





HOW **PHARMACEUTICAL SYSTEMS** ARE ORGANIZED IN ASIA AND THE PACIFIC

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CONTENTS

Executive summary	. 1
Introduction	. 2
Socio-economics	. 3
Human resources	. 3
Health expenditure	. 4
Pharmaceutical expenditure	. 4
Pharmaceutical regulation and pricing	. 6
Pharmaceutical procurement and reimbursement	. 6
Country profiles	. 7

EXECUTIVE SUMMARY

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.

INTRODUCTION

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.

SOCIO-ECONOMICS

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, lifestyles, 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.

HUMAN RESOURCES

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.

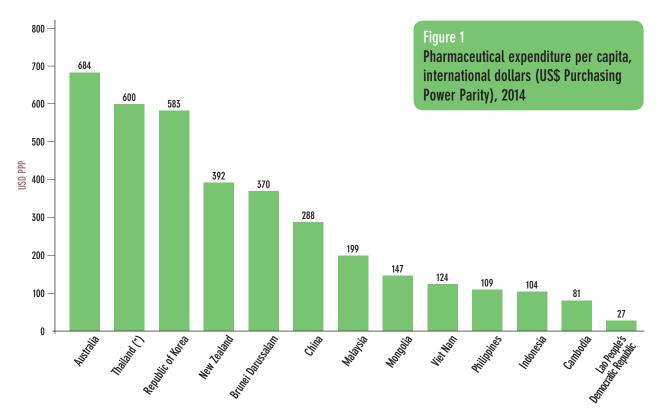
HEALTH EXPENDITURE

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.

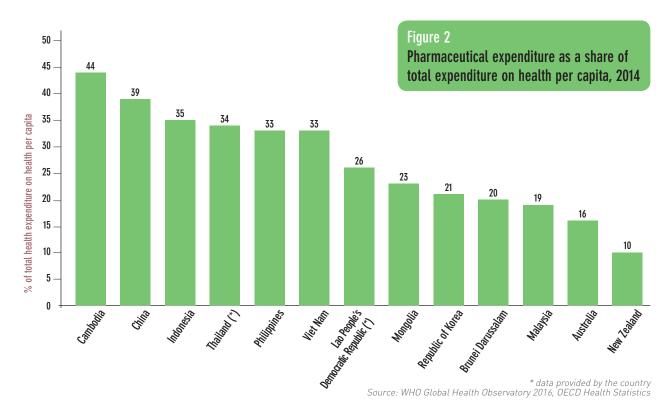
The share of government in total health spending varies from as high as 93.8% in Brunei Darussalam to as low as 18.9% in China, whereas out-of-pocket spending accounts for more than half of the THE in Cambodia (74.2%), the Philippines (53.7%) and the Lao People's Democratic Republic (52.6%). Out-of-pocket 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

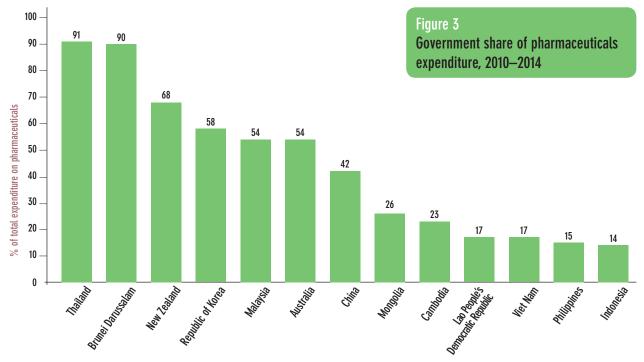
A large variation in pharmaceutical spending is observed across countries in the study. Per capita pharmaceutical spending ranges from \$ 27.3 in the Lao People's Democratic Republic and \$ 683.5 in Australia (Figure 1).



* 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).



Source: WHO Global Health Observatory 2016, OECD Health Statistics

PHARMACEUTICAL REGULATION AND PRICING

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.

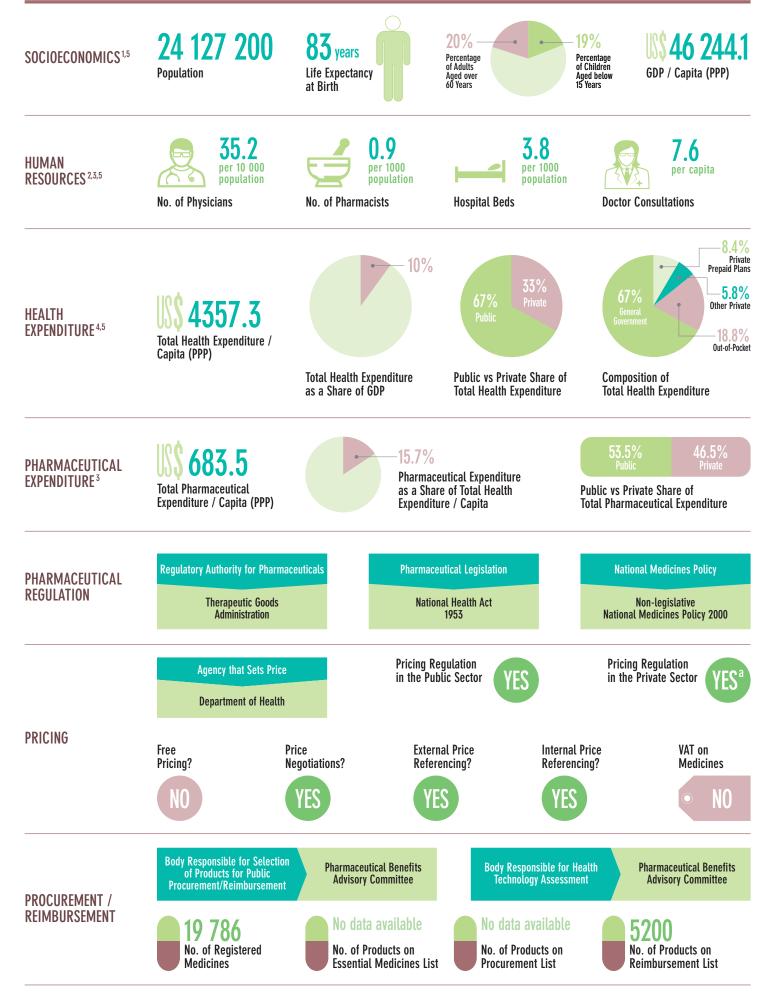
Internal price referencing is not used in Indonesia, the Republic of Korea, Mongolia and Singapore. External price referencing is not used in Indonesia, Mongolia, New Zealand and Singapore. Except for Australia, Brunei Darussalam and Singapore, there is value-added tax on medicines in countries in the study ranging from 5% in Viet Nam to 17% in China.

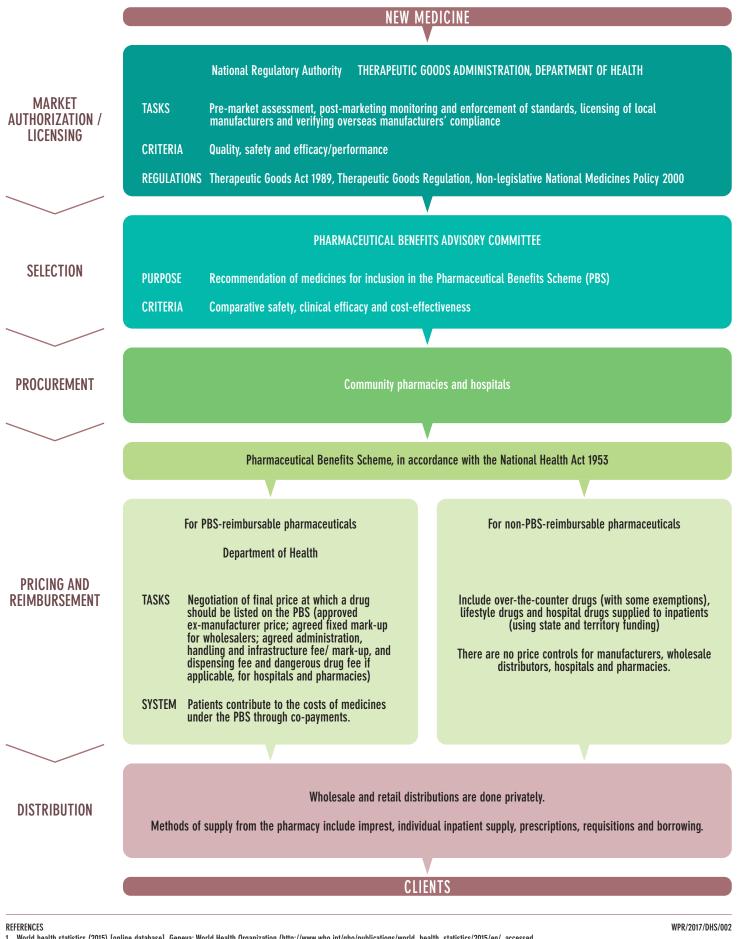
PHARMACEUTICAL PROCUREMENT AND REIMBURSEMENT

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.

