Improving access to medicines in the South-East Asia Region

Progress, Challenges, Priorities
Improving access to medicines in the South-East Asia Region: Progress, Challenges, Priorities
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<th>Full Form</th>
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<tr>
<td>ACTD</td>
<td>ASEAN common technical dossier</td>
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<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
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<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<td>ASU</td>
<td>“Antibiotics Smart Use”</td>
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<td>EML</td>
<td>essential medicines list</td>
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<tr>
<td>FTA</td>
<td>free trade agreement</td>
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<tr>
<td>GAVI</td>
<td>The Vaccine Alliance</td>
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<tr>
<td>GLO/VQ</td>
<td>Global Learning Opportunities for Vaccine Quality</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>HITAP</td>
<td>Health Intervention and Technology Assessment Programme</td>
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<tr>
<td>HTA</td>
<td>health technology assessment</td>
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<tr>
<td>LDC</td>
<td>least developed country</td>
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<tr>
<td>LMIS</td>
<td>logistics management and information system</td>
</tr>
<tr>
<td>MoHFW</td>
<td>Ministry of Health and Family Welfare (India)</td>
</tr>
<tr>
<td>NCD</td>
<td>noncommunicable disease</td>
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<tr>
<td>NRA</td>
<td>national regulatory agency</td>
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<tr>
<td>OECs</td>
<td>Organization of Eastern Caribbean States</td>
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<tr>
<td>SDG</td>
<td>Sustainable Development Goal</td>
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<td>SEA</td>
<td>South-East Asia</td>
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<tr>
<td>SEARN</td>
<td>South-East Asia Regulatory Network</td>
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<tr>
<td>TRIPS</td>
<td>Agreement on Trade-Related Aspects of Intellectual Property Rights</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>UNOPS</td>
<td>United Nations Office for Project Services</td>
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<tr>
<td>WTO</td>
<td>World Trade Organization</td>
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Improving access to medicines in the South-East Asia Region

Priorities for improving access to medicines in the South-East Asia Region

Perspectives from the Regional Director

Universal health coverage and the Sustainable Development Goal (SDG) for health will be achieved in the South-East Asia Region only if there is significant improvement in access to medicines. This paper provides information about the current trends in access to medicines in the Region and identifies five practical areas where Member States and WHO can work together to improve the availability of medicines.

Globally, data on access to medicines are still limited, and the South-East Asia Region is no exception. Nevertheless, the picture that consistently emerges is that overall availability, which is one dimension of access, has improved over the past ten years. However, availability still tends to be lower in the public sector compared with the private sector; lower in health centres than in hospitals; and more of a problem for medicines for noncommunicable rather than communicable diseases. There are sometimes concerns about the ability to assess the quality of medicines being procured and to negotiate prices. We also know that, given attention and resources, access to medicines can be significantly improved in a relatively short period of time: this has been demonstrated in the Region both for selected products such as antiretroviral therapy and vaccines, and for essential medicines as a whole, e.g. in Bhutan, or in the Indian states of Rajasthan and Tamil Nadu.

Many interventions contribute to improving access to medicines, including measures that address the delivery, governance (policy, regulation, monitoring, etc.) and financing of medicines. Regulation and quality assurance are important aspects of access and increasing attention is being given to regulation of medicines in the South-East Asia Region.

In the Region, at least 65 million people are impoverished because of out-of-pocket health spending, much of which is on medicines, while others forego treatment because of the cost. Medicines are only “accessible” if they are paid for in such a way that they actually reach the people who need them.

There are five clear areas where Member States and WHO can work together to improve access to medicines, in addition to WHO’s long-standing guidance and support on selection, use and supply chain management. These are: collaboration in procurement; cooperation in regulation; developing greater capacity to work within intellectual property rules; more rational use of antibiotics through improved antimicrobial stewardship; and improved monitoring of trends in access to medicines.
Collaboration on procurement to improve quality and reduce prices

WHO can support more intercountry collaboration on procurement. This can lead to improvements in both quality and price, which in turn contribute to better overall availability of medicines. Collaboration can take various forms, and there are successful models that can be explored. Examples include informed buying (participating countries share information on prices, quality of products and suppliers’ performance); and joint contracting and procurement, where participating countries conduct joint tenders through a central buying arrangement.

There is increasing interest in the South-East Asia Region in strengthening intercountry and subregional collaboration on procurement and pricing; there is clearly untapped potential for collaboration to improve access to medicines. The key will be to develop fit-for-purpose models for this Region.

Collaboration in regulation: more focus, less duplication

Regulation affects the quality and safety of medicines. Collaboration among countries can contribute to using the Region’s scarce and precious regulatory capacity more efficiently. The South-East Asia Regulatory Network (SEARN) can be instrumental in facilitating this collaboration. Key to this is that some regulatory authorities recognize the value of relying on agencies in other countries for certain regulatory decisions, such as marketing authorization or inspection. This fills gaps where capacity is limited and allows underresourced agencies to focus on priority activities. SEARN can also promote other activities to strengthen regulation and collaboration, such as sharing information, encouraging regulatory convergence, and supporting capacity-building in regulatory skills.

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

The impact of pharmaceutical patents on access to medicines is a much debated issue. The World Trade Organization (WTO)’s Agreement on Trade-related Aspects of Intellectual PropertyRights (TRIPS) should not prevent its Member countries from taking measures to protect public health, including access to medicines. In practice, there is flexibility within TRIPS that gives countries in different situations several options for action, and there is experience within this Region that can be shared. Continued vigilance is needed on other bilateral or multilateral trade agreements that may have harmful “TRIPS-plus” provisions, including patent term extensions and data exclusivity: these can restrict access to affordable medicines. The Regional Office will facilitate greater exchange of knowledge and experience on these trade agreements, helping individual countries to understand better the relevance of the provisions to their own circumstances and how to use TRIPS flexibilities where needed.

More rational use of antibiotics through a sustained focus on improved antimicrobial stewardship

Given the scale of antimicrobial resistance (AMR) in the South-East Asia Region, increasing attention is being paid to more rational antibiotic use. This is the fourth priority in the Regional Office’s work on access to medicines, and requires effective antimicrobial
“stewardship”. There are three critical components of antimicrobial stewardship that will support more rational antibiotic use: improved data on the scale of and trends in antimicrobial consumption; national antimicrobial policies and regulations; and nationwide education and advocacy on antimicrobial use and resistance for both consumers and health-care providers. WHO will support the development of national systems to monitor antimicrobial consumption, as part of the roll-out of national AMR action plans. It will support inclusion of training on AMR in the pre-service curricula of health professionals and conduct advocacy campaigns during World Antibiotic Awareness Week. It will support regulations to dispense antibiotics on a prescription-only basis. It will encourage documentation of experiences in implementing such strategies in the Region.

Improved monitoring of access to medicines

Regular information about the population’s access to medicines alerts decision-makers to problems of drug availability. Without data to prompt action, availability is unlikely to increase significantly. Good monitoring can provide information on how many people cannot afford to buy the medicines they need; where medicines are not available; where unsafe or ineffective products are on sale, and what is being done about it. Action being taken at the regional level includes supporting the development and use of practical indicators, methods and tools for monitoring these different dimensions of access to medicines, and improving reporting on the medicines indicator in the SDGs. In 2016, WHO successfully piloted a smartphone application as a data collection tool for gathering information on the prices and availability of medicines in 19 low- and middle-income countries. This tool will be rolled out as a simple and cost-effective way to collect national data on access to medicines in the Region.

In summary, work related to procurement and intellectual property rules can increase the availability of medicines. Strengthening regulation helps to ensure that these medicines are of an appropriate quality. There is a need for a sustained focus on antimicrobial governance, given the scale of AMR in this Region. And improving information about access to medicines keeps the issue at the forefront of policy-makers’ and managers’ attention.

I see this document as an important step towards identifying key priorities for collective action to improve access to medicines in the South-East Asia Region. I believe intensified action in these five areas will significantly enhance access to essential medicines, and contribute to progress on universal health coverage and the improved health outcomes envisaged in the SDGs.

Dr Poonam Khetrapal Singh
Regional Director
PART I
Improving access to medicines: Where are we now?
**Improved access to medicines is central to achieving universal health coverage and SDG3**

All countries in the South-East Asia (SEA) Region are committed to providing essential medicines to those who need them. Although there has been progress, challenges remain in providing the right medicines at the right time. Procurement and supply chains are weak in some countries and many drug sales are unregulated. Out-of-pocket costs for medicines are high, with some households impoverished by high drug bills and others foregoing treatment because of the cost.

There are important differences in the markets for medicines in the various SEA countries. Some countries are large and have a significant domestic pharmaceutical manufacturing industry. Smaller countries with little local production are in a more difficult position when buying medicines on the international market, because they have few alternatives to importing medicines and have little influence over global prices.

Access to medicines is explicitly recognized in the 2030 Agenda for Sustainable Development. For nearly all of the targets of Sustainable Development Goal (SDG) 3 on health, improved access to medicines plays a role, such as in maternal and child health, non-communicable diseases (NCDs), malaria, and sexual and reproductive health. Access to medicines and vaccines is highlighted explicitly in targets 3.8 and 3.b,

<table>
<thead>
<tr>
<th>Box 1. Reliable access to medicines is needed for progress on many SDG3 targets</th>
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<tbody>
<tr>
<td>3.1. Maternal mortality</td>
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<tr>
<td>3.2. Child mortality</td>
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<td>3.3. Communicable diseases</td>
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<tr>
<td>3.4. Non-communicable diseases</td>
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<td>3.5. Substance abuse</td>
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<tr>
<td>3.7. Sexual and reproductive health</td>
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<tr>
<td>3.8. Achieve universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all.</td>
</tr>
<tr>
<td>3.b Support the research and development of vaccines and medicines 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.</td>
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</table>

“Access to medicines for all” implies equity in access without barriers due to geography, income, ethnicity, migrant status, age or gender. As with other aspects of health service delivery, access to medicines faces the challenge of “leaving no one behind”.

This paper explores the current state of medicines access in South-East Asia and identifies a small number of key regional actions to improve the situation.
THE AVAILABILITY OF ESSENTIAL MEDICINES HAS IMPROVED, BUT NOT UNIFORMLY

Available data on access to medicines is limited, and comes almost entirely from surveys. The World health statistics 2016 report on Monitoring health for the SDGs did not report on the SDG indicator 3b on availability of medicines, partly because the indicator’s definition is still under discussion, but also because insufficient data were available. The data shortage is because only a few countries have fully computerized national information systems for logistics management, which provide information on medicine availability, or conduct periodic surveys. In the SEA Region, only two countries, Myanmar and Thailand, had nationally representative estimates of access to essential medicines at the time of a 2016 report on the SDGs in the Region.

However, some data do exist, which suggest that the availability of essential medicines has improved on average in recent years.

Back in 2009, The Lancet published the results of medicine price and availability surveys in 36 countries in the six WHO regions. The study found availability of less than 80% (the WHO benchmark for availability) in both the public and private sectors in all regions. As shown in Fig. 1, the SEA Region had the second lowest availability of a basket of 15 commonly used medicines in the public sector, but the highest availability in the private sector.

**Fig. 1: Average availability of a basket of essential medicines, by WHO region (2009)**

![Average availability of a basket of essential medicines, by WHO region (2009)](source)


In SEA Region countries, surveys were conducted in seven states of India, in 2004–2005; Indonesia in 2004; and Sri Lanka in 2001.

AFR: African Region; AMR: Region of the Americas; EMR: Eastern Mediterranean Region; EUR: European Region; SEAR: South-East Asia Region; WPR: Western Pacific Region

Most of the 2009 surveys have not been repeated, but a set of smaller studies in seven Member States approximately ten years later found that the average availability of essential medicines improved, but not uniformly.

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\(a\) Basket of medicines: acyclovir, amitriptyline, amoxicillin, atenolol, beclomethasone, captopril, ciprofloxacin, ceftriaxone, co-trimoxazole, fluoxetine, hydrochlorothiazide, glibenclamide, omeprazole, ranitidine, salbutamol.
Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

Fig. 2 shows that in four countries, the availability of medicines exceeded the 80% target availability recommended by WHO (Bhutan, Myanmar, Sri Lanka, Thailand) and two (Bangladesh and Nepal) were just below the target.

