Survey on Pharmaceutical Policy and Financing in Asia-Pacific Countries

2015. 11.

OECD KOREA Policy Centre
Graduate School of Public Health, Seoul National University
(WHO Collaborating Centre for Health System and Financing)

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ADRs (Adverse Drug Reactions)

DDD (Defined Daily Dose)

DOH (Department of Health)

DPRI (Drug Price Reference Index)

DUR (Drug Utilization Review)

GDP (Good Distribution Practices)

GDP (Gross Domestic Product)

GMP (Good Manufacturing Practices)

GPP (Good Pharmacy Practice)

GSP (Good Supplying Practice)

HIRA (Health Insurance Review and Assessment)

HTA (Health Technology Assessment)

INN (International Nonproprietary Name)

KCDC (Korea Center for Disease Control)

MFDS (Ministry of Food and Drug Safety)

MOHW (Ministry of Health and Welfare)

NHIS (National Health Insurance Service)

NHS (National Health Service)

OECD (Organization for Economic Co-operation and Development)

OTC (Over-The-Counter pharmaceuticals)

P&T committee (Pharmaceutical and Therapeutic committee)

PHIC (Philippine Health Insurance Corporation)

PHIS (Pharmaceutical Health Information System)

PNF (Philippine National Formulary)

POM (Prescription-Only Medicines)

PPRI (Pharmaceutical Pricing and Reimbursement Information)

SHI (Social Health Insurance)

STGs (Standard Treatment Guidelines)

TRIPS (Trade Related Intellectual Properties)

UHC (Universal Health Coverage)

WHO (World Health Organization)

WHOCC (World Health Organization Collaborating Centre)

WPRO (Western Pacific Regional Office)

WTO (World Trade Organization)

I. Introduction

1. Background

1.1 Importance of pharmaceutical policies for UHC

One of the key objectives of national health system is to guarantee timely access to health services and reduce financial burden due to healthcare cost. Universal health coverage (UHC) is considered as an well-functioning financing system to achieve those goals. What are covered and/or how much cost is paid as well as how many people are covered are discussed on the way to universal health coverage. However, this discussion has been mainly focused on the use of medical service and rarely dealt with topics about the access to and rational use of medicines (Kwon, 2014).

The pharmaceutical sector influences the performance of health system in terms of population's health, satisfaction of the public health sector, and cost-effectiveness of treatment, etc. In addition, pharmaceutical cost is one of the leading causes of high health expenditure, so the pharmaceutical policy plays an important role in determining the economic burden of payers in health care system (Roberts and Reich 2011).

Access to medicines is also an important issue in health policy, especially for low- and middle- income countries. Pharmaceutical policy can be a main factor that determines people's attitude toward national health system because most of the treatments exclusively depend on the use of medicines in those countries (Roberts and Reich 2011).

Therefore, pharmaceutical policy and financing need to be dealt with in the national health system policy framework for UHC. Health financing systems need to be designed to reduce out-of-pocket (OOP) expenditures due to medicines and improve the cost-effective use of medicines through active management strategies involving medicines selection, purchasing, and contracting and utilization management.

1.2 Need for regional network on pharmaceutical policies

Whereas pharmaceutical policy is usually formed at the national level, the cooperation across countries is increasing in the formulation and implementation of the policy. For example, European countries established network for Pharmaceutical Pricing and Reimbursement Information(PPRI) in 2005 in order to share information and key issues of pharmaceutical policy and to enhance collaboration. Insurers and authorities across twenty eight European countries are included in this network, which produces pharmaceutical indicators based on real data collected from 28 PPRI countries and country reports about their pharmaceutical system and policy.

The need for regional collaboration has been also raised among Asia-Pacific countries for the development of pharmaceutical policy and financing and achieving universal access to medicines. Asia-Pacific countries have diverse health systems, many in transition, with different policies and implementation processes used to increase access to medicines. The need and demand for evidence-based policy decision are now increasing, and the comparison of pharmaceutical system performance across countries therefore can be important as the recent World health Assembly Resolution (WHA 67.22) called on to Members states "to promote collaboration and strengthen the exchange of information on best practices in the development, implementation and evaluation of medicine policies and strategies that enhance access to affordable, safe, effective and quality-assured essential medicines".

Especially, Asia-pacific countries have common policy challenge, which is to design health system that promotes appropriate access and cost-effective use of medicines and decreases the financial burden due to high OOP for medicines. The proportion of OOP payment in total health expenditures is much higher in the Asia Pacific region than in other regions, which reflects the lack of prepayment mechanisms and heavy reliance on OOP payment to finance the costs of health care in the region. Particularly, the relatively high percentage of pharmaceutical expenditure to total health expenditure is one of the key features of Asia Pacific countries (Teh-Wei 2004).

The Asia-Pacific network on access to medicines under UHC was established

in 2014. Tools for data collection using country profile was discussed in the first meeting in Seoul, 2014 and the results of short survey were shared through the second meeting in 2015.

1.3 Need to collect information on national pharmaceutical system and policies using common tools

One of the key objectives of the Asia-Pacific network on pharmaceutical policies is to develop evidence-based policies through comparative policy review and analysis. However, most of low- and middle-income countries of Asia have poor monitoring system for pharmaceutical policies, so accessible data on each country's pharmaceutical system is quite limited. In order to understand country-specific pharmaceutical system and strengthen collaboration across countries, it is important to systematically collect and share information using common tools.

WHO collaborating centre (WHOCC) for health system and financing at Seoul National University has developed the Pharma Profile Template on the basis of two main sources: PPRI/PHIS pharma profile and WHO's pharmaceutical sector country profile questionnaire. It covers all relevant issues of pharmaceutical pricing and reimbursement in a country. Regular collection and exchange of information through this kind of common tool can contribute to in-depth comparison of the pharmaceutical system in Asia-Pacific countries.

2. Purpose of the report

This report aims to investigate and describe the current status of pharmaceutical policies and financing in Asia-Pacific countries. Specifically, this report is to present the results of comparative analysis which was conducted on the key indicators of health system in a country. In addition, it is to provide the results of pilot-survey using the pharma template developed by the WHOCC. Finally, it is to identify the possible limitations of our template through the feedback of participating countries.

3. Structure of the report

The outline of this report is as follows:

Part Ⅱ presents the current status of pharmaceutical system and financing in Asia-Pacific countries. The first section of Part Ⅱ provides the results of the comparative analysis, which is mainly quantitative data about health care and pharmaceutical system. The second section of Part Ⅱ examines the results of the pilot survey for the Philippines and Korea, which were conducted using the Pharma Profile Template.

Part Ⅲ presents the feedback opinion about information need and data availability for pharma template, provided by the countries of the network.

Part Ⅳ highlights the key findings of the survey and comparative analysis.

4. Methodology

4.1 Development of pharma template

We developed two types of survey template to investigate the current status of pharmaceutical policy and financing in a country: brief country profile and long version country profile. Brief country profile is composed of 2-page information on socioeconomic and health expenditure, pharmaceutical policies and flowchart on pharmaceutical systems. Detailed contents are shown in the following table.

Table 1. Brief country profile

Socioeconomics	Population, life expectancy, GDP per capita
Human resource & Health care delivery	No. of physicians/pharmacist, doctor consultation, hospital beds
Expenditure on health	Total health expenditure(public/private share) Composition of THE (government/SHI/OOP etc) OOP composition(in-patient/out-patient/medicines)
Pharmaceutical expenditure	Pharmaceutical expenditure (public/private share) PE share of THE
Pharmaceutical marketing authorization	Regulatory authority for medicines No. of registered medicines
Pricing	Pricing regulation in the public/private sector Pricing policies (free pricing/pricing negotiation/external referencing/internal referencing/VAT on medicines)
Procurement & Reimbursement	Agency for reimbursement decision/public procurement Agency for health technology assessment Procurement/reimbursement list No. of medicines on reimbursement/procurement list No. of essential medicines

Long version of country profile covers all relevant issues of pharmaceutical policy and financing in a country. It contains over 60 pages of information and data on the followings (Appendix 1).

Table 2. Pharma country profile (left) and glossary (right) developed by the WHOCC for Health system and financing

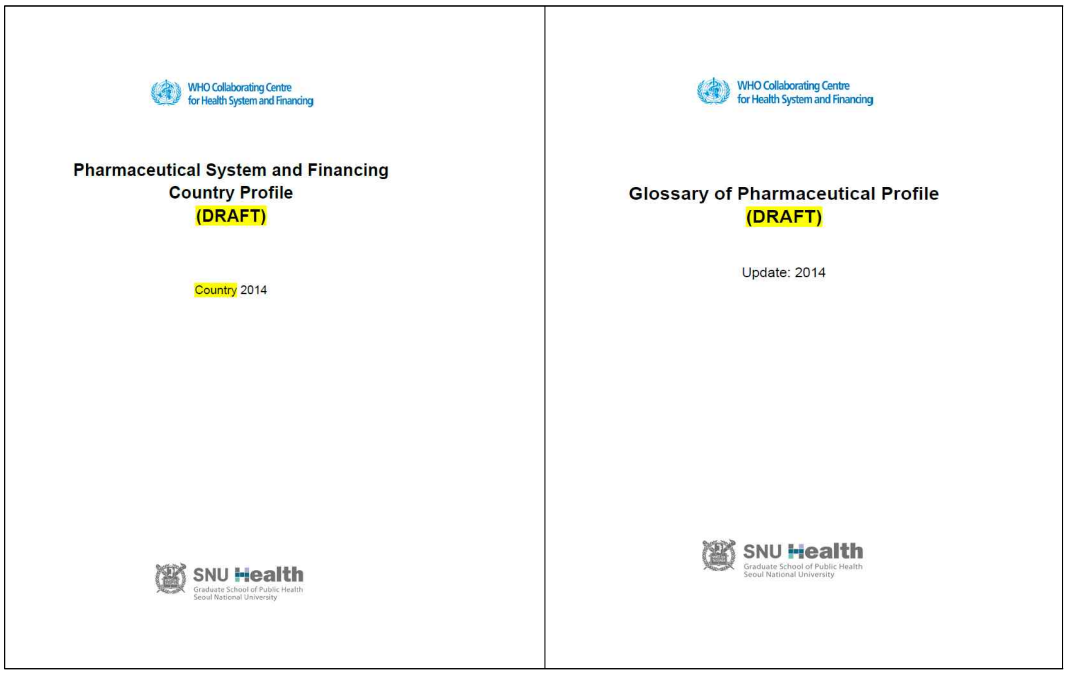

Table 3. Contents of long version of country profile

Part I. Pharmaceutical policy and financing	**Part II. General information and health**
1. Organization of the pharmaceutical system	1. Population structure
2. Market authorization	1.1. Population
2.1. Licensing and inspection	2. Socioeconomic statistics
3. Quality assurance	2.1. Economy
3.1. Quality of medicines	2.2. General
4. Pricing	3. Health
4.1. Pricing policies	4. Health care delivery
4.2. Purchasing policies	4.1. Health care facilities and utilization
4.3. Procurement	4.2. Human resource
4.4. Pricing procedure	5. Health care financing and expenditure
4.5. Discounts / rebates	5.1. Total health expenditure
4.6. Price composition	5.2. Structure of health expenditure
5. Reimbursement	**Part III. Pharmaceutical system**
5.1. Reimbursement policies	1. Pharmaceutical financing and expenditure
5.2. Reimbursement procedure	1.1. Total pharmaceutical expenditure
5.3. Reference pricing system	1.2. Structure of pharmaceutical expenditure
5.4. Risk-sharing schemes/Managed entry agreements	2. Availability and access
5.5. Decision making tools	

5.6. Out-of-pocket payments on medicines 5.7. Reimbursement policies in hospitals 6. Rational use of medicines 6.1. General information 6.2. Monitoring and evaluation 6.3. Generic Promotion 6.4. Medicines advertising and promotion 6.5. Education and training 6.6. Pharmacovigilance 7. Intellectual property laws and medicines	2.1. Market entry 2.2. Essential medicines 3. Pharmaceutical prescription and consumption 3.1. Separation of prescribing and dispensing 3.2. Pharmaceutical consumption 3.3. Generic market share 4. Pharmaceutical industry 4.1. Pharmaceutical manufacturers 4.2. Pharmaceutical distributors

4.2 Survey on pharmaceutical policies and financing in Asia-Pacific countries

This study was performed to examine pharmaceutical policies and financing in Asia-Pacific using available data. Asia-Pacific countries selected for the study were among those who participated in the 1st (YR 2014) and 2nd (YR 2015) Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region, held in Seoul, Korea. Countries included in this study are Australia, Brunei Darussalam, Cambodia, China, Indonesia, Japan, Lao PDR, Malaysia, Mongolia, New Zealand, Philippines, Republic of Korea, Singapore, Thailand, and Viet Nam.

