How pharmaceutical systems are organized in Asia and the Pacific
HOW PHARMACEUTICAL SYSTEMS ARE ORGANIZED IN ASIA AND THE PACIFIC
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There are important differences in the markets for medicines in countries in Asia and the Pacific in this study. These are mainly due to the political, financial and regulatory environments as well as characteristics of the pharmaceutical manufacturing industry. However, all countries face the test of transition brought about by demographic changes, shifting epidemiological trends and increasing inequities, among others. As with other regions of the world, a characteristic of lower- and upper-middle-income countries is that pharmaceuticals account for a high proportion of health expenditures. Medicines account for a larger share of the health budgets in resource-constrained countries.

Pharmaceutical systems are complex and involve several intermediaries between medicines manufacturers and consumers. This suggests the need for better coordination among various agencies and relevant stakeholders involved. The intricate pharmaceutical landscape demands a better understanding of how pharmaceutical markets are organized, regulated and financed to foster policies aimed at achieving universal and equitable access to essential medicines.

Achieving equitable access to affordable, safe, efficacious and quality medicines through sound pharmaceutical policies, programmes and other interventions has remained a continuing challenge at all levels of health system strengthening for countries, with some performing better than others. This reality is even more pronounced in countries that are currently working towards universal health coverage where a large part of pharmaceutical spending is still out of pocket.
Medicines, together with other health technologies, are one of the building blocks of a health system. Without them, it is impossible to achieve desirable health outcomes for individual patients and communities.

As countries make further progress towards universal health coverage, essential medicines, more than ever, are crucial to achieving health and inclusive socioeconomic development. Sustainable Development Goal target 3.8 mentions the importance of “access to safe, effective, quality and affordable essential medicines and vaccines for all” as a central component of universal health coverage.

Access to essential medicines encompasses quality, safety and efficacy of drugs, as well as their availability, affordability and appropriate use. However, improving access to quality-assured essential medicines is not an end in itself. It is a means to improving health status, promoting well-being and achieving equity across populations. Demographic, epidemiological and economic transitions continue to generate major challenges for essential medicines.

Addressing issues around access to medicines requires a comprehensive understanding of how pharmaceutical systems are organized and function. This report presents profiles of 14 countries in Asia and the Pacific – Australia, Brunei Darussalam, Cambodia, China, Indonesia, Republic of Korea, Lao People’s Democratic Republic, Malaysia, Mongolia, New Zealand, Philippines, Singapore, Thailand and Viet Nam – that outline resources, structures and processes relating to ensuring availability and accessibility of pharmaceuticals in specific country settings and their interactions with the health-care system. The report represents an outcome of the activities of the Asia Pacific Network on Access to Medicines under Universal Health Coverage, a joint initiative by the WHO Regional Office for the Western Pacific, the Organisation for Economic Co-operation and Development (OECD) and the OECD Korea Policy Centre, with the support of the WHO Collaborating Centre for Health Systems and Financing at Seoul National University.
Countries featured in this report range from Brunei Darussalam with a population of less than half a million to China with 1.36 billion inhabitants. The median life expectancy at birth across countries in this study is 75 years. The Lao People’s Democratic Republic (64 years), Mongolia (68 years) and the Philippines (69 years) show a life expectancy at birth lower than that of the world population (71.4 years) and much lower than that of OECD countries (80.6 years). Differences in life expectancy across countries may be attributed to differences in income levels, living standards, education and accessibility of quality health services.

Across countries, the highest proportions of children aged below 15 years were observed in the Philippines (32.0%) and Cambodia (31.0%), whereas the lowest proportions were reported in the Republic of Korea (15.0%), Singapore (16.0%) and China (16.6%). The highest proportion of people aged over 60 years (20.0%) was recorded in Australia and New Zealand. Of note is that the proportion of people aged over 60 years is expected to increase significantly in the coming years, which can lead to an increased burden on those of working age to sustain spending for a range of services, including health, for an ageing population.

In terms of gross domestic product (GDP) per capita, the countries featured in this report include high-income countries – Singapore ($ 82 208.90 per capita), Brunei Darussalam ($ 67 131.80), Australia ($ 46 244.10), New Zealand ($ 37 340.00) and the Republic of Korea ($ 34 321.60); upper-middle income countries – Malaysia ($ 24 951.10), Thailand ($ 15 346.70) and China ($ 13 166.70); and lower-middle income countries – Mongolia ($ 11 945.70), Indonesia ($ 10 517.00), the Philippines ($ 6982.40), Viet Nam ($ 5525.80), the Lao People’s Democratic Republic ($ 5278.20) and Cambodia ($ 3228.40). While GDP is a direct measure of economic production, it is also an indirect measure of economic well-being of a country.

Australia has the highest number of physicians per 10 000 population (35.2), followed by the Lao People’s Democratic Republic (29), Mongolia (28.4) and New Zealand (28.4). The Republic of Korea (14.6 per capita) has the highest number of doctor consultations per capita per year, followed by Australia (7.6 per capita), Mongolia (6.1 per capita) and China (5.4 per capita). Across OECD countries, on average 34 doctors per 10 000 population are reported. They guarantee 6.9 consultations per capita per year. The number of pharmacists per 1000 population is consistently low, from lower-middle-income (Cambodia, 0.14) to high-income countries (Brunei Darussalam, 0.17).

The Republic of Korea (10.3 per 1000 population) has the highest number of hospital beds, while Cambodia (0.7 per 1000 population) and Indonesia (0.6 per 1000 population) reported the lowest numbers. On average, OECD countries report 4.7 beds per 1000 population. The health system capacity and utilization of health-care services are correlated with available providers of services. Lower utilization of health-care services may suggest scarcity of resources, including human resources.
HEALTH EXPENDITURE

Total health expenditure (THE) per capita shows a significant variation across the countries in the study, with the highest level reported in Australia ($4357.00) and the lowest in the Lao People’s Democratic Republic ($35.50). THE as a share of GDP is highest in high-income countries such as Australia (10.0%), New Zealand (9.4%) and the Republic of Korea (7.4%), with the exception of Singapore (4.3%) and Brunei Darussalam (1.8%). For comparison, OECD countries spend on average 9% of GDP on health.

The share of government in total health spending varies from as high as 93.8% in Brunei Darussalam to as low as 18.9% in China, whereas out-of-pocket spending accounts for more than half of the THE in Cambodia (74.2%), the Philippines (53.7%) and the Lao People’s Democratic Republic (52.6%). Out-of-pocket spending accounts for a much greater share of health expenditures in lower-middle-income countries than in high-income countries. Some countries have social health insurance systems which constitute a significant portion of THE, such as the Republic of Korea (42.9%), China (37.7%) and Viet Nam (24.07%).

