in 2017

DTP3 and hepatitis B3 immunization coverage

- 100% in 2017

Data from STEPwise approach to surveillance (STEPS) or equivalent population surveys

* S-DDD: Statistical defined daily dose/million/day; *Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.
**Pharmaceutical system flowchart**

### National regulatory authority

**Regulated products:**
- Medicines: YES
- Vaccines: YES
- Medical devices: YES
- Traditional medicines: YES

**Medicine quality control laboratory:**
National Control Laboratory, Dhaka and Central Drug Testing Laboratory, Chittagong

ISO 17025 certified: NO
WHO prequalified: NO

**Number of registered medicines:**
Total 39,844: allopathic 27,624, ayurvedic 3,877, unani 5,624, herbal 406, homeopathic & biochemical 2,313

### Agency responsible for selection

Directorate-General of Drug Administration

**Number of products on essential medicines list:**
- By active ingredient: 285 allopathic drugs
- By dosage form: Not available

**Traditional medicines products included in essential medicines list:** YES

**Medicines availability is indicated by health facility level:** NO

### National formulary

Bangladesh National Formulary (BDNF) 2015

### Public sector

**Agency responsible for public procurement:**
Central Medical Stores Depot (CMSD)

**Procurement done at Central:**
- YES
- State: NO
- Facility: YES

(llocal procurement for district facilities and hospitals)

**Commonly used procurement methods:**
National/ International bidding

**Price control:**
YES

**Agency responsible for price control:**
DGDA

**Patient prices for essential medicines in public sector:**
- Free medicines: YES

### Public sector facilities

- Referral hospitals: 46
- District level hospitals: 64
- Specialized hospitals: 124

### Private sector

**Number of wholesalers:**
1,005

### Private sector

**Agency responsible for price control:**
Price Fixation Committee for 117 primary health care medicines.

**Pricing mechanism:**
- Manufacturer: (Maximum Retail Price is based upon cost of raw material and packaging plus a mark up)
- Wholesale: NO
- Retailer: YES
- DGDA controls retail margin (partially)

**Mark-ups regulated:**
YES

**Fixed or regressive:**
Fixed

### Public sector

**Agency responsible for distribution:**
Essential Drug Company Limited and CMSD

**Number of retail outlets:**
123,800

**Licensed retail pharmacies per 10,000 population:**
7.7

**Number of traditional medicines outlets:**
353

Ayurvedic retail outlets, 616 unani outlets, 10 herbal outlets & 2,056 homeopathic outlets

### Patient


C. Health facility level & drug availability level indicated in Essential health Service Package (ESP) of Ministry of Health & Family Welfare.

D. In the Section 11 Fixation of price of drugs in the Drug (Control) ordinance - 1982 it is noted that “The Government may, by notification in the official Gazette, fix the maximum price at which any medicine may be sold.”

Notes:
A. As per action plan National Control Laboratory is optimistic to get ISO 17025 certificate within 2018.

B. As per action plan National Control Laboratory is optimistic to get WHO Prequalification within 2019.


Notes:
A. As per action plan National Control Laboratory is optimistic to get ISO 17025 certificate within 2018.

B. As per action plan National Control Laboratory is optimistic to get WHO Prequalification within 2019.

C. Health facility level & drug availability level indicated in Essential health Service Package (ESP) of Ministry of Health & Family Welfare.

D. In the Section 11 Fixation of price of drugs in the Drug (Control) ordinance - 1982 it is noted that “The Government may, by notification in the official Gazette, fix the maximum price at which any medicine may be sold.”
Bhutan medical products profile 2019

COUNTRY AT A GLANCE

<table>
<thead>
<tr>
<th>Population (in 000s)</th>
<th>Life expectancy at birth (in years)</th>
<th>GDP (per capita in current US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>763</td>
<td>70.6</td>
<td>3360.3</td>
</tr>
</tbody>
</table>

OVERALL SPENDING ON HEALTH

Current per capita spending on health care (current US$)

- 2006: $30
- 2008: $50
- 2010: $70
- 2012: $90
- 2014: $110
- 2016: $130

Share of government vs out-of-pocket spending on health

- 2006: 20%
- 2008: 30%
- 2010: 40%
- 2012: 50%
- 2014: 60%
- 2016: 70%

SPENDING ON MEDICINES

Spending on medicines as share of total health-care cost

- 2005: 9.7%
- 2008: 14.6%
- 2011: 19.5%
- 2014: 24.4%

Share of public and out-of-pocket spending on medicines

- 2005: 9.7%
- 2007: 33%
- 2009: 67%
- 2011: 91%
- 2013: 100%

MEDICAL AND PHARMACY WORKFORCE

- Medical doctors/10 000 population: 3.7
- Pharmacists/10 000 population: 0.46
- Pharmacy education accreditation: No
- Continuing professional development for pharmacists: No
**Access to Medicines**

**Key Medicines Policies and Guidance**

- **Key Pharmaceutical Legislation**
  - Medicines Act of the Kingdom of Bhutan, 2003;
  - Bhutan Medicines Rules and Regulations, 2012;
  - Blood and Blood Products Regulation, 2016

- **National Medicine Policy**

- **National Essential Medicines List**

- **National Standard Treatment Guidelines**

**Intellectual Property Related Policies and Production**

- Number of local pharmaceutical manufacturers: 15
- Least developed country status: 18
- Member of World Trade Organization: 17
- TRIPS flexibilities used: Not applicable

**Tuberculosis Treatment Coverage**

- Coverage: 80%

**Diphtheria-tetanus-pertussis (DTP3) and Hepatitis B Immunization Coverage**

- 2007: 98%
- 2010: 98%
- 2014: 98%
- 2017: 98%

**Gaps in Diagnosis and Management of Hypertension and Diabetes**

- Male Hypertension: 100%
- Female Hypertension: 80%
- Male Diabetes: 60%
- Female Diabetes: 40%

**Levels of Consumption of Narcotic Drugs**

- Methadone: 1500 S-DDD/million/day
- Total: 1800 S-DDD/million/day
- Morphine: 1000 S-DDD/million/day

*Data from STEPwise approach to surveillance (STEPS) or equivalent population surveys.*

*S-DDD: Statistical defined daily dose/million/day; *Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.*
**National regulatory authority:** Drug Regulatory Authority of Bhutan www.dra.gov.bt

**Regulated products:**
- Medicines: YES
- Vaccines: YES
- Medical devices: NO
- Traditional medicines: YES

**Medicine quality control laboratory:** Drug testing Laboratory, Royal Centre for Disease Control, Ministry of Health, Bhutan and other testing laboratory outside Bhutan based on contract service agreement.
- ISO 17025 certified: NO
- WHO prequalified: NO

**Number of registered medicines:** allopathic-1450 & traditional medicinal products-77

**Agency responsible for selection:** Essential Medicines & Technology Division, Department of Medical Services, Ministry of Health

**Number of products on essential medicines list:**
- By active ingredient: 332
- By dosage form: 429

**Traditional medicines products included in essential medicines list:** YES

**Medicines availability is indicated by health facility level:** YES

**Number of products in national formulary:** 429

**Agency responsible for public procurement:** Medical Supplies Procurement Division under Department of Medical Supplies and Health Infrastructure (DMSHI), Ministry of Health