COUNTRY PROFILES

AUSTRALIA





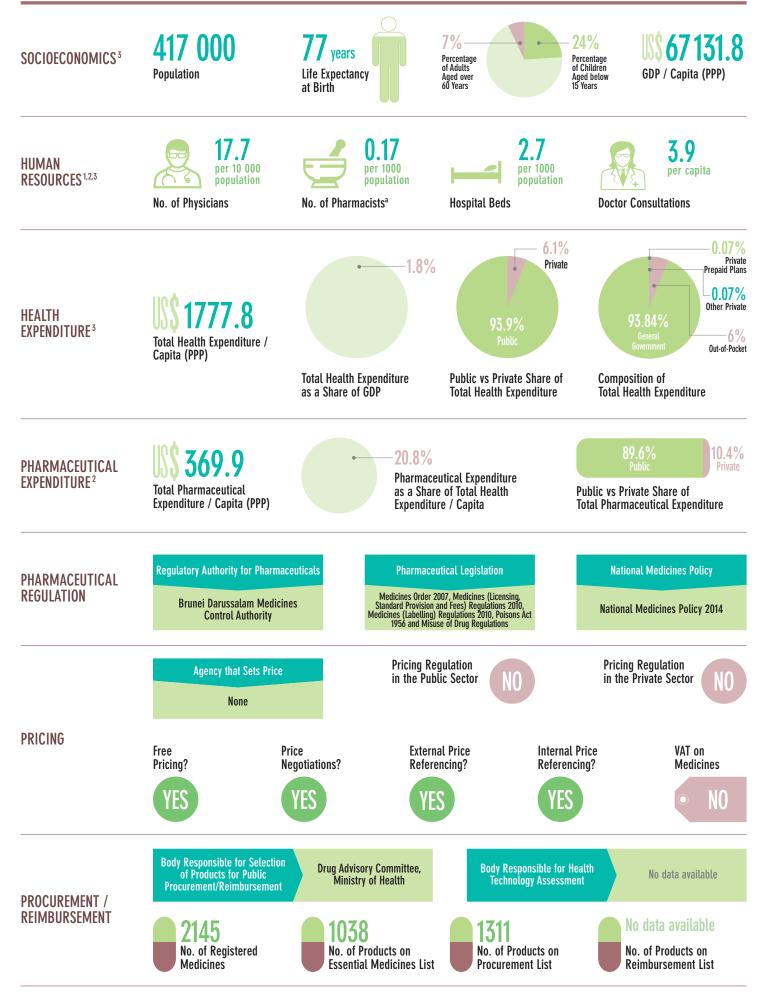
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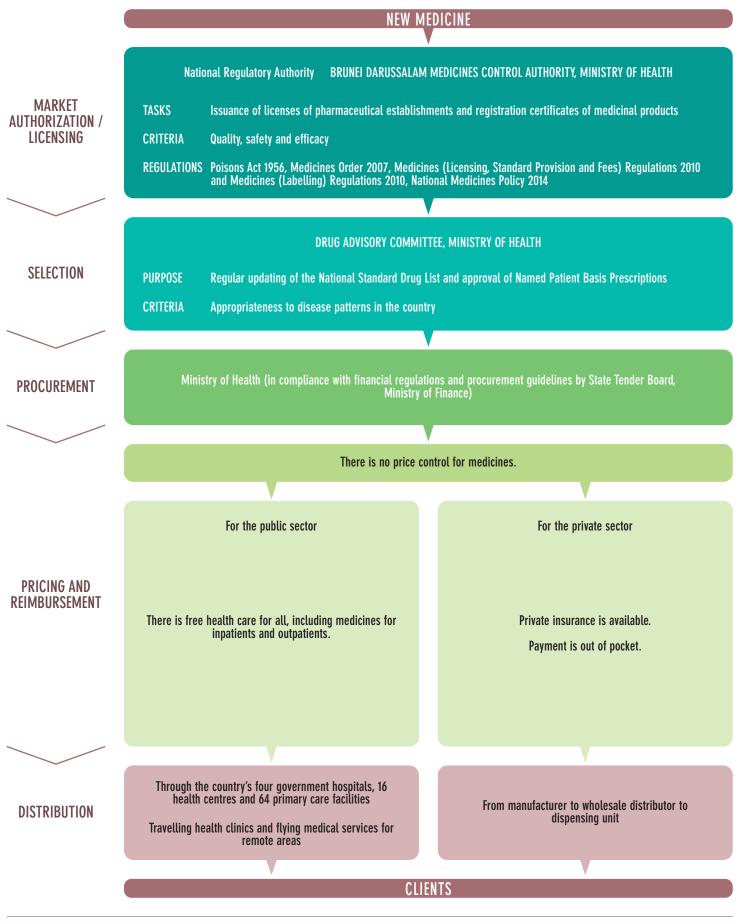
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BRUNEI DARUSSALAM





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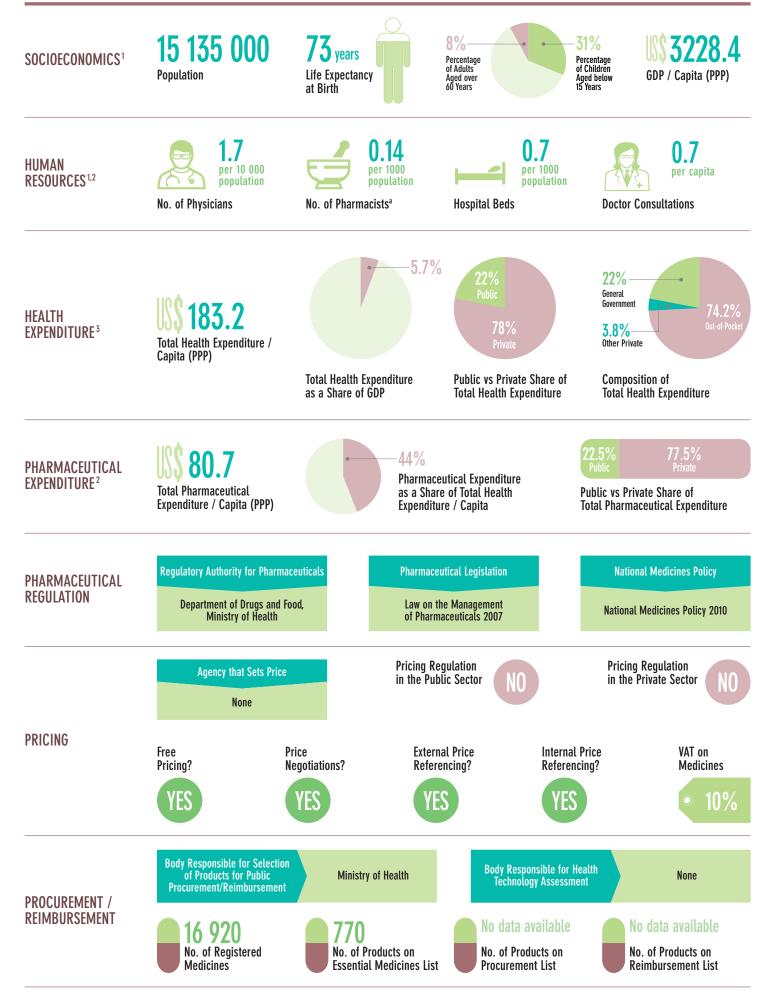
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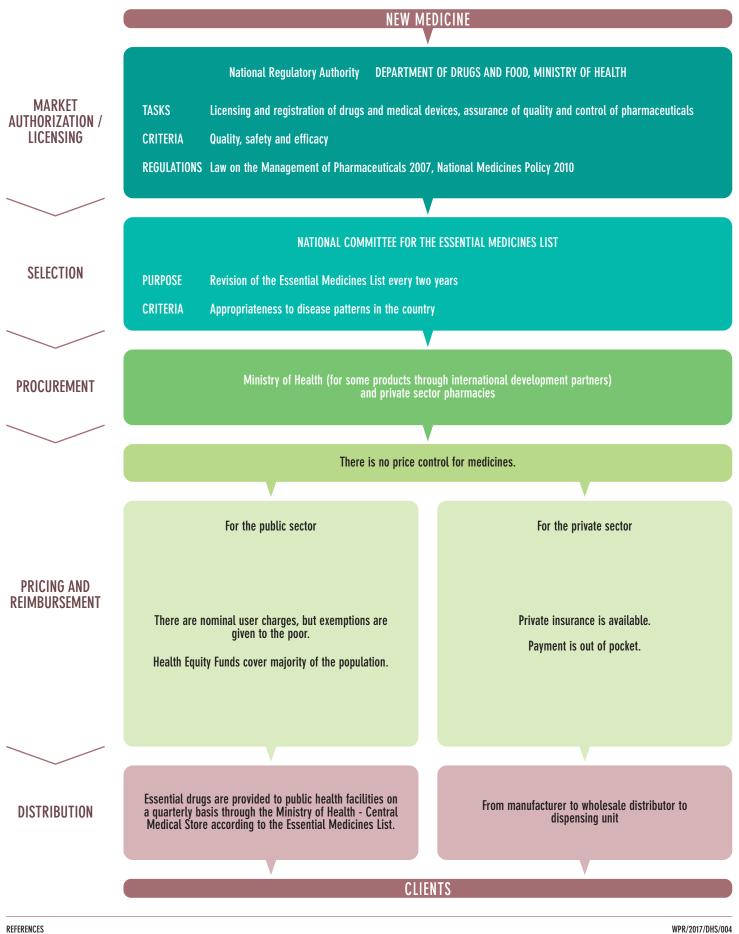
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CAMBODIA