Fig. 2: Average availability of a basket of medicines in public health facilities in 7 SEA Region countries, 2014–15

Source: WHO SEA Region country case studies, 2014–2015

This is an important issue that is discussed in the What next? section of this paper: data on the availability of drugs tells managers and policy-makers a lot about the state of a health system and should be provided on a regular basis. Box 2 describes the experience of Sri Lanka, where information on medicine availability was improved and used to reduce stock-outs and wastage.

Box 2. New logistics management information system helps to improve access to medicines in Sri Lanka

The State Pharmaceutical Corporation of Sri Lanka has developed a cost-efficient logistics management information system to support modern supply chain management practices such as “just-in-time” monitoring of stocks along all storage and service delivery points, as well as in State drug shops, called Rajya osu safas.

By providing timely and accurate data, the logistics information system enables precise forecasting and quantification to facilitate the timely procurement of products. The system helps to reduce stock-outs and wastage due to expired products, while rapidly managing shortages by moving stocks based on available “just-in-time” information.

Access to medicines can improve with attention and resources: the case of antiretroviral therapy

There are many examples of improved access to medicines when national health priorities are supported by external financing, e.g. HIV/AIDS treatment, immunization,

b Basket of medicines: albendazole; amoxicillin; atenolol; ciprofloxacin; enalapril; ferrous sulphate+ folic acid, metformin; metronidazole; oral rehydration sachet; paracetamol; salbutamol.
tuberculosis, malaria. Fig. 3 shows increased ART coverage for eligible patients in seven Member States between 2010 and 2015.

**Fig. 3: Trends in antiretroviral treatment coverage for patients with HIV/AIDS (%)**

![Trends in antiretroviral treatment coverage for patients with HIV/AIDS (%)](image)

Source: UNAIDS annual reports

**Average availability conceals inequities: problems with access to medicines for noncommunicable diseases**

Medicines for NCDs are often less frequently available than medicines for communicable diseases. Surveys have found that the average availability of tracer medicines for NCDs is lower in selected countries in the Region compared to antimicrobial agents for infectious diseases. Fig. 4 illustrates this for selected countries.

**Fig. 4: Availability of antimicrobials and medicines for noncommunicable diseases in public health facilities of seven Member States**

![Availability of antimicrobials and medicines for noncommunicable diseases in public health facilities of seven Member States](image)

Source: WHO SEA Region country case studies, 2014–2015
Availability of medicines also varies by level of care. Myanmar is one of the few countries with disaggregated data. A survey of health facilities in 2015 found high availability of medicines for communicable diseases in public facilities at all level of care, but lower availability of medicines for NCDs, especially at the primary care level. Fig. 5 illustrates the situation, with the comparison for health centres (in green stripes) particularly striking.

**Fig. 5: Availability of tracer medicines for communicable versus noncommunicable diseases at different levels of health facility in Myanmar, 2015**

![Graph](image)


RHC: Rural health centre
UHC: Urban health centre

The final step in the medicines delivery chain is to ensure that people who need treatment actually receive it. WHO STEPS surveys for NCDs in seven Member States between 2010 and 2014 found that the proportion of people with high blood pressure who are on treatment varies widely (Fig. 6).

**Fig. 6: Percentage of people with hypertension* who are NOT on medication**

![Graph](image)

*Defined as systolic blood pressure ≥140 and/or diastolic blood pressure ≥90 mmHg

Source: WHO STEPS surveys on risk factors for NCDs, most recent year 2010-2014.
PART 2

Improving access to medicines: What interventions are being used?
An effective response to improving access to medicines includes the following:

- National medicines policies exist, and are being implemented;
- Working within intellectual property and competition rules to improve access to medicines;
- Having strong and resilient systems to select, price, procure and distribute medicines;
- Having regulation and quality assurance that enhances quality and safety;
- Rational use of medicines fostered through appropriate education and incentives;
- Sufficient, efficient and equitable financing.

This section reviews progress with implementation in these six areas.

**National medicines policies exist and are being implemented**

National medicines policies and laws underpin good governance and coordination in the pharmaceutical sector. An effective national medicines policy sets out the commitment of the government to ensuring equitable access to effective, safe and quality medicines. It provides a framework for organizing, financing and regulating the pharmaceutical sector, and for coordinating stakeholders to achieve targeted objectives.

Most Member States have national medicines policies, which have the concept of essential medicines at their core. WHO recommends that these policies be updated every five years. Table 1 shows the date of the most recent policies in Member States, with a range from 1998 to 2017; updates are currently under way in three countries.

<table>
<thead>
<tr>
<th>Bangladesh</th>
<th>Bhutan</th>
<th>Democratic People’s Republic of Korea</th>
<th>India</th>
<th>Indonesia</th>
<th>Maldives</th>
<th>Myanmar</th>
<th>Nepal</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Timor-Leste</th>
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</thead>
</table>

* Revised NMP in preparation
** National legislation, rule and regulation for drug management
Source: Country pharmaceutical profile information (Part 4).

Updating policies can be time-consuming, but infrequent updating means that countries may miss opportunities to adapt policies to changing circumstances. There is a case to be made for linking the review and updating of national medicines policies with the preparation of new national health sector strategies.

Implementation of national medicines policies varies. It is enhanced when the policy is associated with additional, more specific implementation plans with well-defined budgets.

Roles and responsibilities of national entities need to be well defined for successful implementation, with some clear accountability mechanisms, e.g. on selection and
procurement of medicines; on the development of the domestic pharmaceutical industry; and on strengthening the regulatory system.

**Working within intellectual property and competition rules to improve access to medicines**

One much debated issue in access to medicines is the impact of pharmaceutical patents on delivery of essential medicines, at the same time as encouraging research to develop new medicines. The World Trade Organization’s (WTO) 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires all WTO Member States, except those rated as least developed countries (LDCs), to provide patent protection for both products and processes in pharmaceutical inventions. This has implications for the availability of new generic essential medicines, such as those for the treatment of hepatitis C. The 1994 Agreement has caused concern that the push for patent protection would have detrimental effects on public health, because patents allow monopoly pricing. In practice, there is sufficient flexibility within TRIPS to allow for a number of important actions that improve access to medicines: it is important that governments fully understand the issues in relation to their own country.

In the South-East Asia Region, there are several different situations to be aware of in relation to TRIPS and public health.

- **In the Region, five countries are classified as LDCs.** These are Bangladesh, Bhutan, Myanmar, Nepal and Timor-Leste. Of these, Bhutan and Timor-Leste are not members of WTO and hence not bound by TRIPS or other WTO agreements. The other three LDCs are not required to comply with the TRIPs Agreement until 1 January 2033, and there is flexibility in producing and purchasing generic alternatives for new patented medicines, e.g. drugs for hepatitis C or cancer. Bangladesh has used this flexibility to good effect and is in the unique position of being an LDC which has a sizeable pharmaceutical industry for domestic use and export.

- **In the 2001 Doha Declaration, TRIPS flexibilities for addressing “public health crises” were reaffirmed.** This allows for the use of a product without the patent holder’s permission. In practice, this means issuing compulsory licenses or permitting parallel imports. As shown in Box 3, Thailand has used this rule to good effect to produce antiretrovirals and cancer drugs.

- **Patent criteria are set by domestic legislation, and this can influence price.** India, for example, has set strict standards for what does and does not merit a patent in its patent law, in the interest of public health. India has been able to stop secondary, follow-on patents for multiple medicines. By setting strict patent standards, India has been able to maintain robust generic competition that has

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**A compulsory license** is the authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patentee, on various grounds of general interest (including public health). A **parallel import** is the legal importation (i.e. not pirated/counterfeited) without the permission of the intellectual property right-holder (e.g. the trademark or patent owner). The product is then sold more cheaply in the importing country than it otherwise would be.
kept medicine prices low. Countries may need to consider adapting national legislation in order to use TRIPS flexibilities to the full (Box 4).

**Box 3. Using TRIPS flexibilities: the Thai experience**

Thailand has actively used compulsory licensing since 2006 for multiple antiretroviral and cancer medicines. An evaluation of these government-use licenses found that an additional 84,158 patients received access to the seven drugs studied. The Minister of Public Health, Thailand said at the time “We, of course, also need innovation to develop new pharmaceutical products, and someone has to pay the cost of research and development for new essential drugs. When a government such as ours declares a ‘compulsory license’ to allow for public non-commercial use of patented products by the government for the greater public good, we are doing so to increase access to these essential, often life-saving, medications for the poor and marginalized members of our communities who were not consumers of these expensive, patented drugs.”

- **Competition is a primary means to promote affordable medicines, but trade agreements sometimes unnecessarily restrict this.** There are examples of trade agreements promoting intellectual property rights protection beyond what is required by TRIPS – these are called “TRIPS plus” provisions. These new provisions are often negotiated in new free trade agreements (FTAs) by Member States, e.g. by including data exclusivity in a trade agreement; this prevents drug safety regulators from relying on existing clinical data to grant market approval to generic drugs. As a result, a generic producer has to conduct costly clinical trials, which add to the price of a product. The new FTAs are also onerous for Member States, as unlike the dispute settlement mechanism in WTO, these FTAs have investor dispute arbitration mechanisms that lack transparency. By contrast, WTO encourages Member States to complain if they feel that “TRIPS plus” provisions are being used to discourage trade in generics, as this goes against the spirit of the flexibilities to protect public health.

**Box 4: The way domestic patent legislation is codified ultimately affects prices, an example from India**

In April 2013, the Supreme Court of India ended a seven-year battle around the patentability of imatinib mesylate for the treatment of chronic myeloid leukaemia, marketed by Novartis under the trade name Glivec/Gleevec, and refused the grant of the patent. The Supreme Court rejected the patent application claim for a specific crystalline form (β-crystal form) of imatinib on the grounds that this form is not a new substance, was already known and does not show enhanced therapeutic efficacy. The Supreme Court points out that other positive characteristics, e.g. being less hygroscopic, are not sufficient for grant of the patent.

India’s strict law on what does and does not deserve a patent and the practice of discouraging secondary patenting, such as the above example, is helpful in preventing extension of monopoly on production and high prices, and allows the production of affordable generics after expiry of the primary patent.
**Strong and Resilient Systems to Select, Price, Procure and Distribute Medicines**

**Essential medicines lists remain valuable for guiding selection, and benefit from regular updates**

Government guidance on medicines to be used in the public sector is based upon an essential medicines list (EML) in all countries of the Region. Medicines should be included in this list based on common morbidities, evidence of cost–effectiveness, and affordability for government or health insurance schemes. Regular updating of the national EML should ensure continuing relevance to the current health situation in a country. WHO proposes that EMLs are reviewed and updated every two to three years, to respond to changing needs and ensure inclusion of effective and safe new therapies. WHO revises and publishes the WHO Model Essential Medicines List every two years to assist countries in making decisions on whether to add or remove products from their EMLs, and suggests that countries do the same. In 2017, 30 essential medicines were added to the Model EML.

National EMLs in the Region are updated periodically; most have been updated recently. Revisions in the future will have to look at ways of adopting new, high-impact essential medicines subject to need and health system capacity (including financial).

The Punjab Government (a state in India) has demonstrated in the case of chronic hepatitis that early adoption of new essential treatments can save lives and prevent cancer. It did this through its ground-breaking initiative of treating hepatitis C patients with the latest essential medicines, as recommended by WHO (first listed in 2015); 2500 patients have been treated since June 2016.

*Table 2. National essential medicines lists: dates of the most recent revision*

<table>
<thead>
<tr>
<th>Country</th>
<th>Date</th>
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<tbody>
<tr>
<td>BAN</td>
<td>2017*</td>
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<tr>
<td>BHU</td>
<td>2016</td>
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<tr>
<td>DPRK</td>
<td>2015</td>
</tr>
<tr>
<td>IND</td>
<td>2015</td>
</tr>
<tr>
<td>INO</td>
<td>2017</td>
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<tr>
<td>MAV</td>
<td>2016</td>
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<td>MMR</td>
<td>2016</td>
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<tr>
<td>NEP</td>
<td>2016*</td>
</tr>
<tr>
<td>SRL</td>
<td>2014</td>
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<td>THA</td>
<td>2017</td>
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<tr>
<td>TLS</td>
<td>2015</td>
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*Under revision
Source: Country pharmaceutical profile information (Part 4).