**Procurement done at:**
- Central: ☑
- State: □
- Facility: □

**Commonly used procurement methods:** International tendering

**Public sector**
- **Number of wholesalers:** 27

**Price control:** NO

**Health insurance reimbursement price:** No health insurance scheme

**Patient prices for essential medicines in public sector:**
- Free medicines: YES

**Agency responsible for distribution:** Medical stores and distribution division under department of medical supplies & health infrastructure

**Public sector facilities:**
- Hospitals: 31
- Basic health unit (BHU)-I: 23
- BHU-II: 184
- Sub-Post: 28

**Private sector**
- **Number of retail outlets:** 54

**Licensed retail pharmacies per 10 000 population:** 0.69

**Number of traditional medicines outlets:** 1

**Pharmaceutical system flowchart**
References

15. Data as reported by Drug Regulatory Authority, Bhutan, June 2019.

Notes:
A. One Herbal and one Active Pharmaceutical Ingredient manufacturer.
B. 54 pharmacies spread across the country.
### Democratic People’s Republic of Korea

#### Medical products profile 2019

<table>
<thead>
<tr>
<th>COUNTRY AT A GLANCE</th>
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<tbody>
<tr>
<td><strong>Population</strong></td>
</tr>
<tr>
<td><strong>(in 000s)</strong></td>
</tr>
<tr>
<td><strong>Life expectancy at birth</strong></td>
</tr>
<tr>
<td><strong>(in years)</strong></td>
</tr>
<tr>
<td><strong>GDP</strong></td>
</tr>
<tr>
<td><strong>(per capita in current US$)</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OVERALL SPENDING ON HEALTH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current per capita spending on health care</strong></td>
</tr>
<tr>
<td><strong>(current US$)</strong></td>
</tr>
<tr>
<td><strong>Share of government vs out-of-pocket spending on health</strong></td>
</tr>
<tr>
<td><strong>No data available</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SPENDING ON MEDICINES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spending on medicines as share of total health-care cost</strong></td>
</tr>
<tr>
<td><strong>Share of public and out-of-pocket spending on medicines</strong></td>
</tr>
<tr>
<td><strong>No data available</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEDICAL AND PHARMACY WORKFORCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical doctors/10 000 population</strong></td>
</tr>
<tr>
<td><strong>Pharmacists/10 000 population</strong></td>
</tr>
<tr>
<td><strong>Pharmacy education accreditation</strong></td>
</tr>
<tr>
<td><strong>Continuing professional development for pharmacists</strong></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
</tr>
</tbody>
</table>
KEY MEDICINES
POLICIES AND GUIDANCE

Key pharmaceutical legislation

National Medicine Policy
1. National legislation, Rule & Regulation for drug management available (1998);

National Essential Medicines List
National List of Essential Medicines – 2019

Available

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers
Not available

Least developed country status
No

Member of World Trade Organization since
No

TRIPS flexibilities used
Not applicable
Democratic People's Republic of Korea

Medical products profile 2019

Market Authorization/Licensing/Quality Assurance

Medicine

National regulatory authority\textsuperscript{12}: National Drug Regulatory Authority (NDRA)
Regulated products\textsuperscript{12}:
- Medicines\textsuperscript{12}: YES
- Vaccines\textsuperscript{12}: YES
- Medical devices\textsuperscript{12}: NA
- Traditional medicines\textsuperscript{12}: YES

Medicine quality control laboratory\textsuperscript{13}: One central laboratory under NDRA and one per province
- ISO 17025 certified\textsuperscript{9}: NO
- WHO prequalified\textsuperscript{13}: NO
Number of registered medicines\textsuperscript{13}: 3000-4000

Agency responsible for selection\textsuperscript{9}: National Drug Regulatory Authority (NDRA), Ministry of Public Health
Number of products on essential medicines list:
- By active ingredient\textsuperscript{9}: 439
- By dosage form: Not available
Traditional medicines products included in essential medicines list\textsuperscript{13}: YES
Medicines availability is indicated by health facility level\textsuperscript{13}: YES
Number of products in national formulary\textsuperscript{9}: 1607 (Year 2016)

Public Sector
Agency responsible for public procurement\textsuperscript{13}: Medicines Management Department, Ministry of Public Health
Procurement done at Central\.Check State\.Facility
Commonly used procurement methods\textsuperscript{13}: Local tendering and international tendering for drugs not procured domestically through UN agencies

Private Sector
Number of wholesalers: Not available

Public sector
- Price control\textsuperscript{9}: No
- Health insurance reimbursement price: Not applicable
- Patient prices for essential medicines in public sector:
  - Free Medicines\textsuperscript{13}: YES

Private sector
Agency responsible for price control\textsuperscript{13}: National Price Control Committee
Pricing mechanism\textsuperscript{9}: Method unknown.
- Manufacturer\.Wholesale\.Retailer
Mark-ups regulated\textsuperscript{9}: method unknown
Fixed or regressive\textsuperscript{9}: method unknown

Public sector
Agency responsible for distribution\textsuperscript{13}: Central medicines warehouse, Medicines management department
Public sector facilities\textsuperscript{14}:
- Hospitals: 1708
- Primary health care units: 6263
- Ri clinics/hospitals per village: 1-2

Private sector
Number of retail outlets\textsuperscript{9}: 260 government owned people’s drug stores available in Pyongyang City
Licensed retail pharmacies per 10 000 population: Not available
Number of traditional medicines outlets: No data

Patient
References


Note:
A. Total per capita spending on health care in the year 2013 was US$ 66.
India medical products profile 2019

COUNTRY AT A GLANCE

<table>
<thead>
<tr>
<th>Population (in 000s)</th>
<th>Life expectancy at birth (in years)</th>
<th>GDP (per capita in current US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 366 418</td>
<td>68.8</td>
<td>2015.6</td>
</tr>
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</table>

OVERALL SPENDING ON HEALTH

Current per capita spending on health care (current US$)

Share of government vs out-of-pocket spending on health

Spending on medicines as share of total health-care cost

Share of public and out-of-pocket spending on medicines

SPENDING ON MEDICINES

MEDICAL AND PHARMACY WORKFORCE

<table>
<thead>
<tr>
<th>Medical doctors/10 000 population</th>
<th>Pharmacists/10 000 population</th>
<th>Pharmacy education accreditation</th>
<th>Continuing professional development for pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.8</td>
<td>6.8</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Medical products profile 2019
## Key Pharmaceutical Legislation

- **Drugs and Cosmetics Act, 1940 and Rules 1945** as amended up to 31 December 2016
- **Pharmaceutical Policy 2002**
- **National Vaccine Policy 2011**
- **National List of Essential Medicines (NLEM)-2015**
- **Both individual disease and state-level standard treatment guidelines exist.**

## Intellectual Property-Related Policies & Production

- **Number of local pharmaceutical manufacturers:** 20
- **Least developed country status:** No
- **Member of World Trade Organization since:** 1995
- **TRIPS flexibilities used:** Yes

## Key Medicines Policies and Guidance

### Key Pharmaceutical Legislation

- **National Medicine Policy**
- **National Essential Medicines List**
- **National Standard Treatment Guidelines**

### INTELLECTUAL PROPERTY-RELATED POLICIES & PRODUCTION

- 4900 for formulations and 1500 for active pharmaceutical ingredient

###.eps

**HIV/AIDS and tuberculosis treatment coverage**

- 2008: 56%
- 2010: 65%

**Diphtheria-tetanus-pertussis (DTP3) and hepatitis B3 immunization coverage**

- 2007: 88%
- 2010: 88%
- 2014: 88%
- 2017: 88%

**Gaps in diagnosis and management of hypertension and diabetes**

- Data insufficient to analyse

**Levels of consumption of narcotic drugs**

- S-DDD: Statistical defined daily dose/million/day
- Total
- Methadone
- Total methadone
- Morphine