PHARMACEUTICAL EXPENDITURE

A large variation in pharmaceutical spending is observed across countries in the study. Per capita pharmaceutical spending ranges from $27.3 in the Lao People’s Democratic Republic and $683.5 in Australia (Figure 1).

![Figure 1](Pharmaceutical expenditure per capita, international dollars (US$ Purchasing Power Parity), 2014)

* data provided by the country

Source: WHO Global Health Observatory 2016, OECD Health Statistics
Pharmaceutical spending as a share of THE ranges from 9.7% in New Zealand to 44% in Cambodia (Figure 2). Lower- and upper-middle-income countries have a higher total pharmaceutical expenditure (TPE) as a share of THE when compared to high-income countries. Across OECD countries, pharmaceutical spending represents on average 16% of total health spending.

The contribution of public and private sources to financing TPE varies greatly across countries as well. Countries that have a significantly higher public sector share are either high-income (Brunei Darussalam, New Zealand, Republic of Korea and Australia) or upper-middle income countries (Thailand and Malaysia). Countries that have a significantly higher private sector share are lower-middle-income countries, such as Indonesia (85.7%), the Philippines (85.0%), Viet Nam (83.5%), the Lao People’s Democratic Republic (83.5%), Cambodia (77.5%) and Mongolia (74.0%) (Figure 3).
ALL COUNTRIES HAVE EXISTING REGULATORY AUTHORITY FOR PHARMACEUTICALS AS WELL AS KEY LEGISLATIONS. EXCEPT FOR SINGAPORE, ALL HAVE A FORMAL NATIONAL MEDICINES POLICY. IN TERMS OF PRICING, NOT ALL COUNTRIES HAVE A DEDICATED AGENCY THAT SETS OR CONTROLS THE PRICE OF PHARMACEUTICAL PRODUCTS, SUCH AS IN BRUNEI DARUSSALAM, CAMBODIA, MONGOLIA AND SINGAPORE. IN THESE COUNTRIES, PRICING OF PHARMACEUTICALS IN THE PUBLIC SECTOR IS NOT REGULATED. THE PRICING OF PHARMACEUTICALS IN THE PRIVATE SECTOR IS REGULATED ONLY IN INDONESIA, THE PHILIPPINES AND VIET NAM.

INTERNAL PRICE REFERENCING IS NOT USED IN INDONESIA, THE REPUBLIC OF KOREA, MONGOLIA AND SINGAPORE. EXTERNAL PRICE REFERENCING IS NOT USED IN INDONESIA, MONGOLIA, NEW ZEALAND AND SINGAPORE. EXCEPT FOR AUSTRALIA, BRUNEI DARUSSALAM AND SINGAPORE, THERE IS VALUE-ADDED TAX ON MEDICINES IN COUNTRIES IN THE STUDY RANGING FROM 5% IN VIET NAM TO 17% IN CHINA.

ALL COUNTRIES HAVE A DEDICATED AGENCY THAT SELECTS PHARMACEUTICALS FOR PROCUREMENT AND REIMBURSEMENT, WHILE ONLY BRUNEI DARUSSALAM, CAMBODIA AND INDONESIA DO NOT HAVE AN ORGANIZATION THAT IS TASKED TO CONDUCT HEALTH TECHNOLOGY ASSESSMENT. COUNTRIES HAVE VARYING NUMBERS OF PRODUCTS IN THEIR ESSENTIAL MEDICINES LIST, PROCUREMENT LIST AND REIMBURSEMENT LIST.
**Pharmaceutical System**

**AUSTRALIA**

### Socioeconomics
- **Population**: 24,127,200
- **Life Expectancy at Birth**: 83 years
- **GDP / Capita (PPP)**: US$46,244.1

### Human Resources
- **No. of Physicians**: 35.2 per 10,000 population
- **No. of Pharmacists**: 0.9 per 1000 population
- **Hospital Beds**: 3.8 per 1000 population
- **Doctor Consultations**: 7.6 per capita

### Health Expenditure
- **Total Health Expenditure / Capita (PPP)**: US$4,357.3
- **Total Health Expenditure as a Share of GDP**: 67%
- **Public vs Private Share of Total Health Expenditure**: 53.5% Public, 46.5% Private

### Pharmaceutical Expenditure
- **Total Pharmaceutical Expenditure / Capita (PPP)**: US$683.5
- **Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita**: 15.7%
- **Public vs Private Share of Total Pharmaceutical Expenditure**: 53.5% Public, 46.5% Private

### Pharmaceutical Regulation
- **National Medicines Policy**: National Health Act 1953
- **Non-legislative National Medicines Policy 2000**
- **Regulatory Authority for Pharmaceuticals**: Therapeutic Goods Administration

### Pricing
- **Agency that Sets Price**: Department of Health
- **Pricing Regulation in the Public Sector**: YES
- **Pricing Regulation in the Private Sector**: YES
- **Free Pricing?**: NO
- **Price Negotiations?**: YES
- **External Price Referencing?**: YES
- **Internal Price Referencing?**: YES
- **VAT on Medicines**: NO

### Procurement / Reimbursement
- **No. of Registered Medicines**: 19,786
- **No. of Products on Essential Medicines List**: No data available
- **No. of Products on Procurement List**: No data available
- **No. of Products on Reimbursement List**: 5,200

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*a For medicines included in the Pharmaceutical Benefits Scheme*
Pharmaceutical System Flowchart

NEW MEDICINE

MARKET AUTHORIZATION / LICENSING

National Regulatory Authority  
THERAPEUTIC GOODS ADMINISTRATION, DEPARTMENT OF HEALTH

TASKS  Pre-market assessment, post-marketing monitoring and enforcement of standards, licensing of local manufacturers and verifying overseas manufacturers’ compliance

CRITERIA Quality, safety and efficacy/performance


PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE

PURPOSE Recommendation of medicines for inclusion in the Pharmaceutical Benefits Scheme (PBS)

CRITERIA Comparative safety, clinical efficacy and cost-effectiveness

PROCUREMENT

Community pharmacies and hospitals

For PBS-reimbursable pharmaceuticals

Department of Health

TASKS  Negotiation of final price at which a drug should be listed on the PBS (approved ex-manufacturer price; agreed fixed mark-up for wholesalers; agreed administration, handling and infrastructure fee/ mark-up, and dispensing fee and dangerous drug fee if applicable, for hospitals and pharmacies)

SYSTEM  Patients contribute to the costs of medicines under the PBS through co-payments.

For non-PBS-reimbursable pharmaceuticals

Include over-the-counter drugs (with some exemptions), lifestyle drugs and hospital drugs supplied to inpatients (using state and territory funding)

There are no price controls for manufacturers, wholesale distributors, hospitals and pharmacies.

PRICING AND REIMBURSEMENT

DISTRIBUTION

Wholesale and retail distributions are done privately.

Methods of supply from the pharmacy include imprest, individual inpatient supply, prescriptions, requisitions and borrowing.