**Medicine prices are negotiable; there are opportunities to leverage regional manufacturing capacity**

Well-designed pricing policies and active price negotiations can help to ensure affordability, while maintaining quality. A variety of activities can contribute to reduced prices, including generic prescribing and substitution policies, regulation of mark-ups (wholesale and retail mark-up) and negotiation with manufacturers for differential pricing using TRIPS flexibilities. More complex pricing strategies linked to health insurance programmes are mostly developed in countries with long-standing national health insurance coverage. Thailand regularly uses an evidence-based health technology assessment process to support decisions on what to include and how to set pricing policies for new technologies, as described in Box 5.
Box 5: Using health technology assessment in price negotiations: the Thai experience

Health technology assessment (HTA) is a method for systematically assessing the benefits and costs of medical products to aid decision-making about which products are worth buying in a particular situation. HTA is increasingly used by high- and upper-middle-income countries to help decide which new therapies should be included in publicly financed programmes. The results of HTA can also help in price negotiations because the analysis shows at what price level it is worthwhile buying the product.

Thailand’s Health Intervention and Technology Assessment Programme (HITAP) plays an important role in decision-making regarding the country’s universal health coverage plan and the associated benefit package. HITAP analyses information on safety, effectiveness, cost–effectiveness and budget impact. HITAP’s HTA recommendations are also used for decisions related to the EML. Evolving HTA systems in Thailand and Indonesia can provide important lessons for the increasing number of countries developing HTA capacity in the Region.

Another approach is to introduce more transparency regarding prices to support price negotiation. Box 6 describes how medicine prices paid by the national social insurance scheme in Indonesia were reduced by up to 40% by introducing a transparent procurement method.

Box 6: National health insurance scheme supporting more efficient procurement in Indonesia

Indonesia has been implementing its National Social Health Insurance Scheme (Jaminan Kesehatan Nasional or JKN), moving toward universal health coverage since January 2014. JKN became the largest payer in Indonesian public health. The assessment prior to its launch made it clear that reforms were needed for procurement and management of medicines and medical equipment to ensure efficiency, effectiveness and transparency.

The Ministry of Health introduced two important reforms for improving medicines procurement. One was the new national formulary of medicines containing a list of molecules that aimed to support rational use and cost–effectiveness (Formularium Nasional or FORNAS). The other reform was the introduction of a tool for e-procurement, along with an e-catalogue accessible to all with appropriate authority.

Discussion among multiple levels of government, health-care providers and the pharmaceutical industry led to agreement on acceptable standards and assurance that no unreasonable profits would be generated by doing business with JKN. Ultimately, the prices agreed for JKN medicines were, on average, 30–40% less than before.

Altogether, the SEA Region has the advantage that it is a major producer and exporter of generic medicines. India is commonly referred to as the “pharmacy of the world”, exporting to over 170 economies, and Bangladesh, Indonesia and Thailand also have sizeable domestic production. India, through a package of policies and local production, has maintained low prices: the public procurement prices of a basket of medicines in India was found to be 47% to 18% lower than international reference prices in 2011.10
Several countries, including Bangladesh, India and Nepal, use direct price control to determine maximum retail prices. This can help to keep medicines affordable for many who pay out of pocket, but may not be sufficient to ensure coverage and access for the very poor and vulnerable.

Countries use a number of different procurement methods, from international competitive bidding to negotiated tenders. However, “emergency” direct procurement by individual facilities is also common due to acute shortages or stock-outs. Direct emergency procurement nearly always leads to higher prices and may compromise quality.

When it comes to price negotiations, small countries often have limited bargaining power. They could benefit from joining their neighbours or taking part in subregional collaboration to develop more strategic pricing and procurement arrangements. Such group procurement schemes exist for medicines in other parts of the world, but not in South-East Asia. For example, the Organization of Eastern Caribbean States (OECS) reported an average cost saving of 37% for buying 25 selected medicines over a five-year period by using a regional pooled procurement mechanism.

There is increasing interest in exploring group procurement schemes for vaccines in the Region. The Ministry of Public Health in Thailand brought countries belonging to the Association of Southeast Asian Nations (ASEAN) together in 2015 in a move that resulted in the inclusion of “ASEAN Vaccine Security and Self-Reliance” in the ASEAN Health Development Plan 2016–2020. ASEAN is now looking for a group procurement mechanism to buy selected vaccines in bulk for the 10 ASEAN countries.

There are a number of global procurement mechanisms available to Member States for selected essential medicines and vaccines, through agencies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, The Vaccine Alliance (GAVI), United Nations Office for Project Services (UNOPS) and the United Nations Children’s Fund (UNICEF). Effective use of these global schemes can provide significant savings and security of supply for these selected products, and should be favoured when the supply of low-cost and quality-assured products is not certain from domestic or regional markets.

There are clearly opportunities to improve the affordability of essential medicines in South-East Asia, e.g. by sharing price information, and conducting joint price negotiations or joint procurement. There is a growing interest in more regional or bilateral collaboration in strategic procurement arrangements; this issue is further discussed in the What Next? section below.

Drug distribution

Functional supply chains guarantee the regular availability of affordable medicines in the right quantity at all health service delivery points. They also feed critical information back to supply chain managers and health planners on stock levels and consumption. Fully computerized, robust logistics management and information systems (LMIS) are thus key to well-performing supply chains.
Several countries in the Region, including Bhutan, several states in India (Kerala, Rajasthan and Tamil Nadu) and Sri Lanka have demonstrated that developing and using the right LMIS to provide accurate, real-time information can help to overcome the problems of shortages and stock-outs of free essential medicines. These successful models enhanced supply chain management practices, and created greater accountability and value for money in the purchase of essential medicines. Box 7 describes the experience of Rajasthan, where a suite of measures was deployed to improve access to medicines.

Box 7. Rajasthan: improving access to medicines through improved procurement and better data

Rajasthan is the seventh most populous state of India. In 2011, the State Government launched the Mukhyamantri Nishulk Dava Yojana (MNDY) to improve the availability of essential medicines. The emphasis was on increasing public spending on medicines, setting up a state medical services corporation, and making the procurement and supply chain more efficient.

The Rajasthan State Medical Corporation improved processes for selection, quantification, procurement and quality assurance of medicines supplied to the public health system. An electronic platform, e-Aushadhi, greatly enhanced the efficiency of public procurement.

In 2013, facilities reported fewer shortages and stock-outs compared with earlier studies. Median availability of medicines in primary health care, community health centres and district hospitals in 2013 was found to be 70%, 67% and 85%, respectively.

Increased government expenditure on medicines, together with improved medicines procurement and logistics management practices, resulted in increased availability of medicines and improved service utilization at public health facilities. The success of the Rajasthan model illustrates the importance of the right blend of technical expertise, political will and increased funding for improving access to medicines.

Regulation and quality assurance to enhance quality and safety

National regulatory agencies (NRAs) protect public health by ensuring the efficacy, safety and quality of medicines. Their role is codified in national legislation and put into practice by applying a set of internationally recommended core regulatory functions. Their functions include surveillance of available drugs; registration and marketing authorization; and licensing and inspection of premises that sell or dispense medicines.

All Member States have a legally mandated NRA or a unit within the Ministry of Health responsible for the regulation of medicinal products. Laws on regulation of medicines are also in place and have been updated in the past 10 years, as shown in Fig. 7.
Pharmaceutical markets in the SEA Region are evolving rapidly. One result is that the functions of regulatory agencies, which often have limited financial and human resources, are becoming increasingly complex. This complexity has led to a growing acceptance that not all NRAs need to have the full capacity to perform all core regulatory functions: some may decide, legitimately, to rely on other competent regulatory authorities to fulfil some part of their regulatory mandate. For example, an NRA may rely on information from another competent authority for decisions about marketing authorization of a new medicine or Good Manufacturing Practice (GMP) certification of a manufacturer. When NRAs effectively use such reliance processes they are still considered functional, even though they rely on others for the conduct of certain regulatory functions.

There are a number of ways in which countries can strengthen regulation. Four examples are given here.

- **Seek WHO recognition as a functional regulatory authority.** India, Indonesia and Thailand are already recognized by WHO as functional national vaccine regulatory authorities. By maintaining high regulatory standards, NRAs in these three countries allow their national vaccine manufacturers to participate in WHO’s vaccine prequalification programme and improve global vaccine supplies. The Bangladesh NRA has initiated the same assessment, because it wishes to become recognized as a functional national vaccine regulatory authority in the coming years.

- **Converge towards international standards.** Indonesia, Myanmar and Thailand participate in the use of the ASEAN common technical dossier (ACTD) for the registration of pharmaceuticals for human use. The ACTD is a guideline on the agreed common format for the preparation of a well-structured common technical dossier (CTD), based on internationally recognized requirements for registering medicines. This is a useful form of harmonization towards internationally...
recognized regulatory standards, which itself contributes to improved quality and safety. Indonesia and Thailand are also members of the Pharmaceutical Inspection Co-operation Scheme. This scheme, which has 50 agencies globally, develops and maintains harmonized standards on GMP for medicines and for quality systems of inspectorates.

- **Work towards international accreditation of quality control laboratories.** Several countries have made significant progress in their national quality control laboratories for testing medicines, and have achieved international accreditation. One example is the recent ISO 17025 accreditation of the Food and Drug Administration’s medicines quality control laboratory in Myanmar.

- **Use the global NRA benchmarking tool.** All Member States have used this tool in its original form, which focused solely on vaccines. In 2016, it was updated to include medicines. Five countries (Bangladesh, India, Indonesia, Thailand and Timor-Leste) have evaluated their regulatory capacity using the updated WHO NRA Global Benchmarking Tool, or are in the process of doing so. This helps countries to decide how to develop their necessary institutional capacity, including evaluation of the appropriateness of one authority’s “reliance” on another authority’s work.

  More work is needed in many areas of regulation, notably in relation to substandard or falsified medicines. Poor-quality medicines pose risks to individuals and can be a public health risk; e.g. having substandard antibiotics in circulation leads to increased antibiotic resistance; substandard and falsified antimalarial medicines contributed to the spread of drug-resistant malaria in the Greater Mekong region.

  One of the key functions of any NRA is to be vigilant in monitoring the quality of products on the open market through targeted testing of high-risk products. Several regulatory agencies are taking significant steps to reduce the risk of substandard and falsified medicines by updating regulations; increasing inspection capacity to ensure adherence to best practices by industry; and expanding post-marketing surveillance and enforcement activities. Results of such post-marketing surveillance allow the necessary regulatory actions to be taken. More regional collaboration and participation in regional and global coordinated actions would reinforce this positive work. One potential area for collaboration is capacity-building: there is Regional experience to draw on from capacity-building efforts related to vaccines, as Box 8 shows.

  Countries have been gradually increasing regulatory requirements to ensure the quality of products on the market. Regular monitoring of medicine quality is a way to identify the impact of such enhanced regulatory controls and communicate this transparently to all stakeholders.

  India has conducted medicines quality surveys for a number of years. The latest results from 2014–2016 show a continued decline in substandard and falsified medicines – from 4.75% in 2009\(^\text{13}\) to 3.1% in 2016.\(^\text{14}\)
Box 8. Global learning opportunities related to quality of medical products

WHO established the Global Learning Opportunities for Vaccine Quality (GLO/VQ) network in 1996 to support capacity development in vaccines management. In the SEA Region, there are two GLO/VQ centres running training programmes: one for vaccine lot release in India and one for clinical trial authorization and data analysis in Indonesia. The network’s training programmes are combined with institutional twinning programmes. For example, the Thailand Food and Drug Agency (TFDA) provided technical assistance to the National Directorate for Pharmaceuticals and Medicines (NDPM) in Bhutan. A similar twinning programme is being developed between the National Agency of Drug and Food Control (NADFC), Badanpom, Indonesia and the Department of Drugs Administration in Nepal. This network of resource centres can be expanded to include medicines. A resource centre was established by the Ministry of Health and Family Welfare (MoHFW) in India in 2016 to provide technical support for immunization supply chain management. WHO, UNICEF and the MoHFW are exploring the feasibility of this centre becoming a WHO GLO training resource centre on Good Distribution Practices for medical products more broadly.