*Note: S-DDD: Statistical defined daily dose/million/day. Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.
**National regulatory authority:** Central Drugs Standard Control Organization (CDSCO) www.cdsco.nic.in

**Regulated products**:
- **Medicines**: YES
- **Vaccines**: YES
- **Medical devices**: YES
- **Traditional medicines**: YES (Regulated)

**Medicine quality control laboratory**:
- Total 8: 1- Indian Pharmacopoeia Commission (IPC) Ghaziabad; 5-central drug testing laboratories and 2-regional drug testing laboratories
- ISO 17025 certified: YES
- **WHO prequalified**: YES (IPC, Ghaziabad)

**Number of registered medicines**: Not available

**Agency responsible for selection**: Core Committee on National List of Essential Medicines, Ministry of Health & Family Welfare

**Number of products on essential medicines list**:
- By active ingredient: 376
- By dosage form: Approximately 1000

**Traditional medicines products included in essential medicines list**: YES

**Medicines availability is indicated by health facility level**: YES

**Number of products in national formulary**: National Formulary 2016, Products – 521

**Public sector**
- **Agency responsible for public procurement**: Ministry of Health and Family Welfare (Central Medical Services Society)
- **Procurement done at Central/State/Facility**: Commonly used procurement methods: Competitive tendering (Two bid system)

**Private sector**
- **Number of wholesalers**: Not available

**Price control**: YES

**Agency responsible**: National Pharmaceutical Pricing Authority

**Price mechanism**: Lowest procurement price considered

**Patient prices for essential medicines in public sector**:
- **Free medicines**: YES
- **Fixed price**: YES (Jan Aushadhi Scheme)

**Agency responsible for distribution**:
- Centralized/decentralized at central/state or local government level

**Public sector facilities**:
- Total hospitals: 210 998
- District hospitals: 1251
- Sub-district hospitals: 2724
- Community health centres: 1146
- Primary health centres: 31 824
- Sub centres: 164 053

**Private sector**
- **Number of retail outlets**: 800 000

**Licensed retail pharmacies per 10 000 population**: Not available

**Number of traditional medicines outlets**: Not available

**Distribution**

**Pricing and Reimbursement**
E. \[ P(c) = P(s) \cdot (1 + \frac{M}{100}) \]

D. By self-calculating all the strengths listed.

6) http://nvbdcp.gov.in/iec.html

5) http://clinicalestablishments.nic.in/WriteReadData/448.pdf

Notes:

37.  

35.  

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17.  

16.  

12.  

9.  

8.  

7.  


Notes:

A. 0.78 physicians per 1000 population.
B. Less than 1 pharmaceutical personnel per 1000 population.
C. Other sources:

1) http://obheal.gov.in/JWRM_guideline700169588.pdf
2) http://icmr.nic.in/guidelines/treatment9%20go%20defines%20for%20antimicrobial.pdf
3) http://www.tcbindia.nic.in/index1.php?lang=1&level=1&pubid=koch53176
4) http://clinicalastablishments.nic.in/WriteReadData/93.pdf
5) http://clinicalastablishments.nic.in/WriteReadData/648.pdf
6) http://nvbdcp.gov.in/iec.html

D. By self-calculating all the strengths listed.
E. \[ P(c) = P(s) \cdot (1 + \frac{M}{100}) \]

FM average Price to Retailer for the same strength and dosage of the medicine; \( M \%\) Margin to retailer and its value =16.
F. A manufacturer, distributor or wholesaler shall, sell a formulation to a retailer, unless otherwise permitted under the provisions of this order or any order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen per cent thereof in the case of Scheduled drugs.

India
Indonesia medical products profile 2019

**COUNTRY AT A GLANCE**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (in 000s)²</td>
<td>270 626</td>
</tr>
<tr>
<td>Life expectancy at birth (in years)²</td>
<td>69.3</td>
</tr>
<tr>
<td>GDP (per capita in current US$³)</td>
<td>3893.6</td>
</tr>
</tbody>
</table>

**OVERALL SPENDING ON HEALTH**

<table>
<thead>
<tr>
<th>Year (2006-2016)</th>
<th>Current per capita spending on health care (current US$) $112</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>37%</td>
</tr>
<tr>
<td>2008</td>
<td>63%</td>
</tr>
<tr>
<td>2010</td>
<td>63%</td>
</tr>
<tr>
<td>2012</td>
<td>63%</td>
</tr>
<tr>
<td>2014</td>
<td>63%</td>
</tr>
<tr>
<td>2016</td>
<td>63%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year (2005-2014)</th>
<th>Share of government vs out-of-pocket spending on health $37% $63%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>21%</td>
</tr>
<tr>
<td>2008</td>
<td>79%</td>
</tr>
<tr>
<td>2011</td>
<td>79%</td>
</tr>
<tr>
<td>2014</td>
<td>79%</td>
</tr>
</tbody>
</table>

**SPENDING ON MEDICINES**

<table>
<thead>
<tr>
<th>Year (2005-2014)</th>
<th>Spending on medicines as share of total health-care cost 25.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>25.5%</td>
</tr>
<tr>
<td>2008</td>
<td>25.5%</td>
</tr>
<tr>
<td>2011</td>
<td>25.5%</td>
</tr>
<tr>
<td>2014</td>
<td>25.5%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Year (2005-2014)</th>
<th>Share of public and out-of-pocket spending on medicines 79%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>21%</td>
</tr>
<tr>
<td>2008</td>
<td>79%</td>
</tr>
<tr>
<td>2011</td>
<td>79%</td>
</tr>
<tr>
<td>2014</td>
<td>79%</td>
</tr>
</tbody>
</table>

**MEDICAL AND PHARMACY WORKFORCE**

<table>
<thead>
<tr>
<th>Profession</th>
<th>Number/10 000 population</th>
<th>Accreditation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical doctors</td>
<td>3.8</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>1.7</td>
<td>Yes</td>
</tr>
<tr>
<td>Pharmacy education</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Continuing professional development for pharmacists</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
Key pharmaceutical legislation\(^\text{12}\)  
National Medicine Policy\(^\text{12}\)  
National Essential Medicines List\(^\text{13}\)  
National Standard Treatment Guidelines\(^\text{14}\)  

- Law on registration of medicines, 2008  
- National Medicine Policy 2006  
- National List of Essential Medicines – 2017  
- Clinical Guidance for Physicians in Primary Care, 2014. No national STGs for hospitals

**INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION**  
Number of local pharmaceutical manufacturers  
Least developed country status\(^\text{15}\)  
Member of World Trade Organization since\(^\text{16}\)  
TRIPS flexibilities used\(^\text{17}\)

| 174 | No | 1995 | Yes |
Indonesia Medical products profile 2019

National regulatory authorities: Medicines and vaccines: National Agency of Drug and Food Control;*\(^18\)
Medical device: Ministry of Health; http://infoalkes.depkes.go.id/

Regulated products*\(^18\):
- Medicines: YES
- Vaccines YES
- Medical devices: YES
- Traditional medicines*\(^18\): YES