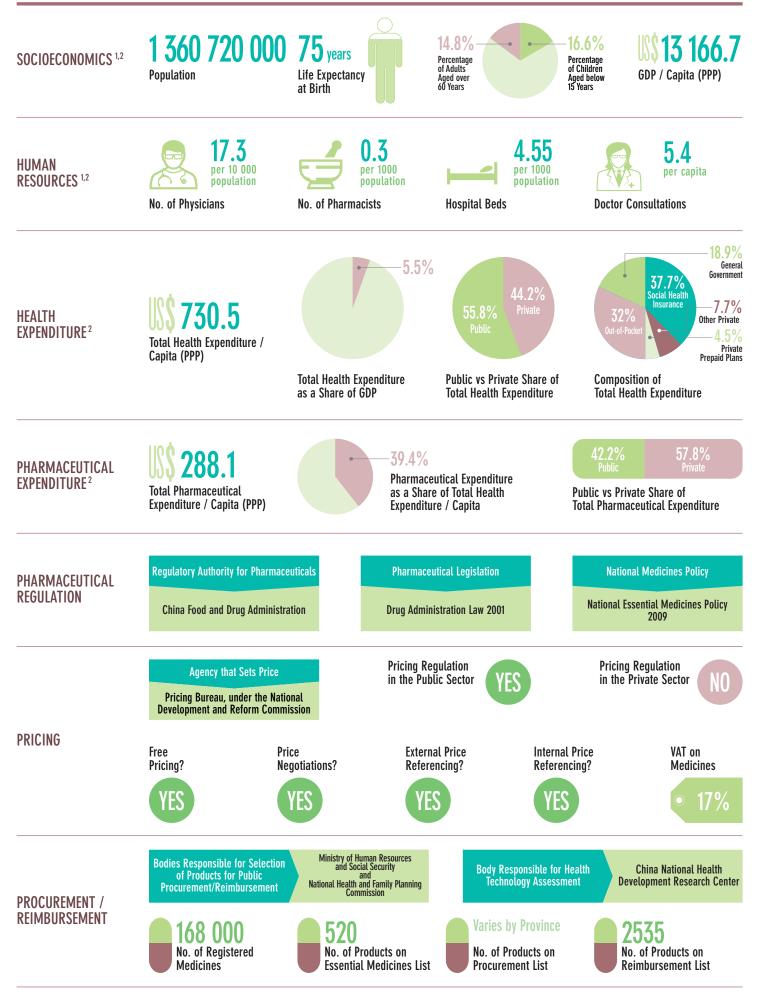


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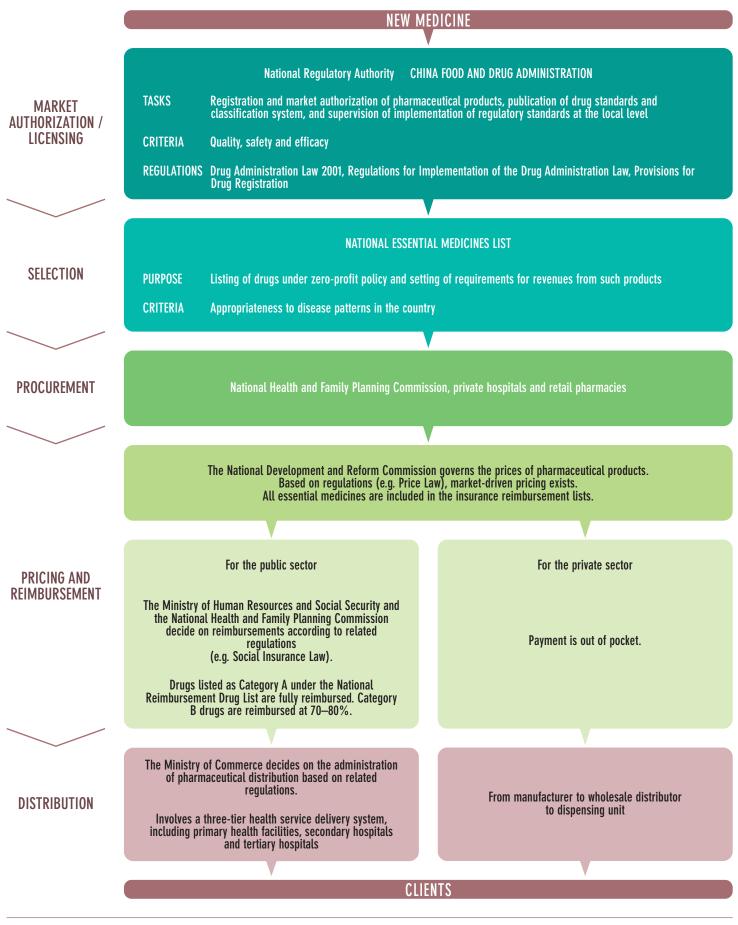
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CHIN



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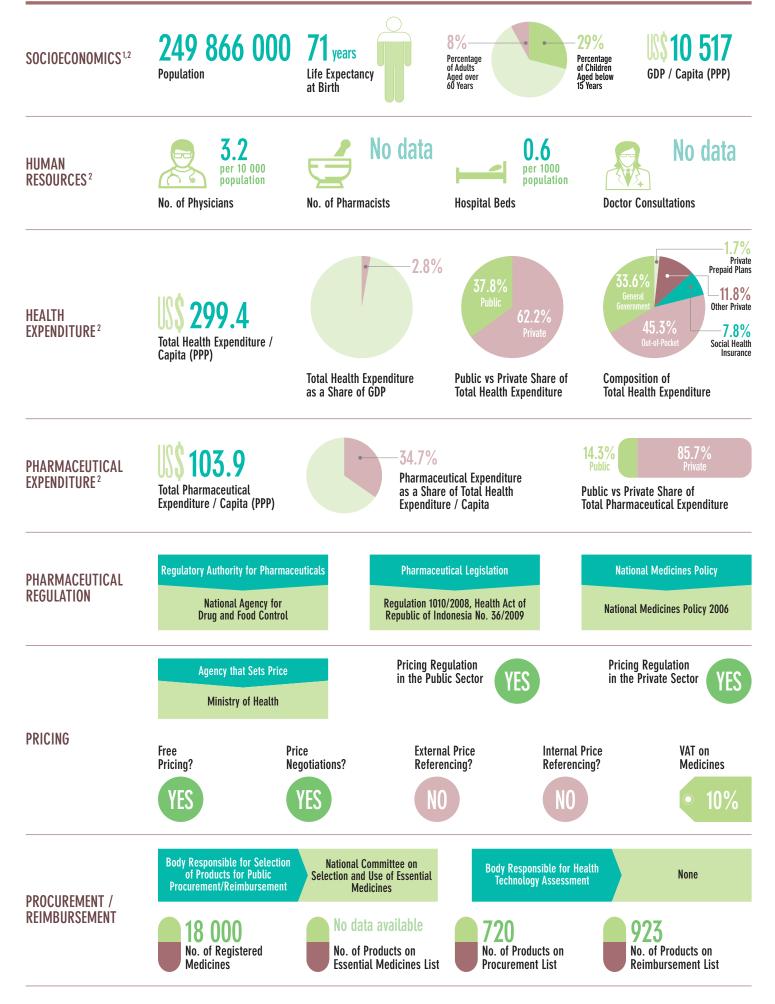
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INDONESIA