Thailand’s regulatory agency has published results from its quality assurance programme annually since 2002. Overall quality monitoring of pharmaceutical products shows a gradual improvement in product quality for both modern and herbal medicines.15

Good regulation means that patients are more likely to consume medicines that are actually effective. NRAs are evolving fast. There is considerable potential for more regional collaboration to help use scarce and precious regulatory resources more efficiently. This need for more collaboration was one of the main driving forces behind the establishment of the South-East Asia Regulatory Network (SEARN) in 2016. NRAs or equivalent from all eleven Member States participate in the network. The objectives of SEARN are shown in Box 9.

Box 9. The South-East Asia Regulatory Network – strengthening regulatory collaboration

The WHO SEA Region Member States launched the South-East Asia Regulatory Network (SEARN) to enhance information-sharing, collaboration and convergence of regulatory practices for medical products across the Region to guarantee access to high-quality medical products.

Regulatory authorities in several countries lack sufficient technical capacity, staff and resources to perform effectively. Even well-resourced authorities are hard-pressed to thoroughly evaluate new products and enforce existing regulations. Therefore, SEARN will be instrumental in encouraging convergence, effective use of resources and rapid exchange of information on medical products for countries in the SEA Region.

SEARN is establishing three initial working groups: on pharmacovigilance; GMP and information-sharing on regulatory practices. Their progress is overseen by a Steering Group.
RATIONAL AND SAFE MEDICINE USE FOSTERED THROUGH APPROPRIATE EDUCATION AND INCENTIVES

Improving rational use of medicines has been a part of national medicines programmes for many years, but remains an elusive goal. Promoting rational use entails changing both prescribers’ and patients’ behaviours. There are a range of recommended interventions, including rational use policies, development of standard treatment guidelines, national formularies, and health workers’ and patients’ awareness and education. Countries in the Region are at different stages of implementing these.

At present, in the SEA Region, particular attention is being paid to rational antibiotic use because of the growing problem of antibiotic resistance. Fig. 8 provides some information on the percentage of patients who were prescribed antibiotics for upper respiratory tract infections (also known as “the common cold”, a viral infection for which antibiotics are ineffective), taken from an audit of prescriptions issued at health facilities.

![Fig. 8: Median percentage of patients with upper respiratory tract infection (URTI) who were prescribed antibiotics](image)

<table>
<thead>
<tr>
<th>Country</th>
<th>Median Percentage of Patients with URTI Prescribed Antibiotics (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>60.3</td>
</tr>
<tr>
<td>Bhutan</td>
<td>30</td>
</tr>
<tr>
<td>Maldives</td>
<td>49</td>
</tr>
<tr>
<td>Myanmar</td>
<td>86.7</td>
</tr>
<tr>
<td>Nepal</td>
<td>73.3</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>72.6</td>
</tr>
<tr>
<td>Thailand</td>
<td>56.3</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>42.9</td>
</tr>
</tbody>
</table>

*Median percentage of patients with URTI prescribed antibiotics (%)*


Countries are taking action to lower rates of unnecessary antibiotic prescribing. In Bhutan, one cannot buy antibiotics over the counter. In Thailand, the Antibiotic Smart Use programme (Box 10) has borne results. India has introduced red-line labelling on antibiotics to promote their appropriate use: all prescription-only antibiotics should be marked with a vertical red line on the packets, and should be dispensed and used according to a doctor’s prescription.

Unsafe medication use and incorrect administration practices are a leading cause of avoidable harm from medicines globally. Medication errors can occur when weak medication documentation systems and/or human factors such as fatigue contribute to errors in prescribing, transcribing, dispensing, or the administration of medicines. These errors cause avoidable harm, disability and sometimes death. The scale and nature of this problem is not well known in the Region due to the lack of reporting and monitoring systems.
Box 10. Thailand’s “Antibiotics Smart Use”, or ASU, programme (ongoing since 2007)

Thailand has developed the “Antibiotics Smart Use” (ASU) programme to promote the responsible use of antibiotics. ASU is a voluntary programme, directly engaging prescribers, dispensers and patients. The Phase 1 pilot showed encouraging results. Phase 2 was a scalability test involving 44 hospitals and 627 primary health centres. Phase 3 was intended to achieve sustainability by stimulating policy advocacy, resource mobilization and public education.

In Phase 1, the overall amount of antibiotics prescribed in the community hospitals targeted by the initiative declined by between 18% and 23%. The decline in primary health centres was steeper, at between 39% and 46%. The outcome of Phase 2 confirmed the outstanding results of the pilot phase of the programme. The National Health Security Office has adopted ASU as a key indicator of quality of services in pay-for-performance agreements with community hospitals.


WHO launched the Global Patient Safety Challenge on Medication Safety in 2017, with the goal of improving medication safety by strengthening the systems for reducing medication errors. Some countries have already prioritized this work; e.g. Sri Lanka has organized national advocacy activities in 2017 to promote medication safety.

Sufficient, efficient and equitable financing

What is sufficient funding for medicines? The 2016 Lancet Commission report on Essential Medicines Policies concluded that for about US$ 1–2 per month, i.e. US$ 12–25 per year, every person in low- and middle-income countries can have access to a basket of around 200 essential medicines.

Spending on medicines is low in many countries of the South-East Asia Region

In the SEA Region, total pharmaceutical spending (i.e. government and out-of-pocket) is commonly low. Fig. 9 shows that it is less than US$ 25 per person per year in seven countries. Strikingly, in some countries, it has changed little over the past 10 years.

Out-of-pocket expenditure on medicines is significant and can cause inequity in access to medicines

In all SEA countries except Thailand, Bhutan and Timor-Leste, expenditure on medicines remains predominately directly out of people’s own pockets, rather than from public resources. As a consequence, it puts a substantial financial burden on households: analyses of household surveys have found that medicine costs account for 80% of out-of-pocket health expenditures in India and 77% in Nepal. The problems of high out-of-pocket payments have been well documented: it may discourage people from...
buying medicines when they are needed; it reduces the funds households have for other necessary living expenses; and it may push them into poverty. Poorer households generally suffer more financial hardship.

*Fig. 9: Trends in total pharmaceutical expenditure per capita (current US$)*


**Increased attention to public spending on essential medicines is needed**

In 2014, the most recent year for which data are available, government spending on medicines as a share of total spending on medicines ranged from 5 % to 91% across Member States (Fig. 10). In five countries, it is below 50%. This is despite the fact that government spending on medicines has increased in several of those countries in recent years. There is still a way to go to achieve more equitable financing; issues of national health financing strategy and access to medicines are thus inextricably linked.

*Fig. 10: Share of government and nongovernment spending on pharmaceuticals as percentage of total pharmaceutical expenditure in 2014*

# Note: data available only for 2013 for Bhutan

Managers of essential medicines programmes have important things to say about both levels of government spending and the way in which health financing is organized (role of insurance, levels of out-of-pocket payments, etc.). These are important issues for universal health coverage. These managers can help to support the case for change by linking these financing issues to practical examples of access to medicines. Good data about medicine availability – which is the subject of one of the recommendations of this paper – can help to develop an evidence-based case for higher government spending on pharmaceuticals and a move away from out-of-pocket purchases.

**Sustained attention to getting better value for money is also needed**

There is also considerable room for greater efficiencies in the use of existing resources for medicines. WHO, in its *World health report 2010: health systems financing: the path to universal coverage*19 estimated that, globally, 20–40% of resources for health were wasted, in both rich and poor countries. Out of the ten leading causes of inefficiency listed, six related to medicines:

- underuse of generics, and higher-than-necessary prices of medicines
- use of substandard and counterfeit medicines
- inappropriate and ineffective use of medicines
- health-care products: overuse or oversupply
- health-care services: medical errors
- health system leakages: waste, corruption and fraud.

This situation applies to the SEA Region as much as to anywhere else. The preceding text has given examples of actions being taken to address these various sources of inefficiency – including increased production and use of generics, post-marketing surveillance and rational prescribing – but much remains to be done.
PART 3
Improving access to medicines:
What next?
As described in the previous section, there has been progress on several dimensions of access to medicines. However, availability remains poorer in the public sector compared with the private; lower in health centres than in hospitals; and more of a problem for noncommunicable rather than communicable diseases. Attention needs to remain on the essential medicines concept and policies for effective implementation. The use of generics needs to remain a core strategy.

There are five clear areas where Member States and WHO can work together to improve access to medicines. These are as follows:

- Collaborate on a range of procurement activities to improve quality and reduce prices.
- Promote collaboration so that regulation is more focused and less duplicative.
- Improve the capacity to work within intellectual property and competition rules, and use TRIPS flexibilities.
- Maintain a sustained focus on antimicrobial stewardship.
- Ensure better monitoring of access to medicines, and use data to make improvements in availability and appropriate use.

**Collaborate on procurement activities to improve quality and reduce prices**

Joint working in relation to procurement can bring about improvements in both quality and price. Collaboration can take various forms and involve different levels of joint working. Examples include informed buying (participating countries share information on prices, quality of products and suppliers’ performance); sharing Healths Technology Assessment results for better price negotiations but procuring separately for each country; and central or bilateral contracting and procurement, where participating countries conduct joint tenders through a central or bilateral buying unit. Fig. 11 illustrates a range of possible forms of collaboration – the closer to the top right corner, the higher the requirements in terms of level of commitment to collaboration/harmonization, and levels of skilled staffing and financing.

**Fig. 11: Different forms of collaboration on procurement and pricing**
Regional collaborative schemes in other parts of the world are effective and there is increasing interest in intercountry or subregional collaboration, even among high-income countries. There is clearly untapped potential in the SEA Region for collaboration on procurement and pricing to improve access to medicines.

**Collaboration in regulation: more focus, less duplication**

Regulation affects the quality and safety of medicines. Collaboration among countries can contribute to using the Region’s scarce and precious regulatory capacity more efficiently. SEARN can be instrumental in facilitating this collaboration. Key to this collaboration is that some regulatory authorities recognize the value of relying on agencies in other countries for certain regulatory decisions such as marketing authorization or inspection. This fills gaps where capacity is limited and allows underresourced agencies to focus on priority activities. SEARN will promote several forms of collaboration such as sharing regulatory information and good practices, encouraging regulatory convergence, and leveraging regional capacities to strengthen regulatory skills and competencies.

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

WTO’s Agreement on TRIPS should not prevent its Member countries from taking measures to protect public health, including access to medicines. In practice, there is flexibility within TRIPS that gives countries in different situations several options for action, and there is experience within this Region that could be shared. Increased use of TRIPS flexibilities can help to enhance the availability of affordable essential medicines. Continued vigilance is needed with regard to other bilateral or multilateral trade agreements, which may have harmful “TRIPS-plus” provisions, including patent term extensions and data exclusivity: these can restrict access to affordable medicines.

The Regional Office will facilitate greater exchange of knowledge and experience in this complex area, helping individual countries to understand better the relevance of the provisions in existing trade agreements to their own circumstances, and how to use TRIPS flexibilities where needed.

**Sustained focus on antimicrobial stewardship**

Given the scale of antimicrobial resistance (AMR) in the SEA Region, greater attention is being paid to more rational antibiotic use. This is the fourth priority in the Region’s work on access to medicines, and it requires effective antimicrobial “stewardship”. There are three critical components in antimicrobial stewardship that will support more rational antibiotic use:

- improved data on scale of and trends in antimicrobial consumption;
- national antimicrobial policies and regulations that include provisions to reduce over-the-counter sales of antibiotics, and stipulations that health facilities must have explicit guidance on preventing and reporting health-care-associated infections and on antibiotic prescribing;
nationwide education and advocacy on antimicrobial use and resistance for both consumers and health-care providers.