Medicine quality control laboratory*\(^19\): Drug Testing Laboratory of National Quality Control Laboratory
ISO 17025 certified*\(^19\): YES
WHO prequalified: NO

Number of registered medicines*\(^20\): 15 072 allopathic and 13 000 traditional medicines

Agency responsible for selection*\(^21\): Ministry of Health
Number of products on essential medicines list:
- By active ingredient: 321
- By dosage form: 503

Traditional medicines products included in essential medicines list: No data available
Medicines availability is indicated by health facility level: Primary care, Referral care (hospitals)

Latest National Formulary*\(^21\): 586

Agency responsible for public procurement*\(^22\): Directorate General of Pharmaceutical and Medical Devices
Procurement done at Central*\(^22\): State □ Facility*\(^22\): ☐

Commonly used procurement methods*\(^22\): Local tendering

Agency responsible for public procurement*\(^22\): Directorate General of Pharmaceutical and Medical Devices
Procurement done at Central*\(^22\): ☑ State ☐ Facility*\(^22\): ☐

Public sector facilities*\(^22\):
- Public hospitals: 2406
  (1855 general hospitals and 552 special hospitals)
- Health centres: 9731

Price control: YES
Price mechanism*\(^22\): Lowest price bid accepted

Health Insurance reimbursement price*\(^22\): Universal Health coverage (BPJS Kesehatan)
Patient prices for essential medicines in public sector: No data available

Agency responsible for price control: Ministry of Health
Pricing mechanism: Market based pricing
Manufacturer ☑ Wholesale*\(^22\): 40% Retailer ☐
Mark-ups regulated: No data available

Fixed or regressive*\(^22\): Generic medicines prices fixed by Ministry of Health and other medicines prices set by manufacturers

Number of retail outlets*\(^22\): 22 634 and 8009 drug stores
Licensed retail pharmacies per 10 000 population: Not available
Number of traditional medicines outlets: Not available
References

Maldives medical products profile 2019

**OVERALL SPENDING ON HEALTH**

Current per capita spending on health care (current US$):

![Graph showing per capita spending on health care from 2006 to 2016, with 2016 spending at $1048.]

Share of government vs out-of-pocket spending on health:

![Bar chart showing percentage of government vs out-of-pocket spending on health from 2006 to 2016, with government spending at 81% and out-of-pocket spending at 19%.]

**SPENDING ON MEDICINES**

Spending on medicines as share of total health-care cost:

![Graph showing percentage of spending on medicines from 2005 to 2014, with 2014 spending at 9.7%.]

Share of public and out-of-pocket spending on medicines:

![Bar chart showing share as percentage of public and out-of-pocket spending on medicines from 2005 to 2014, with 2014 share at 52% public and 48% out-of-pocket.]

**COUNTRY AT A GLANCE**

- **Population (in 000s)**: 531
- **Life expectancy at birth (in years)**: 78.4
- **GDP (per capita in current US$)**: 10,233.6

**MEDICAL AND PHARMACY WORKFORCE**

- **Medical doctors/10,000 population**: 10.4
- **Pharmacists/10,000 population**: 4.8
- **Pharmacy education accreditation**: Yes
- **Continuing professional development for pharmacists**: Yes
**Key pharmaceutical legislation**

**National Medicine Policy**
- National Medicine Policy – 2007

**National Essential Medicines List**
- Essential Medicines List – 2016

**National Standard Treatment Guidelines**
- Individual disease guidelines exist

**INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION**
- Number of local pharmaceutical manufacturers: 0
- Least developed country: No
- Member of World Trade Organization: 1995
- TRIPS flexibilities used: Not applicable

**Tuberculosis treatment coverage**
- 80% coverage

**Diphtheria-tetanus-pertussis (DTP3) and hepatitis B immunization coverage**
- 99% coverage

**Gaps in diagnosis and management of hypertension and diabetes**
- Data from STEPwise approach to surveillance (STEPS) or equivalent population surveys

**Levels of consumption of narcotic drugs**
- *S-DDD: Statistical defined daily dose/million/day; *Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.

**ACCESS TO MEDICINES**

Data from STEPwise approach to surveillance (STEPS) or equivalent population surveys
## Maldives Medical Products Profile 2019

### Market Authorization/Licensing/Quality Assurance

- **National regulatory authority**[^1]: Maldives Food and Drug Authority (MFDA)  
  http://www.mfda.gov.mv

- **Regulated products:**
  - Medicines[^2]: YES
  - Vaccines[^2]: YES
  - Medical devices: NA
  - Traditional medicines[^2]: YES

- **Medicine quality control laboratory**[^3]: National Health Laboratory.
  - ISO 17025 certified: NA
  - WHO prequalified[^4]: NO

- **Number of registered medicines**: 3,818

### Medicine Selection

- **Agency responsible for selection**[^5]: Maldives Food and Drug Authority

- **Number of products on essential medicines list:**
  - By active ingredient[^6]: 326
  - By dosage form[^7]: 510

- **Traditional medicines products included in essential medicines list**: NA

- **Medicines availability is indicated by health facility level**[^8]: YES

- **National formulary[^9]**: No national formulary manual

### Medicine Procurement

- **Agency responsible for public procurement**[^10]: State Trading Organization (STO)

- **Procurement done at Central[^11]**

- **Commonly used procurement methods[^12]**: Purchasing directly from manufacturers and from third parties for importing medicines

### Pricing and Reimbursement

- **Public sector**
  - **Price control[^13]**: NO
  - **Health insurance reimbursement Price[^14]**: Public health insurance (Asandha Insurance system) covers the entire population
  - **Patient prices for essential medicines in public sector:**
    - **Free medicines[^15]**: NO
    - **Fixed price[^15]**: YES

- **Private sector**
  - **Agency responsible for price control[^16]**: MFDA and Ministry of Economic Affairs
  - **Pricing mechanism[^17]**: Under review
    - Manufacturer
    - Wholesale
    - Retailer
  - **Mark-ups regulated**: Under review
  - **Fixed or regressive**: Under review

### Distribution

- **Public sector facilities[^18]**:
  - Tertiary hospital: 1
  - Regional hospitals: 6
  - Atoll hospitals: 13
  - Health-care centres: 132
  - Health aid posts: 108

- **Private sector**
  - **Number of retail outlets[^19]**: 197
  - **Licensed retail pharmacies per 10,000 population[^20]**: 5.6
  - **Number of traditional medicines outlets**: Not available

### Patient

- **Public sector**
  - **Agency responsible for distribution[^21]**: Health Supply Unit, Administration Division

- **Private sector**
  - **Number of wholesalers[^22]**: 15

---

[^1]: Maldives Food and Drug Authority (MFDA)  
[^2]: YES
[^3]: National Health Laboratory.
[^4]: NA
[^5]: NO
[^6]: YES
[^7]: NA
[^8]: YES
[^9]: NO
[^10]: YES
[^11]: NA
[^12]: YES
[^13]: YES
[^14]: NA
[^15]: YES
[^16]: YES
[^17]: NA
[^18]: YES
[^19]: NA
[^20]: YES
[^21]: NA
[^22]: YES

---

**Pharmaceutical system flowchart**

- **National regulatory authority**
- **Regulated products**
- **Medicine quality control laboratory**
- **Number of registered medicines**
- **Agency responsible for selection**
- **Number of products on essential medicines list**
- **Procurement done at Central**
- **Commonly used procurement methods**
- **Price control**
- **Health insurance reimbursement Price**
- **Patient prices for essential medicines in public sector**
- **Agency responsible for distribution**
- **Number of wholesalers**

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**Medical products profile 2019**

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**Maldives**

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References


11. As reported by Ministry of Health, Republic of Maldives, June 2017.


20. As reported in Ministry of Health, Republic of Maldives, Annual Report.

Notes:

A. National Medicine Policy is presently being revised.

B. As per National list of Essential Medicines -2013.

C. Approved list of registered drugs is available, but there is no national formulary manual.

D. Currently, there is no public procurement agency. However, State Trading Organization (STO) is responsible for procuring medicines for government health facilities as per their need.