REFERENCES

5 Data provided by country.
Pharmaceutical System Flowchart

**MARKET AUTHORIZATION / LICENSING**

- **Tasks**: Issuance of licenses of pharmaceutical establishments and registration certificates of medicinal products
- **Criteria**: Quality, safety and efficacy

**SELECTION**

- **Purpose**: Regular updating of the National Standard Drug List and approval of Named Patient Basis Prescriptions
- **Criteria**: Appropriateness to disease patterns in the country

**PROCUREMENT**

- Ministry of Health (in compliance with financial regulations and procurement guidelines by State Tender Board, Ministry of Finance)

There is no price control for medicines.

**PRICING AND REIMBURSEMENT**

- For the public sector: There is free health care for all, including medicines for inpatients and outpatients.
- For the private sector: Private insurance is available. Payment is out of pocket.

**DISTRIBUTION**

- Through the country’s four government hospitals, 16 health centres and 64 primary care facilities
- Travelling health clinics and flying medical services for remote areas

**Clients**

**REFERENCES**

3. Data provided by country
Pharmaceutical System Flowchart

NEW MEDICINE

MARKET AUTHORIZATION / LICENSING

NATIONAL COMMITTEE FOR THE ESSENTIAL MEDICINES LIST

SELECTION

PROCUREMENT

PRICING AND REIMBURSEMENT

DISTRIBUTION

CLIENTS

REFERENCES

### Pharmacological System: China

#### Socioeconomics

- **Population**: 1,360,720,000
- **Life Expectancy at Birth**: 75 years
- **GDP / Capita (PPP)**: $13,166.7
- **Percentage of Children Aged below 15 Years**: 16.6%
- **Percentage of Adults Aged over 60 Years**: 14.8%

#### Human Resources

- **No. of Physicians**: 17.3 per 10,000 population
- **No. of Pharmacists**: 0.3 per 1000 population
- **Hospital Beds**: 4.55 per 1000 population
- **Doctor Consultations**: 5.4 per capita

#### Health Expenditure

- **Total Health Expenditure / Capita (PPP)**: $730.5
- **Total Health Expenditure as a Share of GDP**: 55.8%
- **Public vs Private Share of Total Health Expenditure**: 44.2% Public
- **Composition of Total Health Expenditure**:
  - **Out-of-Pocket**: 32%
  - **Social Health Insurance**: 37.7%
  - **Other Private**: 7.7%
  - **Private Prepaid Plans**: 4.5%

#### Pharmaceutical Expenditure

- **Total Pharmaceutical Expenditure / Capita (PPP)**: $288.1
- **Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita**: 39.4%
- **Public vs Private Share of Total Pharmaceutical Expenditure**: 42.2% Public

#### Pharmaceutical Regulation

- **Regulatory Authority for Pharmaceuticals**: China Food and Drug Administration
- **Pharmaceutical Legislation**: Drug Administration Law 2001
- **National Medicines Policy**: National Essential Medicines Policy 2009

#### Pricing

- **Agency that Sets Price**: Pricing Bureau, under the National Development and Reform Commission
- **Pricing Regulation in the Public Sector**: YES
- **Pricing Regulation in the Private Sector**: NO
- **Free Pricing?**: YES
- **Price Negotiations?**: YES
- **External Price Referencing?**: YES
- **Internal Price Referencing?**: YES
- **VAT on Medicines**: 17%

#### Procurement / Reimbursement

- **No. of Registered Medicines**: 168,000
- **No. of Products on Essential Medicines List**: 520
- **No. of Products on Procurement List**: Varies by Province
- **No. of Products on Reimbursement List**: 2,535
Pharmaceutical System Flowchart

NEW MEDICINE

MARKET AUTHORIZATION / LICENSING

National Regulatory Authority  CHINA FOOD AND DRUG ADMINISTRATION

TASKS  Registration and market authorization of pharmaceutical products, publication of drug standards and classification system, and supervision of implementation of regulatory standards at the local level

CRITERIA  Quality, safety and efficacy


NATIONAL ESSENTIAL MEDICINES LIST

PURPOSE  Listing of drugs under zero-profit policy and setting of requirements for revenues from such products

CRITERIA  Appropriateness to disease patterns in the country

PROCUREMENT

National Health and Family Planning Commission, private hospitals and retail pharmacies

The National Development and Reform Commission governs the prices of pharmaceutical products. Based on regulations (e.g. Price Law), market-driven pricing exists. All essential medicines are included in the insurance reimbursement lists.

PRICING AND REIMBURSEMENT

For the public sector

The Ministry of Human Resources and Social Security and the National Health and Family Planning Commission decide on reimbursements according to related regulations (e.g. Social Insurance Law).

Drugs listed as Category A under the National Reimbursement Drug List are fully reimbursed. Category B drugs are reimbursed at 70–80%.

For the private sector

Payment is out of pocket.

DISTRIBUTION

The Ministry of Commerce decides on the administration of pharmaceutical distribution based on related regulations.

Involves a three-tier health service delivery system, including primary health facilities, secondary hospitals and tertiary hospitals

From manufacturer to wholesale distributor to dispensing unit

REFERENCES

MARKET AUTHORIZATION / LICENSING

TASKS
Assessment, organization, implementation and monitoring of national policy in food and drug evaluation field; registration, marketing authorization and licensing

CRITERIA
Quality, safety, efficacy, risk and people’s needs

REGULATIONS
NA-DFC decree number HK.00.05.3.1950 (Criteria and Procedure of Drug Registration), National Medicines Policy 2006, No. 1010/MENKES/PER/XI/2008 (Regulation 1010/2008), National Health Policy (Health Act of Republic of Indonesia No. 36/2009)

SELECTION

PURPOSE
Selection of medicines and development of the National Medicines Formulary

CRITERIA
Appropriateness to disease patterns in the country

PROCUREMENT

Ministry of Health, local governments and private sector pharmacies

The Ministry of Health sets both the ceiling prices for tender of generic medicines for public sector procurement, and the maximum retail price in the private sector.

PRICING AND REIMBURSEMENT

For the public sector
Primary health-care facilities are reimbursed based on capitation payment, with medicines costed at prices listed on the E-catalogue.

For public hospitals contracted under BPJS Kesehatan, there is fixed fee per patient visit (including 7-day medicines supply) based on diagnostic groups, as well as fee-for-service price for other medicines.

District governments establish retribution fee for patients based on their capacity to subsidize health services.

For the private sector
Payment is out of pocket.

For private hospitals contracted under BPJS Kesehatan, there is fixed fee per patient visit (including 7-day medicines supply) based on diagnostic groups, as well as fee-for-service price for other medicines.