WHO has tools to measure antimicrobial consumption and monitor hospital antibiotic use. It will support the use of these tools as part of the roll-out of national AMR action plans. It is developing guidance for pre-service curricula of health professionals on AMR and will support their implementation, along with advocacy campaigns such as on World Antibiotic Day. A step-wise approach to enforcing regulations on dispensing antibiotics on a prescription-only basis will probably be needed. There is little documented experience in this Region with implementing such strategies; WHO will encourage better documentation.

**Improved monitoring of access to medicines**

Better planning and implementation to improve access to medicines requires good information. Good monitoring can provide information on the following:

- who cannot afford to buy the medicines they need (pharmaceutical expenditure analysis, disaggregated where possible by important variables such as place of residence and wealth quintile);
- where medicines are not available and which institutions are not performing well in providing good access to medicines (monitoring of availability and accessibility of essential medicines in the public and private sectors);
- where unsafe or ineffective products are on sale and what is being done about it (monitoring of quality and safety of products, and of regulatory actions);
- the misuse or wastage of medicines (monitoring medicines consumption and appropriate use, with a particular focus on antibiotics).

Regular information about the population’s access to medicines is necessary to alert decision-makers to problems of drug availability. Without data to prompt action, availability is unlikely to increase more speedily. Actions at the Regional level can support the development and use of practical indicators, methods and tools for monitoring access to medicines, and can strengthen reporting on the medicines indicator in the SDGs. The introduction of a smartphone application to monitor availability and prices will be instrumental in supporting this in the Region.

Intensified action in these five areas – procurement, regulation, trade rules, antibiotic use and monitoring – will significantly enhance access to essential medicines, and contribute to progress on universal health coverage and the improved health outcomes envisaged in the SDGs.
References


PART 4
Country profiles
Bangladesh pharmaceutical profile 2017

COUNTRY AT A GLANCE

**Population (in 000s)**
- **160996**

**Life expectancy at birth (in years)**
- **71.8**

**GDP (per capita in current US$)**
- **1212**

OVERALL SPENDING ON HEALTH

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Current US $</th>
</tr>
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<tbody>
<tr>
<td>2005</td>
<td>13</td>
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<td>2008</td>
<td>15</td>
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<tr>
<td>2011</td>
<td>25</td>
</tr>
<tr>
<td>2014</td>
<td>31</td>
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</table>

Total per capita spending on medicines (current US$)

<table>
<thead>
<tr>
<th>Year</th>
<th>Current US $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
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<td>2008</td>
<td>33</td>
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<tr>
<td>2011</td>
<td>33</td>
</tr>
<tr>
<td>2014</td>
<td>33</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>
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<tbody>
<tr>
<td>2005</td>
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<tr>
<td>2008</td>
<td>67%</td>
</tr>
<tr>
<td>2011</td>
<td>67%</td>
</tr>
<tr>
<td>2014</td>
<td>33%</td>
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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>20</td>
</tr>
<tr>
<td>2008</td>
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</tr>
<tr>
<td>2011</td>
<td>44.6</td>
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<tr>
<td>2014</td>
<td>44.6</td>
</tr>
</tbody>
</table>

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

- No data available

MEDICAL AND PHARMACY WORKFORCE

- **Medical practitioners/10 000 population**
  - **47.2**

- **Pharmacists & pharmacy technicians/10 000 population**
  - **48.1**

- **Registered pharmacists/10 000 population**
  - **7.6**
**Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities**

**Bangladesh**

### Key Medicines Policies and Guidance

<table>
<thead>
<tr>
<th>Key Pharmaceutical Legislation</th>
<th>National Medicine Policy</th>
<th>National Essential Medicines List</th>
<th>National Standard Treatment Guidelines</th>
</tr>
</thead>
</table>

### Intellectual Property Related Policies & Production

- **814** pharmaceutical manufacturers including 266 allopathic, 202 ayurvedic, 272 unani, 32 herbal & 42 homeopathic manufacturers
- **1975**
- **1995**
- Not applicable until graduation from least developed country status

### Access to Medicines

#### HIV/AIDS, Malaria and Tuberculosis

- Treatment coverage
  - 2005: 15%
  - 2008: 57%
  - 2011: 100%
  - 2014: 15%

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

- 2005: 94%
- 2010: 94%
- 2015: 94%

#### Hypertension treatment coverage

- 2005: 17.9%

#### Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone

- 1999: 0.05
- 2004: 0.1
- 2009: 0.1966

Data for age group 18-69 years

Data on Diabetes Mellitus treatment coverage not available

Data for > 25

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency
Pharmaceutical system flowchart

National Regulatory Authority\textsuperscript{14}: Directorate General of Drug Administration (DGDA) www.dgda.gov.bd

Regulated products:
- Medicines: YES
- Vaccines: YES
- Medical devices: YES
- Traditional medicines\textsuperscript{16}: YES

Medicine Quality Control Laboratory\textsuperscript{26}: National Control Laboratory, Dhaka and Central Drug Testing Laboratory, Chittagong

ISO 17025 certified\textsuperscript{15,A}: NO
WHO prequalified\textsuperscript{15,B}: NO

Number of registered medicines\textsuperscript{16}: Total 39844: allopathic 27624, ayurvedic 3877, unani 5624, herbal 406, homeopathic & biochemical 2313

Agency responsible for selection\textsuperscript{14}: Directorate General of Drug Administration

Number of products on essential medicines list:
- By active ingredient\textsuperscript{14}: 285 allopathic drugs
- By dosage form\textsuperscript{16}: Not available

Traditional medicines products included in essential medicines list: YES

Medicines availability is indicated by health facility level\textsuperscript{C}: NO

National formulary: Bangladesh National Formulary (BDNF) 2015

Public sector

Agency responsible for public procurement\textsuperscript{21}: Central Medical Stores Depot (CMSD)

Procurement done at Central: ☑️ State: ☐️ Facility\textsuperscript{22}: ☑️
(local procurement for district facilities and hospitals)

Commonly used procurement methods\textsuperscript{23}: National/International bidding

Price control\textsuperscript{13,24,D}: YES
Agency responsible for price control\textsuperscript{15}: DGDA

Patient prices for essential medicines in public sector\textsuperscript{25}:
- Free medicines: YES

Public sector facilities\textsuperscript{27}:
- Referral hospitals: 46
- District level hospitals: 64
- Specialized hospitals: 124

Private sector

Number of wholesalers\textsuperscript{22}: 1005

Agency responsible for price control\textsuperscript{25}: Price Fixation Committee for 117 primary health care medicines.

Pricing mechanism\textsuperscript{26}:
- Manufacturer: ☑️ (Maximum Retail Price is based upon cost of raw material and packaging plus a mark up)
- Wholesale: ☐️ Retailer: ☑️ DGDA controls retail margin (partially)

Mark-ups regulated: YES
Fixed or regressive: Fixed

Public sector

Agency responsible for distribution\textsuperscript{22}: Essential Drug Company Limited and CMSD

Private sector

Number of retail outlets\textsuperscript{28}: 123800
Licensed retail pharmacies per 10 000 population\textsuperscript{29}: 7.7

Number of traditional medicines outlets\textsuperscript{30}: 353
Ayurvedic retail outlets, 616 unani outlets, 10 herbal outlets & 2056 homeopathic outlets

Government of Bangladesh

Bangladesh

Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

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6. Data taken from South East Asia Region health workforce survey April 2016.


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 pharmaceutical profile 2017

**Country at a glance**

- **775** Population (in 000s)
- **69.8** Life expectancy at birth (in years)
- **2656** GDP (per capita in current US$)

**Overall spending on health**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total per capita spending on health care (current US$)</th>
<th>Total per capita spending medicines (current US$)</th>
<th>Share of government vs. out-of-pocket spending on health</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>$89</td>
<td>$9</td>
<td>75%</td>
</tr>
<tr>
<td>2007</td>
<td>$125</td>
<td>$100</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>$125</td>
<td>$100</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>$125</td>
<td>$100</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>$125</td>
<td>$100</td>
<td></td>
</tr>
</tbody>
</table>

**Spending on medicines**

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage of total health-care cost</th>
<th>Share of public and out-of-pocket spending on medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>9.7%</td>
<td>33%</td>
</tr>
<tr>
<td>2007</td>
<td>9.7%</td>
<td>33%</td>
</tr>
<tr>
<td>2009</td>
<td>9.7%</td>
<td>33%</td>
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<tr>
<td>2011</td>
<td>9.7%</td>
<td>33%</td>
</tr>
<tr>
<td>2013</td>
<td>9.7%</td>
<td>33%</td>
</tr>
</tbody>
</table>

**Medical and pharmacy workforce**

- **3.7** Medical practitioners/10 000 population
- **No data** Pharmacists & pharmacy technicians/10 000 population
- **0.3** Registered pharmacists/10 000 population

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Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities
Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

Bhutan

**KEY MEDICINES POLICIES AND GUIDANCE**

|---------------------|--------------------------------|--------------------------|----------------------------------|-------------------------------------|

**INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION**

<table>
<thead>
<tr>
<th>Number of Local pharmaceutical manufacturers</th>
<th>Least Developed country status since</th>
<th>Member of World Trade Organization since</th>
<th>TRIPS flexibilities used</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1971</td>
<td>No</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**Malaria and Tuberculosis treatment coverage**

- 2005: 100%
- 2007: 80%
- 2009: 100%
- 2011: 80%
- 2013: 100%
- 2015: 80%

HIV/AIDS data insufficient

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

- 2005: 100%
- 2010: 99%
- 2015: 99%

No data available

**Hypertension and Diabetes Mellitus treatment coverage**

- Percentage coverage: 35.7%
- Data for age group 18-69 years

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone**

- Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency

- No data available
**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:**
- Central: ✔
- State: ☐
- Facility: ☐

**Commonly used procurement methods:** International tendering

**Public sector**

**Number of wholesalers:** 27

**Private sector**

**Agency responsible for price control:** Drug Regulatory Authority

**Pricing mechanism:** Price structure to be submitted at the time of registration of product.

**Mark-ups regulated:** YES

**Fixed or regressive:** Fixed Maximum Retail Price (MRP), which is the same MRP as in India

**Number of retail outlets:** 54

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

**Number of traditional medicines outlets:** 1

**Public sector**

**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**

**Agency responsible for price control:**

**Pricing mechanism:** Price structure to be submitted at the time of registration of product.

**Mark-ups regulated:** YES

**Fixed or regressive:** Fixed Maximum Retail Price (MRP), which is the same MRP as in India


15. Data as reported by Drug Regulatory Authority, Bhutan, June 2017.


Notes:
A. One Herbal and one Active Pharmaceutical Ingredient manufacturer.
B. 54 pharmacies spread across the country.
Democratic People’s Republic of Korea pharmaceutical profile 2017

<table>
<thead>
<tr>
<th>COUNTRY AT A GLANCE</th>
<th>25155 Population (in 000s)¹</th>
<th>71 Life expectancy at birth (in years)²</th>
<th>Not available GDP (per capita in current US$)</th>
</tr>
</thead>
</table>

**OVERALL SPENDING ON HEALTH**

<table>
<thead>
<tr>
<th>Total per capita spending on health care (current US$)³,4</th>
<th>Total per capita spending medicines (current US$)</th>
<th>Share of government vs. out-of-pocket spending on health</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
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</table>

**SPENDING ON MEDICINES**

<table>
<thead>
<tr>
<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>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**MEDICAL AND PHARMACY WORKFORCE**

<table>
<thead>
<tr>
<th>36 Medical practitioners/10 000 population⁵</th>
<th>No data Pharmacists &amp; pharmacy technicians/10 000 population</th>
<th>3.8 Registered pharmacists/10 000 population⁶</th>
</tr>
</thead>
</table>
Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

Democratic People’s Republic of Korea

**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 – 2015

- **National Standard Treatment Guidelines**
  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

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone**

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency

**Hypertension and Diabetes Mellitus treatment coverage**

No data available

**Malaria and Tuberculosis treatment coverage**

HIV/AIDS data insufficient for analysis

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

Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency
Democratic People’s Republic of Korea

Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

**National Regulatory Authority**: National Drug Regulatory Authority (NDRA)

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

**Medicine Quality Control Laboratory**: One central laboratory under NDRA and one per province
- ISO 17025 certified: NO
- WHO prequalified: NO

Number of registered medicines: 3000-4000

**Agency responsible for selection**: National Drug Regulatory Authority (NDRA), Ministry of Public Health

Number of products on essential medicines list:
- By active ingredient: 439
- By dosage form: Not available

Traditional medicines products included in essential medicines list: YES

Medicines availability is indicated by health facility level: YES

Number of products in National Formulary: 1607 (Year 2016)

**Public Sector**

Agency responsible for public procurement: Medicines Management Department, Ministry of Public Health

Procurement done at Central ✔ State ☐ Facility ☐

Commonly used procurement methods: Local tendering and international tendering for drugs not procured domestically through UN agencies

**Price control**: No

Health insurance reimbursement price: Not applicable

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

**Private Sector**

Number of wholesalers: Not available

**Agency responsible for price control**: National Price Control Committee

Pricing mechanism: Method unknown.
- Manufacturer ☐ Wholesale ☐ Retailer ☐

Mark-ups regulated: Method unknown

Fixed or regressive: Method unknown

**Public sector**

Agency responsible for distribution: Central medicines warehouse, Medicines management department

Public sector facilities:
- Hospitals: 1708
- Primary health care units: 6263
- Ri clinics/hospitals per village: 1-2

**Private sector**

Number of retail outlets: 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

**Market Authorization/Licensing/Quality Assurance**

Medicine Selection

**Medicine Procurement**

Pricing and Reimbursement

**Distribution**

**Patient**


4. Data taken from South East Asia Region health workforce survey April 2016.


Note:

A. Total per capita spending on health care in the year 2013 was US$ 66.
India pharmaceutical profile 2017

**OVERALL SPENDING ON HEALTH**

- **Total per capita spending on health care (current US$)**
  - Current US$: $24.3
  - Current US$: $75

- **Share of government vs. out-of-pocket spending on health**
  - Percentage (%): 38%
  - Percentage (%): 62%

**SPENDING ON MEDICINES**

- **Spending on medicines as share of total health-care cost**
  - Percentage (%): 34.7%

- **Share of public and out-of-pocket spending on medicines**
  - Share as percentage: 90%
  - Share as percentage: 10%

**COUNTRY AT A GLANCE**

- **Population (in 000s)**: 131
- **Life expectancy at birth (in years)**: 68
- **GDP (per capita in current US$)**: 1593

**MEDICAL AND PHARMACY WORKFORCE**

- **Medical practitioners/10 000 population**: 7.3
- **Pharmacists & pharmacy technicians/10 000 population**: <10
- **Registered pharmacists/10 000 population**: 5.2
**HIV/AIDS, Malaria and Tuberculosis treatment coverage**

- 2005: 59%
- 2008: 44%
- 2011: 100%
- 2015: 100%

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

- 2005: 0%
- 2010: 87%
- 2015: 87%

**Hypertension and Diabetes Mellitus treatment coverage**

Data insufficient to analyse

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone**

- 1999: 0 mg/person
- 2004: 0.41 mg/person
- 2009: 0.41 mg/person
- 2014: 0.41 mg/person

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency.

### Key Medicines Policies and Guidance

**Key Pharmaceutical Legislation**
- Drugs and Cosmetics Act, 1940 and Rules 1945 as amended up to 31 December 2016

**National Medicine Policy**
- Pharmaceutical Policy 2002
- National Vaccine Policy 2011

**National Essential Medicines List**
- National List of Essential Medicines (NLEM)-2015

**National Standard Treatment Guidelines**
- 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**: 21
- **Member of World Trade Organization since**: 22
- **TRIPS flexibilities used**: 23

- 4900 for formulations and 1500 for active pharmaceutical ingredient
- No
- 1995
- Yes
## Pharmaceutical system flowchart

### Medicine

- **National Regulatory Authority:** Central Drugs Standard Control Organization (CDSCO)
- **Regulated products:**
  - Medicines: YES
  - Vaccines: YES
  - Medical devices: YES
  - Traditional medicines:
  - WHO prequalified: YES (IPC, Ghaziabad)
- **Medicine Quality Control Laboratory:**
  - Total: 8
  - 1: Indian Pharmacopeia Commission (IPC) Ghaziabad
  - 5: Central drug testing laboratories
  - 2: Regional drug testing laboratories
- **ISO 17025 certified:** YES
- **Number of registered medicines:** Not available

### Public sector

- **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

### Private 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)

### Public sector

- **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)

### Private sector

- **Agency responsible for price control:** National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers
- **Pricing mechanism:** Market Based Pricing
  - Manufacturer ✔️ Wholesale ✔️ Retailer ✔️
- **Mark-ups regulated:** YES
- **Fixed or regressive:** Fixed. Ceiling of drug prices based upon Market Based Pricing (MBP)

### Public sector

- **Agency responsible for distribution:**
  - Centralized/decentralized at central/state or local government level
  - **Public sector facilities:**
    - Total hospitals: 210998
    - District hospitals: 1251
    - Sub-district hospitals: 2724
    - Community health centres: 1146
    - Primary health centres: 31824
    - Sub centres: 164053

### Private sector

- **Number of retail outlets:** 800000
- **Licensed retail pharmacies per 10 000 population:** Not available
- **Number of traditional medicines outlets:** Not available

### Distribution

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

### Mark-ups regulated:

- **YES**
- **Fixed or regressive:** Fixed. Ceiling of drug prices based upon Market Based Pricing (MBP)
India


Notes:
A. 0.725 physicians per 1000 population.
B. Less than 1 pharmaceutical personnel per 1000 population.
C. Other sources:
1) http://chbhealth.gov.in/IMAR_guideline700149588.pdf
2) http://icmcmic.nic.in/guidelines/treatment%20with%20antimicrobial.pdf
3) http://www.tcbindia.nic.in/index1.php?lang=1&Dev=b1&zubid=645712&hid=3176
4) http://clinicalestablishments.nic.in/WriteReadData/93.pdf
5) http://clinicalestablishments.nic.in/WriteReadData/448.pdf
6) http://nvbdcp.gov.in/ilec.html

By self-calculating all the strengths listed.
E. PC = P[1+(M/100)], where P = 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.
Indonesia pharmaceutical profile 2017

**COUNTRY AT A GLANCE**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (in 000s)</td>
<td>257564</td>
</tr>
<tr>
<td>Life expectancy at birth (in years)</td>
<td>69.1</td>
</tr>
<tr>
<td>GDP (per capita in current US$)</td>
<td>3347</td>
</tr>
</tbody>
</table>

**OVERALL SPENDING ON HEALTH**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total per capita spending on health care (current US$)</td>
<td>$99</td>
</tr>
<tr>
<td>Total per capita spending medicines (current US$)</td>
<td>$31.76</td>
</tr>
<tr>
<td>Share of government vs. out-of-pocket spending on health</td>
<td>53%</td>
</tr>
</tbody>
</table>

**SPENDING ON MEDICINES**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spending on medicines as share of total health-care cost</td>
<td>25.5%</td>
</tr>
<tr>
<td>Share of public and out-of-pocket spending on medicines</td>
<td>79%</td>
</tr>
</tbody>
</table>

**MEDICAL AND PHARMACY WORKFORCE**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical practitioners/10,000 people</td>
<td>1.1</td>
</tr>
<tr>
<td>Pharmacists &amp; pharmacy technicians/10,000 population</td>
<td>0.5</td>
</tr>
<tr>
<td>Registered pharmacists/10,000 people</td>
<td>0.3</td>
</tr>
</tbody>
</table>
**Key Medicines Policies and Guidance**

<table>
<thead>
<tr>
<th>Key Pharmaceutical Legislation</th>
<th>National Medicine Policy</th>
<th>National Essential Medicines List</th>
<th>National Standard Treatment Guidelines</th>
</tr>
</thead>
</table>

**Intellectual Property Related Policies & Production**

<table>
<thead>
<tr>
<th>Number of Local Pharmaceutical Manufacturers</th>
<th>Least Developed Country Status</th>
<th>Member of World Trade Organization since</th>
<th>TRIPS flexibilities used</th>
</tr>
</thead>
<tbody>
<tr>
<td>174</td>
<td>No</td>
<td>1995</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**HIV/AIDS, Malaria and Tuberculosis treatment coverage**

- 2005: 7%
- 2008: 32%
- 2011: 11%
- 2014: 9%

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

- 2005: 81%
- 2010: 81%
- 2015: 81%

**Hypertension and Diabetes Mellitus treatment coverage**

Data insufficient to analyse

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone**

- 1999: 0 mg/person
- 2004: 0.1 mg/person
- 2009: 0.6775 mg/person
- 2014: 0.9 mg/person

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency.
**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 products¹⁸:
- Medicines: YES
- Vaccines: YES
- Medical devices: YES
- Traditional medicines¹⁹: YES

**Medicine Quality Control Laboratory¹²:** Drug Testing Laboratory of National Quality Control Laboratory
- ISO 17025 certified¹²: YES
- WHO prequalified: NO

Number of registered medicines¹²: 15072 allopathic and 13000 traditional medicines

**Agency responsible for selection¹³:** 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 Formulary²¹: 586

**Public sector**

Agency responsible for public procurement¹²: Directorate General of Pharmaceutical and Medical Devices

Procurement done at Central¹²: ✔ State ☐ Facility¹² ☐

Commonly used procurement methods¹²: Local tendering

**Private sector**

Number of wholesalers²²: 2846

**Public sector**

Price control: YES

Price mechanism¹²: Lowest price bid accepted

Health Insurance reimbursement price²¹: Universal Health coverage (BPJS Kesehatan)

Patient prices for essential medicines in public sector: No data available

**Private sector**

Agency responsible for price control: Ministry of Health

Pricing mechanism: Market Based Pricing
- Manufacturer ☐ Wholesale¹² ✗ 40%
- Retailer ☐

Mark-ups regulated: No data available

Fixed or regressive¹²: Generic medicines prices fixed by Ministry of Health and other medicines prices set by manufacturers

**Public sector**

Agency responsible for distribution¹²: Directorate General of Pharmaceutical and Medical Devices

Public sector facilities²²:
- Public Hospitals: 2406
  (1855 general hospitals and 552 special hospitals)
- Health centres: 9731

**Private sector**

Number of retail outlets²²: 22634 and 8009 drug stores

Licensed retail pharmacies per 10 000 population: Not available

Number of traditional medicines outlets: Not available

**Patient**
References


Maldives pharmaceutical profile 2017

COUNTRY AT A GLANCE

<table>
<thead>
<tr>
<th>OVERALL SPENDING ON HEALTH</th>
</tr>
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<tbody>
<tr>
<td>Total per capita spending on health care (current US$)</td>
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</table>

<table>
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<td>Spending on medicines as share of total health-care cost</td>
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<td>Medical practitioners/10 000 population</td>
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<tr>
<td>Pharmacists &amp; pharmacy technicians/10 000 population</td>
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<tr>
<td>Registered pharmacists/10 000 population</td>
</tr>
</tbody>
</table>
**ACCESS TO MEDICINES**

**KEY MEDICINES POLICIES AND GUIDANCE**

**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 since**
1995

**TRIPS flexibilities used**
Not applicable

---

**Tuberculosis treatment coverage**
- 2005: 80%
- 2010: 80%
- 2015: 80%

**Diphtheria-tetanus-pertussis (DTP3) and Hepatitis B3 immunization coverage**
- 2005: 99%
- 2010: 99%
- 2015: 99%

**Hypertension treatment coverage**
- 2005: 16.6%
- 2010: 16.6%
- 2015: 16.6%

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone**
- 1999: 0.32 mg per person
- 2004: 0.32 mg per person
- 2009: 0.32 mg per person
- 2014: 0.32 mg per person