E. Decentralized to State Trading Organization and private importers.

F. Work in process to include pricing under medicine regulation. MFDA has worked on a costing structure for MRP in consultation with stakeholders and working on its finalization. It will address price control mechanisms at manufacturer, wholesaler and retailer level. Mark-ups will be regulated according to the costing structure.
## Myanmar Medical Products Profile 2019

### Country at a Glance

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (in 000s)</td>
<td>54,045</td>
</tr>
<tr>
<td>Life expectancy at birth (in years)</td>
<td>66.8</td>
</tr>
<tr>
<td>GDP (per capita in current US$)</td>
<td>1,326</td>
</tr>
</tbody>
</table>

### Overall Spending on Health

**Current per capita spending on healthcare (current US$)**

![Graph showing current per capita spending on healthcare increasing from 2006 to 2016.]

**Share of government vs out-of-pocket spending on health**

![Bar chart showing percentage distribution of government and out-of-pocket spending on health from 2006 to 2016.]

### Spending on Medicines

**Spending on medicines as share of total health-care cost**

![Graph showing percentage of spending on medicines decrease from 2005 to 2014.]

**Share of public and out-of-pocket spending on medicines**

![Bar chart showing percentage of public and out-of-pocket spending on medicines from 2005 to 2014.]

### 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>8.6</td>
</tr>
<tr>
<td>Pharmacists/10,000 population</td>
<td>0.4</td>
</tr>
<tr>
<td>Pharmacy education accreditation</td>
<td>No</td>
</tr>
<tr>
<td>Continuing professional development for pharmacists</td>
<td>No</td>
</tr>
</tbody>
</table>
**ACCESS TO MEDICINES**

**KEY MEDICINES POLICIES AND GUIDANCE**

<table>
<thead>
<tr>
<th>Key pharmaceutical legislation (^{13})</th>
<th>National Medicine Policy (^{13,5})</th>
<th>National Essential Medicines List (^{14})</th>
<th>National Standard Treatment Guidelines (^{12})</th>
</tr>
</thead>
</table>

**INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION**

<table>
<thead>
<tr>
<th>Number of local pharmaceutical manufacturers (^{13,0})</th>
<th>Least developed country status since (^{15})</th>
<th>Member of World Trade Organization since (^{16})</th>
<th>TRIPS flexibilities used (^{17})</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>1987</td>
<td>1995</td>
<td>Not applicable until graduation from least developed country status</td>
</tr>
</tbody>
</table>

---

Data from STEPwise approach to surveillance (STEPS) or equivalent population surveys

* S-DDD: Statistical defined daily dose/million/day; * Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.
### National regulatory authority
- **18**: Department of Food and Drug Administration (DFDA)
  
  ![Website](http://www.fdamyanmar.gov.mm)

### Regulated products:
- **Medicines**: YES
- **Vaccines**: YES
- **Medical devices**: YES
- **Traditional medicines**: NO

### Medicine quality control laboratory
- **12**: One main drug testing laboratory and two small branch labs in Mandalay and Yangon
  
  ![ISO Certification](ISO 17025 certified: YES)

### WHO prequalified:
- **NO**

### Number of registered medicines
- **21**: 21 000 allopathic & 12 712 traditional medicines

### Agency responsible for selection
- **14**: Essential Drug Program, Medical Care Division, Department of Medical Services

### Number of products on essential medicines list:
- **By active ingredient**: 341
- **By dosage form**: >400

### Traditional medicines products included in essential medicines list
- **YES** (59 products)

### Medicines availability is indicated by health facility level
- **YES**

### National formulary
- **Not available**

### Public sector
- **Agency responsible for public procurement**: Central Medical Supplies Department (CMSD) and some local procurement
- **Procurement done at Central**, State, Facility
- **Commonly used procurement methods**: Mainly procured from Myanmar Pharmaceutical Factory and for other products through national competitive tenders

### Private sector
- **Number of wholesalers**: 170

### Price control
- **YES**

### Mechanism
- **Lowest priced quotation is chosen**

### Health insurance reimbursement Price
- **No health insurance**

### Patient prices for essential medicines in public sector
- **Free medicines**: YES

### Public sector
- **Agency responsible for distribution**: Central Medical Supplies Department (CMSD) and local warehouses
- **Public sector facilities**:
  - Government run hospitals: 1974
  - Primary and secondary health centres: 86
  - Maternal & child health centres: 348
  - Rural health centres: 1565
  - Traditional medicines hospitals: 14

### Private sector
- **Number of retail outlets**: 10 000 outlets selling both allopathic and traditional medicines
- **Licensed retail pharmacies per 10 000 population**: 1.9
References

20. Data taken from SEAR workshop on Traditional Medicines in 2015, Pyongyang.

Notes:
B. Only bachelor & master degree.
C. Revising the draft National Medicine Policy in 2019.
D. 8 allopathic manufacturers and 1 government manufacturing unit called Myanmar Pharmaceutical Factory (MPF).
E. Department of Traditional Medicine is regulatory authority for traditional medicines.
F. Data from National List of Essential Medicines, 2010.
G. No national formulary available but Myanmar Pharmaceutical Index 2010 is available.
H. Local procurement by regional and state health authorities.
I. Local procurement by hospitals.
J. Wholesale level mark-ups (5-7%) and retailer level mark-ups (5-10%).
Nepal medical products profile 2019

OVERALL SPENDING ON HEALTH

Current per capita spending on health care (current US$) 4

Share of government vs out-of-pocket spending on health 4

SPENDING ON MEDICINES

Spending on medicines as share of total health-care cost 5

Share of public and out-of-pocket spending on medicines 5

MEDICAL AND PHARMACY WORKFORCE

Medical doctors/10 000 population6A

Pharmacists/10 000 population6B

Pharmacy education accreditation6C

Continuing professional development for pharmacists6C
### Key pharmaceutical legislation

- **Drug Act 1978**

### National Medicine Policy


### National Essential Medicines List

- National List of Essential Medicines – 2016

### National Standard Treatment Guidelines

Guidelines-2012 available for health posts and sub-health posts

### Intellectual Property Related Policies & Production

- **Number of local pharmaceutical manufacturers**: 130
- **Least developed country status since**: 1971
- **Member of World Trade Organization since**: 2004
- **TRIPS flexibilities used**: Not applicable until graduation from least developed country status

### Key Medicines Policies and Guidance

#### HIV/AIDS and tuberculosis treatment coverage

- 2008: 0%
- 2010: 20%
- 2012: 40%
- 2014: 60%
- 2016: 80%
- 2018: 70%

#### Diphtheria-tetanus-pertussis (DTP3) and hepatitis B3 immunization coverage

- 2007: 90%
- 2010: 90%
- 2014: 90%
- 2017: 90%

#### Gaps in diagnosis and management of hypertension and diabetes

- **Hypertension**
  - Male: 20%
  - Female: 10%
- **Diabetes**
  - Male: 30%
  - Female: 20%

