Access to medical products in the South-East Asia Region

2021

Review of progress

World Health Organization
REGIONAL OFFICE FOR South-East Asia

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Foreword by the Regional Director

The WHO South-East Asia Region is committed to ensuring access for all to safe, effective, affordable and quality medical products, in line with the 2018 Delhi Declaration on Improving Access to Essential Medical Products, and the Region's Flagship Priority Programme on achieving universal health coverage (UHC).

Across the Region, spending on medicines comprises a large proportion of out-of-pocket costs. To reduce those costs, Member States have in recent years begun implementing medical products pricing policies, which play a key role in ensuring that medicines are affordable. Several Member States have improved governance in medicine management, including by strengthening national policies and procurement systems. The finalization of the Initiative for Collaborative Procurement in South-East Asia (iCAPS) procedures, which guides implementation, is an important milestone towards collaborative procurement. The interest in leveraging the Initiative to increase access to essential antidotes, even from countries outside the Region, has been inspiring.

To build resilient supply chains, especially during the COVID-19 pandemic, efforts to reduce risks and dependency, and increase domestic production, are ongoing. Such efforts will diversify the supply base and secure sufficient stockpiles of medical products. Partnership with the private sector, alongside ongoing regulatory system strengthening, is necessary for technology transfer and enhanced local production of high-priority medical products. Initiatives such as the COVID-19 Technology Access Pool could be effective in achieving these outcomes by providing a one-stop shop for developers of health products to share their intellectual property, knowledge and data.

Monitoring access to medical products remains a complex endeavour that requires gathering of information from multiple sources and ensuring the interoperability of data collection systems. More complete and timely data on access to medicines will better enable countries to identify access disparities between population groups and understand the effects of interventions across their medicine supply and distribution chains.

The COVID-19 pandemic has resulted in massive human and economic costs, partly on account of shortages of critical medical products. It has exposed vulnerabilities that impact the global supply chain. This report provides Member States, partners and other stakeholders an opportunity to review progress and identify and leverage new opportunities to improve access to essential medical products for a fairer, healthier Region for all.

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WHO South-East Asia

PART I

Improving access to medical products: where are we now?

Every disease management strategy requires access to essential medical products for prevention, diagnosis and effective management for treatment, palliative care and rehabilitation. Health-care services rely on access to essential medical products that include medicines, vaccines, medical devices, diagnostics, protective equipment and assistive devices. These products must be of assured quality, safety and efficacy, as well as appropriate, available and affordable.

At the Seventy-first session of the WHO Regional Committee in September 2018, intercountry technical consultations following the Decision SEA/RC70(3) that was adopted by the Seventieth session of the Regional Committee led to the adoption of the ministerial "Delhi Declaration on Improving Access to Essential Medical Products in the Region and Beyond". The Delhi Declaration[1] was significant as it included a commitment for access to the entire range of medical products for achieving universal health coverage and the 2030 Agenda for Sustainable Development.

In addition, SEA Region Member States actively participated in global consultations that led to the adoption of significant World Health Assembly resolutions on this subject. In Health Assembly resolution WHA72.8 of 2019 on "Improving the transparency of markets for medicines, vaccines and other health products", the World Health Assembly expanded the scope of "health products" to include "medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies".

Despite improvements in the availability of essential medical products in the Region, access of essential medicines and other essential medical products continues to pose a challenge. The high level of out-of-pocket (OOP) spending on health care in many SEA Region countries is a matter of concern, and is pushing around 65 million into poverty every year. This is mainly on account of spending on medical products, particularly medicines that account for the major share of OOP payment, in several countries of the Region.

The current COVID-19 pandemic resulted in devastating human and economic costs, partly on account of shortages of critical medical supplies including PPEs, essential medicines, diagnostics, vaccines and medical devices. Production capacity was unable to meet the rapid surge in demand. Furthermore, lockdowns, travel and export bans, and suspended transport services had a direct impact on dwindled production, disrupted distribution and also increased cost of not only emergency medical supplies but other critical medicines required for essential health-care services.

The pandemic has significantly highlighted the importance of timely access to quality, safe, effective medical products. Accordingly, all SEA Region Member States have supported World Health Assembly resolution WHA 73.1 of 2020 on access to medical products. Member States recognized "the need for all countries to have unhindered, timely access to quality, safe, efficacious and affordable diagnostics, therapeutics, medicines and vaccines, and essential health technologies and their components, as well as equipment".

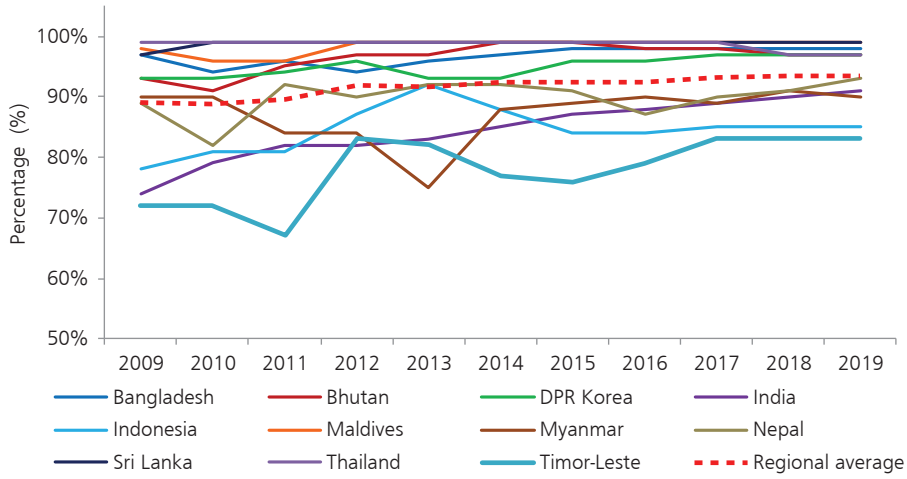
Status of access indicators in the South-East Asia Region

This publication provides an update to the 2019 report on access to medicines.[2]

Proportion of target population covered by vaccines

Immunization coverage is an important indicator to monitor access to medical products. Regional immunization coverage with three doses of diphtheria, tetanus and pertussis (DTP3)[3] vaccine has been maintained at above 90% since 2012, with DPT coverage ranging between 83% and 99% in 2019. In the last five years, five countries sustained high (>95%) coverage.

Fig. 1. **Regional Immunization overage with three doses of diphtheria, tetanus and pertussis (DTP3) vaccines, 2009–2019**



Source: WHO_UNICEF coverage estimates: Vaccines monitoring system, 2021 Global Summary (https://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html)

Availability of essential medicines in health facilities

The availability and affordability of medicines, as per the standard method for reporting the SDG Target 3. b.3. indicator[4] of medicines availability, is not yet regularly monitored globally or in the South-East Asia Region. Hence, the most recent health facility surveys from the Member States were used to provide insight.

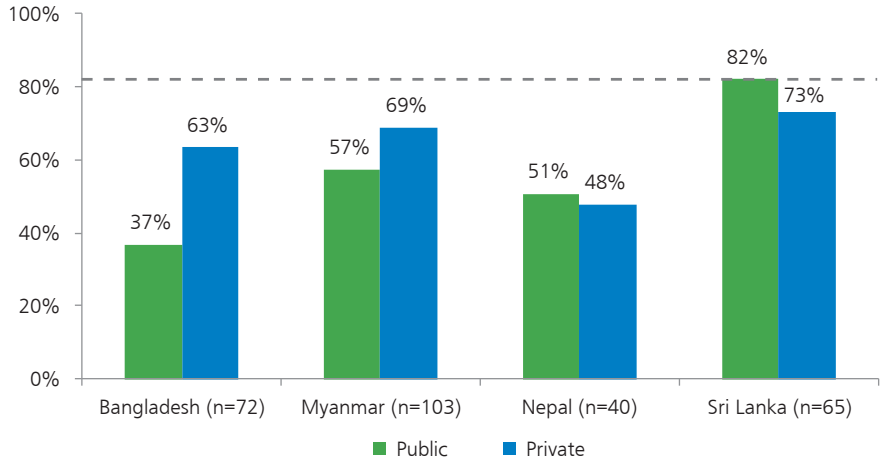
Table 1. Recent health facility surveys in the Region which collect information on medicines availability and price

Country	Year	Reference	Availability	Prices
Bangladesh	2020	Bangladesh Health Facility Survey 2017 Final Report. 2019 https://dhsprogram.com/publications/publication-SPA28-SPA-Final-Reports.cfm- (accessed 25 January 2021).	✓	χ
Bangladesh	2019	Evaluating medicine prices, availability and affordability in Bangladesh using World Health Organization and Health Action International methodology. BMC Health Services Research 2019; 19(1):383. https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-019-4221-z (accessed 25 June 2019).	✓	✓
Bangladesh	2018	Service Availability and Readiness Assessment (SARA) survey for NCDs and Disability Service Delivery System in Bangladesh. 2018; 1–47 (internal communication).	✓	χ
Myanmar	2015	Nationwide Service Availability and Readiness Assessment (SARA) Myanmar 2015 (internal communication).	✓	χ
Nepal	2015	Aryal KK, Dangol R, Gartoulla P, Subedi GR. Health services availability and readiness in seven provinces of Nepal: further analysis of the 2015 Nepal Health Facility Survey, DHS Further Analysis Report No. 115. Ministry of Health and Population, Nepal, 2018. https://dhsprogram.com/pubs/pdf/FA115/FA115.pdf (accessed 18 June 2019).	✓	χ
Sri Lanka	2017	Rathish D, Premarathna I, Jayathilake T, Kandegedara C, Punchihewa K, Ananda L, et al. Availability of essential medicines in selected public, primary and secondary health care institutions of a rural Sri Lankan district: A spot survey. BMC Health Services Research.2017;17(1):1–9. http://dx.doi.org/10.1186/s12913-016-1969-2 (accessed 18 June 2019).	✓	χ
Sri Lanka	2017	Service availability and readiness assessment 2017 Sri Lanka. 2018;1-314. http://www.searo.who.int/srilanka/sara_sri-lanka_2107_report.pdf (accessed 18 June 2019).	✓	χ

Country	Year	Reference	Availability	Prices
Sri Lanka	2014	Dabare PRL, Wanigatunge CA, Beneragama BH. A national survey on availability, price and affordability of selected essential medicines for noncommunicable diseases in Sri Lanka. BMC Public Health. 2014;14(1):817. http://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-14-817 (accessed 25 June 2019).	✓	✓

Fig. 2 reports the overall availability of a nationally defined basket of essential medicines from recent national surveys in four countries. It ranges from 37% to 82% and is on average higher in private than public facilities, as was reported in the Access to medical products in South-East Asia Region 2019 publication.[ii]

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



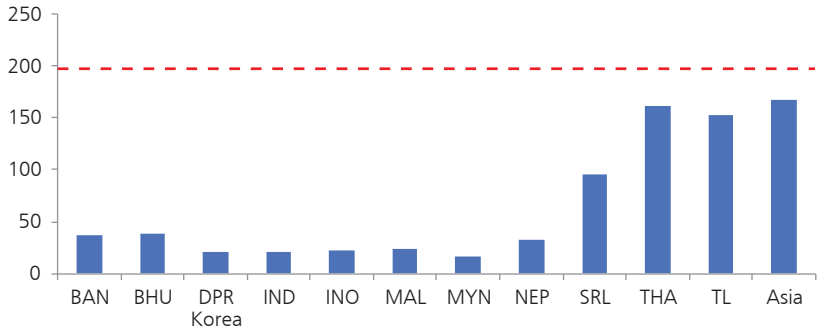
n = number of medicines in the basket

Source: Service Availability and Readiness Assessments (SARA) survey in Myanmar, 2015, Sri Lanka, 2017; Service Provision Assessments (SPA) surveys Nepal 2015, Health Facility Survey, Bangladesh, 2017.

Access to pain medication

Improving access to pain relief and palliative care has received increased attention in the Region. In 2014 Member States passed the first WHO global resolution on palliative care. WHO has included an indicator in its Thirteenth General Programme of Work 2019–2023 Impact Framework, with a target to increase the availability of oral morphine in facilities providing palliative care from 25% to 50%. Over 15 million people in the South-East Asia Region are estimated to experience serious health-related suffering, with a significant gap in access to adequate pain relief. The medical use of opioids for pain relief is low in the Region compared with other regions and significantly below the globally accepted adequate level of 200 S-DDD per million inhabitants per day.

Fig. 3. **Total opioid consumption, excluding methadone* (defined daily dose/million population/day (S-DDD))**



*Methadone is mainly used as part of treatment for addiction to narcotics, hence it is excluded from this analysis. 200 S-DDD per million inhabitants per day threshold below consumption considered inadequate according to INCB[5]

With the growing prevalence of chronic diseases, cancer and other disorders associated with severe pain, it is timely to consider how to improve access to medicines that relieve severe pain.

National medicines policies

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

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

Table 2. Latest year of national medicines policies being updated

BAN	BHU	DPR Korea	IND	INO	MAV	MMR	NEP	SRL	THA	TLS
2016	2007	2019	2012	2006	2018*	2019	2007	2020	2020	2018

*National Medicine Policy 2007 has been reviewed in 2018

Source: Country pharmaceutical profile information (Part 3)

Essential medicines lists

The concept of essential medicines is a long-established approach to improve access to pharmaceuticals. The 1st edition of WHO's Model List of Essential Medicines was published in 1977. Since then, all countries have developed their own national essential medicines lists (EMLs) in the Region. National essential medicines lists are used both to

improve efficiency of public sector procurement and promote rational use. The criteria for the selection of medicines in such lists include common morbidities, evidence of cost–effectiveness, and affordability for government or health insurance schemes.

WHO suggests that countries update their EMLs every two years. Since 2019, five countries have updated their national EMLs (Table 3).

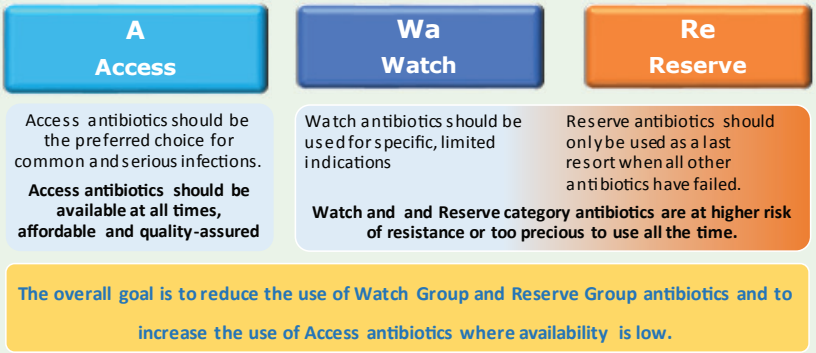
Table 3. National essential medicines lists: dates of most recent revision

BAN	BHU	DPR Korea	IND	INO	MAV	MMR	NEP	SRL	THA	TLS
2016	2018	2019	2015	2019	2020	2016	2020	2014	2020	2015

Source: Country pharmaceutical profile information (Part 4)

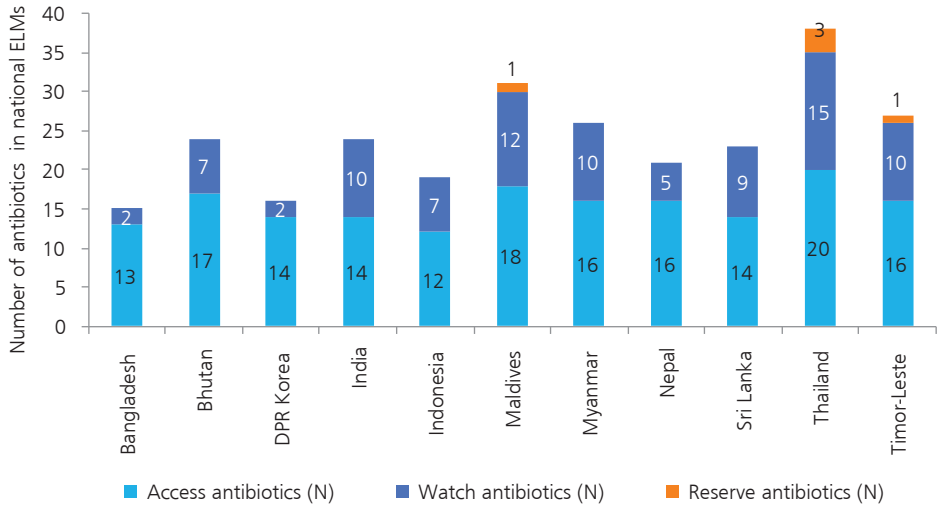
EML updates in South-East Asia Region countries are now incorporating WHO's Access/Watch/Reserve "AWaRe" classification for antibiotics, introduced in 2017 (Box 1). Antibiotics have been grouped into the three categories, with recommendations on when each category should be used. The change aims to ensure that antibiotics are available when needed, and that the right one is prescribed for the appropriate infection.

Box 1. The WHO AWaRe categorization



The Fig. 4 showcases the inclusion of essential antibiotics as per the "AWaRe" classification in the essential medicines lists in 10 countries of the South-East Asia Region[6]

Fig. 4. **Essential antibiotics listed in the national essential medicines lists of 11 countries of the WHO SEA Region according to the WHO AWaRe classification**



Source: Adekoya et al, 2021. Comparison of antibiotics included in national essential medicines lists of 138 countries using the WHO Access, Watch, Reserve (AWaRe) classification: a cross-sectional study. The Lancet Infectious Diseases 2021. 1-12. (https://doi.org/10.1016/ S1473-3099(20)30854-9 – accessed 31 July 2021).

PART 2

Improving access to quality medical products: what interventions are being used?

Improving quality, safety and efficacy of medical products

A first-of-its-kind pilot virtual current good manufacturing practices (cGMP) online workshop in December 2020 was organized and implemented by all three levels of WHO (country office, Regional Office and headquarters) in collaboration with JSS Academy of Higher Education & Research, Mysuru, India, the Ministry of Health and Family Welfare of India, partners, USAID-funded programmes, MTaPS (the Medicines, Technologies and Pharmaceutical Services Programmes) and PQM+ (Promoting the Quality of Medicines Plus).

The workshops are in pursuit of World Health Assembly resolution on the Global Strategy and Plan of Action on public health, innovation and intellectual property (GSPA) (resolution WHA61.21), and in line with the resolution of the Seventy-fourth World Health Assembly in May 2021 on "Strengthening local production of medicines and other health technologies to improve access" (resolution WHA74.6). The six series of workshops that began with a pilot contributed to further improve access to quality, safe, effective and affordable medicines and other health technologies and efforts to achieve the objectives of the SEA Region health ministers' Delhi Declaration of 2018.

Table 4. Pilot and subsequent cGMP workshops

Workshop	Category	Dates 2020–2021	Number of Participating Units	Number of Participants	Duration (in days)
Pilot	Formulation	1–14 December	33	101	12
1.	Formulation	5 May–18 May	40	143	12
2.	APIs	24 May–5 June	35	139	12
3.	APIs	14 June to 26 June	49	166	12
4.	Medical Devices	5 July to 9 July	51	165	05
5.	APIs	19 July to 30 July	115	401	12
Total			323	1115	

The COVID-19 outbreak with the consequent restrictions on in-person workshops was turned into an opportunity whereby pharmaceutical unit personnel could attend workshop sessions while also attending to shop-floor production and related activities, thus improving outcomes. The workshops were offered at no cost to pharmaceutical units so as to cover a wide range of pharmaceutical manufacturers including small-scale producers of quality products. The workshops were rolled out with technical assistance from the Indian Pharmaceutical Alliance to ensure meaningful and relevant content and outcomes.