	NEW MEDICINE		
MARKET Authorization / Licensing	National Regulatory AuthorityNATIONAL AGENCY FOR DRUG AND FOOD CONTROL (NA-DFC)TASKSAssessment, organization, implementation and monitoring of national policy in food and drug evaluation field; registration, marketing authorization and licensingCRITERIAQuality, safety, efficacy, risk and people's needsREGULATIONSNA-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	NATIONAL COMMITTEE ON SELECTION AND USE OF ESSENTIAL MEDICINES, MINISTRY OF HEALTH 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		
PRICING AND REIMBURSEMENT	The Ministry of Health sets both the ceiling prices for tende maximum retail price 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.	r of generic medicines for public sector procurement, and the en in the private sector. 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 530 public warehouses in the secondary tier of public distribution	From manufacturer to wholesale distributor to dispensing unit and with many players at each level	
	CLIENTS		

REFERENCES

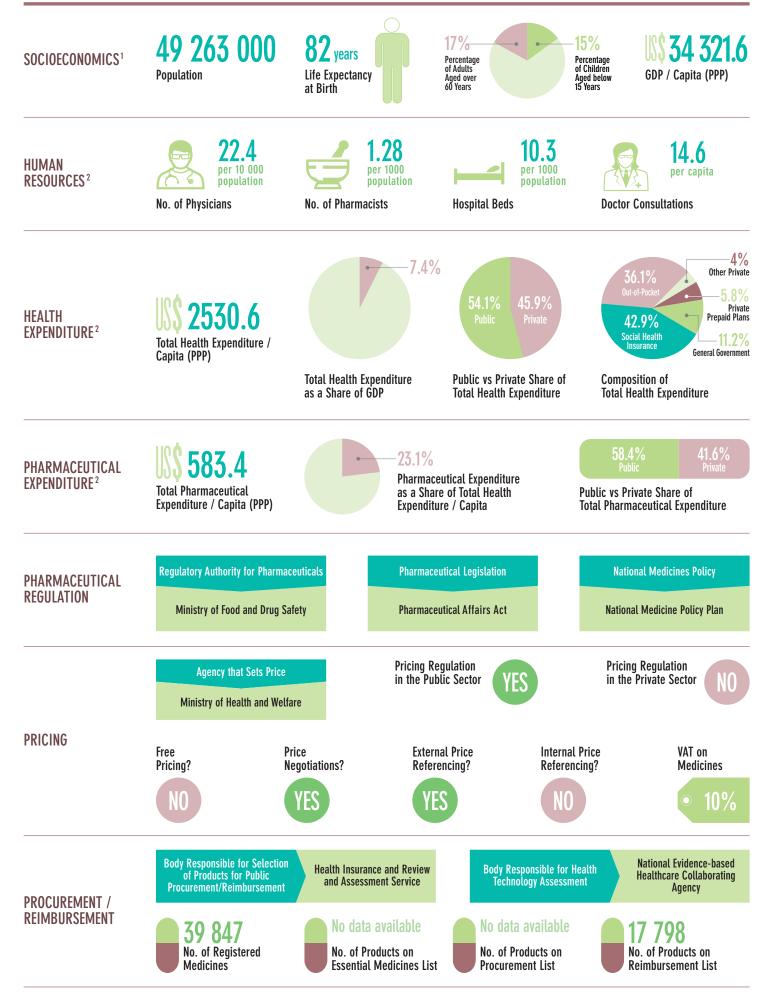
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REPUBLIC OF KOREA



	NEW MEDICINE		
	National Regulatory Authority PHARMACEUTICAL	SAFETY BUREAU, MINISTRY OF FOOD AND DRUG SAFETY	
MARKET AUTHORIZATION / LICENSING	TASKSDrug approval and registrationCRITERIAQuality, safety, efficacy and information on production and sale in origin country (for imported products)REGULATIONSPharmaceutical Affairs Act		
SELECTION	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 impa	act	
PROCUREMENT	Public and private hospitals, clinics and pharmacies employing medical tenders and competitive bids		
	Medicine prices are regulated if such costs are reimbursed by the National Health Insurance Service.		
PRICING AND REIMBURSEMENT	For pharmaceuticals in the Positive List Reimbursement ceilings for new products are determined through negotiations between the National Health Insurance Service and the manufacturer, reviewed by the NHIPDC and announced by the Minister of Health and Welfare.	For pharmaceuticals not in the Positive List	
	Pharmaceutical Benefit Review Committee sets listed price for essential drugs if price negotiation fails. The prices are reviewed by NHIPDC and announced by the Minister of Health and Welfare.	Payment is out of pocket.	
	Reimbursement ceiling price for generic products and off-patent drugs is 53.55% of the innovator product's price, pursuant to the regulations of the Ministry of Health and Welfare.		
	Zero margin policy is applied in order for the reimbursement to be based on actual transaction price.		
DISTRIBUTION	All public and private hospitals, clinics and pharmacies are legally obliged to subscribe as providers.		
	CLIENTS		