DISTRIBUTION

Through a Central Medical Store at national level with 550 public warehouses in the secondary tier of public distribution

From manufacturer to wholesale distributor to dispensing unit and with many players at each level

REFERENCES
### Pharmaceutical System

**Republic of Korea**

#### Socioeconomics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Population</td>
<td>49,263,000</td>
<td></td>
</tr>
<tr>
<td>Life Expectancy at Birth</td>
<td>82 years</td>
<td></td>
</tr>
<tr>
<td>Percentage of Adults Aged over 60 Years</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Percentage of Children Aged below 15 Years</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>GDP / Capita (PPP)</td>
<td>US$34,321.6</td>
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#### Human Resources

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<th>Resource</th>
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<tbody>
<tr>
<td>No. of Physicians</td>
<td>22.4 per 10,000 population</td>
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<tr>
<td>No. of Pharmacists</td>
<td>1.28 per 1000 population</td>
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</tr>
<tr>
<td>Hospital Beds</td>
<td>10.3 per 1000 population</td>
<td></td>
</tr>
<tr>
<td>Doctor Consultations</td>
<td>14.6 per capita</td>
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</table>

#### Health Expenditure

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>Total Health Expenditure / Capita (PPP)</td>
<td>US$2,530.6</td>
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<tr>
<td>Total Health Expenditure as a Share of GDP</td>
<td></td>
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<tr>
<td>Public vs Private Share of Total Health Expenditure</td>
<td>54.1% Public, 45.9% Private</td>
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#### Pharmaceutical Expenditure

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Total Pharmaceutical Expenditure / Capita (PPP)</td>
<td>US$583.4</td>
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<tr>
<td>Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita</td>
<td>23.1%</td>
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<tr>
<td>Public vs Private Share of Total Pharmaceutical Expenditure</td>
<td>58.4% Public, 41.6% Private</td>
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</table>

#### Pharmaceutical Regulation

- **Regulatory Authority for Pharmaceuticals**: Ministry of Food and Drug Safety
- **Pharmaceutical Legislation**: Pharmaceutical Affairs Act
- **National Medicines Policy**: National Medicine Policy Plan

#### Pricing

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
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<tr>
<td>Free Pricing?</td>
<td>No</td>
<td></td>
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<tr>
<td>Price Negotiations?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>External Price Referencing?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Internal Price Referencing?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>VAT on Medicines</td>
<td>10%</td>
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#### Procurement / Reimbursement

<table>
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<tr>
<th>Metric</th>
<th>Value</th>
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<tbody>
<tr>
<td>No. of Registered Medicines</td>
<td>39,847</td>
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<tr>
<td>No. of Products on Essential Medicines List</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>No. of Products on Procurement List</td>
<td>No data available</td>
<td></td>
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<tr>
<td>No. of Products on Reimbursement List</td>
<td>17,798</td>
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</tbody>
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Pharmaceutical System Flowchart

NEW MEDICINE

MARKET AUTHORIZATION / LICENSING

Tasks: Drug approval and registration
Criteria: Quality, safety, efficacy and information on production and sale in origin country (for imported products)
Regulations: Pharmaceutical Affairs Act

HEALTH INSURANCE REVIEW AND ASSESSMENT SERVICE AND PHARMACEUTICAL BENEFIT REVIEW COMMITTEE

Purpose: Decision on which medicines are to be included and not in the Positive List for reimbursement by the National Health Insurance Service, reviewed by the National Health Insurance Policy Deliberation Committee (NHIPDC)
Criteria: Clinical and cost effectiveness, and budget impact

PROCUREMENT

Public and private hospitals, clinics and pharmacies employing medical tenders and competitive bids

DISTRIBUTION

All public and private hospitals, clinics and pharmacies are legally obliged to subscribe as providers.

REFERENCES

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Pharmaceutical System Flowchart

**MARKET AUTHORIZATION / LICENSING**

- **National Regulatory Authority**
  - **FOOD AND DRUG DEPARTMENT, MINISTRY OF HEALTH**
  - **TASKS**: Medicines evaluation and registration
  - **CRITERIA**: Quality, safety and efficacy
  - **REGULATIONS**: Law on Drugs and Medical Products 2011, Regulation on Drug Registration 2003, National Medicines Policy 2003

**SELECTION**

- **PUBLIC HOSPITAL PHARMACY DIVISION, FOOD AND DRUG DEPARTMENT, MINISTRY OF HEALTH**
  - **PURPOSE**: Listing of medicines in the Essential Medicines List and subsequent review every 2 to 3 years
  - **CRITERIA**: Quality, safety, efficacy, therapeutic advantage and cost

**PROCUREMENT**

- Different methods of procurement are used in the public sector, such as collective negotiation procurement, centralized procurement and decentralized procurement.
- There are no price controls for manufacturers, importers and wholesale distributors.

**PRICING AND REIMBURSEMENT**

- **For the public sector**
  - As of 2015, 21% of the population is covered by health insurance schemes. This number is expected to rise with the launch of a new tax-based system.
  - Selling price of medicines is determined by the retail price with maximum of 25% mark-up in accordance with the guidelines of the drug revolving funds.
  - Medicines are free for all insurance members and other vulnerable groups (e.g. mothers, children under 5, and the poor).
- **For the private sector**
  - There is no regulation on margins or mark-ups.
  - Payment is out of pocket.

**DISTRIBUTION**

- **Through seven central-level hospitals (of which three are specialized centres), four regional hospitals, 16 provincial hospitals, 130 district hospitals and 894 health centres**
- **Through 222 private clinics and 1993 private pharmacies**

**REFERENCES**

3. Data provided by country

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**Pharmaceutical System**

### MALAYSIA

#### SOCIOECONOMICS

| Population | 29 717 000 |
| Life Expectancy at Birth | 74 years |
| Percentage of Adults Aged over 60 Years | 9% |
| Percentage of Children Aged below 15 Years | 26% |
| GDP / Capita (PPP) | US$ 24 951.1 |

#### HUMAN RESOURCES

| No. of Physicians | 12.6 per 10 000 population |
| No. of Pharmacists\(^a\) | 0.34 per 1000 population |
| Hospital Beds | 1.9 per 1000 population |
| Doctor Consultations | 3.5 per capita |

#### HEALTH EXPENDITURE

| Total Health Expenditure / Capita (PPP) | US$ 1040.2 |
| Total Health Expenditure as a Share of GDP | 55.2% Public, 44.8% Private |
| Public vs Private Share of Total Health Expenditure | 54.6% General Government, 35.3% Out-of-Pocket, 7.1% Other Private, 0.6% Social Health Insurance |

#### PHARMACEUTICAL EXPENDITURE

| Total Pharmaceutical Expenditure / Capita (PPP) | US$ 198.8 |
| Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita | 19.1% |
| Public vs Private Share of Total Pharmaceutical Expenditure | 54.3% Public, 45.7% Private |