The selection of participating pharmaceutical units was done randomly using statistical sampling methods. The Annual Survey of Industries database of registered Indian pharmaceutical units till 31.03.2019 under the Factories Act and maintained by the Ministry of Statistics and Programme Implementation formed the basis of selection.

Mentorship: The workshops are being followed by a mentorship programme designed to assist adoption of WHO prequalification in the units to promote access to quality medical products.

It is envisaged to expand the activity for pharmaceutical units in other countries; and based on initial discussions it has been suggested that the course content may be aligned to specific country requirements.

South-East Asia Regulatory Network (SEARN) update

Since 2016, the South-East Asia Regulatory Network (SEARN) has been working to promote regional collaboration, convergence and reliance in medical product regulation to improve their quality and safety. The SEARN annual meetings enable one-to-one interaction among regulators from the Region, resulting in better understanding of the complex regulatory systems for different medical products – medicines, vaccines, devices, diagnostics. The following meetings were organized by SEARN in recent years:

- First Annual Meeting of SEARN in New Delhi, India, on 11–12 April 2017: resulted in setting up a Steering Group and four Working Groups (WGs) on (i) quality assurance and standards of medical products; (ii) good regulatory practices (GRP); (iii) vigilance for medical products; and (iv) the SEARN information sharing platform.
- Second SEARN Meeting in Colombo, Sri Lanka, on 21–23 March 2018: set up a fifth Working Group on (v) medical devices and diagnostics to cater to the special needs of the sector.
- Third SEARN Meeting in New Delhi, India, on 22–23 April 2019: led to specific regional collaborative activities to improve quality assurance and regulation practices, to move forward on WHO prequalification, medical product vigilance and medical device regulation.

Progress was also achieved through the successive annual meetings on regulatory cooperation on five specific areas identified by the regulatory agencies. Information on all the 11 state drug regulators in the SEA Region has been made accessible to the public through a single ISP gateway. The ISP gateway can be accessed here: https://www.searn-isp.org/

The activities outlined below were guided by regulatory agencies of Member countries of the South-East Asia Regulatory Network:

(1) WHO External Quality Assurance Assessment Scheme (EQAAS) workshop for laboratories from the South-East Asia Region on 3–5 December 2019 in New Delhi, India.

(2) One-day satellite meeting on 12 November 2019 in Bangkok, Thailand on joint assessment of fixed-dose combinations of antiretrovirals for accelerated registration of priority health products.

(3) Vigilance guidance for SEARN being developed with the Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom of Great Britain and Northern Ireland.

(4) Workshop on SEARN Working Group 5 on Medical devices regulatory requirements for assessment of in vitro diagnostic medical devices (IVDs) on 11–12 December 2019 in Jakarta, Indonesia.

(5) Three national regulatory authorities also took up self-assessment using the WHO global benchmarking tool and are implementing institutional development plans.

SEARN activity for COVID-19

In 2020, virtual meetings of SEARN were held for scaling up regulatory approval for diagnostics, medicines and vaccines for the COVID-19 response as outlined below:

(1) SEARN Virtual Meeting on Regulatory Updates on the COVID-19 pandemic on 7 May 2020 to provide updates on regulatory parameters for access to medical products related to the pandemic.

(2) Virtual meetings have been organized on 29 April 2020 and 10–11 December 2020 with SEARN regulatory authorities and vaccines manufacturers to fast-track COVID-19 vaccine rollout in Member countries and decide timelines for fast-track registration of COVID-19 vaccines in countries using the emergency use listing procedures while factoring in the COVID-19 vaccine production scales in the Region.

(3) Regulatory brief and virtual session on vaccine clinical trial solidarity protocol on 28 August 2020.

Regulatory updates including sharing of regulatory information on quality personal protective equipment/diagnostic kits/devices and related updates from international agencies for COVID-19 were provided to regulators through the information sharing platform.

Member State-led international conferences promoting access to medical products

The World Conferences (2017, 2018, 2019) on Access to Medical Products in India focused on the GSPA-PHI agenda including TRIPS flexibilities and IPR licensing mechanisms.

In addition, Thailand's annual International Trade and Health (ITH) virtual Conference contributed to sustained engagement on access issues for health products. As part of the run-up to the Prince Mahidol Award Conference (PMAC) 2021, the following meetings held by Thailand and supported by WHO contributed to global discussions:

- Assessing the situation of COVID-19 and international trade and health, on 4 November 2020 virtual conference from Thailand.
- Making international intellectual property and trade regimes work to address the health response to COVID-19, on 5 November 2020 virtual conference from Thailand .

Discussions during PMAC 2021 on the above-mentioned topics focused on drawing the world's attention to access to medical products during the prevalence of COVID-19.

Improving affordability of medical products

The recent national surveys in four countries of the Region showed that the availability of a defined basket of essential medicines is better in private facilities compared with public facilities. Since the availability of medicines in the public sector is often low, there is no choice for individuals but to purchase medicines from the private sector. Even more disconcerting is the fact that many households may have to forgo the expenses of buying necessary medicines and face adverse health outcomes as a consequence. This inequity has long-term social and economic consequences for the countries of the Region.

Several countries in the Region where prepaid and/or public financing of medicines is very low, access to essential medicines for the population is affected. This impedes the progress towards universal health coverage (UHC). In about one third of the WHO SEA Region countries, a large proportion of households face catastrophic expenditures due to unaffordable prices of medicines in the private sector.

Pricing policies

Pricing policies play a key role in keeping the prices of medicines affordable. WHO conducted an analysis and organized an expert consultation virtually in February 2021 to discuss pricing policies adopted in the Region and their implications. Results show that policies commonly used in all countries are promotion of generic medicines, tendering, and making available free essential medicines in the public sector. All these policies are recommended by the WHO pricing guideline.

Some policies such as value-based pricing and price negotiation or special price agreements are used in only a few countries as these policies require technical capacity and continuous investment. There is, however, limited evidence on the effectiveness of these policies in many countries of the Region. Countries are encouraged to invest in studying the impact of their pricing policies.

Conflict of interest management policies and practices

Weak pharmaceutical sector governance is one of the factors that contributes to poor access and inappropriate use of essential health products, inflated prices, and wastage of scarce health system resources. Pharmaceutical systems are technically complex

and involve extensive interactions between the private sector and the public sector. Private sector interests can influence what products are selected for reimbursement or procurement, prices of health products, and how health products are used. Without adequate regulation, public trust and confidence in policy-makers, the policy process and its outcomes can be undermined.

Conflicts of interest are situations in which the existence of personal or private interests risk compromising an individual's primary obligation. Private sector ownership, employment, receipt of payments for consulting or advisory roles, and gifts and hospitality offers create conflicts of interest for committee members. Because conflicts of interest are a situation, rather than an act, they do not in themselves constitute a breach of duty or trust. Conflict of interest thus differs from corruption, which is defined by outcome and intent as "the abuse of entrusted power for private gain".

Members of public sector pharmaceutical committees are entrusted to make decisions on behalf of the public and in the interest of public health; thus, conflicts of interest should be prevented wherever possible. Thus, appropriate policies and standards are needed to assure that conflicts of interest are appropriately disclosed and managed. Though many countries use disclosure mechanisms to address conflicts of interest, other management strategies are possible but may be underutilized.

Pharmaceutical committees are often heavily reliant on technical and clinical experts. Globally, financial relationships between experts and the pharmaceutical industry are pervasive. As in many high-income countries, physicians and researchers in SEA Region Member States rely on pharmaceutical industry funding for continuing education and research or serve as consultants and advisors to industry. In countries with a limited pool of experts, identifying experts that are independent of industry influence is a key challenge. Thus, mechanisms are needed to promote stakeholder engagement and access necessary expertise while also ensuring transparency, independence and integrity in decision-making processes.

WHO conducted an analysis on conflict-of-interest management policies and practices in the pharmaceutical sector in the Region. The results show that only few policies explicitly addressed conflicts of interest, many discussed committee governance, ethics, integrity and underlying values more generally. Processes for preventing or managing conflicts of interest are much less well developed, overall, with the exception of a few key public procurement processes. To strengthen good governance, there is a need for capacity-building in Member States around the management of such conflict; this must include defining and identifying the types of conflict, developing criteria for the selection of independent committee members with requisite expertise, and creating effective redressal mechanisms.

Collaboration on procurement

Initiative for Coordinated Antidote Procurement (iCAPS)

Improving access to safe, efficacious, quality and affordable medicines remains a critical focus of the South-East Asia Region. The Regional Committee Decision (SEA/RC70(3)) advised the Regional Director to convene technical consultations to develop intercountry cooperation, on a voluntary basis, that included initiating a collaboration on the procurement of antidotes for improved access to limited supplies of medicines for life-threatening conditions.

The Initiative for Coordinated Antidotes Procurement in the South-East Asia Region (iCAPS) was launched in early 2018 to procure antidotes for a number of common poisonings. This systematic approach for antidote procurement is expected to improve procurement efficiency by aggregating demand, reducing costs and coordinating quality assurance. Mahidol University of Thailand was designated as a WHO collaborating centre (WHO CC) in 2018 for the control and prevention of poisoning as part of the efforts to support the initiative.

A High-Level Virtual Regional Meeting was conducted in October 2020. The meeting was attended by representatives from all the Member states and persons involved in health policy, poison management and procurement agencies. The objective of the Regional Meeting was to review, agree and adopt the operational framework to guide countries in accessing essential antidotes through iCAPS.

This Regional Meeting led to the finalization and publication of the iCAPS manual and the promotional video. The manual was based on the inputs provided by representatives of the Member States of the WHO South-East Asia Region, the Thai Working Group, regional experts and WHO. It provides clear guidance on the steps to be followed to ensure the effective coordination and timely provision of antidotes in response to poisoning emergencies.

There has been significant interest in accessing essential antidotes even from countries outside the Region. In 2020 two countries outside the SEA Region accessed antidotes through the emergency response pathway in response to poisoning emergencies.

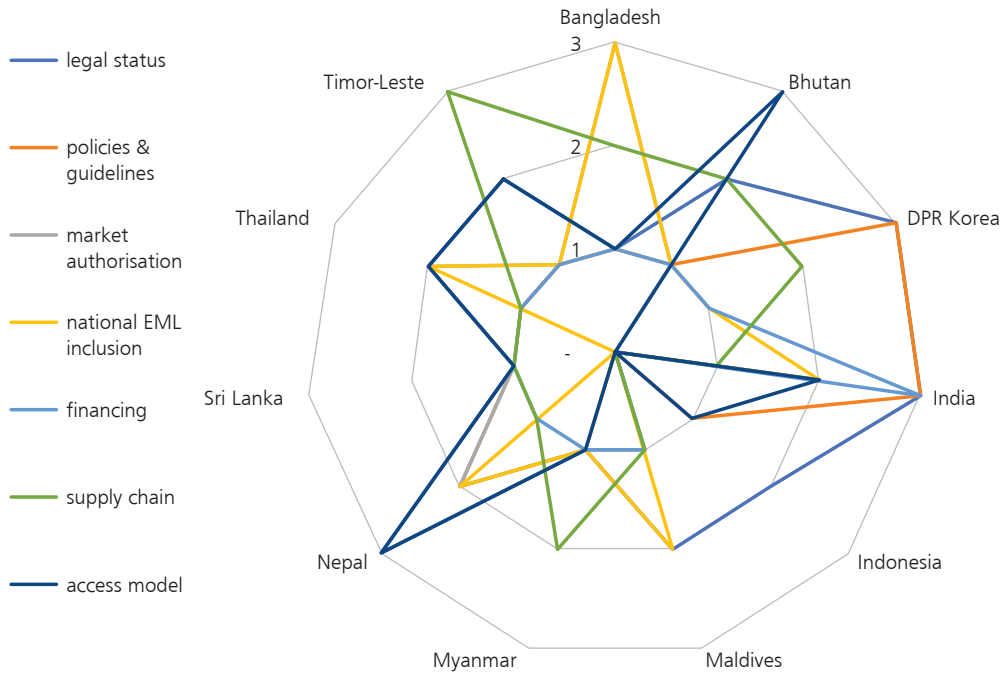
Improving access to medical abortion medicines

It is estimated that 44% of the total number of pregnancies recorded annually in the world are unintended, and 56% of them end in abortion. Unsafe abortions remain a major public health issue and cause 8–11% of global maternal deaths that occur predominantly in low- and middle-income countries where the most restrictive access policies are concentrated. Access to safe comprehensive abortion care remains uneven and complications due to unsafe abortion are still significant causes of maternal morbidity and mortality.

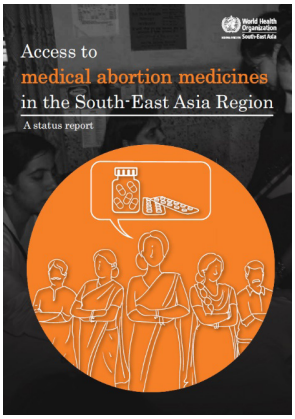
In the SEA Region, very few countries have included all the medical abortion (MA) medicines (mifepristone, misoprostol and the mifepristone 200 mg + misoprostol 200 mcg combination pack) in their national essential medicine lists. Bangladesh, India, Maldives and Nepal have included at least two of the medicines in their NEML. The combi-pack has been included in the NEML of only Thailand and Nepal. In Indonesia, misoprostol 200 mcg and 100 mcg are currently under review and a decision regarding their inclusion in the NEML is awaited.

Market authorization of medical abortion medicines is still very low in the Region. At least eight countries in the Region do not have market authorization of at least one of the medical abortion medicines. Only Bangladesh, India and Nepal have authorized the use of all the different medical abortion medicines in the country.

Fig 6: Overview of access to medical abortion medicines in SEA Region



Policy-makers should encourage registration and market authorization of multiple sources of products for each MA medicine to ensure sustainable access and encourage market competition for better pricing. In countries where legal and policy provisions permit, misoprostol 200 mcg, mifepristone 200 mg and their combi-pack should be included in the NEMLs. Task-sharing, and the potential use of telemedicine, to expand the provider base will be required to strengthen and expand the capacity of the supply chain. For the public sector, access to medicines through non-physician health workers such as nurses and midwives should be considered, and for the private sector, access through certified pharmacists.



A comprehensive set of policies and interventions aimed at ensuring the availability and easy access to safe, effective and quality-assured MA medicines is key to improving or expanding access to medical abortion medicines. Access to MA medicines can be promoted in the Region as they are safe, non-invasive and inexpensive.

Improving access to safe blood and blood products

Safe blood and blood products save lives in all sorts of circumstances, not least in emergency and epidemic settings. Safe, effective and quality-assured blood products contribute to improving and saving millions of lives every year, as they are of immense importance in tackling child mortality and maternal health – improving the life expectancy and quality of life of patients suffering from life-threatening inherited blood disorders such as haemophilia, thalassaemia, immune deficiency, and acquired conditions such as cancer and traumatic haemorrhage.

Ensuring access of all patients who require transfusion to safe, effective and quality-assured blood products is a key component of an effective health system and is vital for patient safety. WHO has provided guidelines, physical standards, training and technical support to improve blood product quality, safety and availability in countries for last several decades and has established a Global Database on Blood Safety (GDBS) to understand country needs in order to advance access to safe blood. The WHO Regional Office has organized several online workshops on the recruitment of voluntary non-remunerated donors. quality assurance system in blood safety, hemovigilance, and establishing an integrated quality assured system of blood transfusion services based on voluntary non- remunerated donations.

Combating antimicrobial resistance

Global antimicrobial resistance and use of the surveillance system (GLASS) for antimicrobial consumption

Antimicrobial resistance (AMR) is a significant threat to health and human development, affecting our ability to treat a range of infections. Consumption and use of antimicrobials are the main drivers for the development of AMR. To obtain a thorough and comprehensive picture of AMR and to be able to identify areas in which actions are needed, data from surveillance of antimicrobial consumption (AMC) are essential. These data should be easily compared and exchanged, and should be used locally, nationally, regionally and globally.

WHO developed a methodology for the global programme on surveillance of AMC that was extended as a component of the Global Antimicrobial Resistance and Use Surveillance System (GLASS) in 2020. GLASS-AMC provides a common technical basis for setting up national surveillance systems on AMC that can produce reliable and comparable data at national and global levels. The methodology will be used by all countries, regardless of the level of development of a country's national AMC surveillance system.

Enrolment into GLASS-AMC is underway in the Region. Currently Bhutan, Indonesia, Maldives, Nepal and Timor-Leste have enrolled into GLASS-AMC and set up AMC surveillance systems. Bangladesh, Maldives and Nepal have been supported by WHO to conduct initial antimicrobial consumption multiyear data analysis using the standardized WHO methodology.

A pool of regional experts was trained in February 2020 and the consultants are available to support national AMC surveillance and use in Member States. Maldives and Nepal have benefited from the technical support provided by these regional experts.

To understand how antibiotics are imported, manufactured and sold, Thailand mapped out all antibiotic distribution channels across all sectors to ensure complete data registration. The Thai Working Group on Surveillance of Antimicrobial Consumption developed an integrated method to collect consumption data and validated the methodology through an external peer-review mechanism.

Bangladesh has established the Antimicrobial Consumption Monitoring Task Force with WHO support. As over 95% of pharmaceuticals are produced by the domestic pharmaceutical sector in Bangladesh, most of the antimicrobial production and sales information is collected at the regulator level. Information from distribution (distributor and wholesaler) and retail sales (pharmacies and medicine stores) has not yet been digitized, therefore it was necessary first to apply Anatomical Therapeutic Chemical (ATC) classification and build a database of antimicrobials to be monitored. The Antimicrobial Consumption Monitoring Task Force developed the database for data collection and is progressing with implementation of the AMC monitoring system.

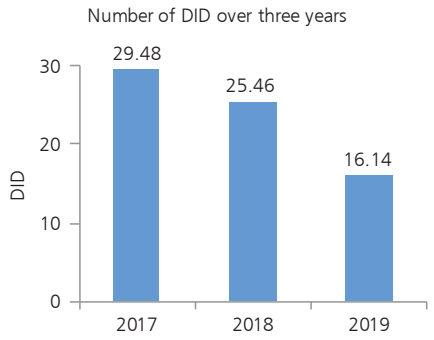
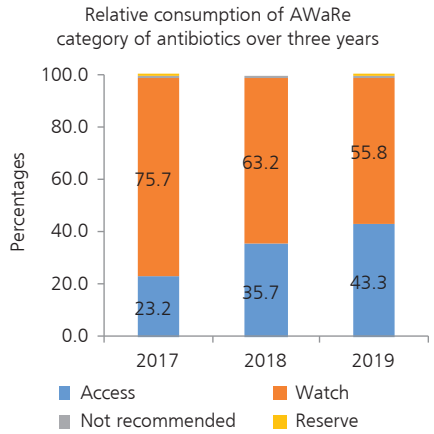
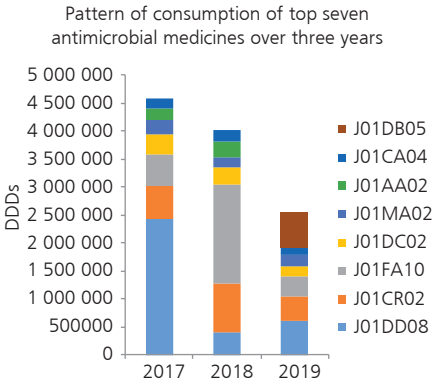
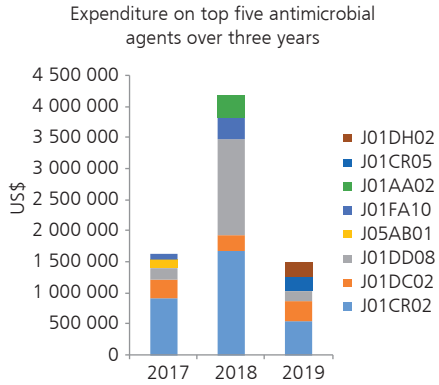
Maldives conducted a data analysis on the antimicrobial consumption for human use for the year 2017,2018, and 2019 using the standardized methodology developed by the WHO. The three years of data generated good evidence for trends and patterns on the level of use and type of antimicrobial used in the country. The Defined Daily Dose (DDD) and the DDD per 1000 inhabitants per day (DID) was used to analyze antimicrobial consumption in the country. Table 5 summarizes the trends and patterns in consumption of antimicrobial in Maldives.