Quantitative data were collected from WHO Health Statistics, Health at a glance in Asia/Pacific (2014), World Bank Data, published articles, and reports. Data collected includes Socio-economic characteristics (size of population, composition of population, life expectancy at birth and at age 60, GDP per capita), human resource in the health sector (Numbers of physicians, pharmacists and/or pharmaceutical personnel, and pharmacy graduates), Health care delivery (Number of Doctor consultations, Number of hospital beds), health expenditure, and pharmaceutical expenditure. Qualitative data were gathered through websites of Ministries of health and/or relevant organizations in each countries, research articles, and reports. English was used as search language. Data collection through E-mails with relevant experts were also done

as needed. The study also collected detailed data on pharmaceutical policy and financing of Korea and the Philippines using a (long) version of the pharma template.

4.3 Feedback survey for detailed (long) version of pharma country profile

For feedback, the long version of the pharma template was given to experts in each country who participated in the 2nd Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region, Korea (17-18 September, 2015). Survey for feedback showed the participants the items in the detailed (long) version of the pharmaceutical template and asked the following questions as follows: (1) The level of importance for each item (information to be shared) with 1-5 scale (from 1=not important ~ 5=very important), and (2) the level of information availability with 1-5 scale (from 1=very difficult to collect ~ 5=always available).

II. Current situation of pharmaceutical policies and financing in Asia-Pacific countries

1. Overview of main indicators for health and pharmaceutical system

Available data were collected for the total of 15 countries included in the study. Specifically, these countries include Australia, Brunei Darussalam, Cambodia, China, Indonesia, Japan, Lao PDR, Malaysia, Mongolia, New Zealand, Philippines, Republic of Korea, Singapore, Thailand, and Viet Nam.

1.1 Health system

The health system of countries in Asia-Pacific were classified using two types: those with (1) National Health Service (NHS) and (2) Social Health Insurance (SHI), except for Singapore. Population coverage for health system varied across countries. Many countries in the Asia-Pacific region have expanded the level of population coverage in their respective health systems to achieve universal health coverage.

High income countries such as Australia (NHS), New Zealand (NHS), Japan (SHI), and Republic of Korea (SHI) have already achieved universal coverage. Thailand (SHI/NHS) and Malaysia (NHS) on the other hand, also achieved the same despite their middle-income status.

In addition, China (SHI, 90%, YR 2009), Philippines (SHI, 87%, YR 2014), and Singapore (Mixed, 93%, YR 2012) have achieved a considerable level of population coverage. Population coverage in Indonesia (SHI, 60%, YR 2012), Mongolia (SHI, 77.6%, YR 2009), and Viet Nam (SHI, 70%, YR 2014) were considered to have middle to high coverage. However, Cambodia (24%, YR 2012) and Lao PDR (15%, YR 2012) have shown low levels of population coverage. Coverage status in other dimension – width (services) and depth (cost) - are difficult to collect and were not included.

Table 4. The type of health system and population coverage in each countries

Countries	Health System	Year	Health insurance coverage as % of total population
Australia	National Health Service	2010	100
Brunei Darussalam	National Health Service	NA	NA
Cambodia		2012	24
China	Social Health Insurance	2009	90
Indonesia	Social Health Insurance	2012	60
Japan	Social Health Insurance	2011	100
Lao PDR		2012	15
Malaysia	National Health Service	2012	100
Mongolia	Social Health Insurance	2009	77.6
New Zealand	National Health Service	2013	100
Philippines	Social Health Insurance	2014	87
Rep. Korea	Social Health Insurance	2014	100
Singapore	Mixed (Medifund/MediShield/Medisave)	2012	93
Thailand	Social Health Insurance/ National Health Service	2012	100
Viet Nam	Social Health Insurance	2014	70

NA: Not Available

(Source: OECD, 2014; World Health Statistics, 2015; WPRO, 2015; Tan et al., 2014; Van Minh et al., 2014)

1.2 Socio-economic status

1.2.1 Population

1.2.1.1 Number of population

Among the selected countries, China ranked first as the most populated (1.3 billion, YR 2014). Indonesia (254 million, YR 2014), Japan (127 million, YR 2014), Philippines (99 million, YR 2014), and Viet Nam (90 million, YR 2014) followed China. Table 5 shows the population size of countries selected in this study as of year 2014.

Table 5. The size of population in surveyed countries

Country	(in thousand)
China	1,364,270
Indonesia	254,455
Japan	127,132
Philippines	99,139
Viet Nam	90,730
Thailand	67,726
Rep. Korea	50,424
Malaysia	29,902
Australia	23,491
Cambodia	15,328
Lao PDR	6,689
Singapore	5,470
New Zealand	4,510
Brunei Darussalam	417

(Source, World Bank Data) YR 2014

1.2.1.2 Composition of population

This study classified 0-14 years, 15-64 years, 65 years or more to see the composition of population.

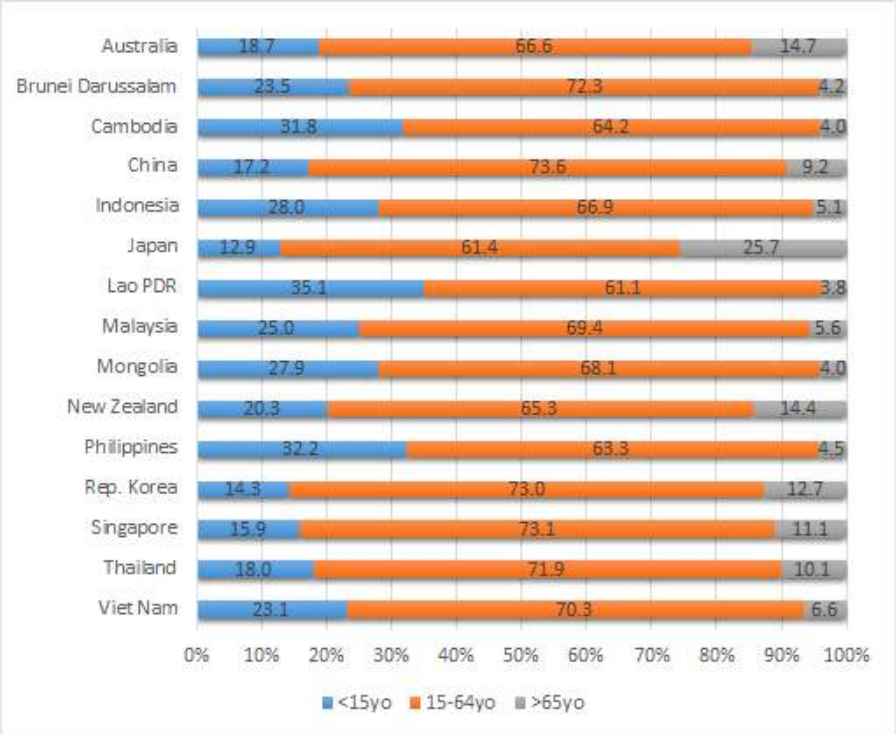

Figure 1. Composition of population in Asia-Pacific countries

(Source: World Bank data, YR 2014)

The proportion of 0-14 years old in the population of the Asia-Pacific countries varies from 12.9% (Japan) to 35.1% (Lao PDR). The proportion of 65 years or more in population is also diverse with countries having as low as 3.8% (Lao PDR) to as high as 25.7% (Japan), which is a direct opposite with the trends in the proportion of 0-14 years. The proportion of 15-64 years, which represents the size of the economically active population ranges from 61.1% (Lao PDR) to 73.6% (China) with less deviation compared with 0-14 years and 65 years or more.

The proportion of 0-14 years is largest in Lao PDR (35.1%, YR 2014) and Philippines (32.2% YR 2014), followed by Cambodia (31.8%, YR 2014), Mongolia (27.9%, YR 2014), Indonesia (28.0%, YR 2014), and Malaysia (25.0%,

YR 2014). In contrast, high income countries such as Australia, Japan, Republic of Korea, and Singapore, and other developing countries such as China and Thailand have population of 0-14 years accounting for less than 20% of the total.

Further, the proportion of 15-64 years, which represents the economically active, is largest in China (73.6%, YR 2014), followed by Singapore (73.1%, YR 2014), Republic of Korea (73%, YR 2014), Brunei Darussalam (72.3%, YR 2014), and Thailand (71.9%, YR 2014).

1.2.2 Life expectancy at birth, at age 60

□ Two types of life expectancy was examined – at birth and at age 60.

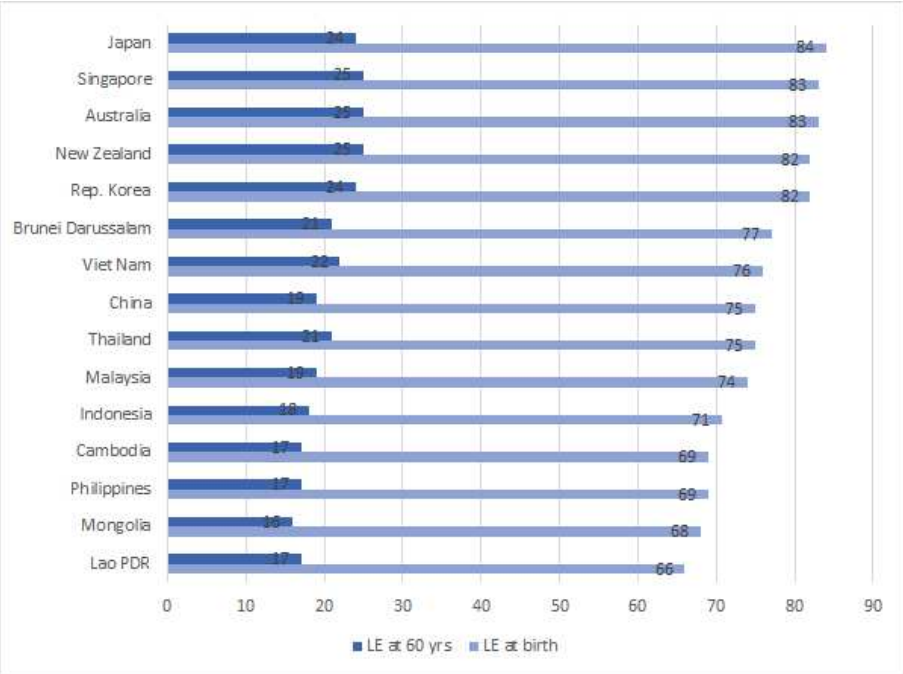

Figure 2. Life expectancy (dark: at age 60, light: at birth)

(Source: World Bank data YR 2014)

Life expectancy at birth is longest in Japan (83 years, YR 2014) and shortest in Lao PDR (63.9 years, YR 2014). On the other hand, life expectancy at age 60 is longest in Singapore, New Zealand, and Australia (25 years, YR 2014). Japan and Korea (24 years, YR 2014) ranked next. Life expectancy at age 60

was the shortest in Mongolia (16 years, YR 2014) followed by Cambodia and Philippines (17 years, YR 2014).

1.2.3 GDP per capita

Variation in GDP per capita was large among the surveyed countries in the Asia-Pacific region. Australia had the highest GDP per capita (USD 61,887, YR 2014) and Cambodia the lowest (USD 1,090) among the surveyed countries. Singapore (USD 56,287, YR 2014), New Zealand (USD 42,409, YR 2014), Brunei Darussalam (USD 41,344, YR 2014), and Japan (USD 36,194, YR 2014) were ranked next in terms of GDP per capita. Developing countries including Cambodia (USD 1,090, YR 2014), Lao PDR (USD 1,760, YR 2014), and Viet Nam (USD 2,052, YR 2014) showed low level of GDP per capita.

Table 6. GDP per capita

Country	GDP per capita
Australia	61,887
Singapore	56,287
New Zealand	42,409
Brunei Darussalam	41,344
Japan	36,194
Rep. Korea	27,970
Malaysia	10,933
China	7,594
Thailand	5,519
Mongolia	4,129
Indonesia	3,492
Philippines	2,871
Viet Nam	2,052
Lao PDR	1,760
Cambodia	1,090

(Source: World Bank data, YR 2014)

1.3 Human resource

The study collected the numbers of physicians, pharmacists and/or pharmaceutical personnel, and pharmacy graduates.