#### PHARMACEUTICAL REGULATION

- **Regulatory Authority for Pharmaceuticals**: National Pharmaceutical Regulatory Agency
- **Pharmaceutical Legislation**: Poisons Act 1952, Sale of Drugs Act 1952, Control of Drugs and Cosmetics Regulations 1984
- **National Medicines Policy**: National Medicines Policy 2012

#### PRICING

- **Free Pricing?**: YES
- **Price Negotiations?**: YES
- **External Price Referencing?**: YES
- **Internal Price Referencing?**: YES
- **VAT on Medicines**: 6%\(^c\)

#### PROCUREMENT / REIMBURSEMENT

| No. of Registered Medicines | 10 680 |
| No. of Products on Essential Medicines List | 4300 |
| No. of Products on Procurement List | 1695\(^d\) |
| No. of Products on Reimbursement List | 1695 |

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\(^a\) Pharmaceutical personnel

\(^b\) Monitoring function only

\(^c\) Zero for prescription drugs and items listed on the National Essential Medicines List

\(^d\) Number of international nonproprietary names of medicines listed
MARKET AUTHORIZATION / LICENSING

National Regulatory Authority

TASKS
Authorization and categorization of drugs in the market

CRITERIA
Quality, safety and efficacy

REGULATIONS
Poisons Act 1952, Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984

SELECTION

PHARMACEUTICAL SERVICES DIVISION, MINISTRY OF HEALTH

PURPOSE
Listing of medicines in the Ministry of Health Formulary for use in the public sector

CRITERIA
Clinical advantage (comparative efficacy/effectiveness and safety), best and current treatment options, population needs, current treatment guidelines and economic criteria (cost of treatment, overall budget and pharmacoeconomic impact)

PROCUREMENT

Ministry of Health and public health facilities use any of the following methods: through appointed concession company, by central tender for purchases above a set limit, or by local purchasing for purchases below a set limit according to the procedures and instruction of Ministry of Finance.

There are no price controls.

Pricing is managed in the public sector through tenders depending on annual turnover value for all. Further price negotiation is carried out for single-source medicines.

PRICING AND REIMBURSEMENT

For the public sector

Pricing is managed through the procurement procedures and instruction of Ministry of Finance.

For the private sector

Private insurance is available.
Payment is out of pocket.

DISTRIBUTION

Through 366 hospitals and 11 212 clinics, both public and private

REFERENCES

**Pharmaceutical System**

**MONGOLIA**

### Socioeconomics

- **Population**: 3,119,935
- **Life Expectancy at Birth**: 68 years
- **GDP / Capita (PPP)**: $11,945.7

### Human Resources

- **No. of Physicians**: 28.4 per 10,000 population
- **No. of Pharmacists**: 0.6 per 1,000 population
- **Hospital Beds**: 7 per 1,000 population
- **Doctor Consultations**: 6.1 per capita

### Health Expenditure

- **Total Health Expenditure / Capita (PPP)**: $565.1
- **Public vs Private Share of Total Health Expenditure**: 55.4% Public, 44.6% Private

### Pharmaceutical Expenditure

- **Total Pharmaceutical Expenditure / Capita (PPP)**: $147.2
- **Public vs Private Share of Total Pharmaceutical Expenditure**: 26% Public, 74% Private

### Pharmaceutical Regulation

- **Regulatory Authority for Pharmaceuticals**: Ministry of Health, Center for Health Development and General Agency for State Inspection
- **Pharmaceutical Legislation**: Law on Medicines and Medical Devices 2010
- **National Medicines Policy**: National Medicines Policy 2014

### Pricing

- **Agency that Sets Price**: None
- **Pricing Regulation in the Public Sector**: NO
- **Pricing Regulation in the Private Sector**: NO
- **Free Pricing?**: YES
- **Price Negotiations?**: NO
- **External Price Referencing?**: NO
- **Internal Price Referencing?**: NO
- **VAT on Medicines**: 10%

### Procurement / Reimbursement

- **No. of Registered Medicines**: 4,688
- **No. of Products on Essential Medicines List**: 486
- **No. of Products on Procurement List**: No data available
- **No. of Products on Reimbursement List**: 190
Pharmaceutical System Flowchart

**MARKET AUTHORIZATION / LICENSING**

**NEW MEDICINE**

National Regulatory Authority

**MEDICINES AND MEDICAL DEVICES UNIT, CENTER FOR HEALTH DEVELOPMENT,**

**HUMAN DRUG COUNCIL, MINISTRY OF HEALTH**

**TASKS**

Medicines and diagnostics evaluation and registration

**CRITERIA**

Quality, safety and efficacy

**REGULATIONS**

Law on Medicines and Medical Devices 2010, National Medicines Policy 2014

**ESSENTIAL MEDICINES LIST**

**PURPOSE**

National registration of medicines, guidance for public sector procurement and insurance/reimbursement schemes

**CRITERIA**

Appropriateness to disease patterns in the country

**PROCUREMENT**

Public hospitals purchase medicines and diagnostics from private companies through competitive tender as guided by Law of Procurement 2000. Local health departments conduct tender through the procurement division of aimag and city government offices.

There are no price controls for manufacturers, importers and wholesale distributors.

**PRICING AND REIMBURSEMENT**

For the public sector

There are margins in the distribution chain: central medical stores, 10%; regional store, 15%; and public medicine outlet, 10%.

Discounted rate of medicines in the reimbursement list is 50–70% of the approved price. Insurer pays the rest.

For the private sector

There is no regulation on margins or mark-ups.

Payment is out of pocket.

**DISTRIBUTION**

Through 16 specialized hospitals, four regional diagnostic and treatment centres, 17 aimag general hospitals, 12 district general hospitals, six rural general hospitals and 546 primary health care facilities that include family health centres, soum health centres, inter-soum hospitals and village hospitals

Through 1184 private hospitals and clinics

**REFERENCES**

3. Data provided by country
**Socioeconomics**

- **Population**: 4,647,300
- **Life Expectancy at Birth**: 82 years
- **GDP / Capita (PPP)**: US$37,340

**Human Resources**

- **No. of Physicians**: 28.4 per 10,000 population
- **No. of Pharmacists**: 0.77 per 1000 population
- **Hospital Beds**: 2.8 per 1000 population
- **Doctor Consultations**: 3.7 per capita

**Health Expenditure**

- **Total Health Expenditure / Capita (PPP)**: US$4,018.3
- **Public vs Private Share of Total Health Expenditure**: 82.3% Public, 17.7% Private
- **Composition of Total Health Expenditure**: 9.4% Private, 82.3% Public

**Pharmaceutical Expenditure**

- **Total Pharmaceutical Expenditure / Capita (PPP)**: US$391.6
- **Public vs Private Share of Total Pharmaceutical Expenditure**: 68.1% Public, 31.9% Private

**Pharmaceutical Regulation**

- **Regulatory Authority for Pharmaceuticals**: Medicines and Medical Devices Safety Authority
- **National Medicines Policy**: Medicines New Zealand 2007

**Pricing**

- **Free Pricing?**: No
- **Price Negotiations?**: Yes
- **External Price Referencing?**: No
- **Internal Price Referencing?**: Yes
- **VAT on Medicines**: 15% GST

**Procurement / Reimbursement**

- **No. of Registered Medicines**: 6,262
- **No. of Products on Essential Medicines List**: more than 4,500
- **No. of Products on Procurement List**: more than 4,500
- **No. of Products on Reimbursement List**: more than 4,500

*Products on the Pharmaceutical Schedule*
Pharmaceutical Management Agency as the single purchaser of pharmaceuticals on a willing buyer - willing seller basis using strategies such as negotiation, tendering, request for proposals, rebates and reference pricing. An annual tender process is employed when medicines come off patent with the winning supplier getting the sole supply of the public health care market for a fixed term of usually three years.