**HIV/AIDS data insufficient for analysis**

**Data for age group 15-64 years**

*Data for Diabetes Mellitus treatment insufficient to analyse*
Maldives

Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

- **National Regulatory Authority**: Maldives Food and Drug Authority (MFDA)  
  - [Website](http://www.mfda.gov.mv)
  - Regulated products:
    - Medicines: Yes
    - Vaccines: Yes
    - Medical devices: No
    - Traditional medicines: Yes
  - Medicine Quality Control Laboratory: National Health Laboratory.
    - ISO 17025 certified: No
    - WHO prequalified: No
  - Number of registered medicines: 3818

- **Agency responsible for selection**: Maldives Food and Drug Authority

- **Number of products on essential medicines list**:
  - By active ingredient: 326
  - By dosage form: 510

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

- **Medicines availability is indicated by health facility level**: Yes

- **National Formulary**: No national formulary manual

- **Agency responsible for public procurement**: State Trading Organization (STO)

- **Procurement done at**: Central

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

- **Price control**: No

- **Health insurance reimbursement**: Public health insurance (Asandha Insurance system) covers the entire population

- **Patient prices for essential medicines in public sector**:
  - Free medicines: No
  - Fixed price: Yes

- **Agency responsible for distribution**: Health Supply Unit, Administration Division

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

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

- **Agency responsible for price control**: MFDA and Ministry of Economic Affairs

- **Pricing mechanism**:
  - Manufacturer: Under review
  - Wholesale: Under review
  - Retailer: Under review

- **Number of retailers**: 197

- **Number of traditional medicines outlets**: Not available
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 pharmaceutical profile 2017

COUNTRY AT A GLANCE

- **Population (in 000s)**: 53897
- **Life expectancy at birth (in years)**: 66.6
- **GDP (per capita in current US$)**: 1162

OVERALL SPENDING ON HEALTH

- **Total per capita spending on health care (current US$)**
  - $8 in 2005
  - $20 in 2014

- **Total per capita spending medicines (current US$)**
  - 5

- **Share of government vs. out-of-pocket spending on health**
  - 49% (government)
  - 51% (out-of-pocket)

SPENDING ON MEDICINES

- **Spending on medicines as share of total health-care cost**
  - 28.8% in 2014

- **Share of public and out-of-pocket spending on medicines**
  - 94.5% (public)
  - 5.5% (out-of-pocket)

MEDICAL AND PHARMACY WORKFORCE

- **Medical practitioners**: 37154
- **Pharmacists & pharmacy technicians/10 000 population**: 1.2
- **Registered pharmacists/10 000 population**: 0.6
**Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities**

**Myanmar**

### Key Medicines Policies and Guidance

**Key Pharmaceutical Legislation**
- National List of Essential Medicines – 2016
- National Standard Treatment Guidelines – 2013 for primary health care providers

**Intellectual Property Related Policies & Production**
- Number of Local pharmaceutical manufacturers: 9
- Least Developed country status since: 1987
- Member of World Trade Organization since: 1995
- TRIPS flexibilities used: Not applicable until graduation from least developed country status

### HIV/AIDS, Malaria and Tuberculosis treatment coverage

- 2005: 0%
- 2007: 47%
- 2009: 70%
- 2011: 100%

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

- 2005: 0%
- 2010: 83%
- 2015: 83%

### Hypertension and Diabetes Mellitus treatment coverage

- **Hypertension**: 34.9%
- **Diabetes Mellitus**: 3.2%
- % of respondents (both sexes) currently taking blood pressure drugs prescribed by doctor or health worker, among those diagnosed with hypertension
- % of respondents (both sexes) currently taking insulin and oral diabetes medication, among those previously diagnosed with diabetes

**Data for age group 25-64 years age group**

### Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone

- 1999: 0 mg per person
- 2004: 3.71 mg per person
- 2009: 3.71 mg per person
- 2014: 3.71 mg per person

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency.
**National Regulatory Authority**:
Department of Food and Drug Administration (DFDA)
http://www.fdamyanmar.gov.mm

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

**Medicine Quality Control Laboratory**: One main drug testing laboratory and two small branch labs in Mandalay and Yangon
- ISO 17025 certified: YES
- WHO prequalified: NO

**Number of registered medicines**: 21000 allopathic & 12712 traditional medicines

**Agency responsible for selection**: 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

**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

**Public sector**
- **Price control**: YES
- **Mechanism**: Lowest priced quotation is chosen
- **Health insurance reimbursement Price**: No
- **Patient prices for essential medicines in public sector**:
  - Free medicines: YES

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

**Agency responsible for public procurement**: Myanmar Pharmaceutical and Medical Equipment & Entrepreneur Association in collaboration with Ministry of Commerce

**Pricing mechanism**:
- Manufacturer
- Wholesale
- Retail

**Mark-ups regulated**: NO

**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**: 10000 outlets selling both allopathic and traditional medicines

**Licensed retail pharmacies per 10 000 population**: 1.9

---

**About Myanmar**

**Pharmaceutical system flowchart**

**Medicine**

---

**Market Authorization/Licensing/Quality Assurance**

**Medicine Selection**

**Medicine Procurement**

**Pricing and Reimbursement**

**Distribution**

**Patient**
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 2015.

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 state and local health authorities.

I. Local procurement by hospitals.

J. Wholesale level mark-ups (5-7%) and retailer level mark-ups (5-10%).
Nepal pharmaceutical profile 2017

**COUNTRY AT A GLANCE**

<table>
<thead>
<tr>
<th></th>
<th>28514</th>
<th>69.2</th>
<th>743</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (in 000s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life expectancy at birth (in years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GDP (per capita in current US$)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**OVERALL SPENDING ON HEALTH**

<table>
<thead>
<tr>
<th></th>
<th>Total 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>$40</td>
<td>52%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Total per capita spending medicines (current US$)</th>
<th>Share of public and out-of-pocket spending on medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$12</td>
<td>88%</td>
</tr>
</tbody>
</table>

**SPENDING ON MEDICINES**

<table>
<thead>
<tr>
<th></th>
<th>Spending on medicines as share of total health-care cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>29.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Share of public and out-of-pocket spending on medicines as percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12%</td>
</tr>
</tbody>
</table>

**MEDICAL AND PHARMACY WORKFORCE**

<table>
<thead>
<tr>
<th></th>
<th>4.7</th>
<th>1.6</th>
<th>0.8</th>
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</thead>
<tbody>
<tr>
<td>Medical practitioners/10 000 population</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacists &amp; pharmacy technicians/10 000 population</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered pharmacists/10 000 population</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Key Pharmaceutical Legislation\textsuperscript{13.A}
- Drug Act 1978

### National Medicine Policy\textsuperscript{14}
- 1. National Drug Policy 1995

### National Essential Medicines List\textsuperscript{13.B}
- National List of Essential Medicines – 2016

### National Standard Treatment Guidelines\textsuperscript{15.C}
- Guidelines-2012 available for health posts and sub-health posts

### Number of Local pharmaceutical manufacturers\textsuperscript{16.D}
- 130

### Least Developed country status since\textsuperscript{17}
- 1971

### Member of World Trade Organization since\textsuperscript{18}
- 2004

### TRIPS flexibilities used\textsuperscript{19}
- Not applicable until graduation from least developed country status

---

### Key Medicines Policies and Guidance

**HIV/AIDS, Malaria and Tuberculosis**

<table>
<thead>
<tr>
<th>Year</th>
<th>Treatment Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>75%</td>
</tr>
<tr>
<td>2007</td>
<td>75%</td>
</tr>
<tr>
<td>2009</td>
<td>31%</td>
</tr>
<tr>
<td>2011</td>
<td>17%</td>
</tr>
<tr>
<td>2013</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Immunization Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>91%</td>
</tr>
<tr>
<td>2010</td>
<td>91%</td>
</tr>
<tr>
<td>2015</td>
<td>91%</td>
</tr>
</tbody>
</table>

**Hypertension and Diabetes Mellitus**

<table>
<thead>
<tr>
<th>Year</th>
<th>Treatment Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>25.7%</td>
</tr>
<tr>
<td>2007</td>
<td>25.7%</td>
</tr>
<tr>
<td>2009</td>
<td>3.6%</td>
</tr>
<tr>
<td>2011</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
</tr>
</tbody>
</table>

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone\textsuperscript{12}**

<table>
<thead>
<tr>
<th>Year</th>
<th>Opioid Consumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>0.391 mg/person</td>
</tr>
<tr>
<td>2004</td>
<td>0.05 mg/person</td>
</tr>
<tr>
<td>2009</td>
<td>0.1 mg/person</td>
</tr>
<tr>
<td>2014</td>
<td>0.25 mg/person</td>
</tr>
</tbody>
</table>

---

Data for age group 15-69 years

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency.
Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

**National Regulatory Authority**: Department of Drug Administration (DDA), Ministry of Health
www.dda.gov.np

- **Regulated products**: Medicines: YES, Vaccines YES, Medical devices: YES, Traditional medicines: YES
- **Medicine Quality Control Laboratory**: National Medicine Laboratory
- **ISO 17025 certified**: NO, WHO prequalified: NO
- **Number of registered medicines**: 17162

**Agency responsible for selection**: Department of Drug Administration

- **Number of products on essential medicines list**:
  - By active ingredient: 359
  - By dosage form: Not available

- **Traditional medicines products included in essential medicines list**: YES
- **Medicines availability is indicated by health facility level**: NO
- **Latest National Formulary**: National Formulary 2010

**Public sector**

- **Agency responsible for public procurement**: Logistic Management Division
- **Procurement done at Central**: Yes, State, Facility
- **Commonly used procurement methods**: Tendering from list of standard manufacturers identified by government

**Private sector**

- **Number of wholesalers**: 1921

**Public Sector**

- **Health insurance reimbursement**: In 8 districts
- **Patient prices for essential medicines in public sector**:
  - Free medicines: YES, upto district level
  - Fixed price: No data

**Private sector**

- **Agency responsible for price control**: DDA and Drug Pricing Monitoring Committee
- **Pricing mechanism**: To fix the Maximum Retail price using mean median method
- **Manufacturer**
- **Wholesale**
- **Retailer**
  - (Mark up 8-10%)
  - (Mark up 16%)
- **Mark-ups regulated**: NO

**Public sector**

- **Agency responsible for distribution**: Logistics Management Division for centrally supplied drugs and District Public Health Offices (DPHOs) and hospital directors for locally purchased drugs

**Private sector**

- **Number of retail outlets**: Allopathic – 8642
- **Licensed retail pharmacies per 10 000 population**: 4.5
- **Number of traditional medicines outlets**: 2270 (Ayurveda:1800, Homeopathy: 453, Unani:17)

**Distribution**

**Patient**
Data as per renewal status.

The price list.

Government of Nepal has fixed the retail price of 96 different medicines including commonly used drugs, essential medicines.

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

The scheme covers.

As per National List of Essential Medicines, 2016.

Revised draft Drug Act is in process of government approval.

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


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


Data taken from SEAR health workforce survey April 2016.