Antimicrobial stewardship

Antimicrobial stewardship is a coherent set of actions which promote the responsible use of antimicrobials. This definition can be applied to actions at the individual level as well as the national and global levels, and across human health, animal health and the environment sectors. To support such actions, the Antimicrobial Stewardship Programme, an organizational or system-wide health-care strategy to promote appropriate use of antimicrobials through the implementation of evidence-based interventions, has been established by the Member States and WHO. It has carried out the following activities.

- A training of trainers on antimicrobial stewardship was conducted in March 2020 at the Christian Medical College in Vellore, India. A total of 13 regional consultants participated in the training. Two webinars were facilitated in May and June 2020 on AMS soon after the outbreak of the COVID-19 pandemic.

Table 5: Three-year antimicrobial consumption trends in Maldives

Maldives 2017–2019 antimicrobial consumption analysis	
⊙ **Total national DIDs consumed:** Total national antimicrobial consumption, i.e. DDDs/1000 inhabitants/day (DID) for three years was: 29.48; 25.46; and 16.14. It is a good sign that from 2017 to 2019 the total consumption of antimicrobials has drastically decreased (Fig. 1).	Total national DID consumed over three years in Maldives 
⊙ Relative contribution of the access group of antibiotics in these three years has been 23.2%; 35.7% and 43.3% (Fig. 5). Over the three years consumption of the access group is increasing but it is far from the targeted value of at least 60% as recommended by WHO. One antibiotic (linezolid) from the reserve category was consumed in 2017 and 2019.	
 	

Note J01CR02-amixicillin+beta-lactamase inhibitor, J01DC02-cefuroxime, J01DD08-cefixime, J05AB01-aciclovir, J01FA10-azithromycin, J01AA02-doxycycline, J01CR05-piperacillin+beta-lactamase inhibitor, J01DH02-meropenem.

- A virtual series of webinars was conducted in May and June 2020 on antimicrobial stewardship during COVID-19. A total of 651 participants from the Region attended this series of webinars.

During the current COVID-19 pandemic there are potential threats that could affect antimicrobial stewardship activities and drive antimicrobial resistance. For instance, many individuals presenting with mild disease without pneumonia or moderate disease with pneumonia receive antibiotics. A review of studies published on hospitalized COVID-19 patients identified that while 72% of patients received antibiotics, only 8% demonstrated superimposed bacterial or fungal coinfections. WHO has also reports that azithromycin is being widely used with hydroxychloroquine although it is not yet recommended outside of COVID-19 clinical trials.

AMS and COVID-19

- Antimicrobial stewardship activities should be integrated into the pandemic response across the broader health system through five measures:
  - (4) Increase clinical competence among health workers to manage COVID-19.
  - (5) Ensure the continuity of essential health services and regular supply of quality assured and affordable antimicrobials.
  - (6) Reduce the turnaround time of COVID-19 testing by improving testing methods and expanding testing facilities.
  - (7) Exercise maximum caution in the use of biocides for environmental and personal disinfection.
  - (8) Address gaps in research to ensure that antimicrobial stewardship activities become an integral part of the pandemic response and beyond.

Monitoring progress

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

Regional experts from the SEA Region then met to select a sub-set for reporting in the Region. They selected:

- Eleven "core" indicators: Financial protection (2), Pricing (1), Rational Use (1), Selection (1), Availability (2), Regulation (3), and Pharmacovigilance (1).
- Two "aspirational but important" indicators, given current information systems in low- and middle-income countries (LMICs).

- One "complementary" indicator: an ABC analysis to determine the top medicines by expenditure and volume in each country as a way to determine efficiency of selection as well as to diagnose areas for pricing interventions. Experts also noted several complementary indicators that could be derived from the core indicators on financial protection.

Core and complementary indicators are presented in Table below.

Table 6: Recommended key performance indicators to monitor progress on access in the South-East Asia Region

Core indicators	Complementary indicators
Availability	
SDG 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis. SDG 3.b.1 Proportion of the target population covered by all vaccines included in their national programme.	% of medicines on the essential medicine list monitored through a tracking, traceability, or authentication system.
Financial protection	
Total expenditure on medicines, US$ per capita. Share of public and OPP spending on medicines (US$ and %).	Government expenditure on medicine as proportion of total government health expenditure. Out-of-pocket expenditure on medicines as proportion of out-of-pocket expenditure on health. Out-of-pocket expenditure on medicines as a proportion of total expenditure on medicines.
Pricing	
Median price ratio (PPP$) per basket of medicines above reference price.	
Selection and rational use	
% of public procurement based on EML. Quality of prescribing / dispensing in public and private facilities: A. % of medicines from EML, B. % prescribed as generics C. % antibiotics prescribed in Out-patient settings	Quality of prescribing / dispensing in public and private facilities: D. % injectable (optional) E. % poly-pharmacy (optional) ABC analysis (top medicines by expenditure/volume)

Core indicators	Complementary indicators
Regulation	
⊙ NRA Maturity Level according to Global Benchmarking Tool: – based on self-assessment – based on WHO-assessment – with assessment information publicly available – % of products at point of dispensing that have market authorization – % of failed tests out of total sampled and tested medicines at point of dispensing (specifying whether risk-based sampling was used): A. in total B. with results publicly available ⊙ Pharmacovigilance – Number of adverse events per million population	⊙ Pharmacovigilance – % of ADRs reported, investigated, and acted upon.

To enable routine, sustainable monitoring of the price and availability of medicines, WHO has developed the MedMon, the mobile application to monitor the price and availability of WHO-approved essential medicines and health products.

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

Users can routinely monitor medicines' access with MedMon in a sustainable, cost-effective and timely manner. In 2019, WHO further developed MedMon to include an interactive data visualization and analysis platform enabling automated, real-time reporting.

The tool has been piloted in 25 countries in four regions. Member States, such as Bangladesh, Bhutan, Nepal, Sri Lanka, and others will be using it as a way of integrating regular monitoring mechanisms to generate data on availability and affordability of a basket of tracer medicines.

The way forward

Member States can allocate resources more effectively through evidence-based decisions to ensure that essential health products, depending on a country's disease burden, are included in its essential medicines list, essential diagnostics list or reimbursement list, and through more efficient procurement and supply processes, and rational use of medicines. Support for fair pricing and policy implementation to reduce OOP expenditure will be important.

The need for good governance is increasingly recognized as a key step on the road to achieving UHC. Weak governance complicates access to health products by fuelling inefficiency, distorting competitive mechanisms, and leaving the system vulnerable to undue influence and abuse. The relationship between governments and the private sector, such as pharmaceutical companies and medical device companies, requires attention. A question of growing importance is how to support governments to collaborate effectively with the private sector and develop public policies while avoiding the risks of undue influence and maximizing public benefits.

To make accurate and useful decisions to improve access to essential medical products, there is the need for timely and accurate data and information on access to medicines in the country. This may cover the gamut of national expenditures on health products; the procurement of health products, supply chains and distribution; health insurance coverage; prescription prices of health products; and the availability of medicines, vaccines and other health products in health facilities.

Monitoring access to health products is a complex endeavour that requires gathering information from multiple sources and ensuring the interoperability of various data collection systems. More complete and timely data on access to medicines will better enable countries to identify access disparities between population groups and understand the effects of interventions across their medicine supply and distribution chains.

Ensuring appropriate use of medicines is part of ensuring access. Medicines, diagnostics and devices need to be used correctly and rationally to be effective and efficient. Clinical guidelines and essential lists for medicines and for other medical products can help. It is encouraging to see the increasing development of national essential diagnostics lists. However, adherence to guidelines by health professionals is still irregular, and an area worthy of more attention for which the strengthening of pharmacovigilance and post-marketing surveillance is required.

There is a need for effective implementation of the Initiative for Coordinated Antidotes Procurement in the South-East Asia Region and for robust collaboration between key stakeholders and participating countries. The systematic approach to procuring and managing the supply and distribution of quality-assured antidotes and assuring their appropriate use can be used to build further procurement collaboration of essential medical products.

To build resilient supply chains, especially during a global pandemic, efforts are needed to reduce risks and ensure supply security by reducing dependency, increasing domestic production, diversifying the supply base, and financing and securing sufficient

safety stockpiles. Health systems need to establish mechanisms to define shortages and monitor and trace stocks in real time and anticipate any surge in demand and potential shortages early. Partnership with the private sector and regulatory system strengthening are needed for technology transfer and consequent enhanced local production of high-priority medical products while ensuring their quality, safety and efficacy.

Initiatives such as the COVID-19 Technology Access Pool (C-TAP) can be very useful. Such initiatives aim to provide a global one-stop shop for developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge and data with quality-assured manufacturers.

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PART 3
Country profiles

Bangladesh medical products profile 2021

COUNTRY AT A GLANCE

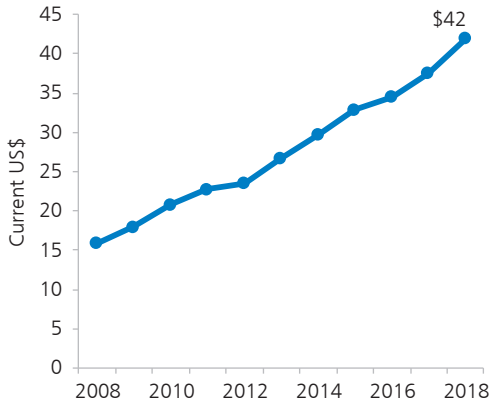
164 689
Population (in 000s)[1]

74.3
Life expectancy at birth (in years)[2]

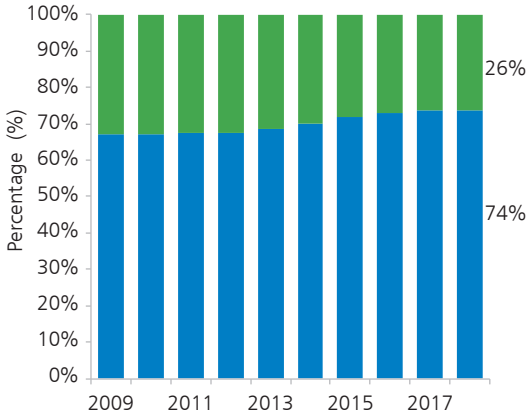
1855.7
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

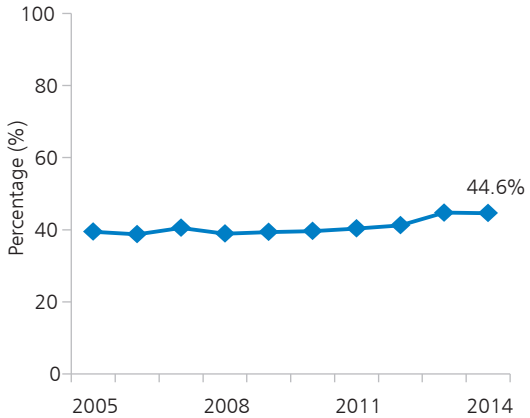


Share of government vs out-of-pocket spending on health[4]



SPENDING ON MEDICINES

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



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

No data available

MEDICAL AND PHARMACY WORKFORCE

6.4
Medical doctors/10 000 population[6A]

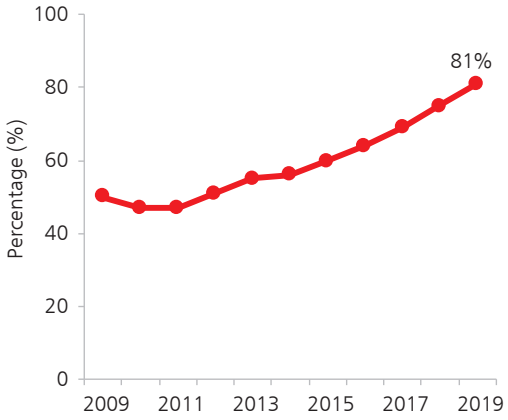
1.8
Pharmacists/10 000 population[6A]

Yes
Pharmacy education accreditation[6B]

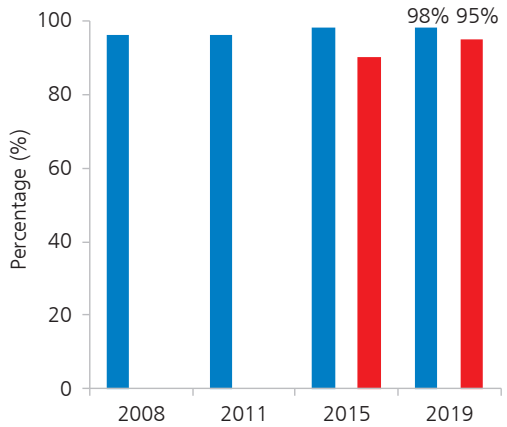
No
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

Tuberculosis treatment coverage[7]

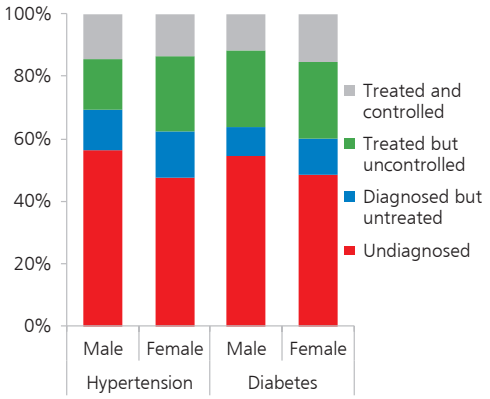


Diphtheria-tetanus-pertussis (DTP3), hepatitis B BD and MCV2 immunization coverage[8]



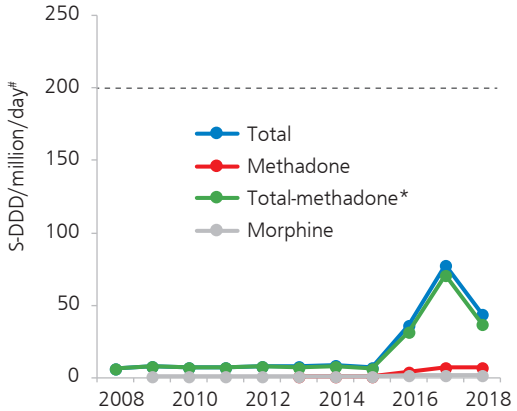
No data available for Hepatitis B BD immunization coverage

Gaps in diagnosis and management of hypertension and diabetes[9]



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

Levels of consumption of narcotic drugs[10]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[5]	National Medicine Policy[5]	National Essential Medicines List[5]	National Standard Treatment Guidelines[5]
Drug Control Ordinance Amendment Act 2006	National Drug Policy 2016	Essential Drug List 2016	Individual guidelines exist

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[11]	Least developed country status since[12]	Member of World Trade Organization since[13]	TRIPS flexibilities used[14]
864 pharmaceutical manufacturers including 266 allopathic & around 500 manufacturers of T&CM medicine products: 261 Unani, 161 ayurvedic and 76 homeopathic, and around 100 or more street vendors or smaller-scale producers	1975	1995	Not applicable until graduation from least developed country status

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[5]: Directorate-General of Drug Administration (DGDA) www.dgda.gov.bd

Regulated products[5]:
Medicines: YES **Vaccines** YES **Medical devices:** YES **Traditional medicines:** YES

Medicine quality control laboratory[5]: National Control Laboratory, Dhaka and Central Drug Testing Laboratory, Chittagong

ISO 17025 certified[15]: YES **WHO prequalified[16]:** YES

Number of registered medicines[5]: Total 39 844, allopathic – 27 624, ayurvedic – 3877, unani – 5624, herbal – 406, homeopathic & biochemical – 2313

Medicine selection

Agency responsible for selection[5]: Directorate-General of Drug Administration

Number of products on essential medicines list:
By active ingredient[5]: 285 allopathic drugs **By dosage form[5]:** Not available

Traditional medicines products included in essential medicines list[11]: NO

Medicines availability is indicated by health facility level[17]: NO

National formulary[5]: Bangladesh National Formulary (BDNF) 2015

Medicine procurement

Public sector

Agency responsible for public procurement[5]: Central Medical Stores Depot (CMSD)

Procurement done at Central[5]: ☑ **State:** ☐ **Facility[5]:** ☑
(local procurement for district facilities and hospitals)

Commonly used procurement methods[5]: National/ International bidding

Private sector

Number of wholesalers[5]: 1005

Pricing and reimbursement

Public sector

Price control[5]: YES

Agency responsible for price control[5]: DGDA

Patient prices for essential medicines in public sector:
Free medicines[5]: YES

Private sector

Agency responsible for price control[5]: Price Fixation Committee for 117 primary health care medicines.