There are no price controls.

For the publicly funded pharmaceuticals, eligible patients pay a co-payment (from $0 to $15), and in some instances additional costs (e.g. when the price is higher than the subsidy, fees for after-hours dispensing and special packaging).

For the non-publicly funded pharmaceuticals, payment is out of pocket.

Pharmaceuticals are mostly distributed by private wholesalers who deliver to public hospitals and to privately owned community pharmacies for dispensing to patients.

REFERENCES

4. Data provided by country.
**PHILIPPINES**

**SOCIOECONOMICS**
- Population: 102,965,300
- Life Expectancy at Birth: 69 years
- GDP / Capita (PPP): US$6,982.4
- Percentage of Children Aged below 15 Years: 32%
- Percentage of Adults Aged over 60 Years: 8%

**HUMAN RESOURCES**
- No. of Physicians: 3.56 per 10,000 population
- No. of Pharmacists: 4.19 per 1000 population
- Hospital Beds: 1.2 per 1000 population
- Doctor Consultations: No data available

**HEALTH EXPENDITURE**
- Total Health Expenditure / Capita (PPP): US$328.9
- Total Pharmaceutical Expenditure / Capita (PPP): US$109.4
- Total Health Expenditure as a Share of GDP: 34.3%
- Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita: 33.3%
- Public vs Private Share of Total Health Expenditure: 65.7% Public, 34.3% Private
- Public vs Private Share of Total Pharmaceutical Expenditure: 15% Public, 85% Private

**PHARMACEUTICAL REGULATION**
- Regulatory Authority for Pharmaceuticals: Food and Drug Administration, Dangerous Drugs Board
- National Medicines Policy: Philippine Medicines Policy

**PRICING**
- Free Pricing? No
- Price Negotiations? Yes
- External Price Referencing? Yes
- Internal Price Referencing? Yes
- VAT on Medicines: 12%

**PROCUREMENT / REIMBURSEMENT**
- No. of Registered Medicines: 19,381
- No. of Products on Essential Medicines List: 676
- No. of Products on Procurement List: 676
- No. of Products on Reimbursement List: 676

**PHARMACEUTICAL SYSTEM**
- Agency that Sets Price: Department of Health
- Formulary Executive Council, Department of Health: Body Responsible for Selection of Products for Public Procurement/Reimbursement
- Body Responsible for Health Technology Assessment: Department of Health

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*a Only for selected medicines through Maximum Drug Retail Price*
Pharmaceutical System Flowchart

NEW MEDICINE

MARKET AUTHORIZATION / LICENSING

National Regulatory Authority
FOOD AND DRUG ADMINISTRATION

TASKS
Licensing, market authorization, regulation and classification of drugs

CRITERIA
Quality, safety and efficacy

REGULATIONS

FORMULARY EXECUTIVE COUNCIL, PHARMACEUTICAL DIVISION, DEPARTMENT OF HEALTH

PURPOSE
Evaluation of application for inclusion to the Philippine National Formulary

CRITERIA
Local public health context, burden of disease, comparative efficacy and safety relative to the current standard of care or medicines listed in the Philippine National Formulary, comparative cost-effectiveness, affordability and equity

PROCUREMENT

Department of Health and local governments using the 2016 Revised Implementing Rules and Regulations of Republic Act No. 9164, otherwise known as the Government Procurement Reform Act

PRIVATE SECTOR HOSPITALS AND PHARMACIES


The Drug Price Reference Index sets reference prices for procurement in public health facilities and for drug reimbursements through social health insurance.

PRICING AND REIMBURSEMENT

For the public sector
Access to basic essential drugs in public primary health care facilities through mixed provision from national and local governments
Under the social health insurance scheme, case rate policy for total inpatient care includes essential drugs.
Currently, there is no outpatient drug benefit.

For the private sector
Payment is out of pocket or through health maintenance organizations.

DISTRIBUTION

Mixed public-private system
Public health services are provided through a network of hospitals, local health units and village health stations.
Private sector supplies health services through hospitals, clinics, diagnostic centres and pharmacies.

REFERENCES
Pharmaceutical System

SINGAPORE

SOCIOECONOMICS¹,²,³

- Population: 5,470,000
- Life Expectancy at Birth: 83 years
- GDP / Capita (PPP): US$ 80,191.5

HUMAN RESOURCES³

- No. of Physicians: 21 per 10,000 population
- No. of Pharmacists: 0.5 per 1000 population
- Hospital Beds: 2.2 per 1000 population
- Doctor Consultations: 1.7 per capita

HEALTH EXPENDITURE²,⁵

- Total Health Expenditure / Capita (PPP): US$ 2,538
- Total Health Expenditure as a share of GDP: 4.3%
- Public vs Private Share of Total Health Expenditure: 54.2% Public, 45.8% Private
- Composition of Total Health Expenditure:
  - General Government: 43.8%
  - Out-of-Pocket: 30.7%
  - Social Health Care: 15.1%
  - Voluntary Health Care Payment: 10.4%

PHARMACEUTICAL REGULATION

- Regulatory Authority for Pharmaceuticals: Health Sciences Authority
- Pharmaceutical Legislation: Health Products Act
- National Medicines Policy: No Formal National Medicines Policy

PHARMACEUTICAL EXPENDITURE

- Total Pharmaceutical Expenditure / Capita (PPP): No data available
- Public vs Private Share of Total Pharmaceutical Expenditure: No data available

PRICING

- Free Pricing?: YES
- Price Negotiations?: YES
- External Price Referencing?: NO
- Internal Price Referencing?: NO
- VAT on Medicines: NO

PROCUREMENT / REIMBURSEMENT

- Body Responsible for Selection of Products for Public Procurement/Reimbursement: Drug Advisory Committee, Ministry of Health
- Body Responsible for Health Technology Assessment: Agency for Care Effectiveness
- No. of Registered Medicines: 5,500
- No. of Products on Essential Medicines List: No data available
- No. of Products on Procurement List: 590
- No. of Products on Reimbursement List: 1,040

a Health-care expenditures paid out from voluntary or private sources
b Combined compulsory medical savings accounts, social health insurance, and other government-supported schemes not classified elsewhere
MARKET AUTHORIZATION / LICENSING

Tasks: Licensing and market authorization of drugs
Criteria: Quality, safety and efficacy
Regulations: Health Products Act

NEW MEDICINE

National Regulatory Authority
Health Sciences Authority

DRUG ADVISORY COMMITTEE, MINISTRY OF HEALTH

Purpose: Recommendation for inclusion of drugs to the Standard Drug List
Criteria: Clinical relevance and cost-effectiveness in the management of common diseases affecting the majority

SELECTION

PROCUREMENT

The Group Procurement Office consolidates drug purchases for the health-care system at the national level.
Private sector hospitals and pharmacies

There are no price controls for manufacturers, importers and wholesale distributors.