1.3.1 Density of physicians (per 1,000 population)

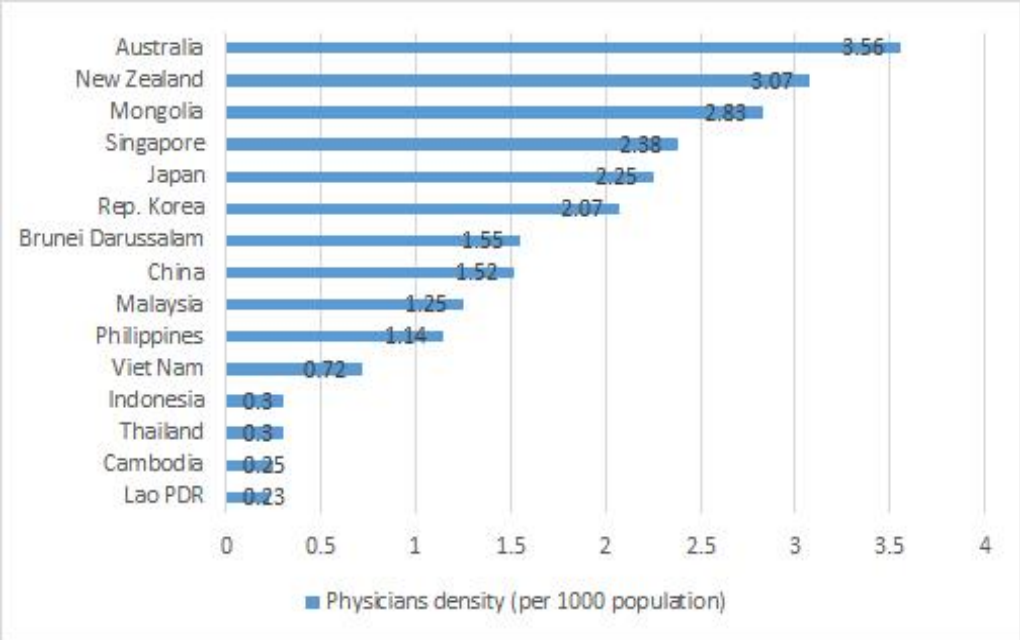

Figure 3. Density of physicians (per 1,000 population)

(Source: WHO World Health Statistics, 2011 or latest year available)

Australia had the largest number of physicians (3.56 per 1,000 population) and Lao PDR had the smallest number of physicians (0.23 per 1,000 population) among studied countries. Countries that have less than 1 physician per 1,000 population are Viet Nam (0.72), Indonesia (0.3), Thailand (0.3), Cambodia (0.25), and Lao PDR (0.23).

1.3.2 Density of pharmacists, pharmaceutical personnel

This study also collected the information on the numbers of pharmacists and graduates in pharmacy. Considering the different definitions of pharmacist in countries, the study examined both the number of pharmacists and the number of pharmaceutical personnel.

1.3.2.1 Density of pharmacists/pharmaceutical personnel (per 1,000 population)

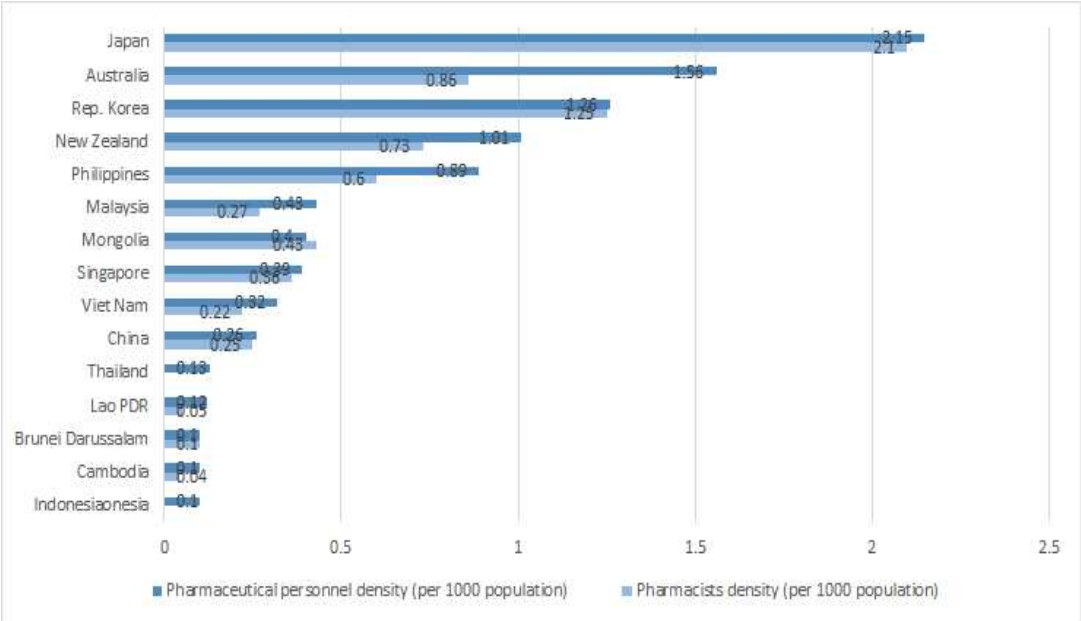

Figure 4. Density of pharmacists (light) and pharmaceutical personnel (dark) (per 1,000 population)

(Source: WHO World Health Statistics YR 2011 or latest year available)

Density of pharmacists and pharmaceutical personnel showed similar pattern. In general, the number of pharmaceutical personnel is greater than the number of pharmacists. Japan had the highest density of pharmacists (2.1 per 1,000 population) in the Asia-Pacific region. Korea went on the second with the density of pharmacists (1.25) but its density is only half of Japan. Australia ranked the third for density of pharmacists (0.86) but had the second highest in terms of density of pharmaceutical personnel (1.56).

Cambodia had the lowest density of pharmacists (0.04 per 1,000 population) followed by Lao PDR (0.05) and Brunei Darussalam (0.1).

The density of pharmacists and pharmaceutical personnel showed a different pattern when compared to the density of physicians (Pharmacists: Japan (2.15) > Korea (1.26) > Australia (0.86) > New Zealand (0.73) > Philippines (0.6); Physicians: Australia (3.56) > New Zealand (3.07) > Mongolia (2.83) > Singapore (2.38) > Japan (2.25)) although the degree of role sharing between physicians and pharmacists can not be explored in detail due to the lack of relevant information. Australia had the greatest difference between the density of pharmacists and pharmaceutical personnels (0.7), followed by New Zealand (0.28) and Philippines (0.29).

1.3.2.2 Number of pharmacy graduates

China had the largest number of pharmacy graduates (56,801) and Brunei Darussalam had the lowest (3).

Table 7. The number of pharmacy graduates

Country	year	value
Australia	2010	1,964
Brunei Darussalam	2011	3
Cambodia	2011	131
China	2011	56,801
Mongolia	2011	169
New Zealand	2009	221
Philippines	2007	1,558
Rep. Korea	2010	1,397
Singapore	2011	107
Viet Nam	2010	1,583

(Source: WHO WPRO statistics)

1.4 Health care delivery

The study examined the number of doctor consultation per capita and the density of hospital beds in the Asia-Pacific countries.

1.4.1 Doctor consultations, per capita

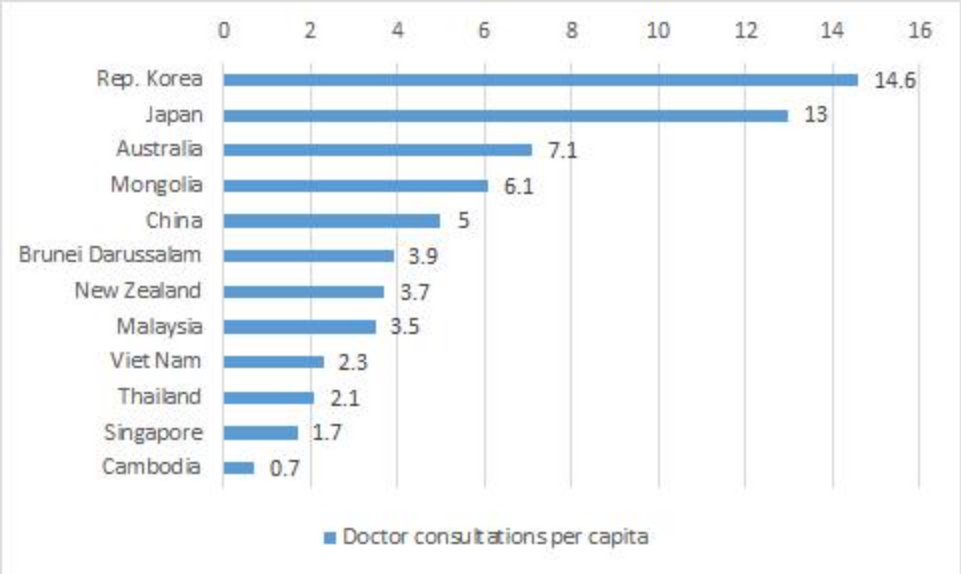

Figure 5. Doctor consultations, per capita

(source: OECD, 2014 YR 2013 or latest year available)

Korea had the largest number of doctor consultations per capita (14.6) followed by Japan (13.0). Both countries had 10 or more number of doctor consultations per capita, which may be related to their very density of physicians (Physicians: Australia > New Zealand > Mongolia > Singapore > Japan). This value is twice or more than that of Australia (7.1), which has the highest density of physicians.

Cambodia had the lowest number of doctor consultations per capita (0.7). It means that one Cambodian visits doctor less than once in a year. Singapore (1.7), Thailand(2.1), and Viet Nam(2.3) were ranked next. On the contrary, Singapore showed a unique pattern between the density of physicians and the number of doctor consultations per capita. Singapore had 1.7 doctor

consultation per capita, which is quite low considering Singapore's high GDP and high density of physicians.

1.4.2 Density of hospital beds (per 1,000 population)

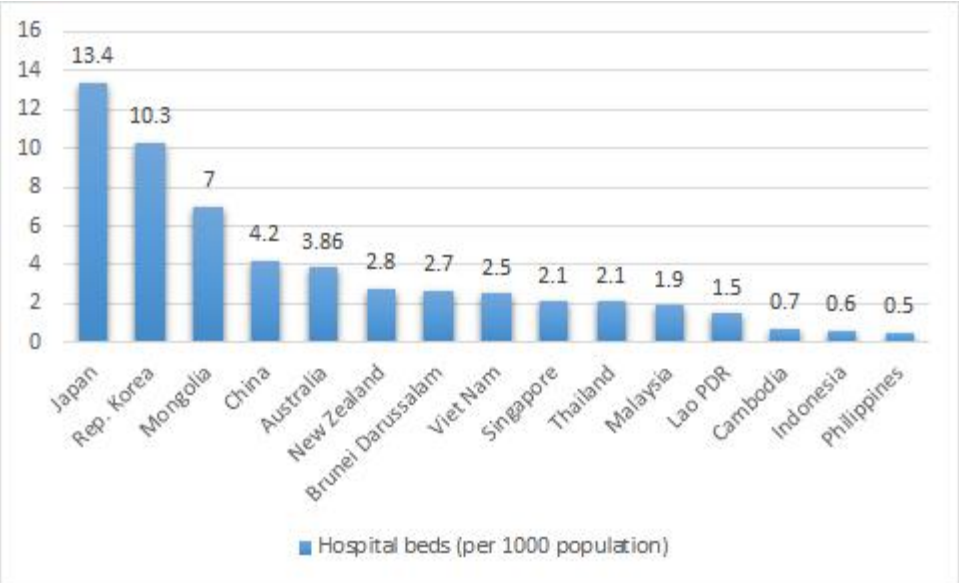

Figure 6. Density of hospital beds (per 1,000 population)

(source: OECD, 2014 YR 2013 or latest year available)

Japan had the largests number of hospital beds (13.4 per 1,000 population) and Korea ranked next (10.3). Density of hospital beds is computed based on the number of existing hospital beds per population in the country. Both countries have the largest number of doctor consultations per capita and highest density of hospital beds. Japan and Korea had three or four times more hospital beds than Australia and New Zealand. Philippines had the lowest density of hospital beds (0.5 per 1,000 population) among studied Asia-Pacific countries. Others with low density include Indonesia (0.6) and Cambodia (0.7) with less than one hospital bed per 1,000 population.