Pricing mechanism[5]:

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

Distribution

Public sector

Agency responsible for distribution[22]: Essential Drug Company Limited and CMSD

Public sector facilities[5]:

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

Private sector

Number of retail outlets[5]: 123 800

Licensed retail pharmacies per 10 000 population[5]: 7.7

Number of traditional medicines outlets[5]: 353 Ayurvedic retail outlets, 616 unani outlets, 10 herbal outlets & 2056 homeopathic outlets

Patient

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Bhutan medical products profile 2021

COUNTRY AT A GLANCE

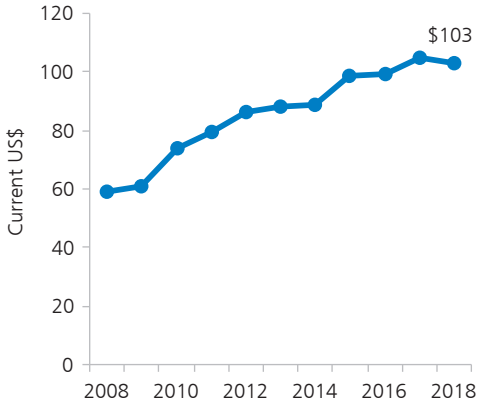
772
Population (in 000s)[1]

73.1
Life expectancy at birth (in years)[2]

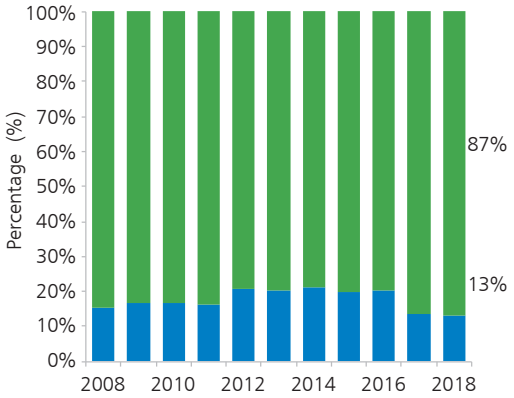
3316.2
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

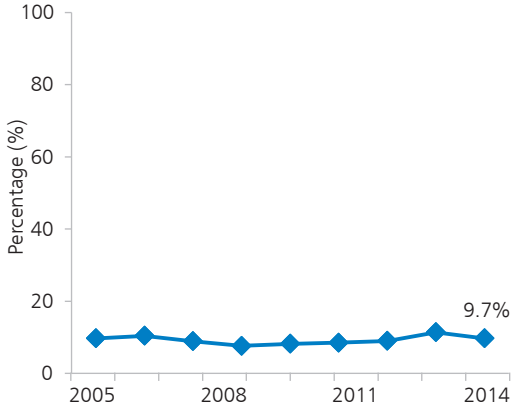


Share of government vs out-of-pocket spending on health[4]



SPENDING ON MEDICINES

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



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

MEDICAL AND PHARMACY WORKFORCE

4.6
Medical doctors/10 000 population[6A]

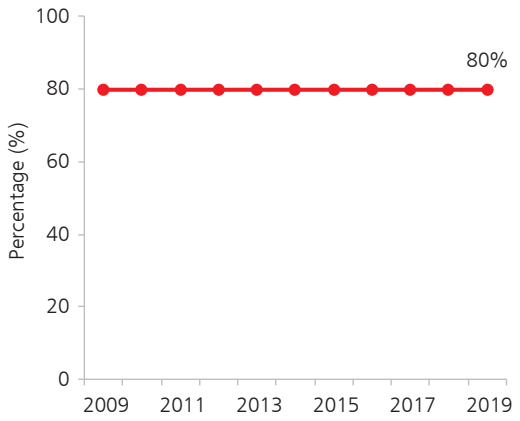
0.6
Pharmacists/10 000 population[6A]

Partly
Pharmacy education accreditation[6B]

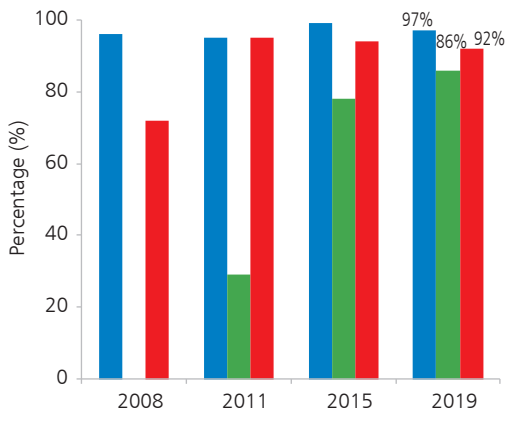
Yes
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

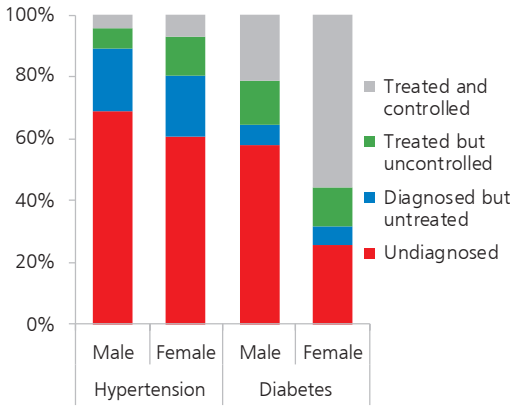
Tuberculosis treatment coverage[7]



Diphtheria-tetanus-pertussis (DTP3) and Hepatitis B BD and MCV2 immunization coverage[8]

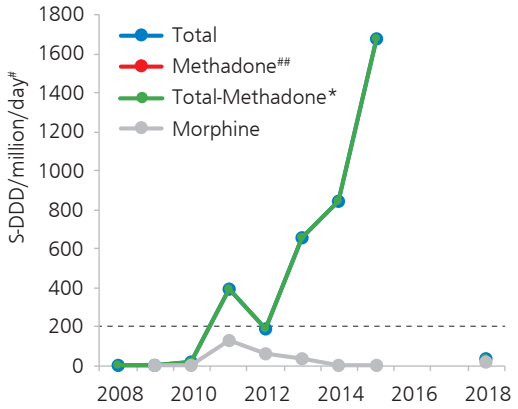


Gaps in diagnosis and management of hypertension and diabetes[9]



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

Levels of consumption of narcotic drugs[10]



#S-DDD; Statistical defined daily dose/million/day; *Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency; ##Data for Methadone consumption not available

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[11]	National Medicine Policy[12]	National Essential Medicine List[13]	National Standard Treatment Guidelines[5]
1. Medicines Act of the Kingdom of Bhutan, 2003 2. Bhutan Medicines Rules and Regulations, 2012 3. Blood and Blood Products Regulation, 2016	National Medicine Policy 2007	National Essential Medicine List 2018	National Standard Treatment Guidelines 2014, distributed to all district facilities

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[14,b]	Least developed country status since[15,c]	Member of World Trade Organization since[16]	TRIPS flexibilities used[17]
7	1971	No	Not applicable

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[d]: Drug Regulatory Authority of Bhutan www.dra.gov.bt

Regulated products[18]:

Medicines: YES **Vaccines** YES **Medical devices[e]:** NO **Traditional medicines[f]:** YES

Medicine quality control laboratory[19]: 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[20]:** NO

Number of registered medicines[21,22]: Total 1875, Human allopathic – 1473 & Herbal Medicines – 218 (till 2018), Veterinary allopathic medicines – 184

Medicine selection

Agency responsible for selection[5]: Essential Medicines & Technology Division, Department of Medical Services, Ministry of Health

Number of products on essential medicines list[13]:

By active ingredient: 341 **By dosage form:** 437

Traditional medicines products included in essential medicines list[g]: YES

Medicines availability is indicated by health facility level: YES

National formulary[23]: Bhutan National Formulary (BNF) 2019

Number of products in national formulary[23]: 437

Medicine procurement

Public sector

Agency responsible for public procurement[24]: Medical Supplies Procurement Division under Department of Medical Supplies and Health Infrastructure (DMSHI), Ministry of Health

Procurement done at Central[12,h] ☑ **State** ☐ **Facility** ☐

Commonly used procurement methods[5]: International tendering

Private sector

Number of wholesalers[25]: 31

Pricing and reimbursement

Public sector

Price control[5]: NO

Health insurance reimbursement price[5]: No health insurance scheme

Patient prices for essential medicines in public sector:

Free medicines[5]: YES

Private sector

Agency responsible for price control[18]: Drug Regulatory Authority

Pricing mechanism[5]: Price structure to be submitted at the time of registration of product

Manufacturer ☐ **Wholesale** ☐ **Retailer[5]** ☑

Mark-ups regulated[5]: YES

Fixed or regressive[5]: Fixed maximum retail price (MRP), which is the same MRP as in India

Distribution

Public sector

Agency responsible for distribution[26]: Medical stores and distribution division under Department of Medical Supplies & Health Infrastructure

Public sector facilities[26,i]:

Hospitals: 49
Primary health centre #: 186
Sub-post: 53
Thromde health centre *: 3
Outreach clinics: 542
Health Information and service centre (HISC): 6

Private sector

Number of retail outlets[27]: 75

Licensed retail pharmacies per 10 000 population[27,j]: 0.93

Number of traditional medicines outlets[22]: Stand alone – 1, co-located – 78 in public health facilities

Patient

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1. United Nations, Department of Economic and Social Affairs, Population Division, World Population Prospects 2019. https://population.un.org/wpp/Download/Standard/Population/- accessed 23rd December 2020.
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3. The World Bank. World development indicators 2020. Washington DC. https://databank.worldbank.org/reports.aspx?source=world-development-indicators#- accessed 23rd December 2020.
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11. Drug Regulatory Authority, Bhutan. Bhutan: DRA. http://dra.gov.bt/dra-guidelines-and-regulations/ - accessed 10 January 2021.
12. National Drug Policy, 2007, Bhutan. http://www.moh.gov.bt/wp-content/uploads/ict-files/2021/02/National-Drug-Policy-2007.pdf- accessed 10 March 2021.
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14. Data as reported by Drug Regulatory Authority, Bhutan, February 2021.
15. United Nations, Department of Economics and Social Affairs, Development Policy and Analysis Division. LDC list. 2020. https https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf - accessed 6th January 2021.
16. World Trade Organization (WTO). Members and Observers. World Trade Organization. Geneva. 2016. https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm -accessed on 6th January 2021.
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18. Drug Regulatory Authority of Bhutan, Bhutan 2021, www.dra.gov.bt- accessed on 10th January 2021.
19. Drug Regulatory Authority, Bhutan. https://dra.gov.bt/?page_id=132- accessed 10th January 2021.
20. WHO List of Prequalified Quality Control Laboratories, 2020. https://extranet.who.int/pqweb/sites/default/files/documents/PQ_QCLabsList_28.pdf - accessed on 6th January 2021.
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22. Traditional medicine in the WHO South-East Asia Region; Review of progress 2014–2019. New Delhi: World Health Organization, Regional Office for South-East Asia; 2020. Licence: CC BY-NC-SA 3.0 IGO.- https://apps.who.int/iris/bitstream/handle/10665/340393/9789290228295-eng.pdf?sequence=1&isAllowed=y -accessed on 17th August 2021.
23. Drug Regulatory Authority, Bhutan. Bhutan: DRA. https://drive.google.com/file/d/1BSu9lngwXeO2j_SZaHtvs9azxZYQ9kwJ/view- accessed 11th January 2021.
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Notes:

a. NELM 2018 was being revised in 2020 but due to COVID-19 pandemic, the review could not be conducted.

b.
   1. Nethsel Private Limited, Pekarzhing, Phuentsholing (API manufacturer)
   2. Menjong Sorig Pharmaceuticals, Kawajangsa, Thimphu (traditional medicine manufacturer)
   3. Biological Production Unit, NCAH, DoL, MoAF, Serbithang, Thimphu (manufactures veterinary vaccine)
   4. Azista Bhutan Healthcare Limited, Motanga, Samdrupjongkhar (manufactures allopathic finished product for human use)
   5. Quality Gases Private Limited, Pasakha, Phuentsholing (medical gases manufacturer)
   6. Aha-oxy Gases Private Limited, Pasakha, Phuentsholing (Medical gases manufacturer)
   7. Medical and Industrial Gases Industry, Pelrikhatoe, Gelephu (medical gases manufacturer).

c. Latest single data; General Assembly resolution A/73/L.40/Rev.1 adopted on 13 December 2018, decided that Bhutan will graduate five years after the adoption of the resolution, i.e. on 13 December 2023.

d. Regulates both allopathic and traditional medicines.

e. The Medical Device regulation is drafted. Currently, only TTI test kits are regulated.

f. Bhutanese traditional medicine gSo-ba Rig-pa is regulated.

g. Manufactures 128 products are included in the national essential traditional medicines list.

h. As per Section 3.2 of National Drug Policy 2007.

i. # earlier referred as satellite clinic; *BHU-II- changes in accordance with Nomenclature change for health facilities (as per the notification no: MoH/DMS/HCDD/DHSP/17/2008-2023/9349 dated 13/01/2020).

j. 72 operational pharmacies spread across the country.

Democratic People's Republic of Korea medical products profile 2021

COUNTRY AT A GLANCE

25 779
Population (in 000s)[1]

72.6
Life expectancy at birth (in years)[2]

Not available
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

No data available

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

No data available

SPENDING ON MEDICINES

Spending on medicines as share of total health-care cost

No data available

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

No data available

MEDICAL AND PHARMACY WORKFORCE

36.8
Medical doctors/10 000 population[4A]

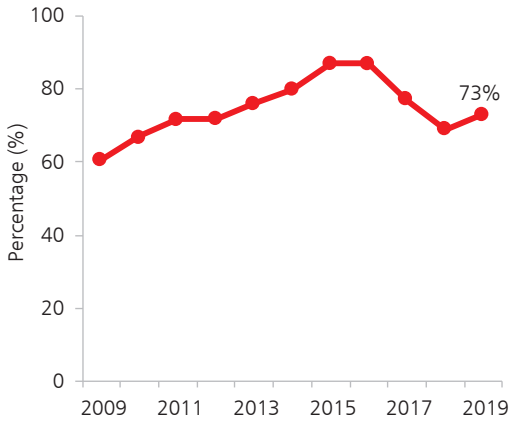
3.9
Pharmacists/10 000 population[4A]

Yes
Pharmacy education accreditation[4B]

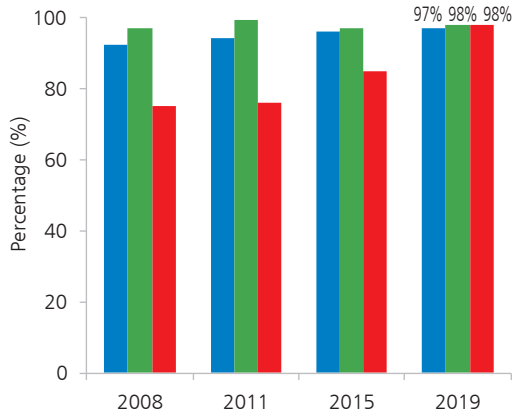
Yes
Continuing professional development for pharmacists[4B]

ACCESS TO MEDICINES

Tuberculosis treatment coverage[5]



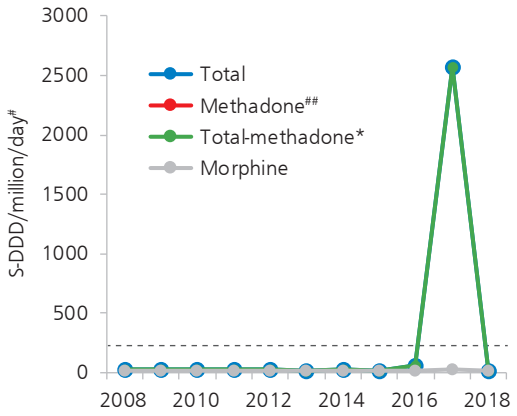
Diphtheria-tetanus-pertussis (DTP3), hepatitis B BD and MCV2 immunization coverage[6]



Gaps in diagnosis and management of hypertension and diabetes

No data available

Levels of consumption of narcotic drugs[7]



#S-DDD; Statistical defined daily dose/million/day; *Total minus methadone shows usage mainly for palliative care, because it excludes methadone treatment for drug dependency; ##Data for Methadone consumption not available

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[8]	National Medicine Policy[8]	National Essential Medicines List[8]	National Standard Treatment Guidelines[9]
National Pharmaceutical legislation(2018), 8th edition	1. National legislation, Rule & Regulation for Narcotic Control was revived on 9 November 2016 2. National legislation, Rule & Regulation for drug management was revised & adapted on 9 May 2019	National List of Essential Medicines 2019	Available

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[9,a]	Least developed country status[10]	Member of World Trade Organization since[11]	TRIPS flexibilities used [12]
210 manufactures for traditional medicinal products	No	No	Not applicable

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[9]: National Drug Regulatory Authority (NDRA)

Regulated products[9,13]:

Medicines: YES **Vaccines:** YES **Medical devices:** NA **Traditional medicines:** YES

Medicine quality control laboratory[9,13]: One central laboratory under NDRA and one per province

ISO 17025 certified[9]: NO **WHO prequalified[14]:** NO

Number of registered medicines[9,10,a]: 3000–4000, 671 traditional medicines registered as of 2010

Medicine selection

Agency responsible for selection[9,13]: National Drug Regulatory Authority (NDRA), Ministry of Public Health

Number of products on essential medicines list:

By active ingredient[9,13]: 439 **By dosage form[9,13]:** Not available

Traditional medicines products included in essential medicines list[15]: YES (28 products included)

Medicines availability is indicated by health facility level[9,13]: YES

Number of products in national formulary[9,13]: 1607 (Year 2016)

Medicine procurement

Public sector

Agency responsible for public procurement[9,13]: Medicines Management Department, Ministry of Public Health

Procurement done at[9,13] Central ☑ **State** ☐ **Facility** ☐

Commonly used procurement methods[9,13]: Local tendering and international tendering for drugs not procured domestically through UN agencies

Private sector

Number of wholesalers[9,13]: Not available

Pricing and reimbursement

Public sector

Price control[9,13]: No

Health insurance reimbursement price[9,13]: Not applicable

Patient prices for essential medicines in public sector:

Free medicines[9,13]: YES

Private sector

Agency responsible for price control[9,13]: National Price Control Committee

Pricing mechanism[9,13]: Method unknown.

Manufacturer ☐ **Wholesale** ☐ **Retailer** ☐

Mark-ups regulated[9,13]: Method unknown

Fixed or regressive[9,13]: Method unknown

Distribution

Public sector

Agency responsible for distribution[9,13]: Central medicines warehouse, Medicines management department

Public sector facilities[9,13]:

Hospitals: 1708

Primary health care units: 6263

Ri clinics/hospitals per village: 1–2

Private sector

Number of retail outlets[9,13]: 260 government owned people's drug stores available in Pyongyang city

Licensed retail pharmacies per 10 000 population[9,13]: Not available

Number of traditional medicines outlets[15]: Stand alone – 21, co-located – 8004 in all public health facilities

Patient

References

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2. World Health Organization. Global Health Observatory (GHO) data: life expectancy. Geneva. https://www.who.int/data/gho/data/indicators/indicator-details/GHO/ life-expectancy-at-birth-(years) -accessed 23rd December 2020.
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4. A. Global Health Observatory data repository. https://apps.who.int/gho/data/view.main.UHCHRHv- accessed on 1st July 2021.
   B. World Health Organization. Regional Office for South-East Asia. (2020). Decade for health workforce strengthening in SEAR 2015-2024, mid-term review. World Health Organization. Regional Office for South-East Asia. https://apps.who.int/iris/handle/10665/334226. License: CC BY-NC-SA 3.0 IGO - accessed on 6th February 2021.
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Notes:

a. Information reviewed by Ministry of Public Health. Democratic People's Republic of Korea, March 2021.