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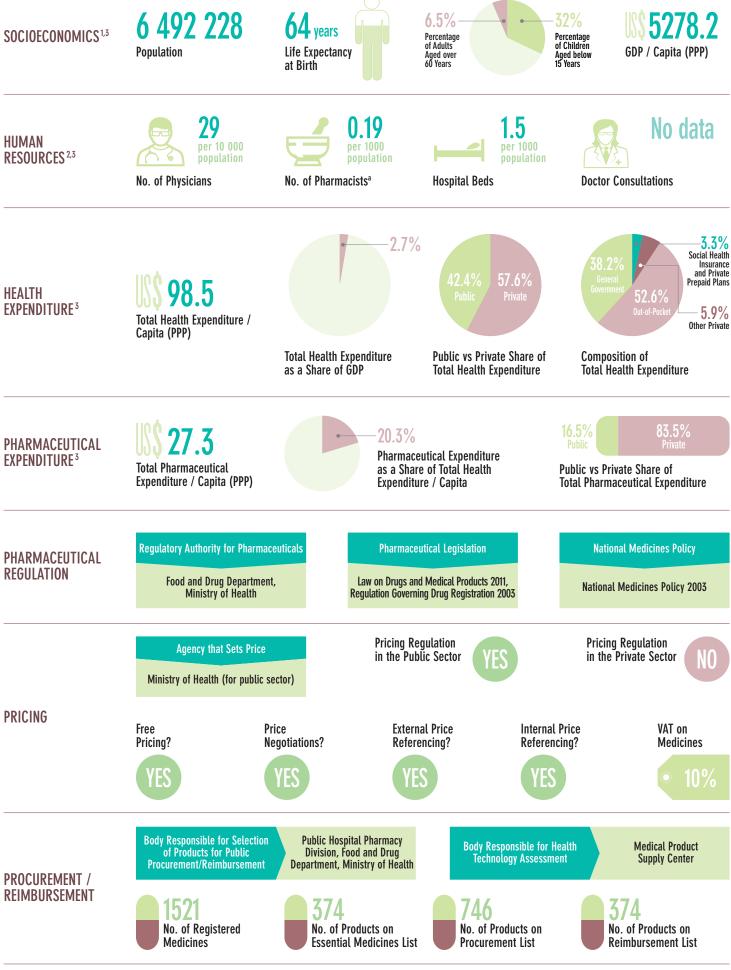
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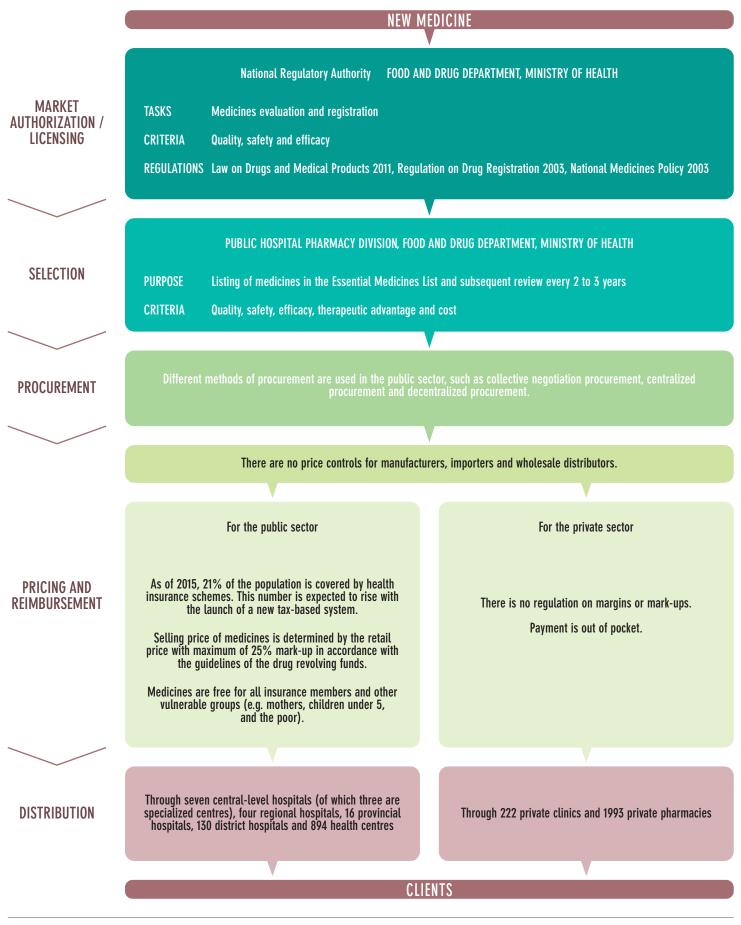
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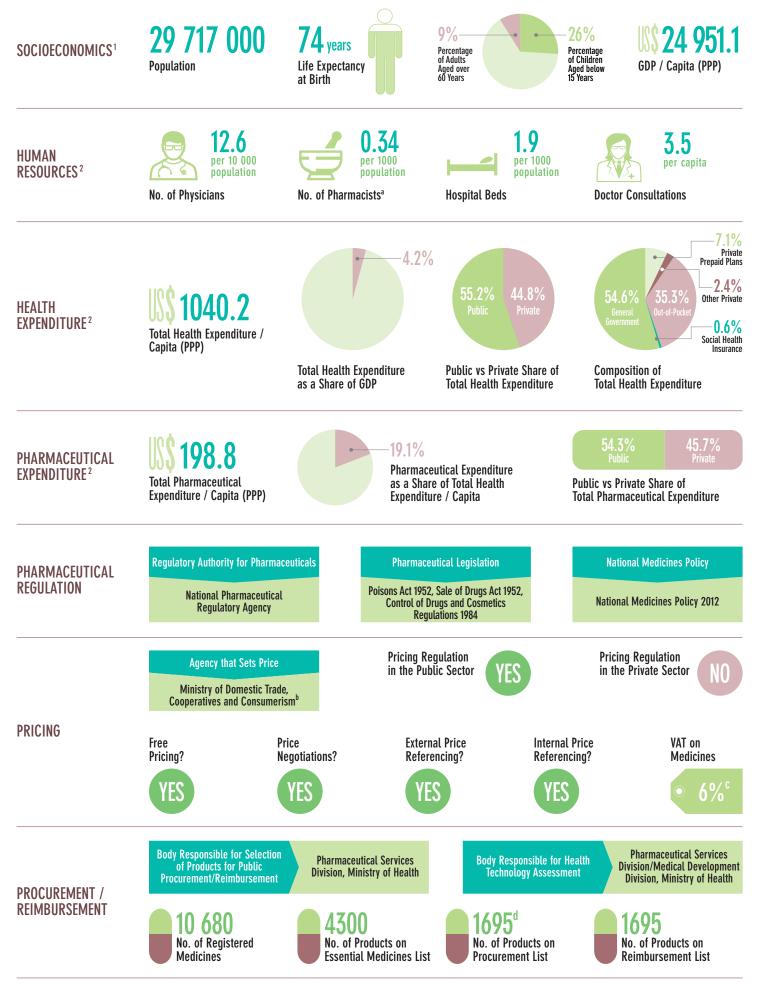
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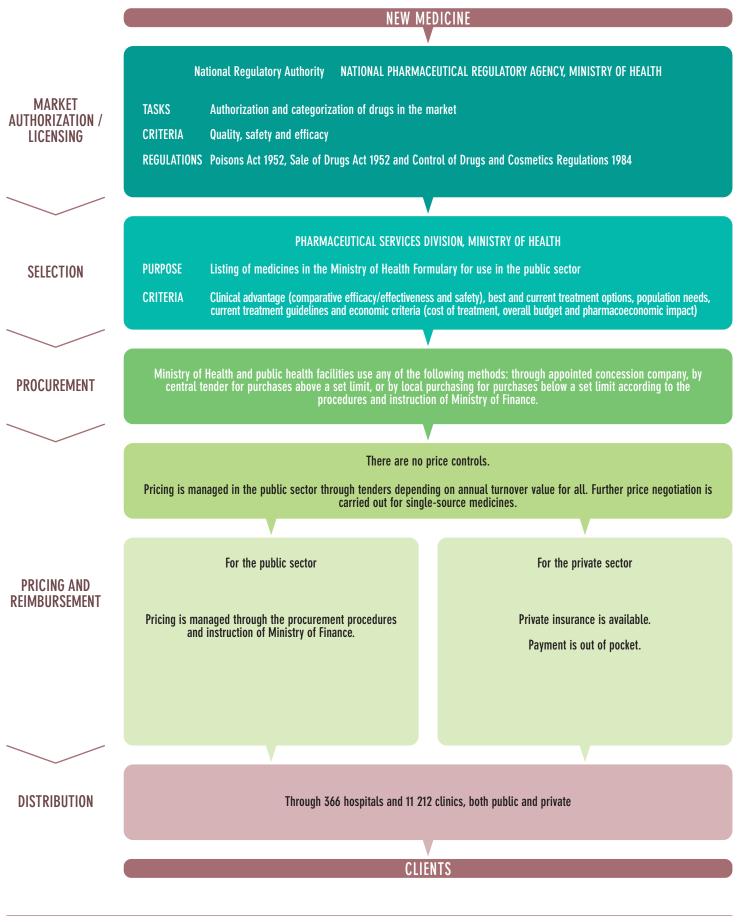
MALAYSIA



Pharmaceutical personnel

b

Monitoring function only Zero for prescription drugs and items listed on the National Essential Medicines List Number of international nonproprietary names of medicines listed c d



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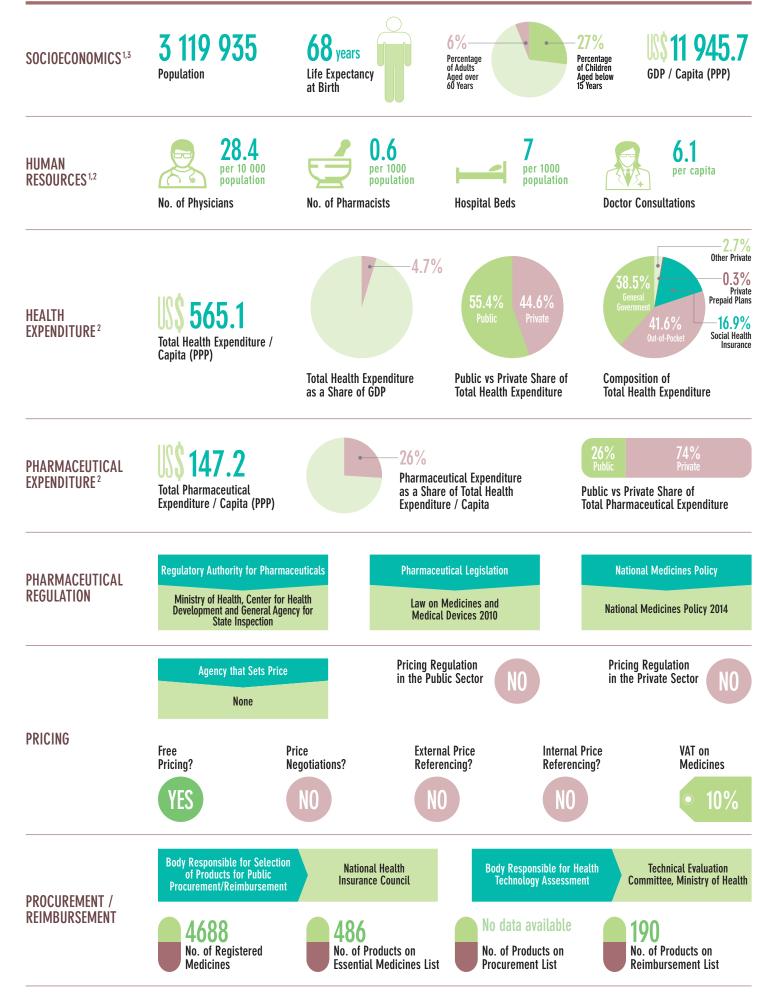
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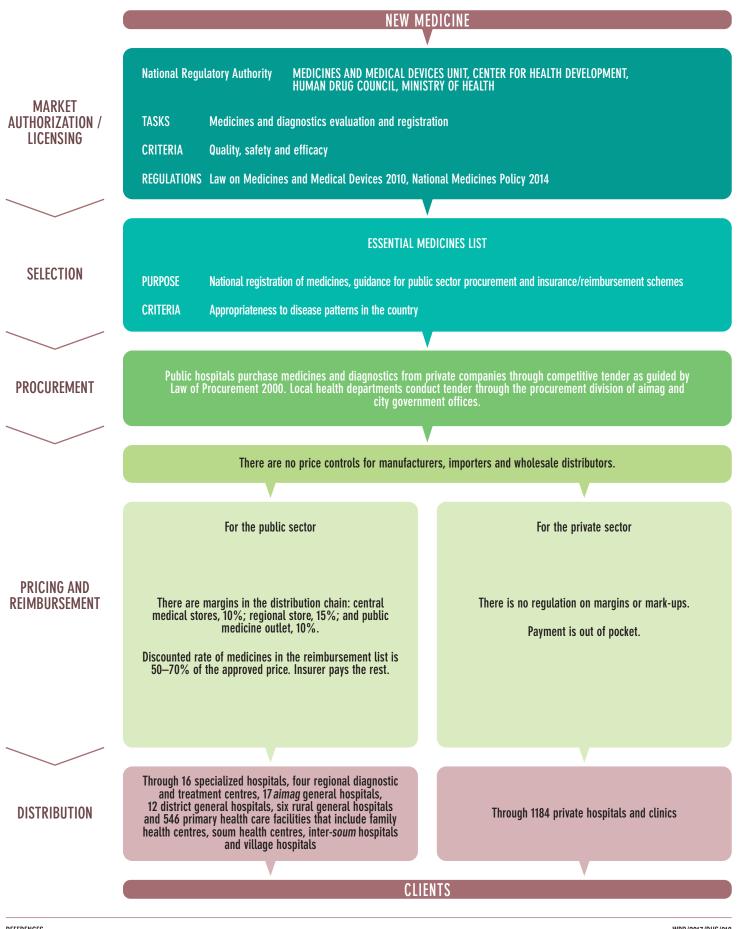
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MONGOLIA