1.5 Total Health Expenditure (THE)

1.5.1 THE per capita (PPP)

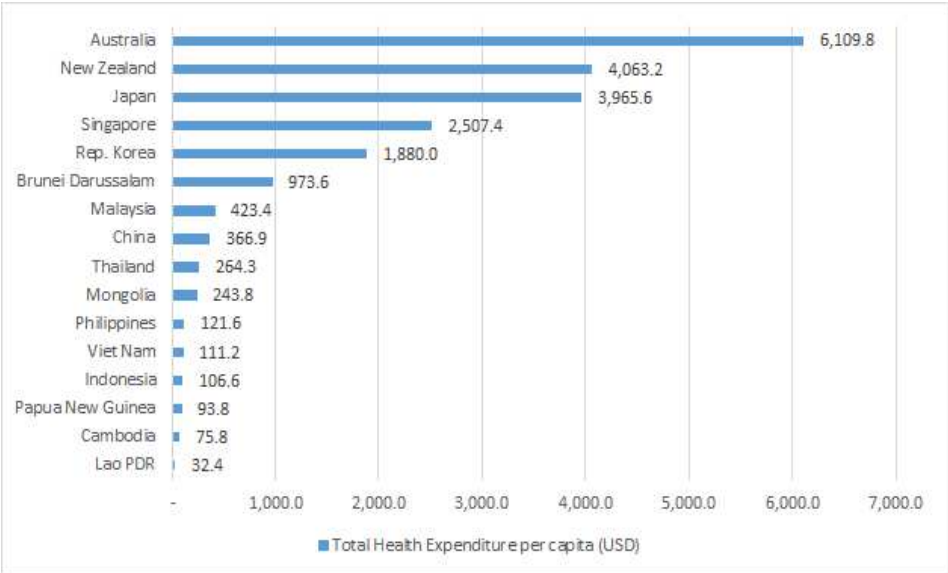

Figure 7. THE per capita (PPP)

(source: World Bank data, YR 2014)

Figure 7 shows the THE per capita (PPP: Purchasing Power Parity) in Asia-Pacific countries. THE per capita is highest in Australia (USD 6,109, YR 2014) among surveyed Asia-Pacific countries. New Zealand (USD 4,063) and Japan (USD 3,965) ranked second and third. THE per capita is lowest in Lao PDR (USD 32.4, YR 2014) among the studied Asia-Pacific countries, followed by Cambodia (USD 75.8, YR 2014) and Papua New Guinea (USD 93.8, YR 2014) with less than USD 100 THE per capita.

1.5.2 THE share of GDP (%)

□ THE as a share GDP is shown as actual value and the mix of public and private expenditure.

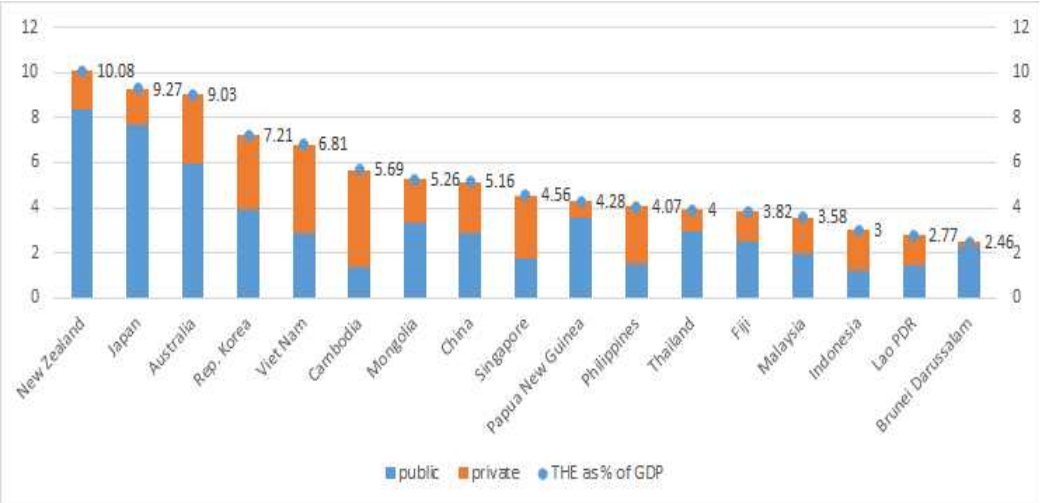

Figure 8. THE share of GDP (%)

(source: WHO World Health Statistics YR 2012 or latest year available)

Most countries in Asia-Pacific, except New Zealand, THE as a share of GDP (%) is less than 10% (2.46% (Brunei) to 10.08% (New Zealand). Regardless of share of THE in GDP, each country has various mix of public and private expenditures in THE. This part will be separately examined in the next section. New Zealand had the highest THE share of GDP (10.08%) among studied Asia-Pacific countries, followed by Japan (9.27%) and Australia(9.03%). Brunei (2.46%) had the lowest THE share of GDP (2.46%), followed by Lao PDR (2.77%) and Indonesia (3%). Viet Nam (6.81%) had the highest THE share of GDP among developing countries in Asia-Pacific.

1.5.3 Composition of THE (public vs. private share of THE)

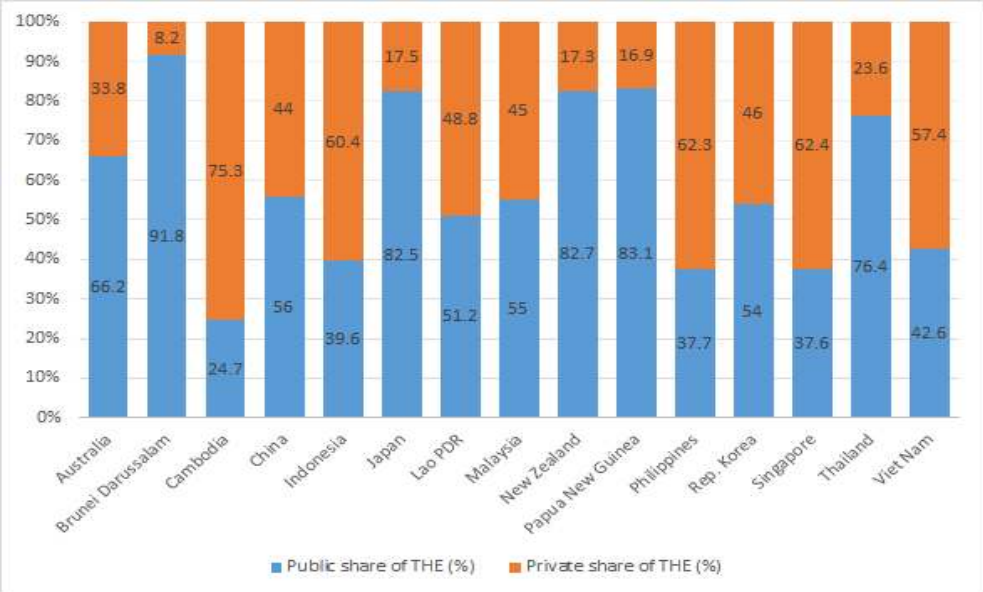

Figure 9. Composition of THE (public vs. private share of THE)
(source: OECD, 2014 YR 2010 or latest available year)

Asia-Pacific countries had various composition of THE in terms of public (24.7%~91.8%) and private (8.2%~75.3%) sector. Public and private share of THE is not directly related to countries' income. Increase in private spending in low-income countries means access barrier to health due to high out-of-pocket (OOP) payment, which will be described in the following section.

Brunei spent the largest portion of THE in public sector (91.8%), followed by Papua New Guinea (83.1%). This value is higher than high income countries such as New Zealand (82.7%), Japan (82.5%), and Australia (66.2%). On the contrary, the private portion of THE is the highest for Cambodia (75.3%), followed by Singapore (62.4%), Philippines (62.3%), and Indonesia (60.4%). Detailed information about the impacts of private spending on income, such as the level of catastrophic health expenditure in each country, is not reported.

1.5.3 Composition of THE by fiancing source

Composition of THE was also examined by financing source – government, social security, out-of-pocket, private prepaid plans, and others.

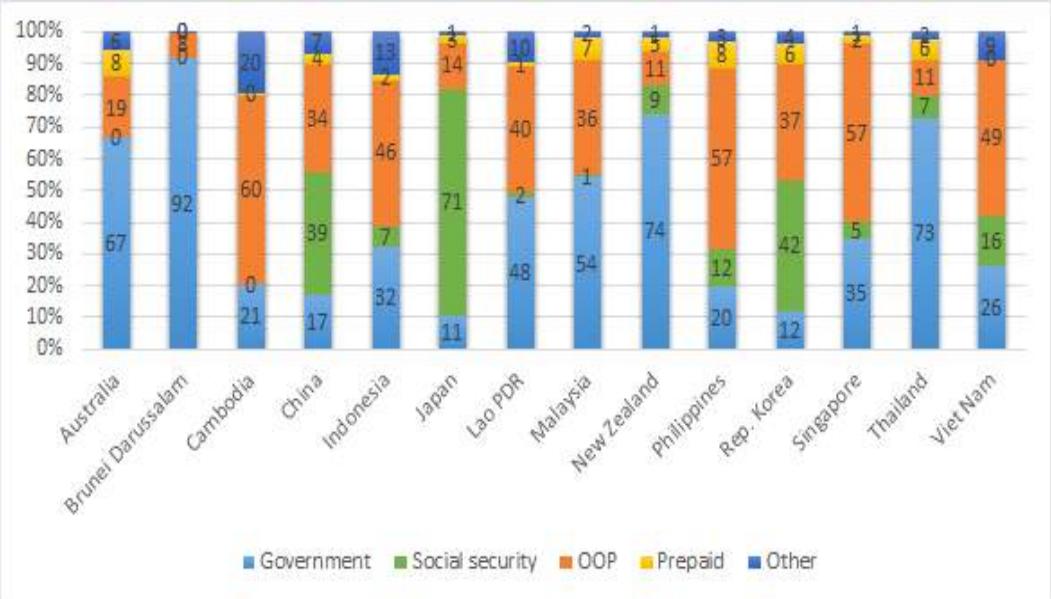

Figure 10. Composition of THE by financing source

(source: WHO, World Health Statistics, YR 2013)

Figure 10 shows the various sources of health spending. The composition of health expenditure is influenced by different health system characteristics in each country. Countries showed different compositions of THE even when they have the same type of health financing system (e.g., NHS or SHI). This is because the coverage in each health system differs in terms of population (breadth), service (width), and cost (depth) coverage (Busse, 2007; WHO, 2010).

General government spending for health (taxes) is high in Brunei (92%). New Zealand (74%) and Thailand (73%). Health spending from social security is highest in Japan (71%), folowed by Korea (42%) and China (39%).

The proportion of out-of-pocket in THE is lowest in Brunei (8%), followed by Thailand (11%), New Zealand (11%), and Japan (14%). The proportion of out-of-pocket in THE is high in Cambodia (60%), Philippines (57%) and Viet

Nam (49%). Brunei, Cambodia, and Viet Nam do not spend on private prepaid plans. The portion of private health insurance in THE is high in Australia (8%), followed by Malaysia (7%) and Korea (6%).

1.6 Pharmaceutical Expenditure (PE)

Sources of pharmaceutical expenditure can be divided into inpatient and outpatient services except for over-the-counter medicines. However, cost for medicines in inpatient services is usually not divided into medical services and medicines as they are not reported separately. Therefore, it is hard to calculate or estimate the exact size of pharmaceutical expenditure, and usually estimate the size of pharmaceutical expenditure in outpatient services. This study collected PE per capita, growth rate, PE share of THE, and the composition of PE. Furthermore, the relationship between these indicators and GDP per capita were also examined.

THE and PE are affected by demographic composition (e.g., the proportion of those aged 65 or older), prevalent diseases (e.g., acute/chronic diseases, tuberculosis, HIV, or malaria). In addition, PE is influenced by accessibility and cost of medicines. However, it is hard to collect detailed information and reflect all of them in this study. Therefore, this section briefly introduces major indicators on PE in Asia-Pacific countries.