PRICING AND REIMBURSEMENT

For the public sector:
All people are entitled to subsidized medical services and treatments at government polyclinics and hospitals.
The Drug Advisory Committee decides on suitability of drugs for subsidy based on disease burden, clinical need, comparative clinical benefits and safety, cost-effectiveness and budget impact.

For the private sector:
Payment is out of pocket.

Mixed public-private system

The primary care sector consists of around 1900 private medical clinics and 17 government polyclinics.
Hospital care in the public sector is organized into two vertically integrated delivery networks, National Healthcare Group and Singapore Health Services.
The Community Health Assist Scheme subsidizes visits to any of the 720 participating medical clinics and 460 dental clinics for acute conditions, specified chronic illnesses, specified dental procedures, and recommended health screening.

REFERENCES

3. Data provided by country
Pharmaceutical System

THAILAND

**Socioeconomics**
- Population: 65,729,000
- Life Expectancy at Birth: 75 years
- 14% Percentage of Adults Aged over 60 years
- 18% Percentage of Children Aged below 15 years
- GDP / Capita (PPP): US$15,346.7

**Human Resources**
- No. of Physicians: 4.9 per 10,000 population
- No. of Pharmacists: 0.19 per 1000 population
- Hospital Beds: 2.3 per 1000 population
- Doctor Consultations: 2.1 per capita

**Health Expenditure**
- Total Health Expenditure / Capita (PPP): US$658.2
- Total Health Expenditure as a Share of GDP: 4.6%
- Public vs Private Share of Total Health Expenditure: 77% Public, 23% Private
- Composition of Total Health Expenditure:
  - 69.1% General Government
  - 10.8% Other Private
  - 12.2% Out-of-Pocket
  - 7.9% Social Health Insurance

**Pharmaceutical Expenditure**
- Total Pharmaceutical Expenditure / Capita (PPP): US$599.84
- Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita: 33.6%
- Public vs Private Share of Total Pharmaceutical Expenditure: 90.6% Public, 9.4% Private

**Pharmaceutical Regulation**
- Regulatory Authority for Pharmaceuticals: Food and Drug Administration
- Pharmaceutical Legislation: Drug Act 1967

**Pricing**
- Free Pricing?: YES
- Price Negotiations?: YES
- External Price Referencing?: YES
- Internal Price Referencing?: YES
- VAT on Medicines: 7%

**Procurement / Reimbursement**
- Body Responsible for Selection of Products for Public Procurement/Reimbursement: National Essential Drugs List Subcommittee
- Body Responsible for Health Technology Assessment: Health Intervention and Technology Assessment Program

**Human Resources**
- No. of Physicians: 4.9 per 10,000 population
- No. of Pharmacists: 0.19 per 1000 population
- Hospital Beds: 2.3 per 1000 population
- Doctor Consultations: 2.1 per capita

**Health Expenditure**
- Total Health Expenditure / Capita (PPP): US$658.2
- Total Health Expenditure as a Share of GDP: 4.6%
- Public vs Private Share of Total Health Expenditure: 77% Public, 23% Private
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**Pharmaceutical Expenditure**
- Total Pharmaceutical Expenditure / Capita (PPP): US$599.84
- Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita: 33.6%
- Public vs Private Share of Total Pharmaceutical Expenditure: 90.6% Public, 9.4% Private

**Pharmaceutical Regulation**
- Regulatory Authority for Pharmaceuticals: Food and Drug Administration
- Pharmaceutical Legislation: Drug Act 1967

**Pricing**
- Free Pricing?: YES
- Price Negotiations?: YES
- External Price Referencing?: YES
- Internal Price Referencing?: YES
- VAT on Medicines: 7%

**Procurement / Reimbursement**
- Body Responsible for Selection of Products for Public Procurement/Reimbursement: National Essential Drugs List Subcommittee
- Body Responsible for Health Technology Assessment: Health Intervention and Technology Assessment Program

**Human Resources**
- No. of Physicians: 4.9 per 10,000 population
- No. of Pharmacists: 0.19 per 1000 population
- Hospital Beds: 2.3 per 1000 population
- Doctor Consultations: 2.1 per capita

**Health Expenditure**
- Total Health Expenditure / Capita (PPP): US$658.2
- Total Health Expenditure as a Share of GDP: 4.6%
- Public vs Private Share of Total Health Expenditure: 77% Public, 23% Private
- Composition of Total Health Expenditure:
  - 69.1% General Government
  - 10.8% Other Private
  - 12.2% Out-of-Pocket
  - 7.9% Social Health Insurance

**Pharmaceutical Expenditure**
- Total Pharmaceutical Expenditure / Capita (PPP): US$599.84
- Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita: 33.6%
- Public vs Private Share of Total Pharmaceutical Expenditure: 90.6% Public, 9.4% Private

**Pharmaceutical Regulation**
- Regulatory Authority for Pharmaceuticals: Food and Drug Administration
- Pharmaceutical Legislation: Drug Act 1967

**Pricing**
- Free Pricing?: YES
- Price Negotiations?: YES
- External Price Referencing?: YES
- Internal Price Referencing?: YES
- VAT on Medicines: 7%

**Procurement / Reimbursement**
- Body Responsible for Selection of Products for Public Procurement/Reimbursement: National Essential Drugs List Subcommittee
- Body Responsible for Health Technology Assessment: Health Intervention and Technology Assessment Program

**Human Resources**
- No. of Physicians: 4.9 per 10,000 population
- No. of Pharmacists: 0.19 per 1000 population
- Hospital Beds: 2.3 per 1000 population
- Doctor Consultations: 2.1 per capita

**Health Expenditure**
- Total Health Expenditure / Capita (PPP): US$658.2
- Total Health Expenditure as a Share of GDP: 4.6%
- Public vs Private Share of Total Health Expenditure: 77% Public, 23% Private
- Composition of Total Health Expenditure:
  - 69.1% General Government
  - 10.8% Other Private
  - 12.2% Out-of-Pocket
  - 7.9% Social Health Insurance