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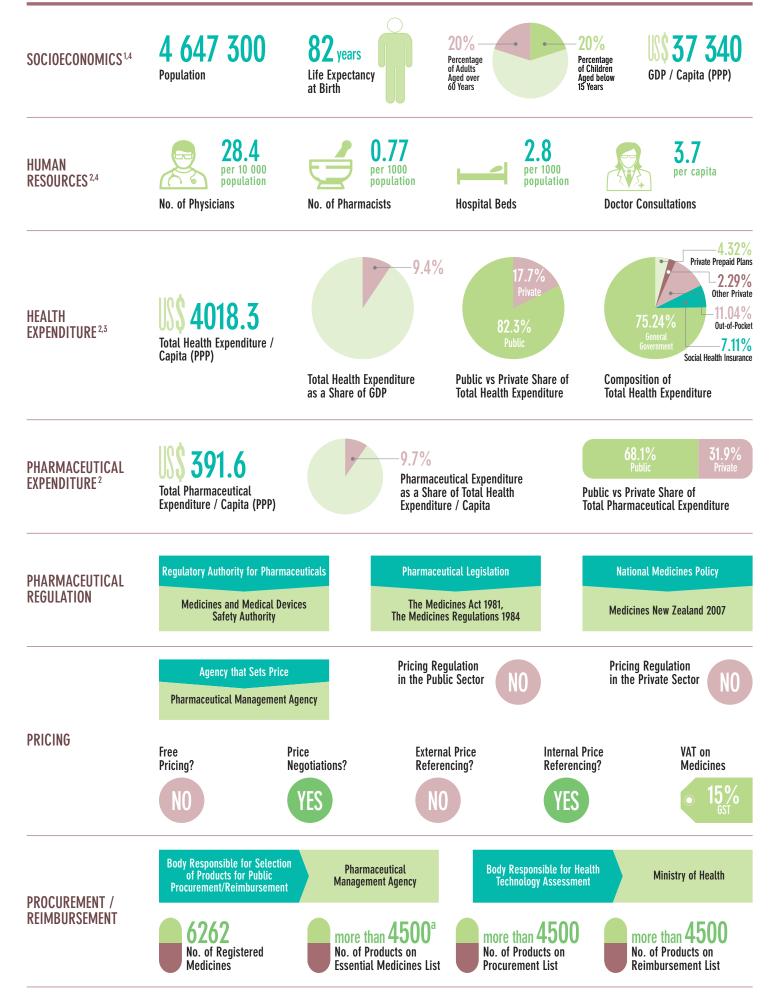
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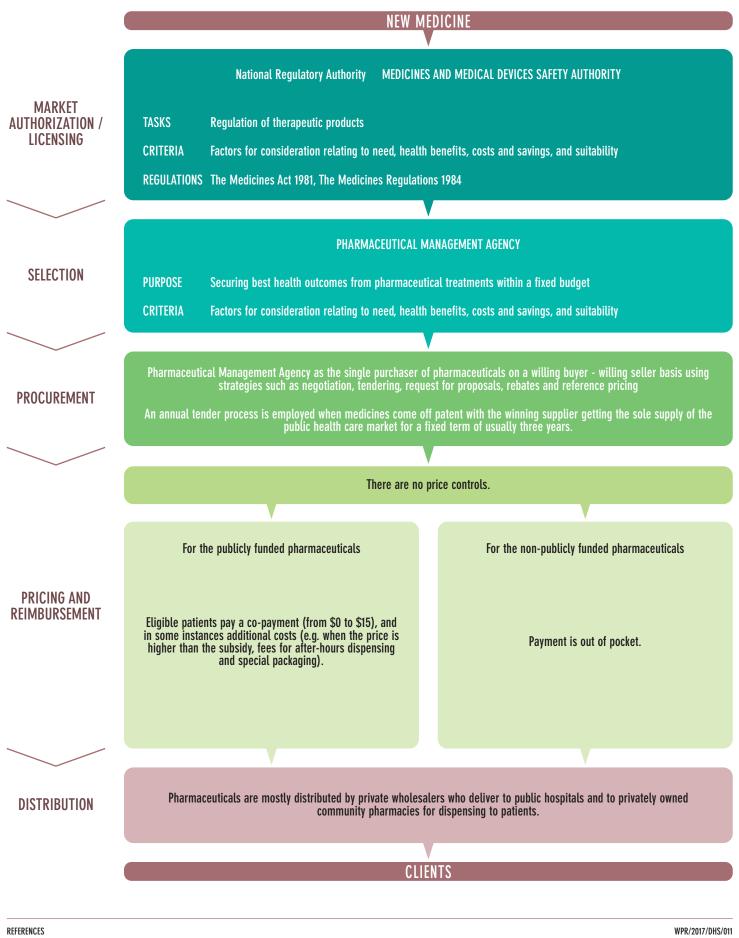
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NEW ZEALAND





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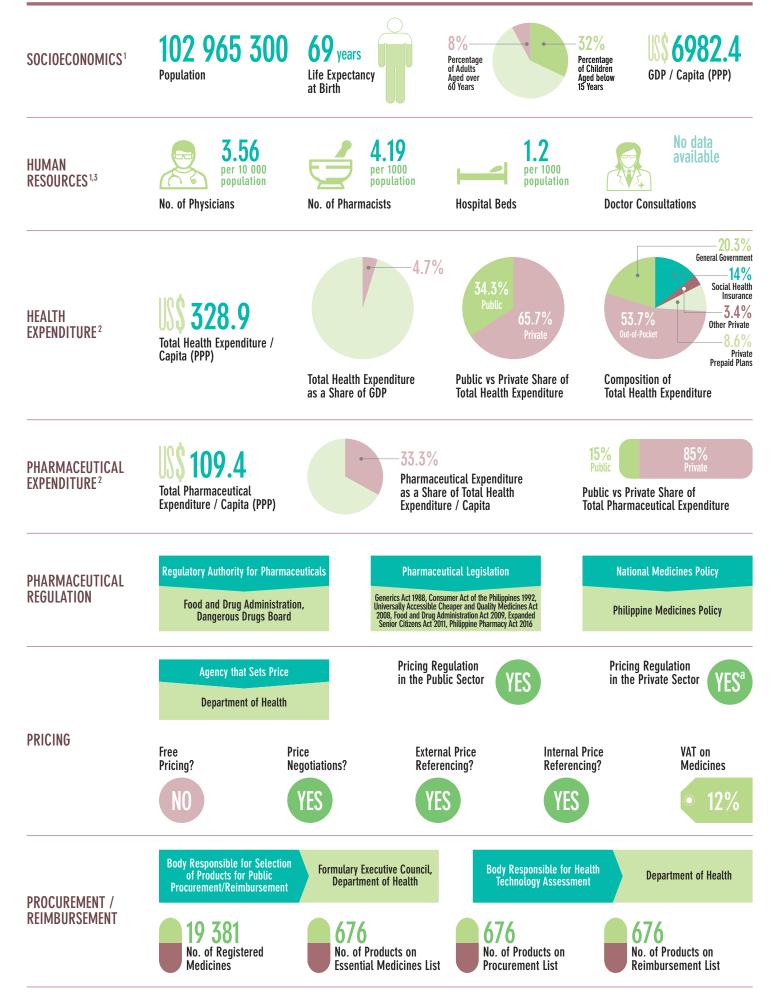
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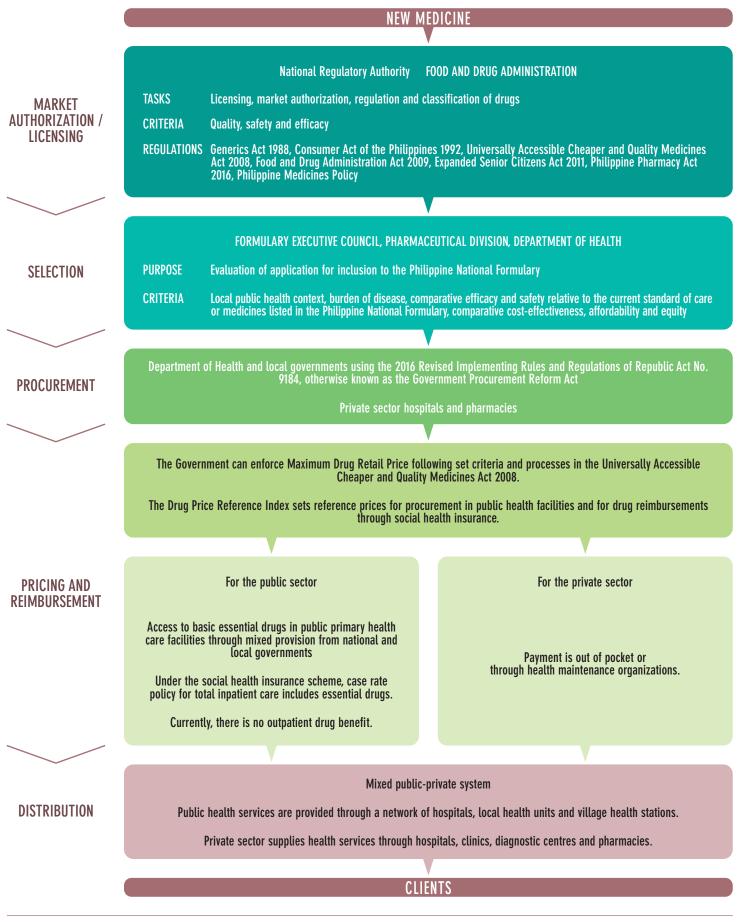
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PHILIPPINES