1.6.1 PE per capita (PPP) and growth rate

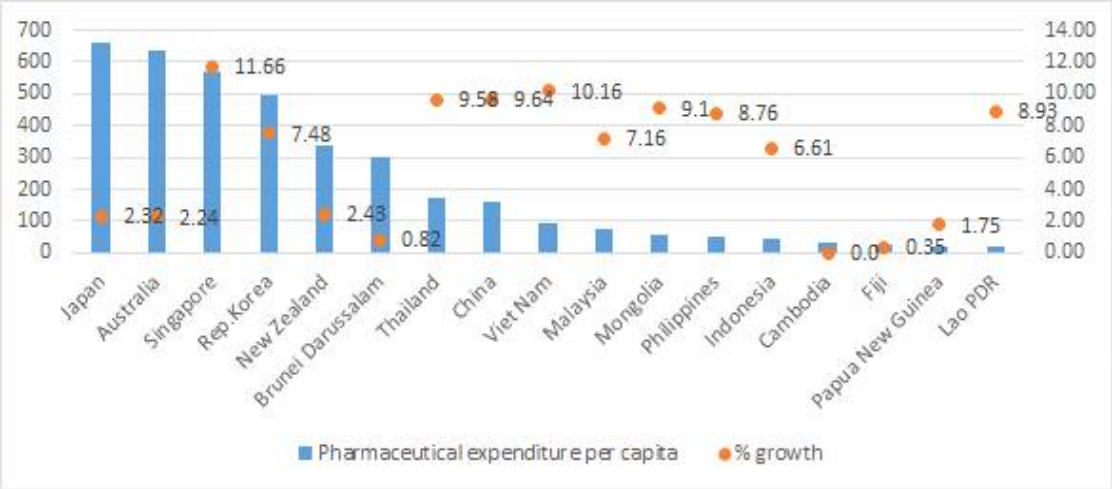

Figure 11. PE per capita (PPP) and growth rate
(source: OECD, 2014 YR 2010 or latest available year)

Countries in Asia-Pacific region had various level of PE per capita from USD 20.4 (Lao PDR) to USD 695.5 (Japan). Growth rate of PE also varies across countries. PE per capita is highest in Japan (USD 695.5), Australia (USD 633.6) and Korea (USD 495). PE per capita on the other hand, is lowest in Lao PDR (USD 20.4). Papua New Guinea (USD 21), Cambodia (USD 34.3), Indonesia (USD 42.3), and Philippines (USD 49.8) spent less than USD 50 per person on medicines.

Growth rate of PE showed different pattern from PE per capita. Top 5 countries with the highest PE per capita are generally from high-income economies (Japan, Australia, Singapore, Korea, and New Zealand) which showed around 2% growth rate in PE. However, Singapore (11.66%) and Korea (7.48%) had the highest PE growth rate. Viet Nam (10.16%), China (9.64%), Thailand (9.58%), Mongolia (9.1%), Philippines (8.76%), Lao PDR (8.93%), and Indonesia (6.61%) also showed higher level of PE growth rate.

1.6.2 Relationship between GDP per cpiata and PE per capita (PPP)

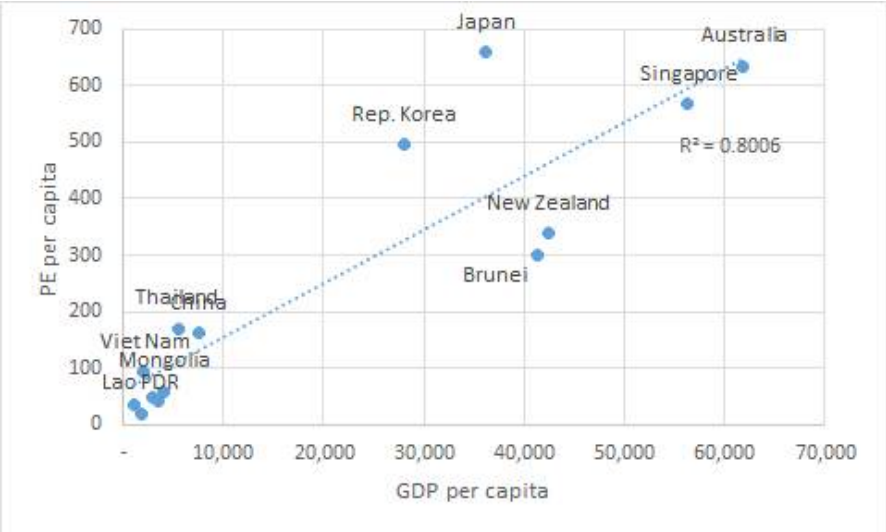

Figure 12. Relationship between GDP per capita and PE per capita in Asia Pacific countries

(source: OECD, 2014 YR 2010 or latest available year)

There is a high correlation between GDP per capita and PE per capita (R^2=0.8006) among the selected countries in the Asia-Pacific. As GDP per capita increases, PE per capita also increases. Japan and Korea tend to spend more on medicines in terms of PE per capita, considering their level of GDP per capita. On the contrary New Zealand and Brunei spend less on medicines compared with their GDP per capita. The correlation between GDP per capita and PE per capita in developing countries is not as high as in high income countries in the Asia-Pacific region.

1.6.3 PE share of THE (%) and growth rate

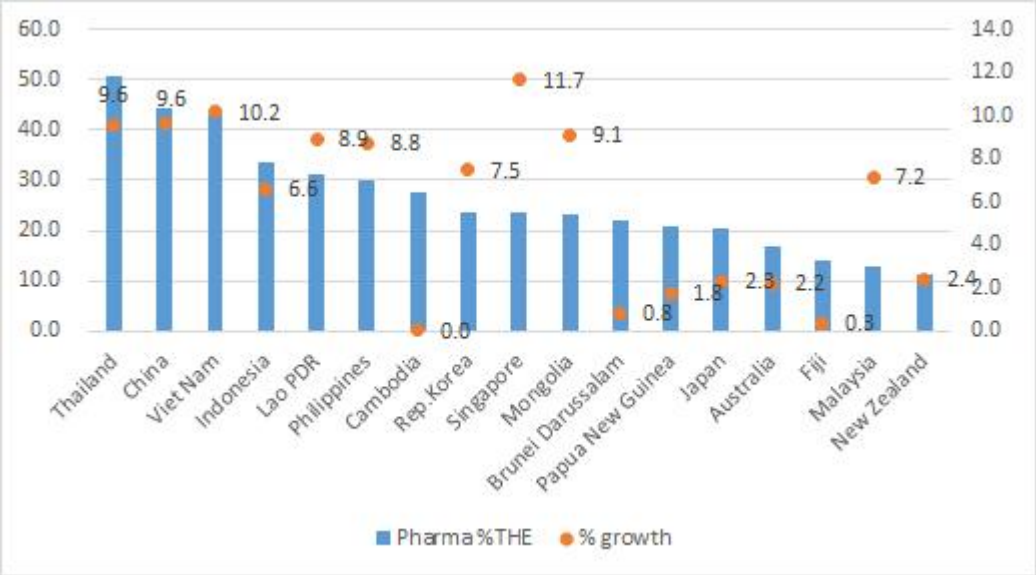

Figure 13. PE share of THE (%) and growth rate

(source: OECD, 2014 YR 2010 or latest available year)

PE share of THE varied across countries in Asia-Pacific countries (from 11.1% (New Zealand) to 50.5% (Thailand)). However, PE share of THE had different pattern from PE per capita. Developing countries in Asia-Pacific region had higher PE share of THE than high income countries in general. The proportion of PE in THE is highest in Thailand (50.5%). China (44.2%) and Viet Nam (43.2%) also have high PE share of THE among the surveyed Asia-Pacific countries.

On the contrary, the proportion of PE in THE was the lowest in New Zealand (11.1%), Malaysia (12.7%), Fiji (13.9%), Australia (16.9%), and Japan (20.5%). Top 5 countries in terms of PE share of THE (Thailand, China, Viet Nam, Indonesia, and Lao PDR) also experience higher PE growth rate whereas bottom 5 countries in terms of PE share of THE (New Zealand, Malaysia, Fiji, Australia, Japan) lower PE growth rate, except for Malaysia.

1.6.4 Relationship between GDP per capita and PE share of THE (%)

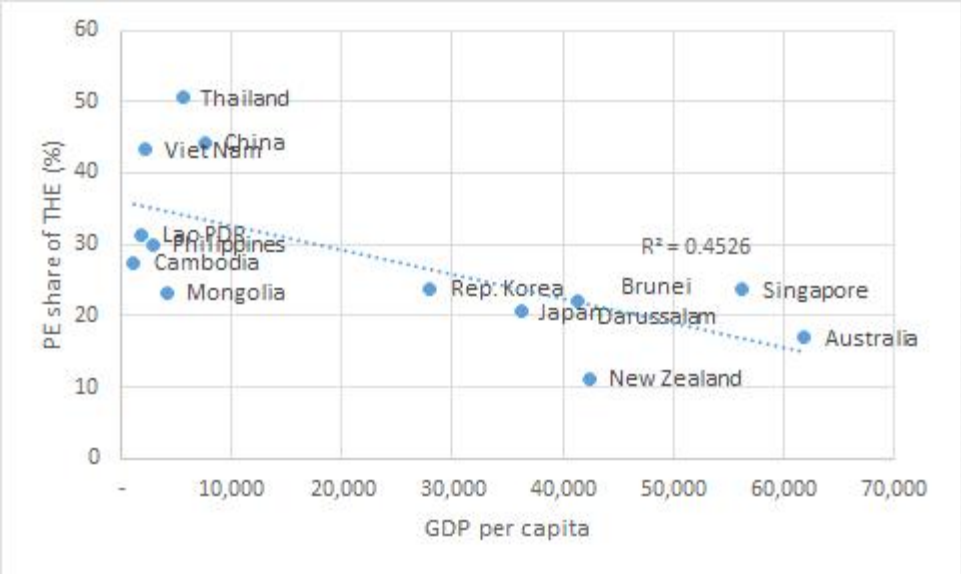

Figure 14. Relationship between GDP per capita and PE share of THE (%) in Asia Pacific countries

(source: OECD, 2014 YR 2010 or latest available year)

The relationship between GDP per capita and PE share of THE showed a bit of negative association (R^2=0.4526) but not higher than the relationship between GDP per capita and PE per capita. New Zealand has lower PE share of THE whereas Thailand, China, and Viet Nam have higher PE share of THE considering GDP per capita. The association between GDP per capita and PE share of THE is weak in developing countries in Asia-Pacific region.

1.6.5 Composition of PE (public vs. private share of PE)

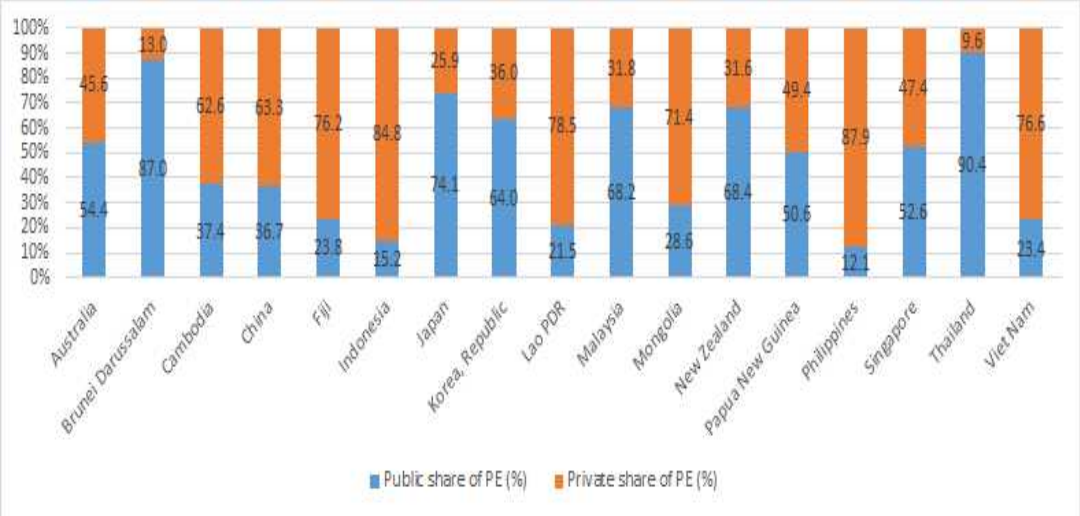

Figure 15. Composition of PE (public vs. private)

(source: OECD, 2014 YR 2010 or latest available year)

The composition of PE is diverse when classified into public (12.1%~90.4%) and private sector (9.6%~87.9%). In general, the trend is similar to the composition of THE (public vs. private sector) with some exceptions. The proportion of the public sector in PE is largest in Thailand (90.4%) which is higher than that in high income countries including Australia (45.6%), Japan (25.9%), New Zealand (31.6%), and Korea (36%). Brunei (87%) and Japan (74.1%) ranked on second and third, respectively.

On the contrary, the proportion of the pubic sector in PE was the lowest in the Philippines (87.9%). Most of developing countries in Asia-Pacific region had 50% or more private share of PE except for Malaysia (31.8%), and Thailand (9.6%). In general, private share of PE was higher than private share of THE. This is because health system in Asia-Pacific countries do not cover medicines and patients buy medicines through out-of-pocket.