India medical products profile 2021

COUNTRY AT A GLANCE

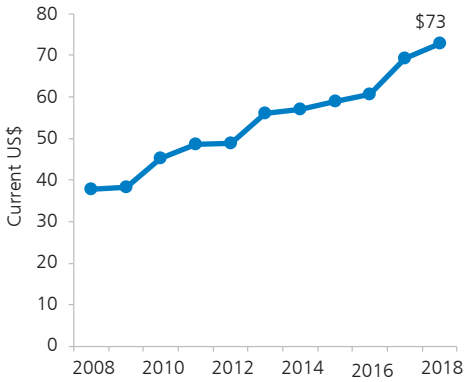
1 380 004
Population (in 000s)[1]

70.8
Life expectancy at birth (in years)[2]

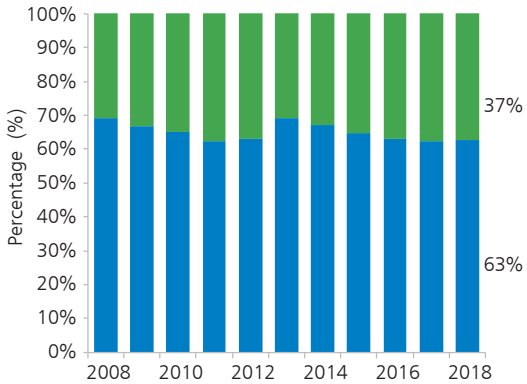
2099.6
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

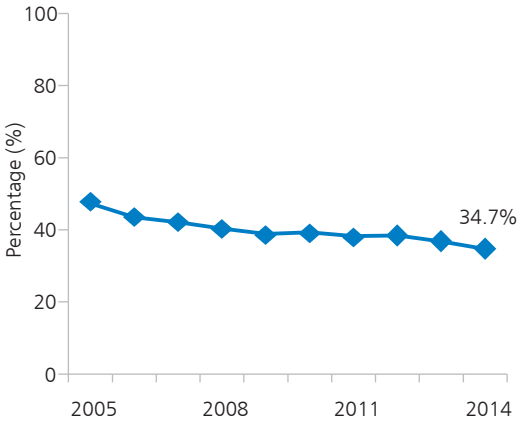


Share of government vs out-of-pocket spending on health[4]

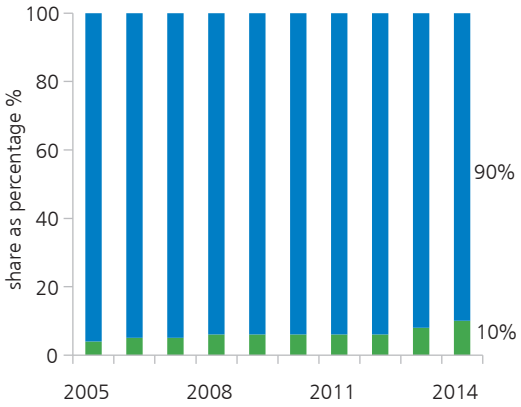


SPENDING ON MEDICINES

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



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



MEDICAL AND PHARMACY WORKFORCE

9.3
Medical doctors/10 000 population[6A]

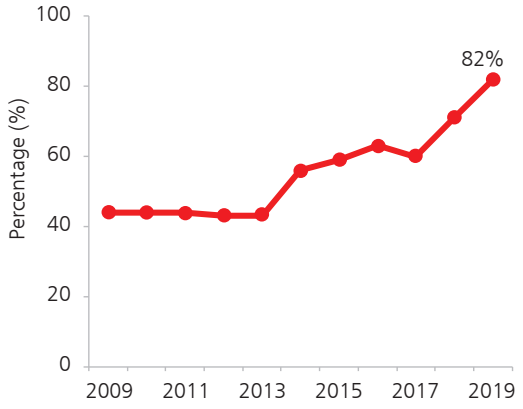
8.8
Pharmacists/10 000 population[6A]

Yes
Pharmacy education accreditation[6B]

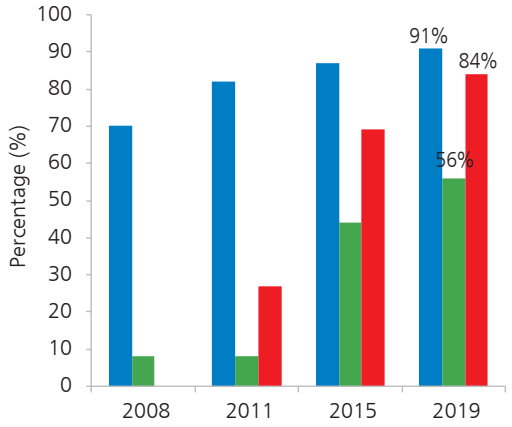
Partly
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

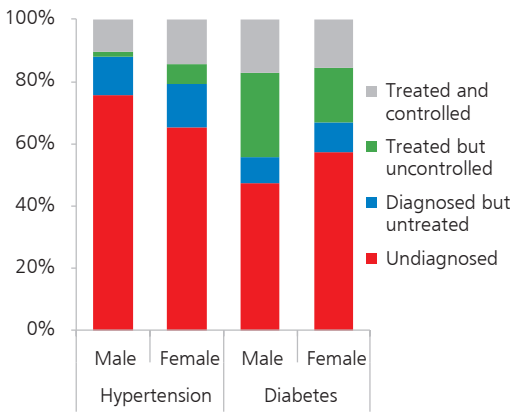
Tuberculosis treatment coverage[7]



Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[8]

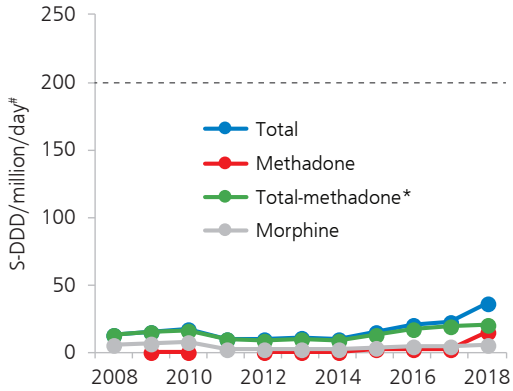


Gaps in diagnosis and management of hypertension and diabetes[9]



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

Levels of consumption of narcotic drugs[10]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[11]	National Medicine Policy[12,13,14]	National Essential Medicines List[15]	National Standard Treatment Guidelines[16,17,18]
Drugs and Cosmetics Act, 1940 and Rules 1945 as amended up to 31 December 2016	1. Pharmaceutical Policy 2002 2. National Vacine Policy 2011 3. National Pharmaceuticals Pricing Policy 2012	National List of Essential Medicines (NLEM) 2015	Both individual disease and state-level standard treatment guidelines exist

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[5,19]	Least developed country status[20]	Member of World Trade Organization since[21]	TRIPS flexibilities used[22]
4900 for formulations, 1500 for active pharmaceutical ingredient, 30 for vaccines, 350 for medical devices and 2800 for surgical dressings, blood banks and disinfectants, 8667 for traditional and complementary medicine (7439 for Ayurvedic, 585 for Unani, 235 for Siddha, 408 for homeopathy (till 2017)	No	1995	Yes

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[23]: Central Drugs Standard Control Organization (CDSCO) www.cdsco.nic.in

Regulated products[23]:

Medicines: YES **Vaccines** YES **Medical devices:** YES **Traditional medicines[24]:** YES

Medicine quality control laboratory[26,27,a,b]: Total 8: 1- Indian Pharmacopoiea Commission (IPC) Ghaziabad; 5-central drug testing laboratories and 2-regional drug testing laboratories

ISO 17025 certified[28,c]: YES **WHO prequalified[29]:** YES (IPC, Ghaziabad)

Number of registered medicines[30]: Traditional medicines – 985 Ayurveda, 1229 Unani and 399 Siddha formulations (as of 2017)

Medicine selection

Agency responsible for selection[31]: Core Committee on National List of Essential Medicines, Ministry of Health & Family Welfare

Number of products on essential medicines list[31,d]:

By active ingredient: 376 **By dosage form:** Approximately 1000

Traditional medicines products included in essential medicines list[32,e]: YES

Medicines availability is indicated by health facility level[5]: YES

Number of products in national formulary[5,33]: National Formulary 2016, Products – 521

Medicine procurement

Public sector

Agency responsible for public procurement[34]: Ministry of Health and Family Welfare (Central Medical Services Society)

Procurement done at Central[5] ☑ **State** ☑ **Facility** ☑

Commonly used procurement methods[5]: Competitive tendering (Two bid system)

Private sector

Number of wholesalers[5]: Not available

Pricing and reimbursement

Public sector

Price control[5]: YES

Agency responsible[35]: National Pharmaceutical Pricing Authority

Price mechanism[34,37]: Lowest procurement price considered

Patient prices for essential medicines in public sector:

Free medicines[38]: YES

Fixed price[39,40]: YES (Jan Aushadhi Scheme)

Private sector

Agency responsible for price control[35]: National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers

Pricing mechanism: Market based pricing[41]

Manufacturer ☑ **Wholesale** ☑ **Retailer[f]** ☑

Mark-ups regulated: YES

Fixed or regressive[42,g]: Fixed. Ceiling of drug prices based upon Market Based Pricing (MBP)

Distribution

Public sector

Agency responsible for distribution[34,36]: Centralized/decentralized at central/state or local government level

Public sector facilities[5]:

Total hospitals: 210 998
District hospitals: 1251
Sub-district hospitals: 2724
Community health centres: 1146
Primary health centres (PHCs): 31 824
Sub centres: 164 053

Private sector

Number of retail outlets[5]: 800 000

Licensed retail pharmacies per 10 000 population[5]: Not available

Number of traditional medicines outlets[43]: 3628 AYUSH hospitals, 550 AYUSH teaching hospitals, 26 405 PHCs with AYUSH dispensaries

Patient

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Notes:

a. 5 Central drug testing labs are CDL, Kolkata; CDTL, Chennai; CDTL-Hyderabad; CDTL, Mumbai; CDL, Kasauli; 2 Regional drug testing labs are RDTL, Guwahati & RDTL, Chandigarh.

b. Indian Pharmacopoiea Commission (IPC), Ghaziabad.

c. Total 3422 labs accredited as of 31st March 2020.

d. By self-calculating all the strengths listed.

e. Four separate lists of EMs published by Ministry of AYUSH, namely,
   i. Essential Drugs List- Ayurveda-https://namayush.gov.in/sites/all/themes/webcms/images/essential_drugs/Ayurveda_EDL_list_final.pdf (200 medicines).
   ii. Essential Drugs List-Siddha Medicine- https://namayush.gov.in/sites/all/themes/webcms/images/essential_drugs/Essential_Drug_List_Siddha.pdf (200 medicines).
   iii. Essential Drugs List- Homoepathy- https://namayush.gov.in/sites/all/themes/webcms/images/essential_drugs/FINAL_Homoeopathy_EDL_list_final.pdf (200 medicines).
   iv. Essential Drugs List-Unani Medicine- https://namayush.gov.in/sites/all/themes/webcms/images/essential_drugs/Unani_EDL_list_final.pdf (200 medicines). Of this list few overlaps observed in NLEM with List of Homeopathy Medicines.

f. P(c) = P(s).(1+M/100), where P(s) = Average Price to Retailer for the same strength and dosage of the medicine ; M = % Mar gin to retailer and its value =16.

g. Document states that 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 medical products profile 2021

COUNTRY AT A GLANCE

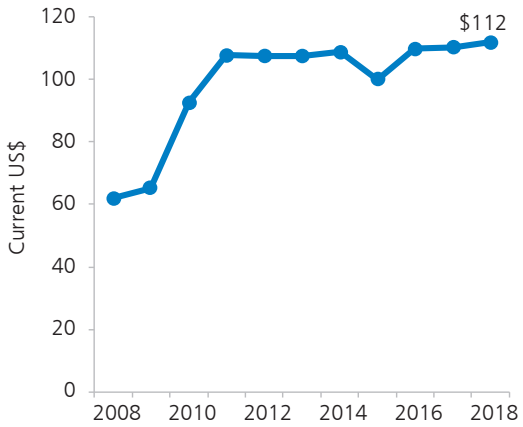
273 524
Population (in 000s)[1]

71.3
Life expectancy at birth (in years)[2]

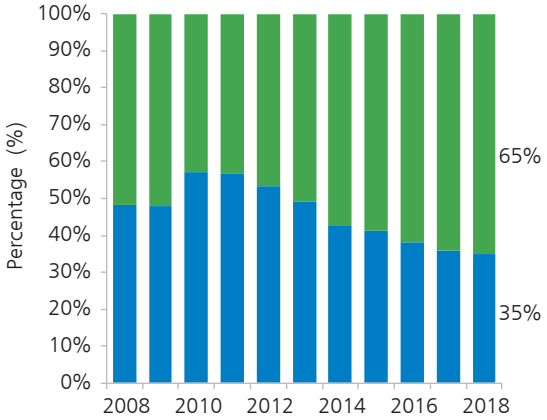
4135.5
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

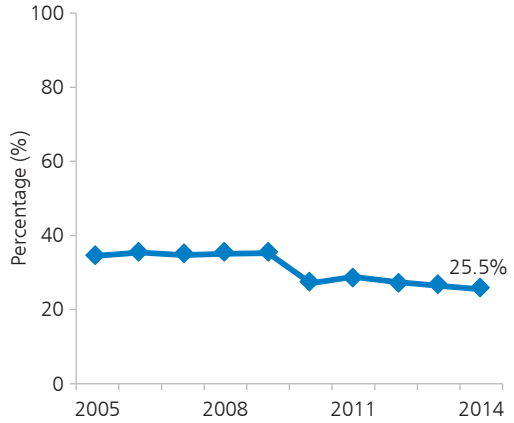


Share of government vs out-of-pocket spending on health[4]

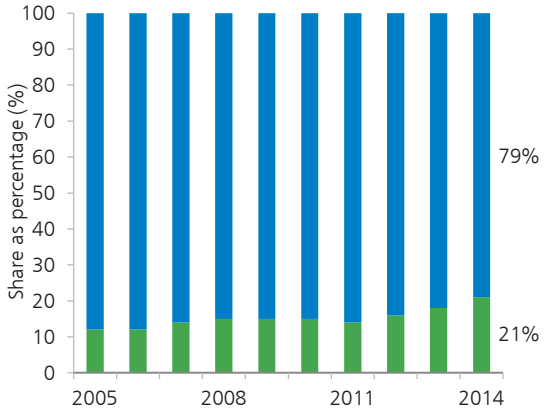


SPENDING ON MEDICINES

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



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



MEDICAL AND PHARMACY WORKFORCE

4.7
Medical doctors/10 000 population[6A]

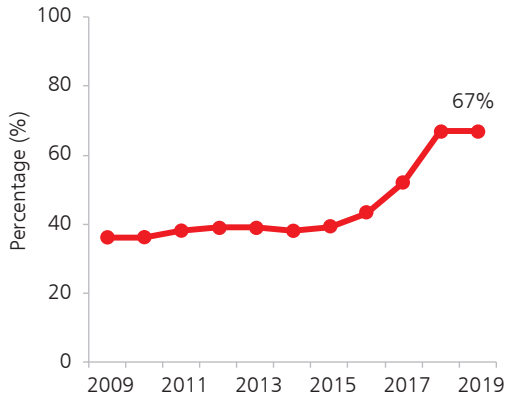
0.8
Pharmacists/10 000 population[6A]

Partly
Pharmacy education accreditation[6B]

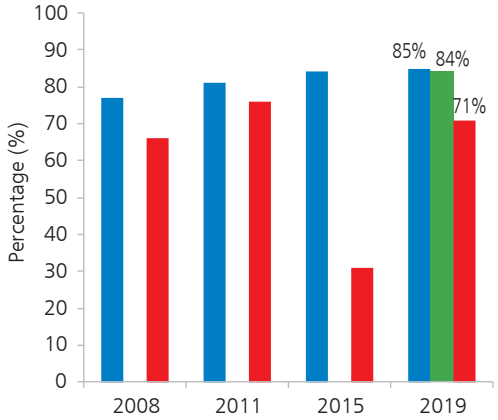
Partly
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

Tuberculosis treatment coverage[7]



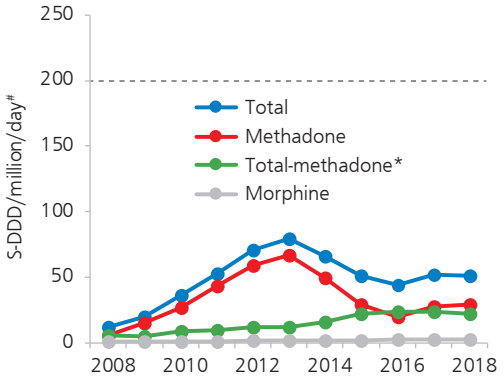
Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[8]



Gaps in diagnosis and management of hypertension and diabetes

Updated data not available

Levels of consumption of narcotic drugs[9]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[5]	National Medicine Policy[5]	National Essential Medicines List[10,a]	National Standard Treatment Guidelines[10]
Law on registration of medicines 2008	National Medicine Policy 2006	National List of Essential Medicine 2019	MOH Decree 4 year 2019 – Technical Standards for Meeting the Quality of Services Policy on the Minimal Service Standards in the Filed of Health

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[11,b]	Least developed country status[12]	Member of World Trade Organization since[13]	TRIPS flexibilities used[14]
174	No	1995	Yes

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authorities[5]: National Agency for Drug and Food Control (NADFC), Republic of Indonesia (BADAN-POM)

Regulated products[15]:

Medicines: YES **Vaccines** YES **Medical devices:** YES **Traditional medicines[5]:** YES

Medicine quality control laboratory[5]: Drug Testing Laboratory of National Quality Control Laboratory

ISO 17025 certified[16,c]: YES **WHO prequalified[17,d]:** YES

Number of registered medicines[5,18]: 15 072 allopathic and 9,057 traditional medicines (till 2018)

Medicine selection

Agency responsible for selection[10]: Ministry of Health

Number of products on essential medicines list[10,e]:

By active ingredient: 386 **By dosage form:** 559

Traditional medicines products included in essential medicines list: No data available

Medicines availability is indicated by health facility level: Primary care, Referral care (hospitals)

Latest National Formulary[19]: 586

Medicine procurement

Public sector

Agency responsible for public procurement[5]: Directorate General of Pharmaceutical and Medical Devices

Procurement done at Central[20] ☑ **State** ☑ **Facility[12]** ☑

Commonly used procurement methods[20,f]: Local tendering

Private sector

Number of wholesalers[5]: 2846

Pricing and reimbursement

Public sector

Price control: YES

Price mechanism[5]: Lowest price bid accepted

Health Insureance reimbursement price[21]: Universal Health Coverage, Badan Penyelenggara Jaminan Sosial (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 ☐ **Wholesale[5]** ☑ 40% **Retailer** ☐

Mark-ups regulated[g]: YES

Fixed or regressive[5]: Generic medicines prices fixed by Ministry of Health and other medicines prices set by manufacturers

Distribution

Public sector

Agency responsible for distribution[20,h]: Directorate-General of Pharmaceutical and Medical Devices

Public sector facilities[22]:

Primary health facilities (which include puskesmas) – 9993 (till Dec 2018) comprising 3623 puskesmas with inpatient care and 6370 puskesmas without inpatient care; 8841 clinics, consisting of 924 main clinics and 7917 primary clinics; General hospitals (RSU) – 2269; Specialized hospitals (RSK) – 554; Blood Transfusion Unit (UTDs) – 421 (2017)

Private sector

Number of retail outlets[22]: Pharmacies – 28 233; Drug Stores – 10 773

Licensed retail pharmacies per 10 000 population: Not available

Number of traditional medicines outlets: Not available

Patient

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Notes:

a. Developed based on MOH decree Kepmenkes HK.01.07 / MENKES / 688/2019.

b. Around 1000 small-, medium- and large-scale manufacturers produce traditional medicine products.

c. Indonesia has received ISO 17025 accreditation since 1998.

d. The assessment was held in February 2019.

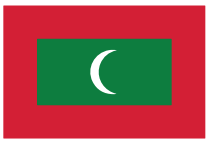
e. Estimated by self-calculation based on medicines enlisted in the National List of Essential Medicine 2019 shared by MoH, Indonesia, 2021.

f. Medicine procurement is processed electronically based on medicine e-catalogue and through transparent e-purchasing mechanism. The whole mechanism is regulated in MOH Decree no 5 year 2019 (PERATURAN MENTERI KESEHATAN REPUBLIK INDONESIA NOMOR 5 TAHUN 2019 TENTANG PERENCANAAN DAN PENGADAAN OBAT BERDASARKAN KATALOG ELEKTRONIK).

g. Mark ups regulated - Maximum Retail Price (MRP)

h. Pharmaceutical manufacturers are expected to deliver the medicine procured at national, subnational, and facility level. The supervision of procurement is carried out by Directorate General of Pharmaceutical and Medical Devices, MoH and the process of distribution should follow the Good Distribution Practice regulated by Indonesia FDA.