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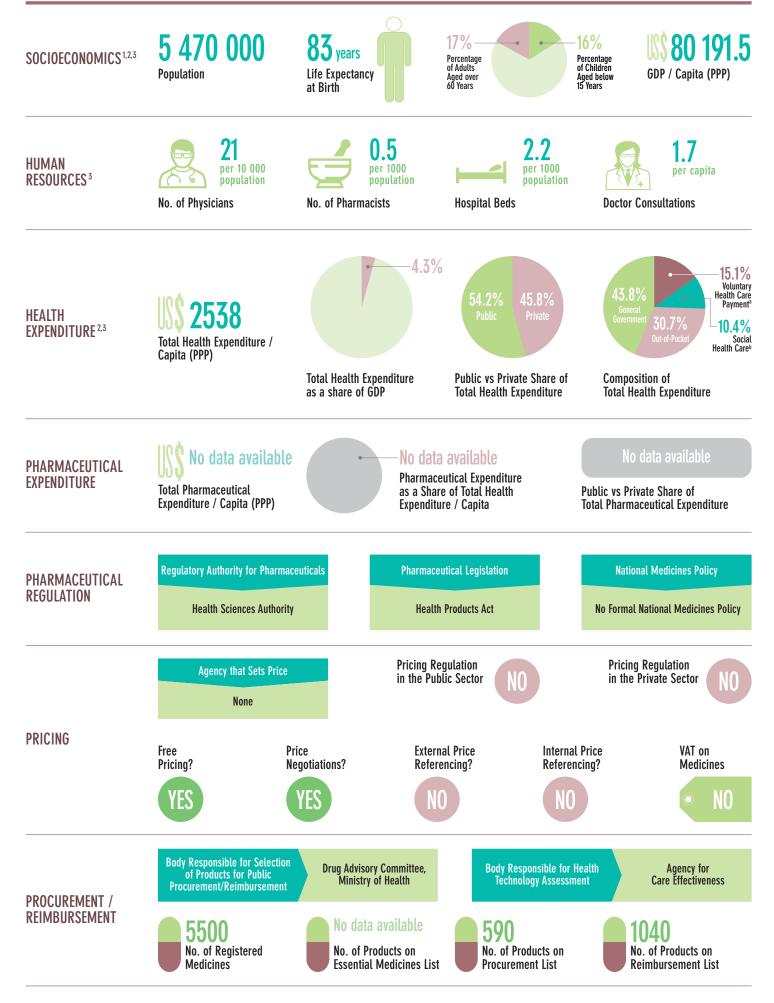
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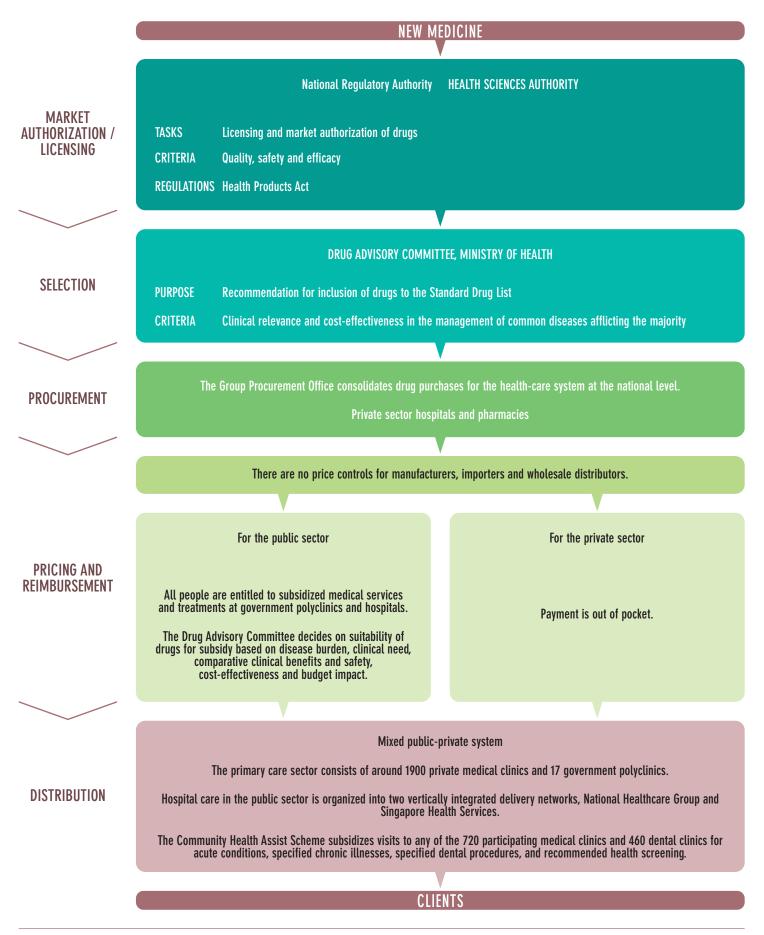
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SINGAPORE



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



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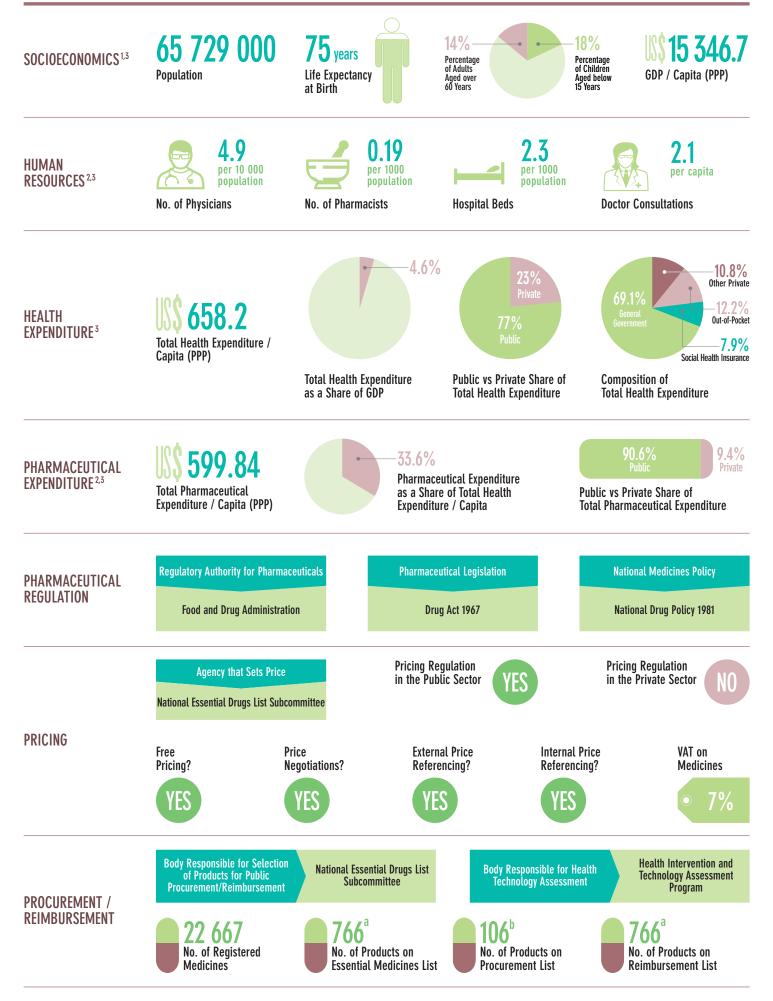
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3 Data provided by country