1.6.6 Relationship between GDP per capita and public share of PE

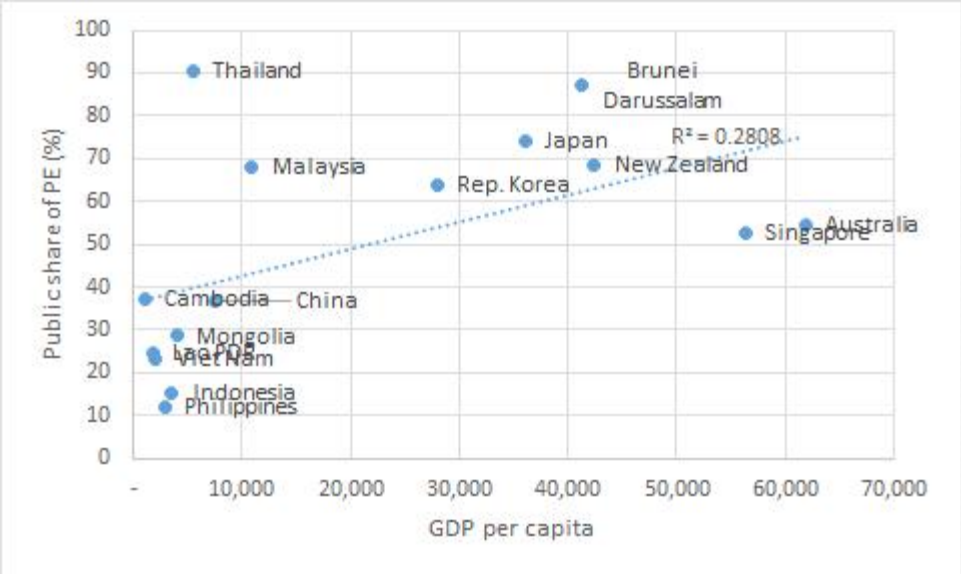

Figure 16. Relationship between GDP per capita and public share of PE in Asia Pacific countries

(source: OECD, 2014 YR 2010 or latest available year)

Although it seemed that there is a little positive association between GDP per capita and public share of PE, it is hard to conclude that there is a trend (R^2=0.2808). Moreover, there is no relationship between GDP per capita and the public share of PE among the developing countries in the Asia-Pacific region. Public share of PE seems to be affected by other factors such as level of medicine coverage in a health system rather than simple GDP per capita.

1.6.7 Composition of PE by patent status

Composition of PE is classified by patent status – original (with patent), branded generics (patent expired generics), and unbranded generics (without patent generics).

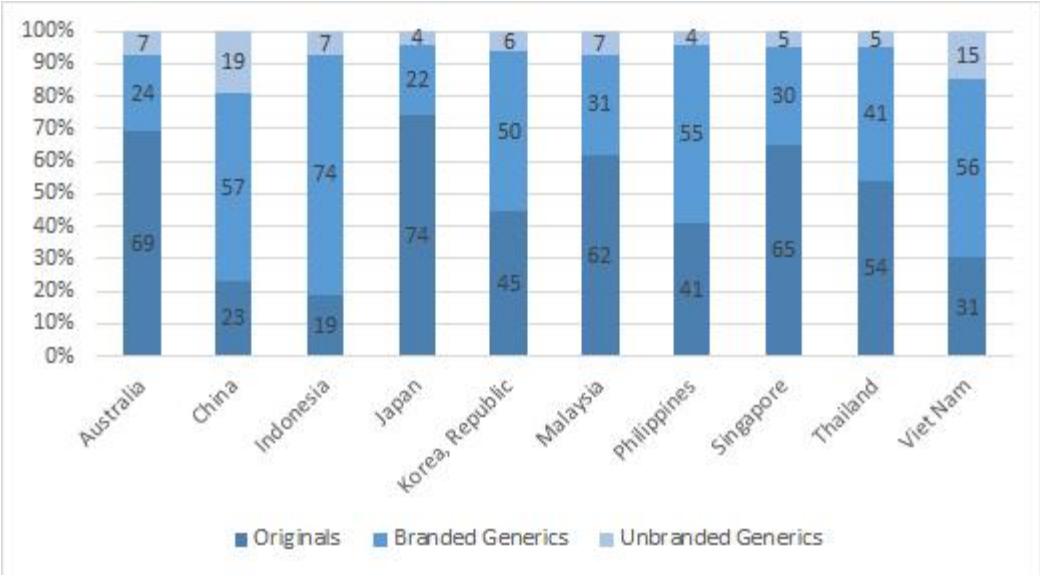

Figure 17. Composition of PE by patent status - (criteria: sales volume)

(source: IMS, 2013, YR 2011)

The composition of PE by patent status varied across different countries. Countries where the proportion of original medicines in terms of sales volume is greater than 50% are Japan (74%), Australia (69%), Singapore (65%), and Malaysia (62%). On the contrary, Indonesia (19%) and China (23%) had the smallest proportion of original medicines in sales volume.

The proportion of branded generics in sales volume is largest in Indonesia (74%). China (57%), Viet Nam (56%), Philippines (55%), and Korea (50%) also showed 50% or more in terms of the proportion of branded generics in sales volume. Japan (22%) and Australia (24%) accounted for less than 30% in branded generics. The proportion of unbranded generics is smaller than original medicines or branded generics. China (19%) and Viet Nam (15%) had the largest proportion of sales volume for unbranded generics whereas

remaining countries had less than 10%.

1.7 Administration of medicines

1.7.1 Number of medicines

The information on the exact number of medicines in each country is hard to collect. The number of medicines were searched by registered medicines, reimbursed medicines, medicines in national formulary, and essential medicine lists. However, it was difficult to identify or unify the exact unit of medicines i.e., criteria – products, (active) chemicals, formulations, and so on. Disaggregation into prescription-only-medicines and over-the-counter medicines is also not available. In addition, not all countries in Asia-Pacific region have essential medicines lists. Some countries also reported that unregistered medicines and low-quality medicines are distributed in the market.

Table 8. Number of medicines in Asia-Pacific countries

Country	No. of medicines
Australia	No. of medicines in reimbursement list: 750 medicines, 1970 formulations, 4500 products
Cambodia	No. of essential medicines: 582 items
Indonesia	No. of medicines in National formulary: 923 dosage forms
Malaysia	No. of registered medicines: 20,000 No. of essential medicines: 341 products No. of medicines in National formulary: 1,642 (YR 2014)
Mongolia	No. of registered medicines: 3,600
Philippines	No. of registered medicines: 24,917 No. of essential medicines: 649
Rep. Korea	No. of registered medicines: 39,474 products (YR 2014) No. of prevention for exit medicines: 681 products (YR 2014) No. of medicines in reimbursement list: 17,750 products (YR 2014)
Viet Nam	No. of registered medicines: 1,143 as active gradients

(source: WPRO, 2015)

1.7.2 Pharmaceutical policies for cost-containment

Many countries, regardless of income status, in the Asia-Pacific region have implemented policies to reduce pharmaceutical expenditure or its growth rates. Pharmaceutical policies for cost-containment tools can be classified into (1) mandatory price cuts; (2) prescribing controls; (3) patient contributions; (4) spending caps; (5) generic promotion; (6) quality/innovation/therapeutic value rating; (7) Health Technology Assessment/Cost-effectiveness assessment; (8) risk sharing agreement. Complexity to control PE is increasing from the former to the latter one and depends on the administrative ability and technical level.

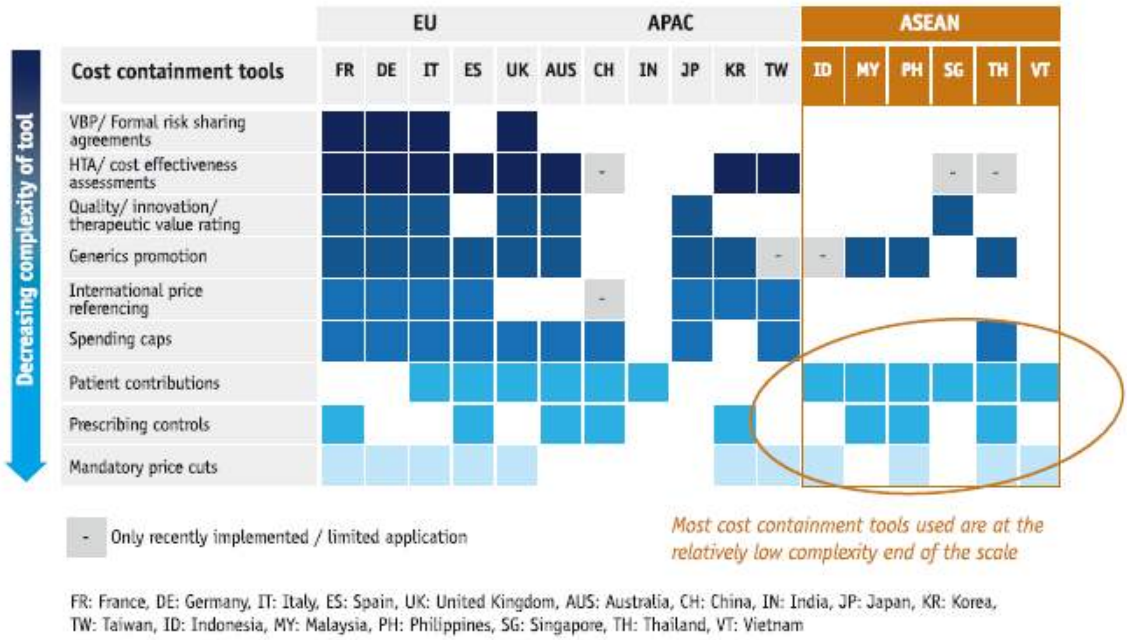

Figure 18. Major countries in EU, APAC, ASEAN and pharmaceutical cost-containment policies

(source: IMS, 2012)

Developed European countries have implemented more broad and complex policies to control PE when compared to policies in the Asia-Pacific region. For example, France have implemented a total of eight types of pharmaceutical policies whereas Australia and Korea have implemented a total six and five types of pharmaceutical policies, respectively. Most of developing countries in

Indonesia, Malaysia, Philippines, and Viet Nam in the Asia-Pacific region have implemented a rather simpler or a small number of policies to control PE when compared to high income counterpart. China, Singapore, and Thailand have recently initiated a more complex measures to control PE.

1.7.3 Procurement

Countries purchase medicines for patients in various ways, and procurement is one of the most common measures to secure the supply of medicines. However, not all countries in the Asia-Pacific region have purchased medicines through procurement. In addition, income status is not associated with the countries' policy choice of procurement. Procurement can be classified into centralized or decentralized. Centralized procurement means that government procure medicines "centrally", and some countries centrally procure medicines in the public sector only. Detailed procurement style varies across countries. Bidding and (competitive) tendering are generally utilized for the procurement of medicines. In some countries like Cambodia, they secure a considerable amount of essential medicines through donation, and the volume of donated medicines is not always stable.

Table 9. The type of procurement for medicines in Asia-Pacific countries

Country	Types of procurement
Cambodia	Centralized Based on the essential medicine lists and review lists every 2-3 years. Essential medicines: depends on donation Procurement: considering decentralization
Indonesia	Decentralized
Lao PDR	Procurement: essential medicines only. bidding Decentralized
Malaysia	Contract, local purchasing Both: centralized and decentralized
Mongolia	Public sector: Individual hospitals: competitive tendering Utilize international reference pricing Considering decentralization

Country	Types of procurement
Philippines	Essential medicines in public sector: tendering Decentralized Government can set maximum retail prices. implemented drug price reference index in all public hospital
Rep. Korea	Public hospital: competitive tendering
Singapore	Centralized
Thailand	Centralized
Viet Nam	Competitive tendering, bidding

(source: WPRO, 2015)

1.8 Related organizations

Organizations working for medicine financing and policy are classified into four - regulatory authority for medicines (approval), agency for price setting, agency for reimbursement decisions or selection of products, agency for Health Technology Assessment (HTA). Most of the relevant organizations are governed by the Ministry of Health. However, detailed information for aims or functions in each organization were difficult to find due to language limitations.

Asia-Pacific countries have operated regulatory agencies, which are not linked with the control of quality, pricing, and/or supply of medicines although some countries have not reported current situation officially. Most countries in the Asia-Pacific region have operated authorization organization. However, many countries in the Asia-Pacific region do not have pricing agency, do not control medicines price in the market, or control medicines price in the public sector only.