Maldives medical products profile 2021



COUNTRY AT A GLANCE

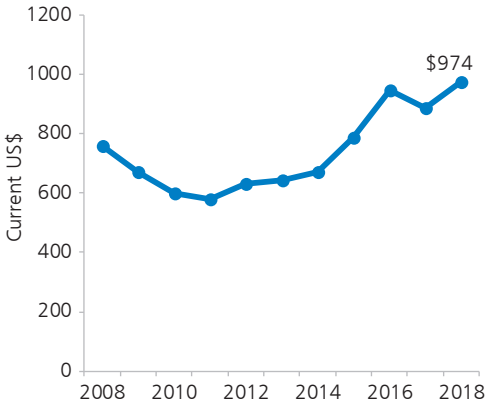
541
Population (in 000s)[1]

79.6
Life expectancy at birth (in years)[2]

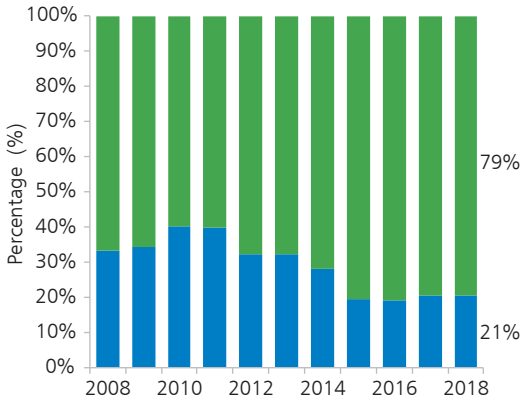
10 626.5
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

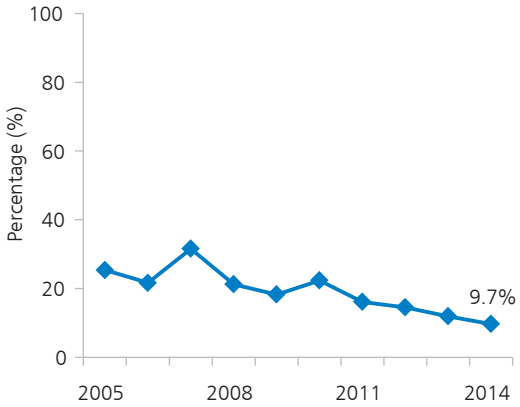


Share of government vs out-of-pocket spending on health[4]

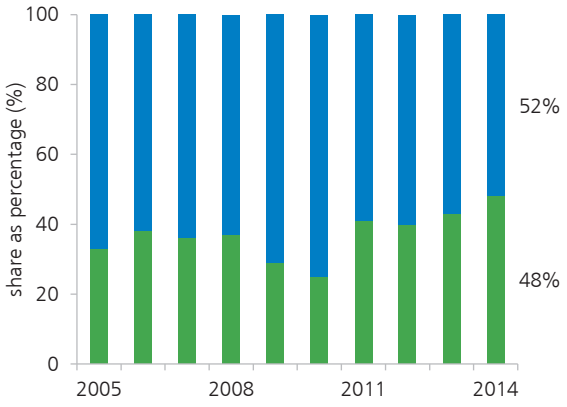


SPENDING ON MEDICINES

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



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



MEDICAL AND PHARMACY WORKFORCE

17.1
Medical doctors/10 000 population[6A,a]

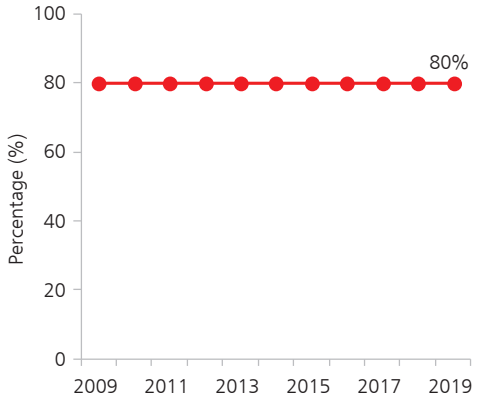
3.5
Pharmacists/10 000 population[6A,a]

Yes
Pharmacy education accreditation[6B]

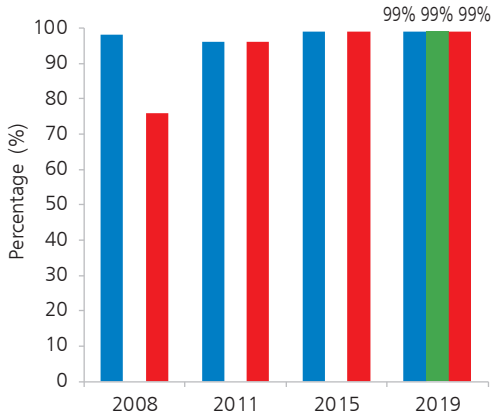
Partly
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

Tuberculosis treatment coverage[7]



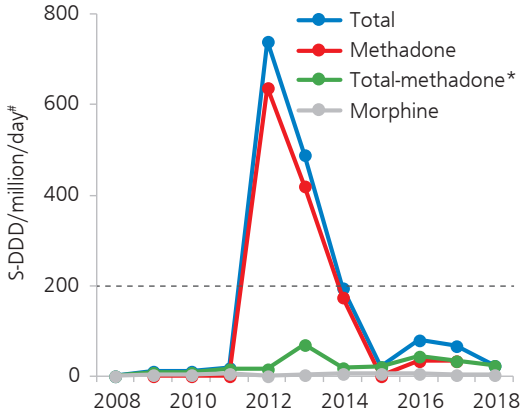
Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[8]



Gaps in diagnosis and management of hypertension and diabetes

Updated data not available

Levels of consumption of narcotic drugs[9]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[10,11]	National Medicine Policy[10,b]	National Essential Medicines List[12,c]	National Standard Treatment Guidelines[5,13]
1. Medicines Act – 1994 2. Medicine Regulation (R-46) in force since, 2015 3. Medicine Regulation Amendment (R-49/2016)	National Medicine Policy 2007	Essential Medicines List 2020	Individual disease guidelines exist

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[5]	Least developed country[14]	Member of World Trade Organization since[15]	TRIPS flexibilities used[16]
0	No	1995	Not applicable

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority: Maldives Food and Drug Authority (MFDA); http://health.gov.mv/GetDepartmentDetails/1005

Regulated products[12]:

Medicines: YES **Vaccines:** YES **Medical devices[d]:** YES **Traditional medicines:** YES

Medicine quality control laboratory[5]: National Health Laboratory.

ISO 17025 certified[17]: NO **WHO prequalified[18]:** NO

Number of registered medicines[19,20]: Total – 1473 (till June 2021) and traditional medicines – 241 (till 2018)

Medicine selection

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

Number of products on essential medicines list:

By active ingredient[21,e]: 440 **By dosage form[13,e]:** 751

Traditional medicines products included in essential medicines list: NO

Medicines availability is indicated by health facility level[21]: YES

National formulary[21,f] : No national formulary manual

Medicine procurement

Public sector

Agency responsible for public procurement[5,g]: State Trading Oganization (STO)

Procurement done at Central[5,22,h] ☐ **State** ☐ **Facility** ☑

Commonly used procurement methods[5]: Purchasing directly from manufactures and from third parties for importing medicines

Private sector

Number of wholesalers[5]: 15

Pricing and reimbursement

Public sector

Price control[10,23,i]: YES

Health insurance reimbursement price[23,j]: National social health insurance scheme (Aasandha) to provide free medical assistance to entire population

Patient prices for essential medicines in public sector:

Free medicines[24,k]: YES

Fixed price[10,l]: YES

Private sector

Agency responsible for price control[5]: MFDA and Ministry of Economic Affairs

Pricing mechanism[10,m]: YES

Manufacturer ☐ **Wholesale** ☐ **Retailer** ☐

Mark-ups regulated[10,n]: Structure finalized

Fixed or regressive[10]: Structure finalized

Distribution

Public sector

Agency responsible for distribution[5]: Health Supply Unit, Administration Division

Public sector facilities[13,o]:

Hospitals: 20
Tertiary hospital, i.e. IGMH: 1
Regional hospitals: 5
Atoll hospitals: 14
Primary healthcare centres: 169
Health posts: 30
Health centres: 139

Private sector

Number of retail outlets[10,p] : 227

Licensed retail pharmacies per 10 000 population[10]: 7

Number of traditional medicines outlets[10]: 10

Patient

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Notes:

a. 2018, single latest data available.
b. National Medicine Policy– 2007 has been reviewed in 2018.
c. Medicines are selected from the Essential medicine List and MFDA is responsible for the updation of EML. Recently list has been reviewed and it will be approved soon.
d. Medical Device Act is not finalised yet but regulating of Medical Device is one of the Mandates of MFDA. Therefore, it will be mandatory to register the Medical Devices from September 2021.
e. Based on self calculation using Essential Medicine List, 2018 as Essential Medicines List– 2020 yet not available from Ministry of Health, Maldives.
f. Approved list of registered drugs is available, but there is no national formulary manual.
g. 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.
h. STO may undertake procurement on behalf of the government & may be considered for some cases that are not hindered by the current stock shortages.
i. Maximum Retail Price Policy has been approved and a structure has been finalised and will be implemented soon.
j. Aasandha covers inpatient and outpatient treatment, including drugs and diagnostics (though subject to certain specified exclusions and conditions), within an overall cap of 100,000 MRF per person per year.
k. Health care services including medical examination, investigations, immunization, antenatal care, drugs etc. are provided free to all Maldivian citizens.
l. Will be fixed for maximum retail price.
m. Pricing being included under medicine regulation as MFDA has worked on a costing structure for MRP in consultation with stakeholders & its finalization ongoing. This will address price control mechanisms at manufacturer, wholesaler and retailer level & mark-ups will be regulated according to the costing structure.
n. MFDA is working with the Ministry of Economic Affairs to set a Maximum Retail Price (MRP) for their medicines.
o. Primary level health care in Maldives is provided through health posts, health centres and Atoll and Regional hospitals and in Male' city through a separate PHC centre (Dhamanaveshi).
p. Greatest number of retail outlets in Male'.

Myanmar medical products profile 2021

COUNTRY AT A GLANCE

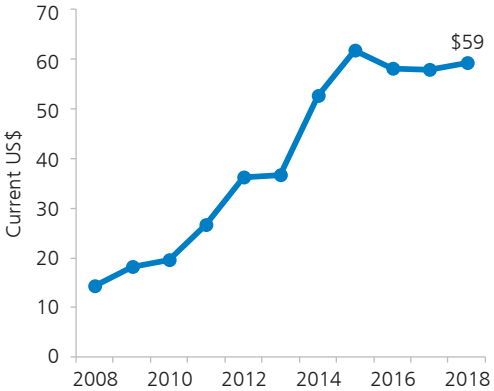
54 410
Population (in 000s)[1]

69.1
Life expectancy at birth (in years)[2]

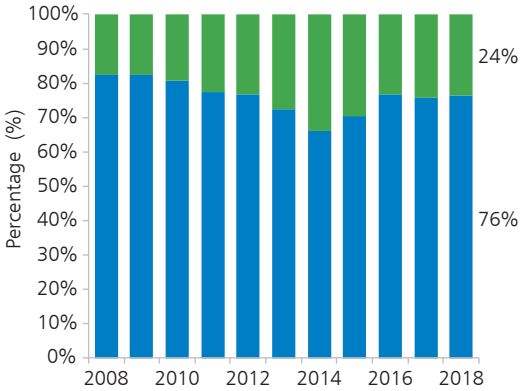
1407.8
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

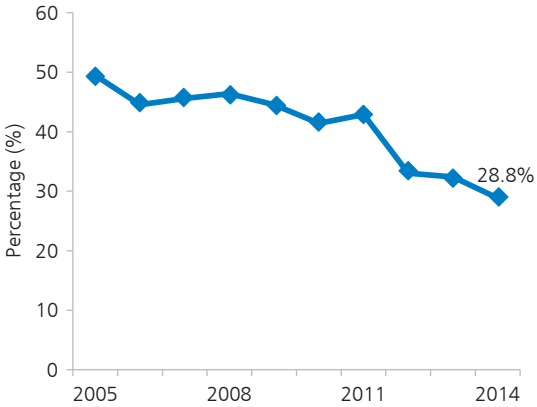


Share of government vs out-of-pocket spending on health[4]

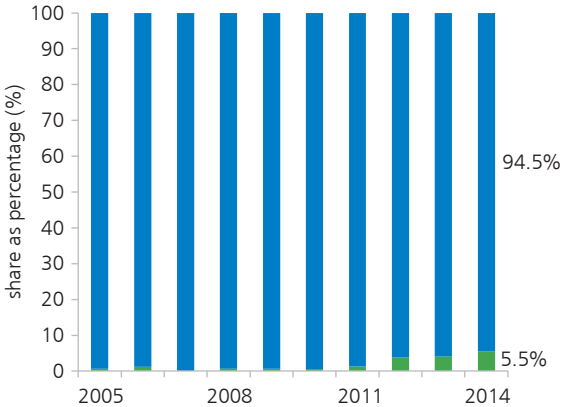


SPENDING ON MEDICINES

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



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



MEDICAL AND PHARMACY WORKFORCE

7.4
Medical doctors/10 000 population[6A]

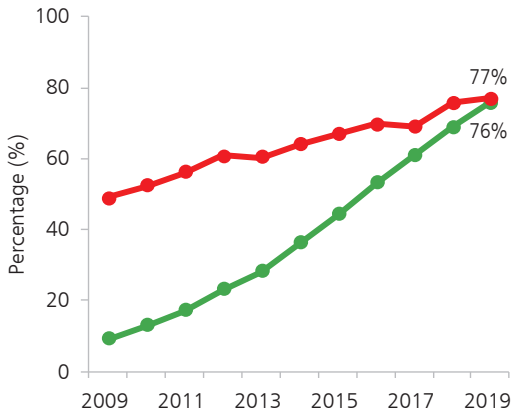
0.8
Pharmacists/10 000 population[6A]

No
Pharmacy education accreditation[6B]

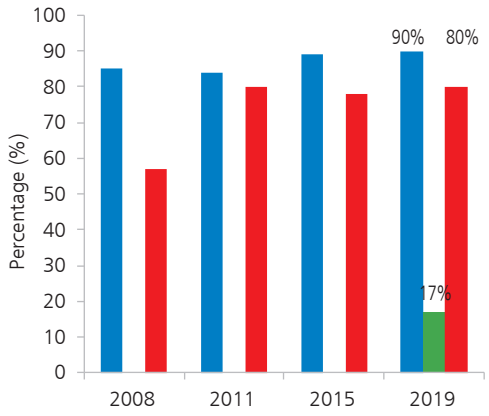
Yes
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

HIV/AIDS and tuberculosis treatment coverage[7,8]



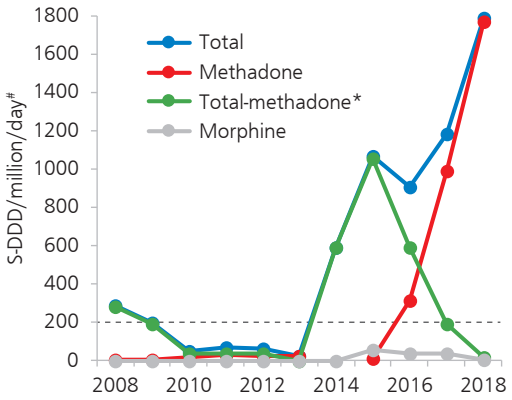
Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[9]



Gaps in diagnosis and management of hypertension and diabetes

Updated data not available

Levels of consumption of narcotic drugs[10]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[11]	National Medicine Policy[12]	National Essential Medicines List[13]	National Standard Treatment Guidelines[14]
1. National Drug Law 1992 2. Amendment to National Drug Law 2014	National Medicines Policy 2019	National List of Essential Medicines 2016	National Standard Treatment Guidelines – 2013 for primary health care providers and disease specific guidelines

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[15]	Least developed country status since[16]	Member of World Trade Organization since[17]	TRIPS flexibilities used[18]
12	1987	1995	Not applicable until graduation from least developed country status

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[19]: Department of Food and Drug Administration (DFDA) http://www.fdamyanmar.gov.mm

Regulated products:

Medicines[19]: YES **Vaccines[19]:** YES **Medical devices[19]:** YES **Traditional medicines[20,a]:** YES

Medicine quality control laboratory[21]: One main drug testing laboratory in Nay Pyi Taw and two small branch labs in Mandalay and Yangon

ISO 17025 certified[21]: YES **WHO prequalified[22]:** NO

Number of registered medicines[5,21]: 21 000 allopathic as of January 2019, there are 14 529 registered drugs in the National Traditional Medicine Formulary

Medicine selection

Agency responsible for selection[13]: Essential Drug Program, Medical Care Divison, Department of Medical Services

Number of products on essential medicines list:

By active ingredient[13,b]: 486 **By dosage form[13,b]:** 795

Traditional medicines products included in essential medicines list[20]: YES (59 products included)

Medicines availability is indicated by health facility level[13]: NO

National formulary[13,c]: Not available

Medicine procurement

Public sector

Agency responsible for public procurement[12,d]: Central Medical Supplies Department (CMSD) and some decentralized procurement

Procurement done at Central[15] ☑ **State[15]** ☑ **Facility[15,e]** ☑

Commonly used procurement methods[5]: Mainly procured from Myanmar Pharmaceutical Factory and for other products through national competitive tenders

Private sector

Number of wholesalers[5]: 170

Pricing and reimbursement

Public sector

Price control[15,f]: YES

Mechanism[5]: Lowest priced quotation is chosen

Health insurance reimbursement price[12,g]: No health insurance

Patient prices for essential medicines in public sector:

Free medicines[5]: YES

Private sector

Agency responsible for price control[5]: Myanmar Pharmaceutical and Medical Equipment & Entrepreneur Association in collaboration with Ministry of Commerce

Pricing mechanism[5]:

Manufacturer ☐ **Wholesale[h]** ☑ **Retailer[h]** ☑

Mark-ups regulated[5]: NO

Distribution

Public sector

Agency responsible for distribution[5]: Central Medical Supplies Department (CMSD) and local warehouses

Public sector facilities[24,25]:

Hospitals[i]: 1054
Primary and secondary health centres: 87
Maternal & child health centres: 348
Rural health centres:1684
Traditional medicines hospitals:16
Traditional medicine clinics: 237

Private sector

Number of retail outlets[5,j]: 10 000 outlets selling both allopathic and traditional medicines

Licensed retail pharmacies per 10 000 population[5,j]: 1.9

Patient

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Notes:

a. In Myanmar, National Food and Drug Authority(FDA) is responsible for regulating TRM manufacture and products including labeling, licensing, advertising and registration.

b. Self calculated based on the NELM 2016.

c. There is no national formulary manual but was proposed to be developed by 2020 end (not available in public domain till July 2021).

d. Decentralized procurement at hospitals with 200 beds and those managed by regional/state health authorities.

e. Hospitals with 200 beds.

f. Central Tender for price arrangement and decentralized procurement in Dept of Public Health in 2019–2020 fiscal year and central tender for price arrangement and decentralized procurement in both Dept of Public Health and Dept. of Medical Services for selected medicines in 2020–2021 fiscal year.

g. Myanmar's National Health Plan (NHP) for 2017–2021 has laid out the vision of achieving Universal Health Coverage (UHC) by 2030. In line with the Myanmar National Health Financing Strategy, the government shall provide the mechanism for social health insurance and reimbursement to cover the cost of medicines to minimize out-of-pocket expenditure (OOPE).

h. Wholesale level mark-ups (5–7%) and retailer level mark-ups (5–10%).

i. 988-under Ministry of Health and Sports; 66-under other Ministries.

j. Information reviewed by Myanmar WHO collaborating office (WCO), 2021.