#### Levels of consumption of narcotic drugs

- **Total**
- **Methadone**
- **Total methadone**
- **Morphine**

Data from STEPwise approach to surveillance (STEPS) or equivalent population surveys

*S-DDD: Statistical defined daily dose/million/day. *Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.
**Nepal Medical products profile 2019**

**Market Authorization/Licensing/Quality Assurance**
- **National regulatory authority**\(^{26}\): Department of Drug Administration (DDA), Ministry of Health
  - www.dda.gov.np

**Medicine**
- **Regulated products**\(^{13}\):
  - Medicines: YES
  - Vaccines: YES
  - Medical devices\(^{13,6}\): YES
  - Traditional medicines\(^{21}\): YES
- **Medical quality control laboratory**\(^{22}\): National Medicine Laboratory
  - ISO 17025 certified: NO
  - WHO prequalified: NO
- **Number of registered medicines**\(^{16, F}\): 17,162

**Agency responsible for selection**\(^{13}\): Department of Drug Administration
- **Number of products on essential medicines list**\(^{13, G}\):
  - By active ingredient: 359
  - By dosage form: Not available
- **Traditional medicines products included in essential medicines list**\(^{21, H}\): YES
- **Medicines availability is indicated by health facility level**: NO
- **Latest national formulary**\(^{23, I}\): National Formulary 2010

**Public sector**
- **Agency responsible for public procurement**: Logistic Management Division
- **Procurement done at Central**\(^{22, J}\) ☑️ State ☑️ Facility\(^{22}\) ☑️
- **Commonly used procurement methods**: Tendering from list of standard manufacturers identified by government

**Private sector**
- **Number of wholesalers**\(^{18, K}\): 1921

**Public Sector**
- **Health insurance reimbursement**\(^{24, L}\): In 8 districts
- **Patient prices for essential medicines in public sector**\(^{22, M}\):
  - Free medicines: YES, upto district level
  - Fixed price: No data

**Private sector**
- **Agency responsible for price control**\(^{22}\): DDA and Drug Pricing Monitoring Committee
- **Pricing mechanism**\(^{13, N}\): To fix the Maximum Retail price using mean median method
- **Manufacturer**\(^{22}\) ☑️ Wholesale\(^{22}\) ☑️ Retailer\(^{22}\) ☑️
  - (Mark up 8-10%) (Mark up 16%)
- **Mark-ups regulated**: NO

**Public sector**
- **Agency responsible for distribution**\(^{22}\): Logistics Management Division for centrally supplied drugs and District Public Health Offices (DPHOs) and hospital directors for locally purchased drugs
- **Public sector facilities**\(^{25}\):
  - Hospitals: 86
  - Primary health centres: 205
  - Health post: 822
  - Sub-health post: 2987

**Private sector**
- **Number of retail outlets**\(^{18, O}\): Allopathic – 8642
- **Licensed retail pharmacies per 10,000 population**\(^{13, P}\): 4.5
- **Number of traditional medicines outlets**\(^{18, O}\): 2270
  - (Ayurveda: 1800, Homeopathy: 453, Unani: 17)
References


13. Data as reported by Department of Drug Administration, Nepal, June 2017.


Notes:

A. Revised draft Drug Act is in process of government approval.

B. National list of Essential Medicines updated in 2016. The list is approved by government and is ready for printing.


D. 49 Allopathic, 8 Veterinary and 73 Ayurvedic /herbal manufacturers.

E. Revised draft Drug act addresses the provision for regulating medical devices. Healthcare Technologies and Medical Supplies Directive, 2017 is introduced.

F. Foreign + Domestic medical products.


H. Stand alone Essential Medicines List for traditional medicines is available.

I. Nepalese National Formulary (NNF), 2010 is under revision. Data on no of products in NNF, 2010 not available.

J. Pooled donor funds also used to procure 40 free drugs.


L. Social Health Security (SHS) program launched in 8 districts of Nepal till May 2017. Under the SHS program, a household of five has to pay Rs 2,500 in annual insurance premium. Each additional household member will have to pay Rs 425. The scheme covers expenses up to Rs 50,000/5 member /year for each household.

M. Above district level, patients must purchase drugs from private pharmacies.

N. Government of Nepal has fixed the retail price of 96 different medicines including commonly used drugs, essential medicines and medicines used for protracted diseases like cancer and chronic ailments and government has ordered all the pharmacies to display the price list.

O. Data as per renewal status.

P. Data as per renewal status of retail pharmacies (Allopathic, Veterinary, Ayurveda, homeopathic and Unani pharmacies).
Sri Lanka medical products profile 2019

<table>
<thead>
<tr>
<th>COUNTRY AT A GLANCE</th>
<th>21 324</th>
<th>75.3</th>
<th>4102.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>(in 000s)</td>
<td>Life expectancy at birth</td>
<td>GDP (per capita in current US$)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OVERALL SPENDING ON HEALTH</th>
<th>Current per capita spending on health care (current US$)</th>
<th>Share of government vs out-of-pocket spending on health</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$153</td>
<td>50%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>SPENDING ON MEDICINES</th>
<th>Spending on medicines as share of total health-care cost</th>
<th>Share of public and out-of-pocket spending on medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>26.5%</td>
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<table>
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<th>MEDICAL AND PHARMACY WORKFORCE</th>
<th>9.6</th>
<th>0.77</th>
<th>No</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical doctors/10 000 population</td>
<td>Pharmacists/10 000 population</td>
<td>Pharmacy education accreditation</td>
<td>Continuing professional development for pharmacists</td>
<td></td>
</tr>
</tbody>
</table>

Medical products profile 2019
**Sri Lanka Medical products profile 2019**

### Key Pharmaceutical Legislation

1. **Cosmetics, Devices and Drugs Act (CDDA) No. 27 of 1980 with several amendments from 1985.**
2. **National Medicines Regulatory Authority Act, 2015.**

### National Medicine Policy

- **National Medicine Policy 2005**

### National Essential Medicines List

- **National List of Essential Medicines-2014**

### National Standard Treatment Guidelines

- Specialist colleges and Sri Lanka Medical Association specific guidelines exist.

### Intellectual Property Related Policies & Production

- **Number of local pharmaceutical manufacturers:** 12
- **Least developed country status:** No
- **Member of World Trade Organization:** 1995
- **TRIPS flexibilities used:** Not applicable

---

**Access to Medicines**

### HIV/AIDS and Tuberculosis Treatment Coverage

- 2008: 37%
- 2014: 62%
- 2018: 37%

### Diphtheria-Tetanus-Pertussis (DTP3) and Hepatitis B Immunization Coverage

- 2007: 99%
- 2010: 99%
- 2014: 99%
- 2017: 99%

---

**Gaps in Diagnosis and Management of Hypertension and Diabetes**

- **Hypertension:**
  - Male: Treated and controlled
  - Female: Treated and controlled
- **Diabetes:**
  - Male: Treated and controlled
  - Female: Treated and controlled

### Levels of Consumption of Narcotic Drugs

- **Total S-DDD/million/day**
  - 2007: 200
  - 2010: 150
  - 2012: 100
  - 2014: 50
  - 2016: 0

- **Total methadone**
  - 2007: 0
  - 2010: 50
  - 2012: 100
  - 2014: 150
  - 2016: 200