Compared with the regulatory authorities, HTA agencies in Asia-Pacific have been more active, given its short establishment history in the Asia-Pacific region (YR 2006 (HiTAP, Thailand); YR 2008 (CDE, Taiwan); YR 2009 (NECA, Korea)). Asian network (HTAsiaLink (Health Technology Assessment Asia Link) was formed in 2012 through volunteering by NECA (National Evidence-based Healthcare Collaborating Agency) in Korea. The members of the Asian network seek to collaborate in the future, although the level of management status and/or activities still varies significantly across countries.

Table 10. Lists of Regulatory authority for medicines, agency for price setting, agency for reimbursement decisions or selection of products, agency for Health Technology Assessment in Asia-Pacific countries

Country	**Regulatory authority for medicines**	**Agency for price setting**	**Agency for reimbursement decisions or selection of products**	**Agency for Health Technology Assessment**
Australia	Therapeutic Goods Administration	Pharmaceutical Benefits Scheme - Federal Department of Health	Department of Health, Pharmaceutical Benefits Advisory Committee	Pharmaceutical Benefits Advisory Committee
Brunei Darussalam	Brunei Darussalam Medicines Control Authority			
Cambodia	Department of Drug and Food, Ministry of Health		Department of Drug and Food, Ministry of Health	
China	China Food and Drug Administration		MOHRSS, NHFPC China Food and Drug Administration	China National Health Development Research Center
Indonesia	National Agency for Drug and Food Control	Ministry of Health		
Japan	Pharmaceuticals and Medical Devices Agency			National Institute of Public Health Pharmaceuticals and Medical Devices Agency
Lao PDR	Food and Drug Department, Ministry of Health	Ministry of Health		Medical Product Supply Center Ministry of Health
Malaysia	National Pharmaceutical Control Bureau	Ministry of Domestic Trade, Cooperatives and	Pharmaceutical Services Division, Ministry of Health	Pharmaceutical Services Division ,Ministry of Health Malaysia

Country	Regulatory authority for medicines	Agency for price setting	Agency for reimbursement decisions or selection of products	Agency for Health Technology Assessment
		consumerism		Health Technology Assessment Section, Ministry of Health Malaysia
Mongolia	Centre for Health Development		National Health Insurance Council Centre for Health Development	Ministry of Health and Sports
New Zealand	New Zealand Medicines and Medical Devices Safety Authority	Pharmaceutical Management Agency	Pharmaceutical Management Agency	Pharmaceutical Management Agency
Philippines	Food and Drug Administration	Department of Health	Philippine Health Insurance Corporation) and Department of Health– Pharmaceutical Division	National Center for Pharmaceutical Access and Management
Rep. Korea	Ministry of Food and Drug Safety	National Health Insurance Service	Health Insurance and Review and Assessment Service	National Evidence-based healthcare Collaborating Agency
Singapore	Health Security Authority			Drug Advisory Committee, Ministry of Health Health Security Authority
Thailand	Food and Drug Administration		National Essential Drugs List Sub-committee (ED sub-committee) Under the National Drug System Development Committee	Health Intervention and Technology Assessment Program, Thailand International Health Policy Program

Country	Regulatory authority for medicines	Agency for price setting	Agency for reimbursement decisions or selection of products	Agency for Health Technology Assessment
			Food and Drug Administration	
Viet Nam	Drug Administration of Vietnam		Department of Health Insurance, Ministry of Health Drug Administration of Vietnam	Health Strategy and Policy Institute

Blank: not available

2. Results of pilot survey

2.1 Pharmaceutical policy and financing

2.1.1 Pharmaceutical system (Overview)

The Korean government implemented the policy of positive listing of reimbursable drugs in 2006. Drugs that demonstrate cost-effectiveness can be included in the reimbursable (positive) list. In Korea, market-based pricing (or incentive system for purchasing low priced medicines) was introduced in Oct 2010 and reintroduced in Feb 2014 after it was suspended for 2 years. Providers are incentivized based on the difference of actual purchasing price and maximum reimbursable price.

The Philippines government has increased government expenditure for healthcare and implemented cost-containment measures and rational drug use policies, such as the strict implementation of the national drug formulary, regular monitoring of prices of essential drugs, creation of a drug price reference system and the rolling out of medicines access programs to reduce out-of-pocket spending and make drugs available for the indigent patients.

The national government is now contemplating to create a drug price negotiating panel with the industry for high cost essential medicines. The outpatient drug benefit scheme for primary care will be implemented in 2016 targeting first the poorest quintile of the population with the end goal of expanding coverage to the population in the next five years.

Table 11. Legal basis and actors

Fields		Legal basis	Scope (in-patient, out-patient sector)	Authorities	Activity / responsibility in the pharmaceutical system	Actors and interest group
Market authorisation	Korea	Pharmaceutical Affairs Act	In- and out-patient sector	MFDS	Responsible for marketing authorisation of medicinal products in Korea	Pharmaceutical companies Interest associations: KPMA (Korea Pharmaceutical Manufacturers Association),
	Philippines	FDA Act of 2009	In- and out-patient sector	Food and Drug Administration	Marketing authorisation, pharmacovigilance, Post-marketing surveillance	PHAP (Pharmaceutical Healthcare Association of the Philippines PCPI (Philippine Chamber of the Pharmaceutical Industry)
Pricing / Purchasing	Korea	National Health Insurance Act	In- and out-patient sector	NHIS	Price negotiation for new medicines with pharmaceutical company	Pharmaceutical company
	Philippines	Cheaper medicines Act of 2008 (RA 9502)	In- and outpatient sector	Pharmaceutical Division, Department of Health	National Drug Policy, price monitoring and regulation, supply chain management	
Reimbursement	Korea	National Health Insurance Act	In- and out-patient sector	HIRA	Decision on registration in positive list	Pharmaceutical company
	Philippines	National Health Insurance Act of 2013 (RA 10606)	In- and out-patient sector	Philippine Health Insurance Corporation (PHIC)	Provide healthcare coverage to reduce out-of-pocket spending for healthcare	
Prom		Pharmaceutic	In- and out-patient sector	MFDS	Advertising of prescription	Pharmaceutical company

Fields		Legal basis	Scope (in-patient, out-patient sector)	Authorities	Activity / responsibility in the pharmaceutical system	Actors and interest group
otion	Korea	al Affairs Act			medicines and OTC drug	
	Philippines	FDA Act of 2009 Cheaper Medicines Act of 2008	In- and out-patient sector	FDA and DOH	Promulgate regulations on the ethical promotional and advertising of pharmaceutical products	
Distribution	Korea	Pharmaceutical Affairs Act	In- and out-patient sector	MFDS & MOHW	Monitoring the manufacture/import and provision of medicine	Pharmaceutical company
		National Health Insurance Act	In- and out-patient sector	HIRA	Monitoring the purchase and use of medicine	Hospitals Wholesalers Manufacturers
		Pharmaceutical Affairs Act	In- and out-patient sector	MOHW	Separation between prescription and dispensing	Pharmacies Hospitals
		National Health Insurance Act	Inpatient sector	HIRA	Procurement: bidding process in hospitals over 300 beds and public hospitals	Hospitals Wholesalers Manufacturers
	Philippines	Cheaper Medicines Act of 2008	In- and out-patient sector	DOH PITC Pharma	Set national standards/guidelines; provide essential health care package for priority programs (TB, EPI, malaria, maternal and child health) Develop a common sourcing mechanism for essential drugs for government health facilities; importation of drugs	

Fields		Legal basis	Scope (in-patient, out-patient sector)	Authorities	Activity / responsibility in the pharmaceutical system	Actors and interest group
		Local Government Code of the Philippines (RA 7160)		Local government units	Manage health care services at the local level covering primary to tertiary care facilities	
Vigilance	Korea	Pharmaceutical Affairs Act	In- and out-patient sector	MFDS	Review of the safety, and efficacy of pharmaceuticals.	pharmaceutical companies Interest associations: KPMA (Korea Pharmaceutical Manufacturers Association),
	Philippines	FDA Act of 2009	In- and out-patient sector	FDA	Develop systems and standards of pharmacovigilance across health facilities	

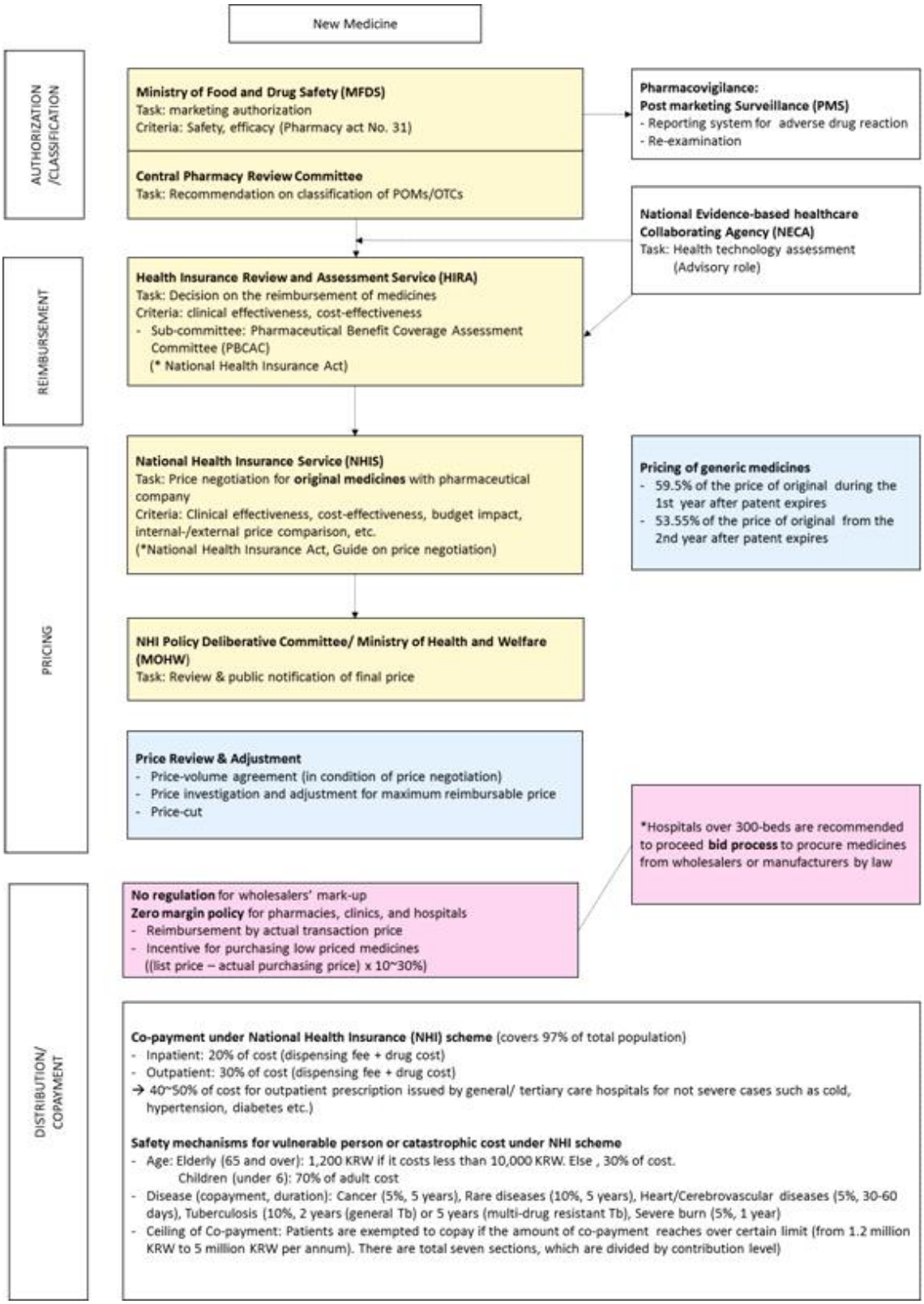

Figure 19. Flowchart of the pharmaceutical system (Korea)