Nepal medical products profile 2021

COUNTRY AT A GLANCE

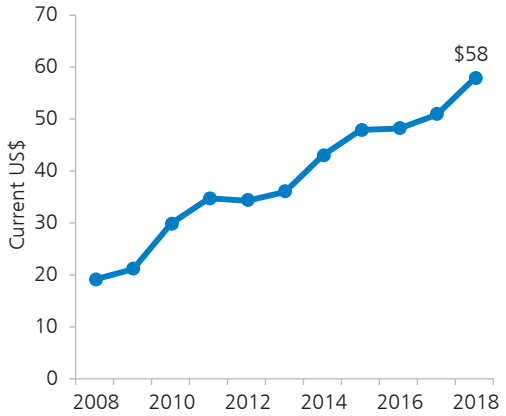
29 137
Population (in 000s)[1]

70.9
Life expectancy at birth (in years)[2]

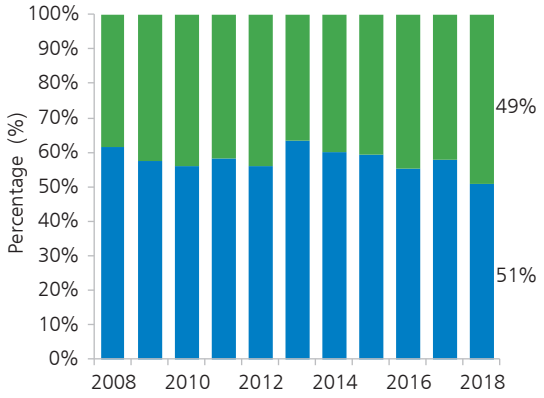
1071.1
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

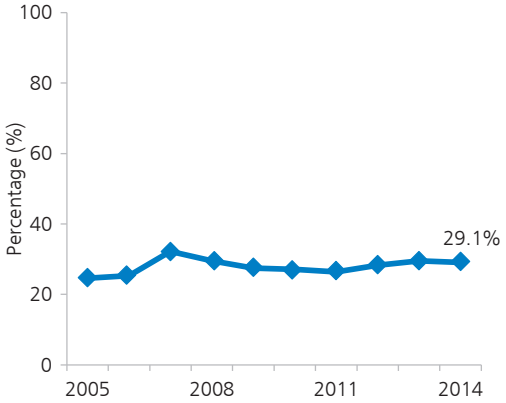


Share of government vs out-of-pocket spending on health [4]

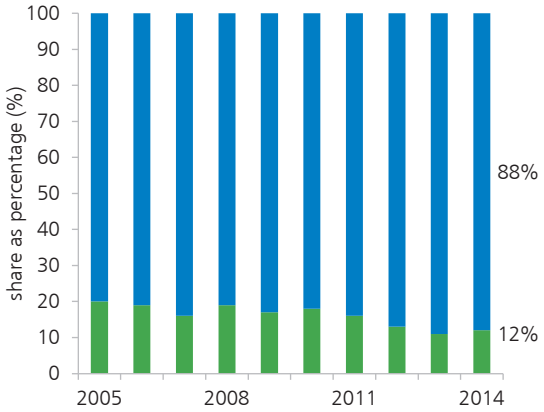


SPENDING ON MEDICINES

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



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



MEDICAL AND PHARMACY WORKFORCE

8.1
Medical doctors/10 000 population[6A]

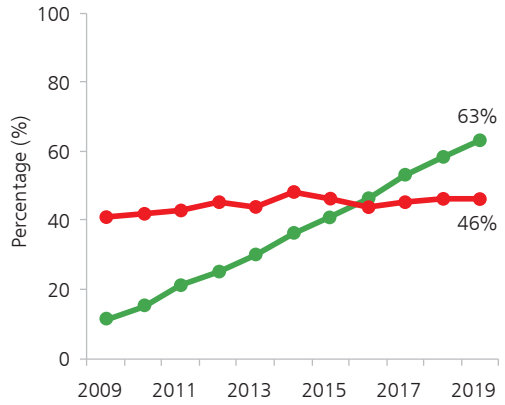
1.3
Pharmacists/10 000 population[6A]

Yes
Pharmacy education accreditation[6B]

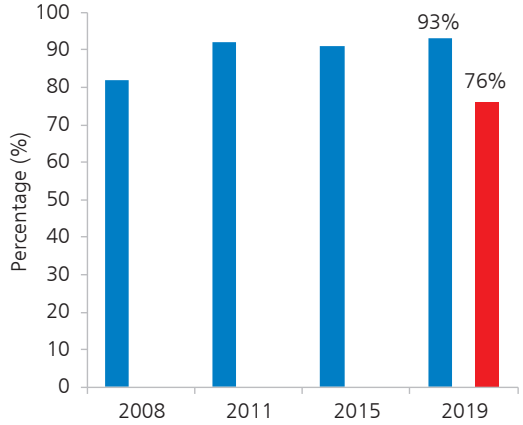
Partly
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

HIV/AIDS and tuberculosis treatment coverage[7,8]

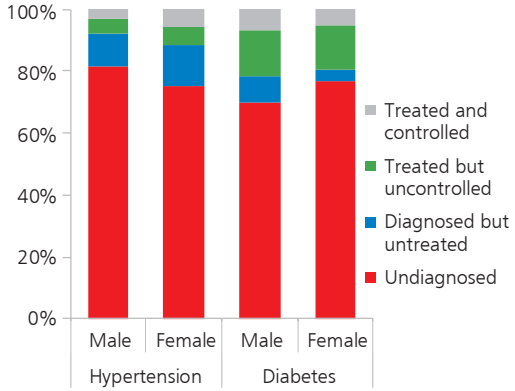


Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[9]



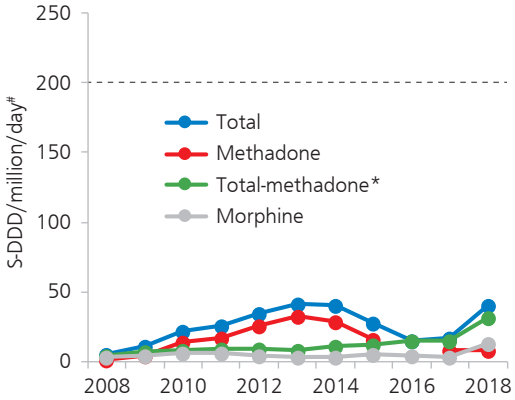
No data available for Hepatitis B BD immunization coverage

Gaps in diagnosis and management of hypertension and diabetes[10]



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

Levels of consumption of narcotic drugs[11]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[12]	National Medicine Policy[13,14]	National Essential Medicines List[15,a]	National Standard Treatment Guidelines[16,17,18,19,20]
Drugs Act, 2035 (1978)	1. National Drug Policy 1995 2. Draft National Medicine Policy 2007	National Essential Medicines List 2020	Guidelines for Primary Health system and disease specific clinical guidelines for treatment available

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[21,b]	Least developed country status since[22]	Member of World Trade Organization since[23]	TRIPS flexibilities used[24]
165	1971	2004	Not applicable until graduation from least developed country status

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[5]: Department of Drug Administration(DDA), Ministry of Health www.dda.gov.np

Regulated products:

Medicines[15]: YES **Vaccines[15]:** YES **Medical devices[15,c]:** YES **Traditional medicines[25]:** YES

Medicine quality control laboratory[26]: National Medicine Laboratory

ISO 17025 certified[27,d]: NO **WHO prequalified[28]:** NO

Number of registered medicines[26,29,e]: Total –19 106 and traditional medicines – 260 (till 2018)

Medicine selection

Agency responsible for selection[30]: Department of Drug Administration

Number of products on essential medicines list[15]:

By active ingredient: 393 **By dosage form:** 510

Traditional medicines products included in essential medicines list[29]: YES (60 products included)

Medicines availability is indicated by health facility level: NO

Latest national formulary[31]: Nepalese National Formulary 2018 (3rd Edition)

Medicine procurement

Public sector

Agency responsible for public procurement[32]: Logistic Management Division

Procurement done at Central[5] ☑ **State[5]** ☑ **Facility[5]** ☑

Commonly used procurement methods: Tendering from list of standard manufacturers identified by government

Private sector

Number of wholesalers[26,g]: 3351

Pricing and reimbursement

Public sector

Health insurance reimbursement[32,h]: Health Insurance Program (HIP) covers 46 districts in the country and 7 districts are in pipeline

Patient prices for essential medicines in public sector:

Free medicines[32,i]: YES, upto district level

Fixed price[12,j]: YES

Private sector

Agency responsible for price control[5]: DDA and Drug Pricing Monitoring Committee

Pricing mechanism[5]: To fix the maximum retail price using mean median method

Manufacturer[5] ☑ **Wholesale[5]** ☑ **Retailer[5]** ☑

(Mark up 8-10%) (Mark up 16%)

Mark-ups regulated[k]: YES

Distribution

Public sector

Agency responsible for distribution[5]: Logistics Management Division for centrally supplied drugs and District Public Health Offices (DPHOs) and hospital directors for locally purchased drugs

Public sector facilities[32]:

Hospitals: 135
Primary health centres (PHCCs): 196
Primary health care outreach clinic (PHCORC) sites: 12 532
Expanded Programme Immunization (EPI) clinics: 16 428

Private sector

Number of retail outlets[26,k]: Allopathic – 14 099

Licensed retail pharmacies per 10 000 population[26,l]: 6.9

Number of traditional medicines outlets[26,k]: 3425 (Ayurvedic: 2811, Homeopathy: 597, Unani: 17)

Patient

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Notes:

a. Approved by Drug Advisory Committee and is in process of MOHP approval.
b. Till June 2019- Allopathy- 73, Veterinary- 12, Ayurveda/Herbal- 80.
c. Health Technology Product and Medical Device Directive 2074 available, however, currently DDA is regulating Intraocular lenses only.
d. 1 Training on ISO 17025 certification done.
e. 9940 Foreign products and 9166 Domestic products.
f. Based on self calculation using National Essential Medicines List 2020.
g. Data based on Number of registered Pharmacy outlets (upto Ashar 2076 (Jul 2019 as updated on DAMS) Allopathic: 2775, Veterinary: 408; Ayurvedic: 140, Homeopathic: 25, Unani: 3.
h. It is a voluntary program based on family contributions. Family up to 5 members have to contribute NPR 3500 per year and NPR 700 per additional member and Government bears contribution for people with Poverty Identity Card and Red Card.
i. Above district level, patients must purchase drugs from private pharmacies.
j. If the Department fixes the price of any drug, a notice thereof shall be published in the Nepal Gazette (Inserted by Second amendment of the Act).
k. Nepal has fixed MRP of selected essential medicines as per the provision of Drug Act 1978, Section 26.
l. Data based on Number of registered Pharmacy outlets (upto Ashar 2076 i.e. July 2019 as updated on DAMS)
m. Data calculated as per registered pharmacy outlets including Allopathic, Veterinary, Ayurveda, homeopathy and Unani pharmacies.

Sri Lanka medical products profile 2021

COUNTRY AT A GLANCE

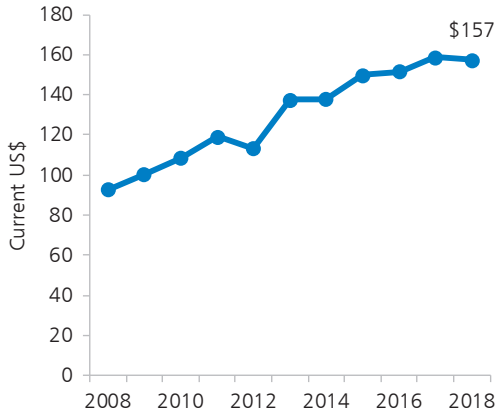
21 413
Population (in 000s)[1]

76.9
Life expectancy at birth (in years)[2]

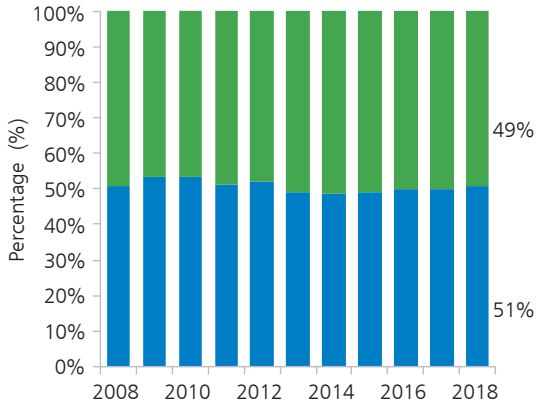
3853.1
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

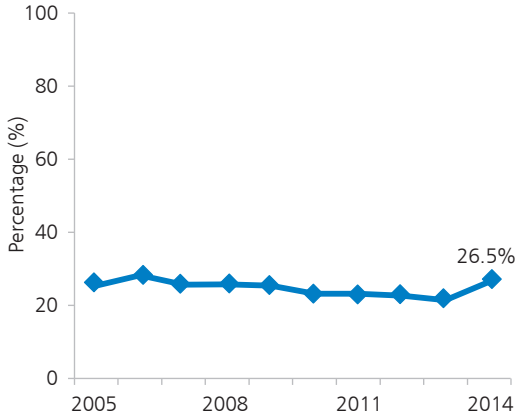


Share of government vs out-of-pocket spending on health[4]



SPENDING ON MEDICINES

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



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

No data available

MEDICAL AND PHARMACY WORKFORCE

11.5
Medical doctors/10 000 population[6A]

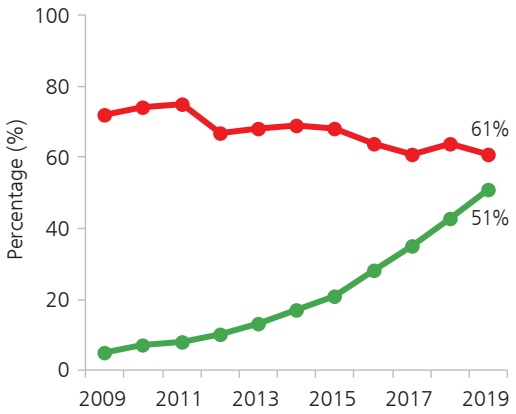
0.9
Pharmacists/10 000 population[6A]

Yes
Pharmacy education accreditation[6B]

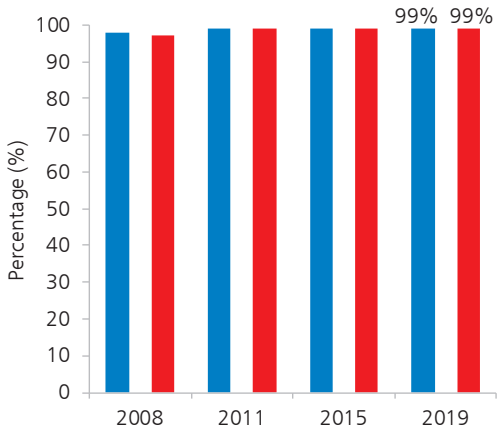
Yes
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

HIV/AIDS and tuberculosis treatment coverage[7,8]



Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[9]

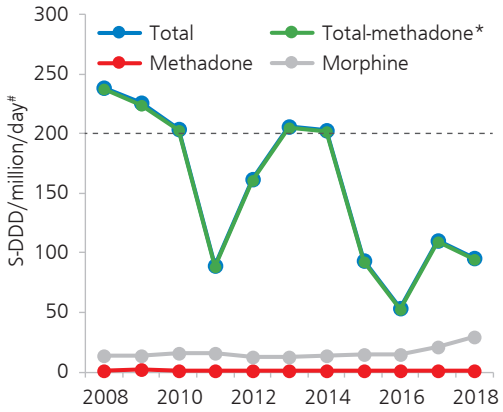


No data available for Hepatitis B BD immunization coverage

Gaps in diagnosis and management of hypertension and diabetes

Updated data not available

Levels of consumption of narcotic drugs[10]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[11]	National Medicine Policy[12]	National Essential Medicines List[13]	National Standard Treatment Guidelines[5]
National Medicines Regulatory Authority Act No. 5 of 2015	Sri Lanka National Medicines Policy 2020–2025	National List of Essential Medicines 2014	Specialist colleges and Sri Lanka Medical Association specific guidelines exist

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[14]	Least developed country status[15]	Member of World Trade Organization since[16]	TRIPS flexibilities used[17]
19	No	1995	Not applicable

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[18]: National Medicines Regulatory Authority (NMRA) http://nmra.gov.lk/

Regulated products:

Medicines[11]: YES **Vaccines[11]:** YES **Medical Devices[11]:** YES **Traditional Medicines[19,a]:** YES

Medicine quality control laboratory[20]: National Medicines Quality Assurance Laboratory (NMQAL)

ISO 17025 certified[21]: NO **WHO prequalified[22]:** NO

Number of registered medicines[12,23]: Approximately 6000 medicines in NMRA database and 960 traditional medicines (till 2018)

Medicine selection

Agency responsible for selection[5]: Medical Supplies Division, Ministry of Health, Nutrition and Indigenous Medicine

Number of products on essential medicines list:

By active ingredient[5]: 361 **By dosage form[5]:** >400

Traditional medicines products included in essential medicines list[5]: None

Medicines availability is indicated by health facility level[13]: YES

Number of products in national formulary[24]: 209

Medicine procurement

Public sector

Agency responsible for public procurement[25]: State Pharmaceutical Corporation

Procurement done at Central[5] ☑ **State** ☐ **Facility[5]** ☑

Commonly used procurement methods[26,b]: International, National Competitive Bidding; Limited/restricted International Competitive Bidding (LIB)

Private sector

Number of wholesalers[12]: 2000

Pricing and reimbursement

Public sector

Price Control[12,c]: YES

Mechanism[5]: Tenders are scheduled according to ascending prices and evaluated technically

Health insurance reimbursement Price[27,28,d]: Only available for public health sector employees

Patient prices for essential medicines in public sector:

Free Medicines[5]: YES

Private sector

Agency responsible for price control[11]: Ministry of Trade and Industry with Sri Lanka Manufacturers Association and Sri Lankan Standards Institute

Pricing mechanism:

Manufacturer[5] ☐ **Wholesale[5]** ☐ **Retailer[12,e]** ☑

Mark-ups regulated[f]: NO

Distribution

Public sector

Agency responsible for distribution[29]: Medical Supplies Division

Public sector facilities[30]:

Hospitals: 641

Central dispensaries/Primary medical care units: 515

Private sector

Number of retail outlets[12]: 4500

Licensed retail pharmacies per 10 000 population[12]: 2.04

Number of Traditional Medicines outlets[31]: 270 institutions providing TM services in the country including 62 Ayurvedic hospitals and 208 central dispensaries (2019)

Patient

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31. Traditional & Complementary medicine products information from WHO Country Collaborating Centers, March 2021 (Internal communication).

Notes:

a. The regulation "Ayurvedic code" was established in 1929 and renewed in 2012.
b. International Competitive Bidding (ICB) and National Competitive Bidding (NCB).
c. For selected medical products in accordance with Government gazette no. 2167/17 of March 20th of 2020, 2167/1 of March 16th 2020, 2123/35 May 15th 2019, 2086/37. August 31st 2018, 2049/31 of December 14th 2017, 2030/47 August 4th 2017, 2006/45 of February 17th 2017.
d. Agrahara is a mandatory social health insurance scheme providing coverage mostly for inpatient care for the public sector employees in Sri Lanka.
e. For selected medical products price controlled under an MRP regime through gazette notifications for essential and life-saving medicines.
f. Mark ups regulated with Maximum Retail Price (MRP). Price ceiling introduced for 48 essential noncommunicable diseases medicines.