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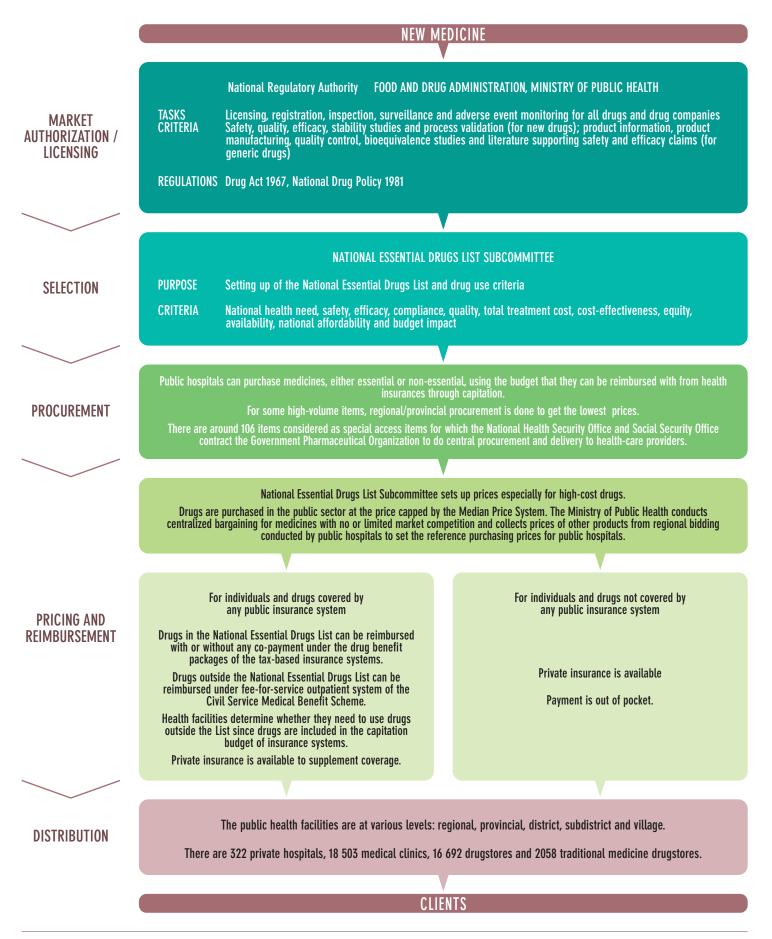
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THAILAND



a Number of international nonproprietary names of medicines listed b Number of international nonproprietary names of medicines on Centr

Number of international nonproprietary names of medicines on Central Procurement List for Universal Coverage Scheme and Social Security Scheme



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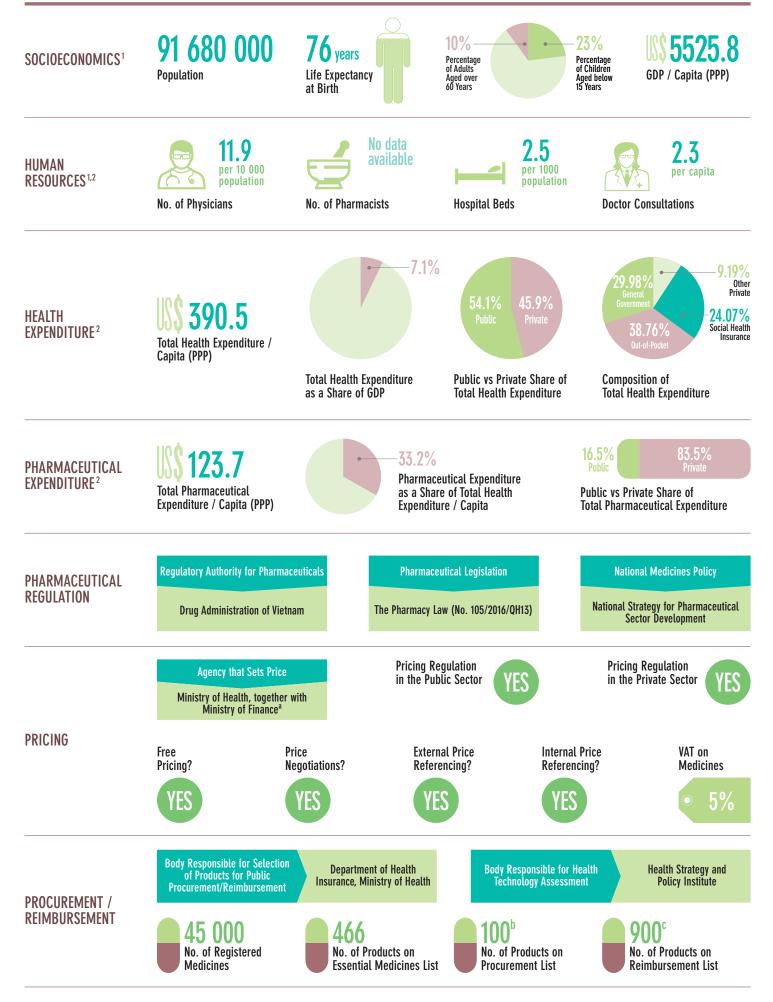
3 Data provided by country

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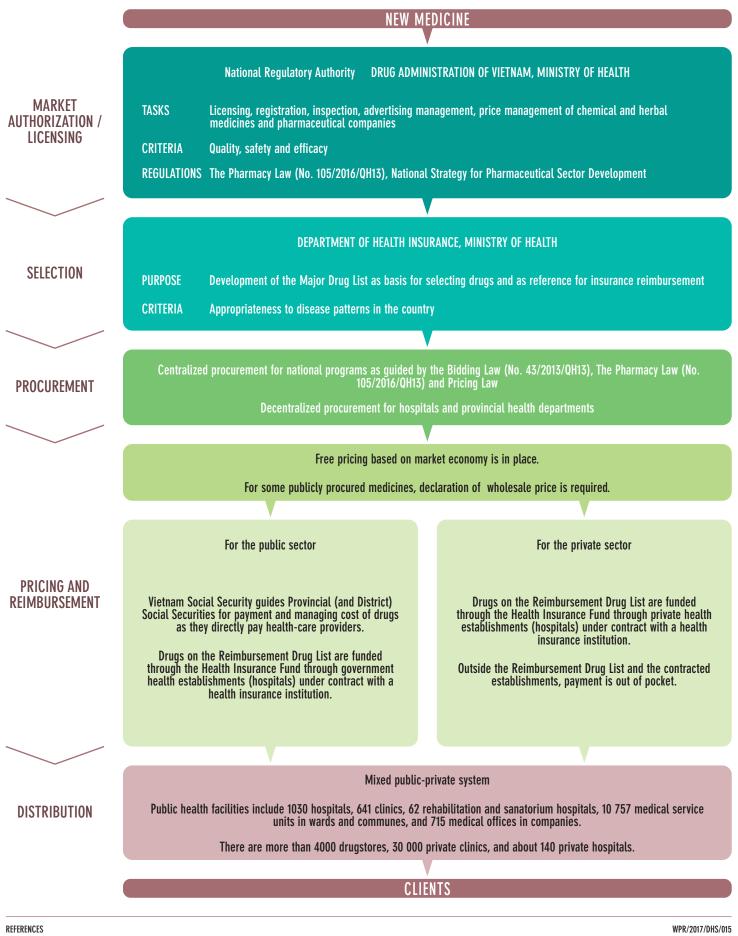
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VIET NAM



a Price control function only b For centralized procurement only c Active pharmacological ingredients



1 World health statistics (2015) [online database]. Geneva: World Health Organization (http://www.who.int/gho/publications/world_health_statistics/2015/en/, accessed 25 November 2016).

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3 Data provided by country

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