- **Morphine**
  - 2007: 0
  - 2010: 50
  - 2012: 100
  - 2014: 150
  - 2016: 200

---

*Data from STEPwise approach to surveillance (STEPS) or equivalent population surveys.*

*S-DDD: Statistical defined daily dose/million/day; *Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency.*
National regulatory authority\textsuperscript{13}: National Medicines Regulatory Authority (NMRA) \url{http://nmra.gov.lk/}

Regulated products:
- Medicines\textsuperscript{18}: YES
- Vaccines\textsuperscript{18}: YES
- Medical Devices\textsuperscript{18}: YES
- Traditional Medicines\textsuperscript{19}: YES

Medicine quality control laboratory\textsuperscript{20}: National Drug Quality Assurance Laboratory.
- ISO 17025 certified\textsuperscript{18}: NO
- WHO prequalified\textsuperscript{13}: NO

Number of registered medicines\textsuperscript{13}: 8095 allopathic and 960 traditional medicines

Agency responsible for selection\textsuperscript{13}: Medical Supplies Division, Ministry of Health, Nutrition and Indigenous Medicine

Number of products on essential medicines list:
- By active ingredient\textsuperscript{13}: 361
- By dosage form\textsuperscript{13}: >400

Traditional medicines products included in essential medicines list\textsuperscript{13}: None

Medicines availability is indicated by health facility level\textsuperscript{13}: YES

Number of products in national formulary\textsuperscript{13}: Not available

Agency responsible for public procurement\textsuperscript{13}: State Pharmaceutical Corporation

Procurement done at Central\textsuperscript{20} ☑️ State\textsuperscript{20} ☐ Facility\textsuperscript{13,18} ☑️

Commonly used procurement methods\textsuperscript{21}: Worldwide tenders

Price Control\textsuperscript{13}: YES

Mechanism\textsuperscript{21}: Tenders are scheduled according to ascending prices and evaluated technically

Health insurance reimbursement Price\textsuperscript{13,18}: No public health insurance for majority of population

Patient prices for essential medicines in public sector:
- Free Medicines\textsuperscript{21}: YES

Agency responsible for distribution\textsuperscript{15}: Medical Supplies Division

Public sector facilities\textsuperscript{24}:
- Hospitals: 622
- Central dispensaries/Primary care units: 475

Number of Retail Outlets\textsuperscript{15}: 3297

Licensed retail pharmacies per 10 000 population\textsuperscript{13}: 1.6

Number of Traditional Medicines outlets: Not available
References


23. As reported by National Medicine Regulatory Authority, Sri Lanka, June 2017.


Notes:

A. 12 locally owned, allopathic manufacturers (1 government; 11 private-sector).
B. Teaching hospitals and some base hospitals are also allowed to do local purchase.
C. Insurance scheme for all government workers exist.
D. Maximum retail price is being introduced.
E. Price set by manufacturers.
### Thailand Medical Products Profile 2019

#### Country at a Glance

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value (unit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (in 000s)</td>
<td>69,626</td>
</tr>
<tr>
<td>Life expectancy at birth (in years)</td>
<td>75.5</td>
</tr>
<tr>
<td>GDP (per capita in current US$)</td>
<td>7,273.6</td>
</tr>
</tbody>
</table>

#### Overall Spending on Health

**Current per capita spending on health care (current US$)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Current US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>100</td>
</tr>
<tr>
<td>2008</td>
<td>150</td>
</tr>
<tr>
<td>2010</td>
<td>200</td>
</tr>
<tr>
<td>2012</td>
<td>250</td>
</tr>
<tr>
<td>2014</td>
<td>300</td>
</tr>
<tr>
<td>2016</td>
<td>350</td>
</tr>
</tbody>
</table>

**Share of government vs out-of-pocket spending on health**

- Government: 12%
- Out-of-pocket: 88%

#### Spending on Medicines

**Spending on medicines as share of total health-care cost**

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>55.5%</td>
</tr>
<tr>
<td>2008</td>
<td>50%</td>
</tr>
<tr>
<td>2011</td>
<td>10%</td>
</tr>
<tr>
<td>2014</td>
<td>9%</td>
</tr>
</tbody>
</table>

**Share of public and out-of-pocket spending on medicines**

- Public: 91%
- Out-of-pocket: 9%

#### 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>8.1</td>
</tr>
<tr>
<td>Pharmacists/10,000 population</td>
<td>4.2</td>
</tr>
</tbody>
</table>

- Pharmacy education accreditation: Yes
- Continuing professional development for pharmacists: Partly
HIV/AIDS and tuberculosis treatment coverage

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>72%</td>
</tr>
<tr>
<td>2010</td>
<td>74%</td>
</tr>
<tr>
<td>2012</td>
<td>80%</td>
</tr>
<tr>
<td>2014</td>
<td>85%</td>
</tr>
<tr>
<td>2016</td>
<td>90%</td>
</tr>
<tr>
<td>2018</td>
<td>99%</td>
</tr>
</tbody>
</table>

Diphtheria-tetanus-pertussis (DTP3) and hepatitis B immunization coverage

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>99%</td>
</tr>
<tr>
<td>2010</td>
<td>99%</td>
</tr>
<tr>
<td>2014</td>
<td>99%</td>
</tr>
<tr>
<td>2017</td>
<td>99%</td>
</tr>
</tbody>
</table>

Gaps in diagnosis and management of hypertension and diabetes

- Male Hypertension: 99% treated and controlled, 97% treated but untreated, 95% diagnosed but untreated, 92% undiagnosed
- Female Hypertension: 98% treated and controlled, 96% treated but untreated, 94% diagnosed but untreated, 91% undiagnosed
- Male Diabetes: 97% treated and controlled, 95% treated but untreated, 93% diagnosed but untreated, 90% undiagnosed
- Female Diabetes: 96% treated and controlled, 94% treated but untreated, 92% diagnosed but untreated, 89% undiagnosed

Levels of consumption of narcotic drugs

- Morphine: 50 S-DDD/million/day in 2008, 80 S-DDD/million/day in 2016

Key pharmaceutical legislation


National Medicine Policy

- National Medicines Policy 2017-2021

National Essential Medicines List

- National List of Essential Medicines-2017

National Standard Treatment Guidelines

- Individual disease guidelines and treatment protocols exist.

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

- Number of local pharmaceutical manufacturers: 186
- Least developed country status: No
- Member of World Trade Organization since: 1995
- TRIPS flexibilities used: Yes
National regulatory authority: Thai Food and Drug Administration (Thai FDA)
http://www.fda.moph.go.th/Pages/HomeP_D1.aspx

Regulated products:
- Medicines: YES
- Vaccines: YES
- Medical Devices: YES
- Traditional Medicines: YES

Medicine quality control laboratory: National Drug Testing Laboratory, Bureau of Drugs and Narcotics.
- ISO 17025 certified: Yes (since 1994)
- WHO prequalified: Yes (since 2012)

Number of registered medicines: Allopathic: 22,726, Biologicals: 647, Narcotics: 145, Traditional: 14,274, Veterinary: 3,537 (Does not include traditional veterinary medicines: 122)

Agency responsible for selection: Division of National Drug Policy, Thai FDA

Number of products on essential medicines list:
- By active ingredient: 687
- By dosage form: 1008

Traditional medicines products included in essential medicines list: Yes (74 products)

Medicines availability is indicated by health facility level: YES

National formulary: Specialties National Formularies available. No national formulary booklet


Procurement done at Central, State, Facility: Competitive tendering

Public Sector

Price Control: In reality no price control

Mechanism: Prices at or below standard price as mentioned in the standard price list

Patient prices for essential medicines in public sector:
- Free Medicines: YES

Private Sector

Number of wholesalers: Normal: 16,892 (include retail also)

Agency responsible for Price Control: Ministry of Trade/Commerce.