Thailand medical products profile 2021

COUNTRY AT A GLANCE

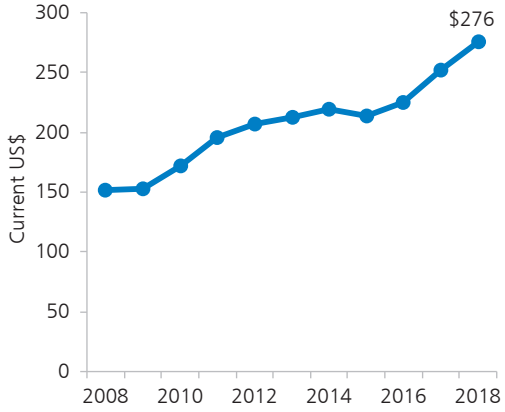
69 800
Population (in 000s)[1]

77.7
Life expectancy at birth (in years)[2]

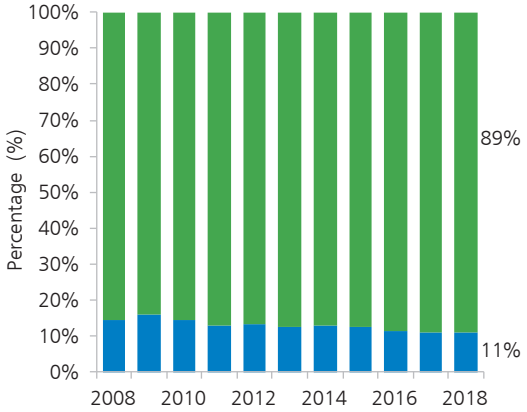
7806.7
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

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

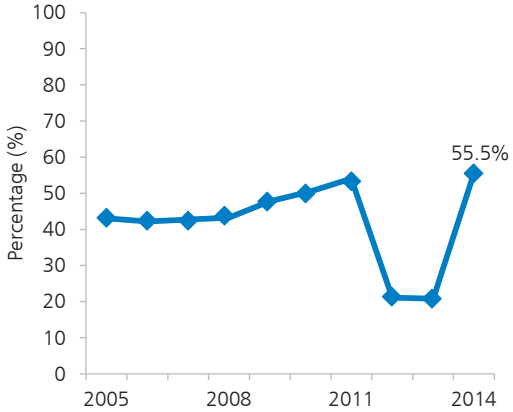


Share of government vs out-of-pocket spending on health[4]

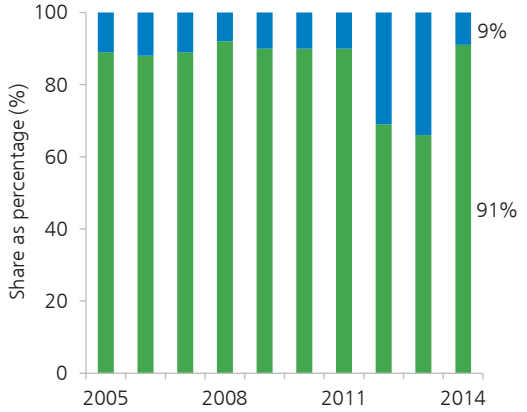


SPENDING ON MEDICINES

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



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



MEDICAL AND PHARMACY WORKFORCE

9.2
Medical doctors/10 000 population[6A]

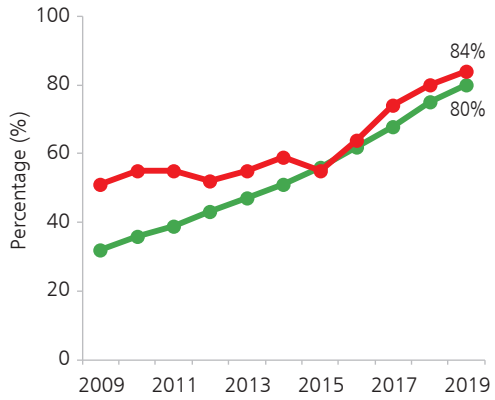
6.3
Pharmacists/10 000 population[6A]

Yes
Pharmacy education accreditation[6B]

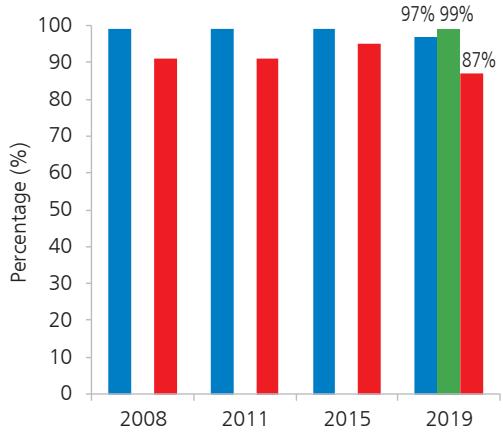
Yes
Continuing professional development for pharmacists[6B]

ACCESS TO MEDICINES

HIV/AIDS and tuberculosis treatment coverage[7,8]



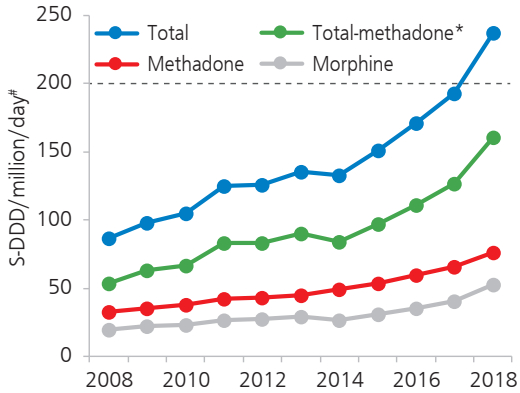
Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[9]



Gaps in diagnosis and management of hypertension and diabetes

Updated data not available

Levels of consumption of narcotic drugs[10]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[11,12,13,a]	National Medicine Policy[14,b]	National Essential Medicines List[15,16]	National Standard Treatment Guidelines[5]
1. Drug Act (No. 6), B.E. 2562 (AD 2019) 2. Narcotics Act B.E. 2522 (1979) and Psychotropic Substance Act B.E. 2559 (2016) 3. Herbal Products Act, B.E. 2562 (AD 2019)	National Drug policy B.E. 2563–2565 (AD 2020–2022)	National List of Essential Medicines B.E. 2563 (AD 2020)	Individual disease guidelines and treatment protocols exist

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of local pharmaceutical manufacturers[5,c]	Least developed country status[17]	Member of World Trade Organization since[18]	TRIPS flexibilities used[19]
Allopathic 186 and Traditional 964	No	1995	Yes

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National regulatory authority[20]: Thai Food and Drug Administration (Thai FDA) https://www.fda.moph.go.th/Pages/HomeP_D2.aspx

Regulated products[5]:

Medicines: YES **Vaccines:** YES **Medical Devices:** YES **Traditional Medicines:** YES

Medicine quality control laboratory[5]: National Drug Testing Laboratory, Bureau of Drugs and Narcotics

ISO 17025 certified[5]: YES (since 1994) **WHO prequalified[21]:** YES (since 2012)

Number of registered medicines[22,23,d]: Allopathic: 22 726, Biologicals: 647, Narcotics: 145, Traditional: 14 805 (till 2018), Veterinary: 3537

Medicine selection

Agency responsible for selection[5]: Division of National Drug Policy, Thai FDA

Number of products on essential medicines list:

By active ingredient[24,25,e]: 740 **By dosage form[24,25,e]:** 1126

Traditional medicines products included in essential medicines list[26,27]: YES (74 products)

Medicines availability is indicated by health facility level[28]: YES

National formulary[5,c]: Specialties National Formularies available. No national formulary booklet

Medicine procurement

Public sector

Agency responsible for public procurement[5]: National Medicine Systems Development Committee

Procurement done at Central[5] ☐ **State[5]** ☐ **Facility[5]** ☑

Commonly used procurement methods[5]: Competitive tendering

Private sector

Number of wholesalers[5,c]: Normal: 16,892 (include retail also)

Pricing and reimbursement

Public sector

Price Control[29]: Reference Prices (RPs) for Public Procurement have purposely been implemented for pharmaceutical cost containment during 5 years (2014–2018)

Mechanism[29]: Prices at or below reference price sets a maximum purchasing price to enable negotiation

Health insurance reimbursement price[29,f]: Universal Coverage Scheme (UCS) covers most of the population

Patient prices for essential medicines in public sector:

Free medicines[5]: YES

Private sector

Agency responsible for price control[5]: Ministry of Trade/ Commerce

Pricing mechanism:

Manufacturer ☐ **Wholesale** ☐ **Retailer[5]** ☑

Mark-ups regulated[5,29]: No price cap/maximum retail price (MRP), price negotiation between industry and purchaser

Distribution

Public sector

Agency responsible for distribution[5]: Directly from supplier to hospitals

Public sector facilities[30,c,g]:

Hospitals: 59
District and provinicial hospitals: 891
Health centers: 9768
Community medical centers: 365

Private sector

Number of retail outlets[29,c,h]: 20 000

Licensed retail pharmacies per 10 000 population[29,c,i]: 2.8

Number of Traditional Medicines outlets[5,c]: 2083

Patient

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Notes:

a. The Herbal Act came into force since 29th June 2019 and now Ministry of Public Health, Thailand is in process of database improvement regarding number of local pharmaceutical manufactures and number of registered traditional medicines.
b. National Medicines Policy 2017-2021: To get cabinet approval.
c. Information reviewed by Ministry of Public Health, Thailand in 2021.
d. Does not include 122 traditional veterinary medicines.
e. Based on self-calculation from National List of Essential Medicines- B.E. 2563 (AD 2020).
f. Total three insurance schemes. Other two are the Civil Servant Medical Benefits Scheme (CSMBS) & Social Security Scheme (SSS).
g. Specialized Hospitals- 48 and University Hospitals-11; District Hospitals- 734, Provincial Hospitals -71, Regional Hospitals-26, Other hospitals- 60.
h. There are 14,000 drugstores in type 1 (koryor 1)(5) in which there are pharmacists available in the stores during opening hours.
i. Calculated by using retail pharmacies/Thai pop. *10,000 = 20000/69800*10,000 = 2.8.

Timor-Leste medical products profile 2021

COUNTRY AT A GLANCE

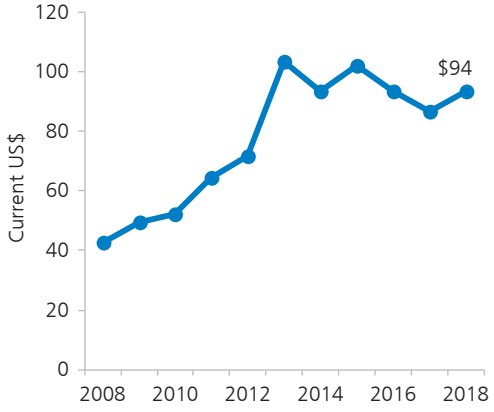
1318
Population (in 000s)[1]

69.6
Life expectancy at birth (in years)[2]

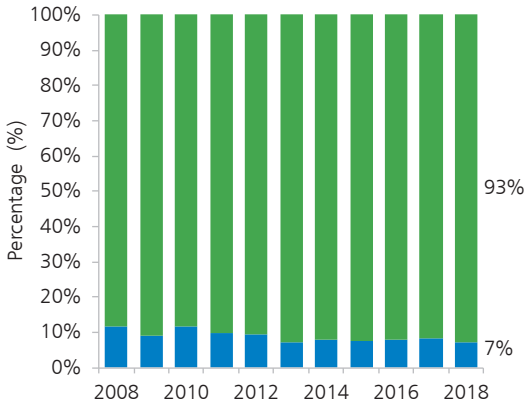
1560.5
GDP (per capita in current US$)[3]

OVERALL SPENDING ON HEALTH

Current per capita spending on healthcare (current US$)[4]

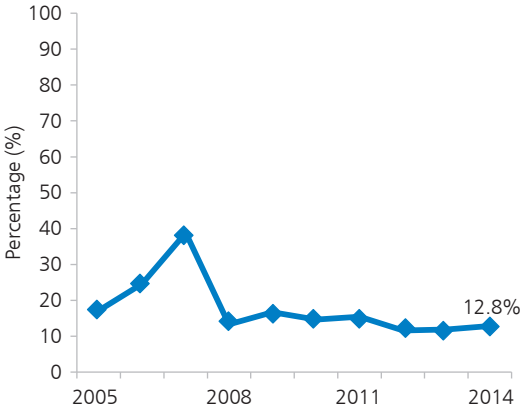


Share of government vs. out-of-pocket spending on health[4]

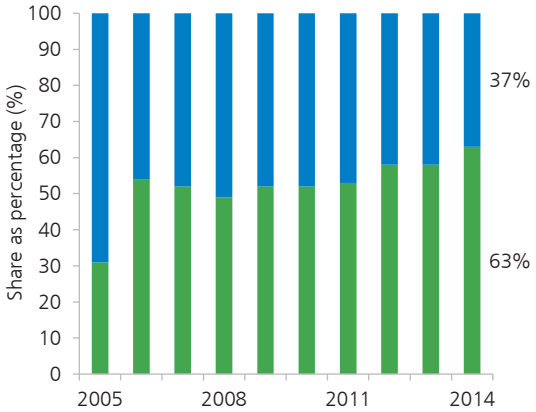


SPENDING ON MEDICINES

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



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



MEDICAL AND PHARMACY WORKFORCE

7.7
Medical doctors/10 000 population[6A]

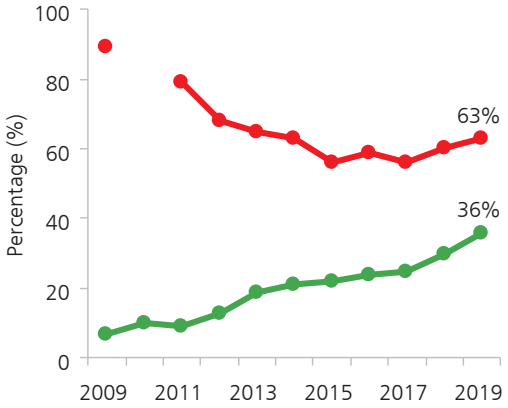
2.1
Pharmacists/10 000 population[6A]

Yes
Pharmacy education accreditation[6B]

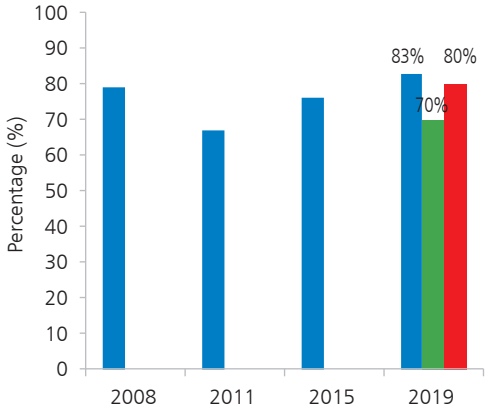
No
Continuing professional development for pharmacist[6B]

ACCESS TO MEDICINES

HIV/AIDS and tuberculosis treatment coverage[7,8]



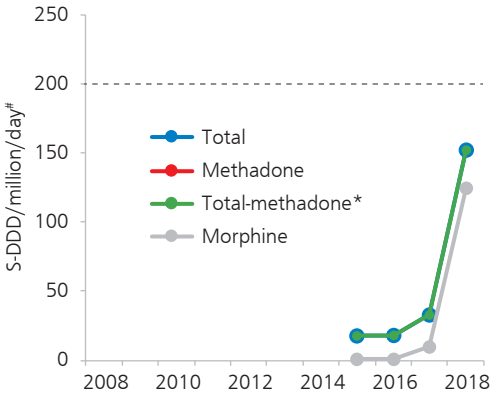
Diphtheria-tetanus-pertussis (DTP3), Hepatitis B BD and MCV2 immunization coverage[9]



Gaps in diagnosis and management of hypertension and diabetes

Updated data not available

Levels of consumption of narcotic drugs[10]



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

KEY MEDICINES POLICIES AND GUIDANCE

Key pharmaceutical legislation[11,a]	National Medicine Policy[12]	National Essential Medicines List[13]	National Standard Treatment Guidelines[13]
DECREE-LAW NO. 12/2004	National Medicines Policy 2018	Timor-Leste Essential Medicines List 2015	Available for Primary Healthcare and Referral hospitals & disease specific guidelines available

INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION

Number of Local pharmaceutical manufacturers[5,b]	Least Developed country status since[14]	Member of World Trade Organization since[15]	TRIPS flexibilities used[16]
None	2003	No	Not applicable until graduation from least developed country status

Pharmaceutical system flowchart

Medicine

Market authorization/ Licensing/Quality assurance

National Regulatory Authority[17]: National Regulatory Authority, National Directorate of Pharmacy and Medicines

Regulated products:

Medicines[5]: YES **Vaccines[5]:** YES **Medical devices[5]:** YES **Traditional Medicines[18]:** NO

Medicine Quality Control Laboratory[19,c]: None

ISO 17025 certified[19]: NO **WHO prequalified[20]:** NO

Number of Registered Medicines[21]: 833

Medicine selection

Agency responsible for selection[17,d]: National Directorate of Pharmacy and Medicines (DNFM)

Number of products on essential medicines list:

By active ingredient[5]: 274 **By dosage form[5]:** 402

Traditional medicines products included in essential medicines list[5]: NO

Medicines availability is indicated by health facility level[5]: YES

Number of Products in National Formulary[5,22]: No national formulary manual

Medicine procurement

Public sector

Agency responsible for Public Procurement[22]: Servico Autonomo de Medicamentos e Equipamentos de Saude (SAMES)

Procurement done at Central[23] ☑ **State[23]** ☐ **Facility[23]** ☐

Commonly used procurement methods[24]: Competitive or public bidding

Private sector

Number of wholesalers[12,f]: 21

Pricing and reimbursement

Public sector

Price control[23]: YES

Mechanism[5,25]: Bid evaluation based upon lowest price criteria

Health insurance reimbursement price[5]: No insurance but national health service provides free treatment of patients

Patient prices for essential medicines in public sector:

Free medicines[5]: YES

Private sector

Agency responsible for price control[17,g]: Marketing Authorization Department, National Regulatory Authority, National Directorate of Pharmacy and Medicines

Pricing mechanism[24]: Under development

Manufacturer ☐ **Wholesale** ☐ **Retailer** ☐

Mark-ups regulated[24]: Policy under development

Distribution

Public sector

Agency responsible for distribution[24]: SAMES

Public Sector Facilities[26,27]:

Referral hospitals: 5
National hospital: 1
Regional hospitals: 3
Community health services: 65
Servisu Integrado Sude Communita (SISCA) Centers: More than 600
Health centres: more than 200

Private sector

Number of retail outlets[12]: 53

Licensed retail pharmacies per 10 000 population[h]: 0.4

Number of Traditional Medicines outlets[12,i]: No data available

Patient

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Note:

a. In 2015, the MoH revised the decree law No.12/2004 and produced two draft legislations namely Decree Law for Pharmacy Establishments and Decree Law for Medicines. As per information received from the Cabinet of Ministers, these draft legislations will be submitted for the revision and approval in 2021.

b. Timor-Lestee has only importers of Medicines and medical products. A list is available from National Regulatory Authority, National Directorate of Pharmacy and Medicines, Timor-Lestee- https://www.ms.gov.tl/dnfm/dnfm1/aim.php?lan=eng - accessed on 25th January 2021.

c. Functional laboratory does not exist. A mini laboratory under warehouse of Drugs and Equipment under Central Medical Stores, SAMES exists.

d. The DNFM is to study and propose legal measures on the use of medicinal products, as well as to keep the National List of Essential and Supplementary Medicines up to date and to ensure their compliance.

e. All suppliers, including the SAMES shall only be allowed to participate in tenders if they are registered with the NRA, DNFM.

f. 21 local licensed importers in Timor-Leste.

g. Monitoring of local and international prices of medicines by an appropriate committee to establish reference pricing, detect undue price increases, and develop policies for fair pricing of medicines in the private sector.

h. Calculated by using retail pharmacies/Timor pop. *10,000 = 53/1318000*10,000 = 0.35; Majority of the pharmacists, pharmacy technicians and pharmacy assistants in Timor-Lestee working at the public institutions and only few work at private and non-governmental organizations.

i. No data available on traditional medicines but some data exists on herbal medicines. Based on the information from DNFM, there are four importers who have a valid product registration for total of 13 herbal medicines. Proargy (6 herbal medicines), GOMI 2 (4 herbal medicines), ACIBEE (1 herbal medicine) and Melia Herbal (2 herbal medicines).

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