**Pharmaceutical Expenditure**
- Total Pharmaceutical Expenditure / Capita (PPP): US$599.84
- Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita: 33.6%
- Public vs Private Share of Total Pharmaceutical Expenditure: 90.6% Public, 9.4% Private

**Pharmaceutical Regulation**
- Regulatory Authority for Pharmaceuticals: Food and Drug Administration
- Pharmaceutical Legislation: Drug Act 1967

**Pricing**
- Free Pricing?: YES
- Price Negotiations?: YES
- External Price Referencing?: YES
- Internal Price Referencing?: YES
- VAT on Medicines: 7%

**Procurement / Reimbursement**
- Body Responsible for Selection of Products for Public Procurement/Reimbursement: National Essential Drugs List Subcommittee
- Body Responsible for Health Technology Assessment: Health Intervention and Technology Assessment Program

[1] Number of international nonproprietary names of medicines listed
[2] Number of international nonproprietary names of medicines on Central Procurement List for Universal Coverage Scheme and Social Security Scheme
## Pharmaceutical System Flowchart

### MARKET AUTHORIZATION / LICENSING

**TASKS**
- Licensing, registration, inspection, surveillance and adverse event monitoring for all drugs and drug companies
- Safety, quality, efficacy, stability studies and process validation (for new drugs): product information, product manufacturing, quality control, bioequivalence studies and literature supporting safety and efficacy claims (for generic drugs)

**CRITERIA**

**REGULATIONS**

### NATIONAL ESSENTIAL DRUGS LIST SUBCOMMITTEE

**PURPOSE**
- Setting up of the National Essential Drugs List and drug use criteria

**CRITERIA**
- National health need, safety, efficacy, compliance, quality, total treatment cost, cost-effectiveness, equity, availability, national affordability and budget impact

### PROCUREMENT

Public hospitals can purchase medicines, either essential or non-essential, using the budget that they can be reimbursed with from health insurances through capitation.

For some high-volume items, regional/provincial procurement is done to get the lowest prices.

There are around 106 items considered as special access items for which the National Health Security Office and Social Security Office contract the Government Pharmaceutical Organization to do central procurement and delivery to health-care providers.

### PRICING AND REIMBURSEMENT

For individuals and drugs covered by any public insurance system

Drugs in the National Essential Drugs List can be reimbursed with or without any co-payment under the drug benefit packages of the tax-based insurance systems.

Drugs outside the National Essential Drugs List can be reimbursed under fee-for-service outpatient system of the Civil Service Medical Benefit Scheme.

Health facilities determine whether they need to use drugs outside the List since drugs are included in the capitation budget of insurance systems.

Private insurance is available to supplement coverage.

For individuals and drugs not covered by any public insurance system

Private insurance is available

Payment is out of pocket.

### DISTRIBUTION

The public health facilities are at various levels: regional, provincial, district, subdistrict and village.

There are 322 private hospitals, 18 503 medical clinics, 16 692 drugstores and 2058 traditional medicine drugstores.

### REFERENCES

3. Data provided by country
Pharmaceutical System

VIET NAM

SOCIOECONOMICS

91,680,000 Population
76 years Life Expectancy at Birth

10% Percentage of Adults Aged over 60 Years
23% Percentage of Children Aged below 15 Years

US$5,525.8 GDP / Capita (PPP)

HUMAN RESOURCES

11.9 per 10,000 population No. of Physicians
No data available No. of Pharmacists
2.5 per 1000 population Hospital Beds
2.3 per capita Doctor Consultations

HEALTH EXPENDITURE

US$390.5 Total Health Expenditure / Capita (PPP)

54.1% Public Total Health Expenditure as a Share of GDP
45.9% Private

29.98% General Government Public vs Private Share of Total Health Expenditure
9.19% Other Private
38.76% Out-of-Pocket
24.07% Social Health Insurance

PHARMACEUTICAL EXPENDITURE

US$123.7 Total Pharmaceutical Expenditure / Capita (PPP)

33.2% Pharmaceutical Expenditure as a Share of Total Health Expenditure / Capita

16.5% Public Public vs Private Share of Total Pharmaceutical Expenditure
83.5% Private

PHARMACEUTICAL REGULATION

Drug Administration of Vietnam Regulatory Authority for Pharmaceuticals
The Pharmacy Law (No. 105/2016/QH13) Pharmaceutical Legislation
National Strategy for Pharmaceutical Sector Development National Medicines Policy

PRICING

YES Agency that Sets Price
Ministry of Health, together with Ministry of Finance

YES Pricing Regulation in the Public Sector

YES Pricing Regulation in the Private Sector

5% VAT on Medicines

PROCUREMENT / REIMBURSEMENT

45,000 No. of Registered Medicines
466 No. of Products on Essential Medicines List
100b No. of Products on Procurement List
900c No. of Products on Reimbursement List

a Price control function only
b For centralized procurement only
c Active pharmacological ingredients
**Pharmaceutical System Flowchart**

**MARKET AUTHORIZATION / LICENSING**

**NEW MEDICINE**

National Regulatory Authority  
**DRUG ADMINISTRATION OF VIETNAM, MINISTRY OF HEALTH**

**TASKS**  
Licensing, registration, inspection, advertising management, price management of chemical and herbal medicines and pharmaceutical companies

**CRITERIA**  
Quality, safety and efficacy

**REGULATIONS**  
The Pharmacy Law (No. 105/2016/QH13), National Strategy for Pharmaceutical Sector Development

**MARKET AUTHORIZATION / LICENSING**

**DEPARTMENT OF HEALTH INSURANCE, MINISTRY OF HEALTH**

**PURPOSE**  
Development of the Major Drug List as basis for selecting drugs and as reference for insurance reimbursement

**CRITERIA**  
Appropriateness to disease patterns in the country

**PROCUREMENT**

Centralized procurement for national programs as guided by the Bidding Law (No. 43/2013/QH13), The Pharmacy Law (No. 105/2016/QH13) and Pricing Law

Decentralized procurement for hospitals and provincial health departments

**DEPARTMENT OF HEALTH INSURANCE, MINISTRY OF HEALTH**

**PURPOSE**  
For the public sector

**PRICING AND REIMBURSEMENT**

**For the public sector**

Vietnam Social Security guides Provincial (and District) Social Securities for payment and managing cost of drugs as they directly pay health-care providers.

**For the private sector**

Drugs on the Reimbursement Drug List are funded through the Health Insurance Fund through private health establishments (hospitals) under contract with a health insurance institution.

**DISTRIBUTION**

Mixed public-private system

Public health facilities include 1030 hospitals, 641 clinics, 62 rehabilitation and sanatorium hospitals, 10 757 medical service units in wards and communes, and 715 medical offices in companies.

**REFERENCES**

3. Data provided by country

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