Pricing mechanism:
- Manufacturer
- Wholesale
- Retailer

Mark-ups regulated: No price cap/maximum retail price (MRP). Price negotiation between industry and purchaser.

Public Sector

Agency responsible for distribution: Directly from supplier to hospitals

Public sector facilities:
- Referral Hospitals excluding Bangkok Metropolitan: 116
- District hospitals (community hospitals): 774
- Primary care centers: 9,796

Private Sector

Number of Retail Outlets: Normal: 16,892
- Ready packed: 2,934
- Licensed retail pharmacies per 10,000 population: 2.5

Number of Traditional Medicines outlets: 2,083

Pharmaceutical system flowchart
References

13. As reported by Ministry of Public Health, Thailand, June 2017.
20. Data taken from South East Asia Regional workshop on Traditional Medicines in 2015, Pyongyang.

Notes:
A. National Medicines Policy 2017-2021: To get cabinet approval.
C. Treatment protocols available for special programs. Standard Treatment Guidelines for about 50 diseases available from Department of Medical Services, Ministry of Public Health.
D. Specialties National Formularies available. No national formulary booklet.
F. Suppliers directly supply to health facilities/ hospitals and community hospitals supply medicines to health centers.
G. 116 Referral Hospitals include - 88 regional hospitals/28 general hospitals. Primary care centers are called District Health Promoting Hospitals.
H. Ready-packed drugs can be sold in drug stores by nurses or other medical professionals. 3,686 “ready packed” includes (veterinary medicines:752, human medicines:2,934).
I. Calculated by using retail pharmacies/Thai pop. ^10,000 = 16,892/67,959,000*10,000 = 2.5.
# Timor-Leste Medical Products Profile 2019

## Country at a Glance

| Population (in 000s)
| Life expectancy at birth (in years)
| GDP (per capita in current US$) |
|-----------------------------|-----------------------------|-----------------------------|
| 1293                        | 68.6                        | 2035.6                      |

## Overall Spending on Health

### Current per capita spending on healthcare (current US$)

<table>
<thead>
<tr>
<th>Year</th>
<th>Current US $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>9%</td>
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<td>2008</td>
<td>91%</td>
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<tr>
<td>2010</td>
<td>0</td>
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<td>2012</td>
<td>10</td>
</tr>
<tr>
<td>2014</td>
<td>20</td>
</tr>
<tr>
<td>2016</td>
<td>30</td>
</tr>
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</table>

### Share of government vs. out-of-pocket spending on health

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>9%</td>
</tr>
<tr>
<td>2008</td>
<td>91%</td>
</tr>
<tr>
<td>2010</td>
<td>0</td>
</tr>
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<td>2012</td>
<td>10</td>
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<tr>
<td>2014</td>
<td>20</td>
</tr>
<tr>
<td>2016</td>
<td>30</td>
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</tbody>
</table>

## Spending on Medicines

### Spending on medicines as share of total health-care cost

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage (%)</th>
</tr>
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<td>2005</td>
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<td>10</td>
</tr>
<tr>
<td>2011</td>
<td>20</td>
</tr>
<tr>
<td>2014</td>
<td>30</td>
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</tbody>
</table>

### Share of public and out-of-pocket spending on medicines

<table>
<thead>
<tr>
<th>Year</th>
<th>Share as percentage (%)</th>
</tr>
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<tr>
<td>2005</td>
<td>63%</td>
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<td>2008</td>
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<tr>
<td>2011</td>
<td>9%</td>
</tr>
<tr>
<td>2014</td>
<td>37%</td>
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## Medical and Pharmacy Workforce

<table>
<thead>
<tr>
<th>Medical doctors/10 000 population</th>
<th>Pharmacists/10 000 population</th>
<th>Pharmacy education accreditation</th>
<th>Continuing professional development for pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2</td>
<td>0.081</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Medical products profile 2019
**Tuberculosis treatment coverage**

![Graph showing tuberculosis treatment coverage with percentage (%) over years 2008 to 2018]

**Diphtheria-tetanus-pertussis (DTP3) and Hepatitis B3 immunization coverage**

![Graph showing immunization coverage with percentage (%) over years 2007 to 2017]

**Gaps in diagnosis and management of hypertension and diabetes**

![Chart showing gaps in diagnosis and management with percentage (%) for different conditions]

**Levels of consumption of narcotic drugs**

![Graph showing levels of consumption with S-DDD/million/day for different drugs]

---

**Key pharmaceutical legislation**


**National Medicine Policy**

National Drug and Medicine Policy 2010

**National Essential Medicines List**

Timor-Leste Essential Medicines List-2015

**National Standard Treatment Guidelines**

Available for Primary Health Care and Referral hospitals, 2010

---

**Number of Local pharmaceutical manufacturers**

None

**Least Developed country status since**

2003

**Member of World Trade Organization since**

No

**TRIPS flexibilities used**

Not applicable until graduation from least developed country status
**Medicine**

**National Regulatory Authority**: No official National Regulatory Authority. Directorate of Pharmacy and Medicines (DNFM) responsible for some regulatory functions

Regulated products:
- **Medicines**: YES
- **Vaccines**: YES
- **Medical Devices**: YES
- **Traditional Medicines**: NO

**Medicine Quality Control Laboratory**: None

ISO 17025 certified: NA
WHO prequalified: NA

Number of Registered Medicines: 900

**Agency responsible for selection**: Committee for selection of medicines, products and medical equipment with Department of Pharmacy, Ministry of Health

**Number of products on essential medicines list**:
- By active ingredient: 274
- By dosage form: 402

**Traditional medicines products included in essential medicines list**: NO

**Medicines availability is indicated by health facility level**: YES

**Number of Products in National Formulary**: No National Formulary

**Public Sector**

**Agency responsible for Public Procurement**: SAMES IP (Service Autonomo de medicamentos e Equipamentos de Saude)

**Procurement done at Central**

**Commonly used procurement methods**: Local and International Tender based upon procurement amount

**Price control**: Yes
**Mechanism**: Bid evaluation based upon Lowest price criteria

**Health insurance reimbursement price**: No insurance but national health service provides free treatment of patients

**Patient prices for essential medicines in public sector**: Free medicines: YES

**Public Sector Facilities**:
- Reference Hospitals: 2
- Regional Hospitals: 3
- Community Health Services: 65
- Health Centres: more than 200

**Private Sector**

**Number of wholesalers**: 12

**Agency responsible for price control**: Not Controlled

**Pricing mechanism**: Not applicable

**Mark-ups regulated**: No policy so far

**Number of Retail Outlets**: 34

**Licensed retail pharmacies per 10 000 population**: 0.3

**Number of Traditional Medicines outlets**: No data

**Patient**
References

17. Data taken from South East Asia Regional workshop on Traditional Medicines in 2015, Pyongyang.

Note:
A. Functional laboratory does not exist. A mini laboratory under warehouse of Drugs and Equipment under Central Medical Stores, SAMES exists.
Access to medical products in the South-East Asia Region 2019

Review of progress