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


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


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 (NFF), 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 5,000/5 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, homeopathy and Unani pharmacies).
Sri Lanka pharmaceutical profile 2017

**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>20715</td>
<td>74.9</td>
<td>3926</td>
</tr>
</tbody>
</table>

**OVERALL SPENDING ON HEALTH**

Total per capita spending on health care (current US$)
Total per capita spending medicines (current US$)
Share of government vs. out-of-pocket spending on health

**SPENDING ON MEDICINES**

Spending on medicines as share of total health-care cost
Share of public and out-of-pocket spending on medicines

**MEDICAL AND PHARMACY WORKFORCE**

<table>
<thead>
<tr>
<th>Medical practitioners/10 000 population</th>
<th>Pharmacists &amp; pharmacy technicians/10 000 population</th>
<th>Registered pharmacists/10 000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4</td>
<td>0.6</td>
<td>0.7</td>
</tr>
</tbody>
</table>
**ACCESS TO MEDICINES**

**KEY MEDICINES POLICIES AND GUIDANCE**

**Key Pharmaceutical Legislation**

**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

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**HIV/AIDS, Tuberculosis and Malaria treatment coverage**

<table>
<thead>
<tr>
<th>Year</th>
<th>2005</th>
<th>2007</th>
<th>2009</th>
<th>2011</th>
<th>2013</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>2005</th>
<th>2010</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Hypertension and Diabetes Mellitus treatment coverage**

<table>
<thead>
<tr>
<th>Year</th>
<th>1999</th>
<th>2004</th>
<th>2009</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone**

<table>
<thead>
<tr>
<th>Year</th>
<th>1999</th>
<th>2004</th>
<th>2009</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/p</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency.
National Regulatory Authority*: National Medicines Regulatory Authority (NMRA)  [http://nmra.gov.lk/]
Regulated products:
- Medicines*: YES
- Vaccines*: YES
- Medical Devices*: YES
- Traditional Medicines*: YES

Medicine Quality Control Laboratory*: National Drug Quality Assurance Laboratory.
- ISO 17025 certified*: NO
- WHO prequalified*: NO

Number of Registered Medicines*: 8095 allopathic and 960 traditional medicines

Agency responsible for selection*: Medical Supplies Division, Ministry of Health, Nutrition and Indigenous Medicine

Number of products on essential medicines list:
- By active ingredient*: 361
- By dosage form*: >400

Traditional medicines products included in essential medicines list*: None

Medicines availability is indicated by health facility level*: YES

Number of Products in National Formulary*: Not available

Agency responsible for Public Procurement*: State Pharmaceutical Corporation

Procurement done at Central*: ✗ State*: ✗ Facility*: ✗

Commonly used procurement methods*: Worldwide tenders

Price Control*: YES

Mechanism*: Tenders are scheduled according to ascending prices and evaluated technically

Health insurance reimbursement Price*: No public health insurance for majority of population

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

Agency responsible for distribution*: Medical Supplies Division

Public Sector Facilities*: Hospitals: 622
- Central dispensaries/Primary care units: 475

Number of Retail Outlets*: 3297

Licensed retail pharmacies per 10,000 population*: 1.6

Number of Traditional Medicines outlets: Not available


Pricing mechanism:
- Manufacturer*: ◗ Wholesale*: ◗ Retailer*: ◗

Mark-ups regulated*: NO
References


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 Pharmaceutical Profile 2017

#### 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>67959</td>
<td>74.9</td>
<td>5815</td>
</tr>
</tbody>
</table>

#### Overall Spending on Health

<table>
<thead>
<tr>
<th>Total per capita spending on health care (current US$)</th>
<th>Total per capita spending medicines (current US$)</th>
<th>Share of government vs. out-of-pocket spending on health (%)</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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</table>

#### Spending on Medicines

<table>
<thead>
<tr>
<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></td>
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</tbody>
</table>

#### Medical and Pharmacy Workforce

<table>
<thead>
<tr>
<th>Medical practitioners/10 000 population</th>
<th>Pharmacists &amp; pharmacy technicians/10 000 population</th>
<th>Registered pharmacists/10 000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.9</td>
<td>Not available</td>
<td>1.9</td>
</tr>
</tbody>
</table>

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Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

**Thailand**

### Key Medicines Policies and Guidance

**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

---

**HIV/AIDS, Tuberculosis and Malaria treatment coverage**

![Graph showing percentage coverage](image)

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

![Graph showing percentage coverage](image)

**Hypertension and Diabetes Mellitus treatment coverage**

Not available

**Access to palliative care: pioid consumption in Morphine Equivalence (ME) minus Methadone**

![Graph showing consumption](image)

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency.
Thailand

Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

Market Authorization/Licensing/Quality Assurance

Medicine

National Regulatory Authority\[^{14}\]: Thai Food and Drug Administration (Thai FDA)
http://www.fda.moph.go.th/Pages/HomeP_D1.aspx

Regulated products:
- Medicines\[^{12}\]: YES
- Vaccines: YES
- Medical Devices\[^{12}\]: YES
- Traditional Medicines\[^{16}\]: YES

Medicine Quality Control Laboratory\[^{12}\]: National Drug Testing Laboratory, Bureau of Drugs and Narcotics.
ISO 17025 certified\[^{12}\]: Yes (since 1994)
WHO prequalified\[^{21}\]: Yes (since 2012)

Number of Registered Medicines\[^{15}\]: Allopathic: 22,726, Biologicals: 647, Narcotics: 145, Traditional: 14,274, Veterinary: 3,537 (Does not include traditional veterinary medicines: 122)

Agency responsible for selection\[^{12}\]: Division of National Drug Policy, Thai FDA

Number of products on essential medicines list:
- By active ingredient\[^{14}\]: 687
- By dosage form: 1008

Traditional medicines products included in essential medicines list\[^{14}\]: Yes (74 products)

Medicines availability is indicated by health facility level\[^{12}\]: YES

National Formulary\[^{22,F}\]: Specialties National Formularies available. No national formulary booklet

Public Sector

Agency responsible for Public Procurement\[^{12,G}\]: National Medicine Systems Development Committee.

Procurement done at Central\[^{12}\] ☐ State\[^{12}\] ☐ Facility\[^{12}\] ✓

Commonly used procurement methods\[^{21}\]: Competitive tendering

Price Control\[^{12}\]: In reality no price control

Mechanism\[^{12}\]: Prices at or below standard price as mentioned in the standard price list

Patient prices for essential medicines in public sector:
- Free Medicines\[^{15}\]: YES

Private Sector

Number of wholesalers\[^{15}\]: Normal: 16,892 (include retail also)

Agency responsible for Price Control\[^{12}\]: Ministry of Trade/Commerce.

Pricing mechanism:
- Manufacturer ☐ Wholesale ☐ Retailer\[^{12}\] ✓

Mark-ups regulated\[^{12}\]: No price cap/maximum retail price (MRP). Price negotiation between industry and purchaser.

Public Sector Facilities\[^{6,I}\]:
- Referral Hospitals excluding Bangkok Metropolitan: 116
- District hospitals (community hospitals): 774
- Primary care centers: 9796

Private Sector

Number of Retail Outlets\[^{15,J}\]: Normal: 16,892
Ready packed: 2934

Licensed retail pharmacies per 10 000 population\[^{15,K}\]: 2.5

Number of Traditional Medicines outlets\[^{15}\]: 2083

Public Sector

Agency responsible for distribution\[^{12,H}\]: Directly from supplier to hospitals

Private Sector

Patient

Distribution

Pharmaceutical system flowchart
Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

Notes:

A. Ratio calculated by Thai population of 65.03 million people.
B. Data only on the number of pharmacists available but the number of technicians are not available.
C. National Medicines Policy 2017-2021: To get cabinet approval.
E. Treatment protocols available for special programs. Standard Treatment Guidelines for about 50 diseases available from Department of Medical Services, Ministry of Public Health.
F. Specialties National Formularies available. No national formulary booklet.
G. National Medicine Systems Development Committee. Monitoring by Pharmacy Unit of Bureau of Health Administration, Ministry of Public Health
H. Suppliers directly supply to health facilities/ hospitals and community hospitals supply medicines to health centers.
I. 116 Referral Hospitals include - 88 regional hospitals/28 general hospitals. Primary care centers are called District Health Promoting Hospitals.
J. Ready-packed drugs can be sold in drug stores by nurses or other medical professionals. 3,686 “ready packed” includes (veterinary.
K. Calculated by using retail pharmacies/Thai pop. *10,000 = 16,892/67,959,000*10,000 = 2.5.

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.
Timor-Leste pharmaceutical profile 2017

COUNTRY AT A GLANCE

<table>
<thead>
<tr>
<th></th>
<th>1185</th>
<th>68.3</th>
<th>1217</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (in 000s)¹</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life expectancy at birth (in years)²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GDP (per capita in current US$)³</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OVERALL SPENDING ON HEALTH

<table>
<thead>
<tr>
<th>Total per capita spending on health care (current US$) ⁴</th>
<th>Share of government vs. out-of-pocket spending on health ⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current US$</td>
<td>share as percentage (%)</td>
</tr>
<tr>
<td>$7</td>
<td>90%</td>
</tr>
<tr>
<td>$57</td>
<td>10%</td>
</tr>
</tbody>
</table>

Total per capita spending medicines (current US$)²

<table>
<thead>
<tr>
<th>Spending on medicines as share of total health-care cost ⁶</th>
<th>Share of public and out-of-pocket spending on medicines ⁷</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage (%)</td>
<td>share as percentage (%)</td>
</tr>
<tr>
<td>12.8%</td>
<td>37%</td>
</tr>
<tr>
<td></td>
<td>63%</td>
</tr>
</tbody>
</table>

SPENDING ON MEDICINES

<table>
<thead>
<tr>
<th>Medical and pharmacy workforce</th>
<th>7.1</th>
<th>1.4</th>
<th>0.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical practitioners/10 000 population⁸</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacists &amp; pharmacy technicians/10 000 population⁹</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered pharmacists/10 000 population⁹</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Key Medicines Policies and Guidance

- **Key Pharmaceutical Legislation**

- **National Medicine Policy**

- **National Essential Medicines List**

- **National Standard Treatment Guidelines**
  - Available for Primary Health Care and Referral hospitals, 2010

### Intellectual Property Related Policies & Production

- **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

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### Access to Medicines

#### Malaria and Tuberculosis treatment coverage

<table>
<thead>
<tr>
<th>Year</th>
<th>2005</th>
<th>2007</th>
<th>2009</th>
<th>2011</th>
<th>2013</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>100%</td>
<td>57%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HIV/AIDS data insufficient**

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

<table>
<thead>
<tr>
<th>Year</th>
<th>2005</th>
<th>2010</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>39.3%</td>
<td>76%</td>
<td>76%</td>
</tr>
</tbody>
</table>

#### Hypertension and Diabetes Mellitus treatment coverage

<table>
<thead>
<tr>
<th>Year</th>
<th>2005</th>
<th>2010</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>100%</td>
<td>57%</td>
<td>57%</td>
</tr>
</tbody>
</table>

*Result for 18-69 years age population

#### Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone

Not available

Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency.
Timor-Leste

Improving access to medicines in the South-East Asia Region: Progress, challenges, priorities

National Regulatory Authority[14]: No official National Regulatory Authority. Directorate of Pharmacy and Medicines (DNFM) responsible for some regulatory functions

Regulated products:
- Medicines[11]: YES  
- Vaccines: YES  
- Medical Devices: YES  
- Traditional Medicines[17]: NO

Medicine Quality Control Laboratory[18, A]: None
- ISO 17025 certified: NA  
- WHO prequalified: NA

Number of Registered Medicines[11]: 900

Agency responsible for selection[11]: Committee for selection of medicines, products and medical equipment with Department of Pharmacy, Ministry of Health

Number of products on essential medicines list[11]:
- By active ingredient[11]: 274  
- By dosage form[11]: 402

Traditional medicines products included in essential medicines list[17]: NO

Medicines availability is indicated by health facility level: YES

Number of Products in National Formulary[11]: No National Formulary

Public Sector

Agency responsible for Public Procurement[14]: SAMES IP (Service Autonomo de medicamentos e Equipamentos de Saude)


Commonly used procurement methods[11]: Local and International Tender based upon procurement amount

Price control[11]: Yes

Mechanism[18]: Bid evaluation based upon Lowest price criteria

Health insurance reimbursement price[11]: No insurance but national health service provides free treatment of patients

Patient prices for essential medicines in public sector[11]:
- Free medicines: YES

Private Sector

Number of wholesalers[11]: 12

Agency responsible for price control[11]: Not Controlled

Pricing mechanism: Not applicable

Manufacturer ☐ Wholesale ☐ Retailer ☐

Mark-ups regulated[11]: No policy so far

Public Sector

Agency responsible for distribution[11]: SAMES and District Health Office

Public Sector Facilities[20]:
- Reference Hospitals: 2  
- Regional Hospitals: 3  
- Community Health Services: 65  
- Health Centres: more than 200

Private Sector

Number of Retail Outlets[11]: 34

Licensed retail pharmacies per 10 000 population[11]: 0.3

Number of Traditional Medicines outlets: No data

Patient
6. Data taken from South East Asia Region Health workforce survey April 2016.
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.
Improving access to medicines in the South-East Asia Region

Progress, Challenges, Priorities