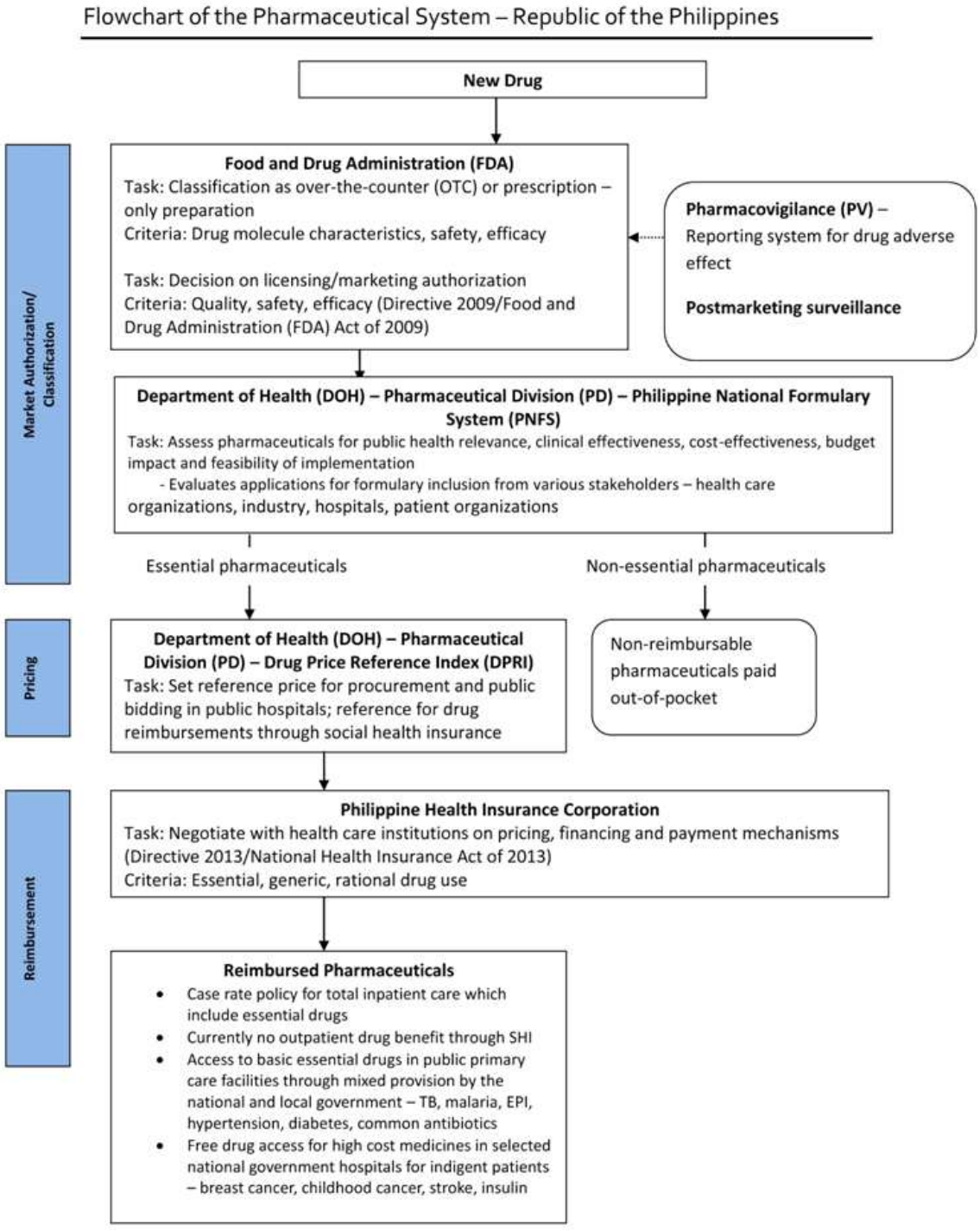

Figure 20. Flowchart of the pharmaceutical system (The Phillipines)

2.1.2 Market authorisation - licensing and inspection

In both Korea and the Philippines, Marketing authorization is required for all medicines. Safety, efficacy and bioequivalence (in the case of generics) are the primary criteria of the marketing authorization. In Both countries, expert committees are involved in the marketing authorization process. Experts involved in the assessment and decision making of registration are required to declare potential conflict of interest. Applicants are allowed to appeal against the decisions of regulatory authority.

There is a Good Manufacturing Practices (GMP) document or guideline in Korea and the Philippines. Both domestic and international manufacturers have to comply with GMP standards. Good Distribution Practices (GDP) (Good Supplying Practice (GSP) in Korea) guideline exists, and wholesalers and distributors have to comply with it. In the Philippines, National Good Pharmacy Practice guidelines was crafted by the government. Recently, the Philippine Pharmacists Association (PPhA) crafted its own guidelines. Korea does not have GPP guideline.

2.1.3 Quality assurance

In both countries, there is an officially defined protocol for ensuring the quality of medicines. While medicines samples are tested for medicines registration and post-marketing surveillance, sample test for medicine registration is not mandatory.

Table 12. Pharmaceutical quality assurance

	Korea	Philippines
Total number of sample(s) tested in 2014	NA	3569
Total number of sample(s) failed to meet quality standards in 2014	NA	98

In Korea, medicines which do not meet quality standards are requested to recall and dispose. Sometimes penalties are given, and production is suspended. In Korea, Negative and bad drug including counterfeit medicine is prohibited and regulated by the Act on special measures for the control of public health crimes. "Negative and bad drug means ① a drug not authorized under the legislation of pharmacist, ② a less effective drug from the licensed content, ③ and a counterfeited or tampered drug.

In the Philippines, the Special Law on Counterfeit Medicines, enacted on 06 September 2006, aimed to safeguard the health of the Filipino people by providing protection against counterfeit medicines. The Act generally prohibits the activities related to the manufacture, sale, importation, distribution, donation, or mere possession of counterfeit drugs. Monitoring of counterfeit drugs, administrative proceedings, administrative sanctions and penalties for violations are also included in the act. Regular monitoring to detect and combat counterfeit medicines is conducted by national authorities, specific or ad hoc studies, pharmaceutical sector, civil society or NGO in both countries.

2.1.4 Pricing

2.1.4.1 pricing policies

□ Korea

The price of prescription medicines in the reimbursable list of health insurance follows statutory pricing. The price of innovative (patent) medicines is determined through price negotiation between NHIS (National Health Insurance Service) and pharmaceutical company based on information about cost-effectiveness, budget impact and international prices. The price of medicines after patent expiration is determined based on generic price linkage. In the first year after patent expiration, 30% reduction in the price of originator, 85% of which (59.5% of the originator price before patent expiration) is set for the price of generic medicines. From the second year after patent expiration: 53.5% of originator price (further 10% reduction from the first year) for all generic medicines and original drug, regardless of the

order of entry. Prices for non-reimbursable prescription medicines and over-the-counter medicines are not regulated (free pricing)

□ The Philippines

Currently, there is free pricing of medicines in the Philippines with the non-transparent systems of mark-up leading to inefficiencies in the market and high out-of pocket costs for patients. In 2008, the Cheaper Medicines Act was passed to give instruments to the national government through the DOH to monitor and regulate drug prices. Drug price regulation was implemented albeit limited covering only five drugs in 2008 and setting a ceiling price for consumers. In 2013, the DOH began implementing a drug price reference index, which sets a cap on procurement prices of essential drugs in national DOH hospitals. This is to be implemented government-wide by 2016 to cover all government agencies and public health facilities.

□ Medicine prices in inpatient and outpatient sectors

In Korea, maximum reimbursable price for the same medicine is not different between inpatient and outpatient sector. But a provider may purchase a medicine cheaper than other providers through price negotiation. If providers purchase a medicine cheaper than its maximum reimbursable price, they will be reimbursed the purchasing cost plus the fixed portion of the difference between maximum reimbursable price and the purchasing cost.

In the Philippines, there is currently a wide variation of prices across hospitals and pharmacies in different regions because of information asymmetry. Public hospitals and the DOH were found to have the lowest prices whereas chain drugstores charge higher prices to patients. Private hospitals have the highest price charged to patients with no standards in setting reasonable mark ups.

Table 13. Types of pricing of medicines and price regulation

Pricing policies		(Non) prescription market		(Non) reimbursement market		Specific groups of medicines		
		POM	OTC	Reimbursable	Non-reimbursable	Generics	Parallel traded	Others, specify: e.g., biosimilars
Free pricing		Phil, Kor	Phil, Kor	Phil	Phil, Kor	Phil	Phil	
Price control	Statutory pricing	Kor		Kor		Kor		Kor(biosimilar)
	Price negotiations			Kor				Phil(EPI new vaccines)
	Tendering	Phil	Phil			Phil	Phil	
	Others-specify: (eg. Price-volume agreements)			Kor (price-volume agreement)				

2.1.4.2 Purchasing policies

□ Korea

There is no procurement mechanism at national or local level in Korea as health care providers purchase medicines directly. Public hospital and hospital over 300 beds are recommended to purchase medicines through bidding process. In hospitals, committee of pharmaceutical affair (for large hospital) is in charge of deciding at what price medicines are purchased. Hospital pharmacists participate in purchasing medicines as a member of the committee of pharmaceutical affair. In the out-patient sector, owner (pharmacist) is in charge.

□ The Philippines

Tendering is the default mechanism of procurement of essential medicines in

the public sector especially for multi-source products. For single-source products, direct price negotiation may be done. Price negotiations for high-cost medicines will likely be implemented by the DOH and Philhealth in the next medium to long-term. Philhealth is allowed by law to purchase services from health providers including pharmacies for its benefit packages. However, until now an outpatient drug benefit scheme has not yet been implemented by Philhealth. For the outpatient sector, there is free pricing and wide variations of drug prices.

The bids and awards committees (BACs) in public health facilities/hospitals set ceiling prices for drug procurement. This is now being guided through a Drug Price reference Index. Government Bids and Award Committees (BACs) determine ceiling prices of contracts for essential drugs. Hospital pharmacists are involved as members of the Therapeutics Committees and Bids and Award Committees in public health facilities.

2.1.4.3 Procurement

In Korea, medical institutions usually carry out their own procurement. Sometimes they purchase medicines through private procurement agency. The Philippines also has independent procurement system: hospitals and pharmacies independently carry out their own procurement in general. However, the Department of Health carries out national procurement for public health programs (i.e. TB, EPI, malaria, neglected infectious diseases, HIV, reproductive health services.). In 2009, a common tendering process was also initiated by DOH for cancer drugs and medicines for hypertension and diabetes distributed in public health facilities. The Therapeutics Committees of each hospital determine drugs needed for common cases seen in the facility. The list identified by the hospital therapeutics committees is forwarded to the Bids and Award Committees (BACs) which is responsible for the tender process.

2.1.4.4 Pricing procedure

□ Main pricing procedures

Table 14. Main pricing procedures

		In use: (yes/no)	Price type[1]	Scope[2]
External price referencing	Korea	No		Supportive tool for price negotiation for the new drug
	Philippines	Yes	manufacturer	Drugs in the essential drug list particularly single-source products
Internal price referencing	Korea	No		
	Philippines	Yes	manufacturer	Drugs in the essential drug list
Cost-plus pricing	Korea	No	-	-
	Philippines	No		
(Indirect) profit control	Korea	No	-	-
	Philippines	Yes	Pharmacy purchasing	Reimbursable inpatient drugs by Philhealth through case rate policy to hospitals
Risk/cost sharing	Korea	Yes	reimbursed price (retail price)	Reimbursable medicine (expensive cancer drug and the new treatment for rare disease without alternatives)
	Philippines	No		
Price/volume agreements	Korea	Yes	reimbursed price (retail price)	Reimbursable medicine
	Philippines	Yes	manufacturer	New EPI vaccines, high cost medicines
Others, specify: _____	Korea		Market-based actual price	Reimbursable medicine
	Philippines			

1 Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

2 Scope = a pricing procedure does not always refer to all medicines: e.g., a pricing procedure could only refer to reimbursable medicines, whereas for Over-The-Counter medicines there is free pricing.

□ Pricing procedure in Korea

The price of medicines is set considering the following criteria: expected consumption, total expected expenditure, expected financial impact on NHI fund, etc. The price of patent drug is decided through negotiation between NHIS and pharmaceutical company, and external reference pricing is used as a supportive tool. However, if the proposed price of new medicines is lower than the weighted price of alternative medicines, price negotiation is waived. At the time of price negotiation, pharmaceutical company and the NHIS sign an agreement with an expected sales volume sold. If the volumes are 30% greater than those expected at the time of price negotiation, the agreement would go into effect. The agreement is based on the total expenditure of all products of a company within the same ingredient and same formulation.

Risk-sharing agreement was implemented in 2014. NHIS agrees to fund the new treatment for diseases without alternative treatment (e.g., expensive cancer drugs or new treatments for rare diseases) but be refunded by the company if the expected outcome is not gained. Several types of risk-sharing agreements are available: conditional treatment continuation plus money back guarantee (based on health outcomes), expenditure cap, refund or utilization cap/fixed cost per patient (based on budget impact).

□ Pricing procedure in the Philippines

When the price of a medicines is set, it is compared with international reference prices (i.e. MSH, Thailand, India). Budgetary impact to DOH and Philhealth is also considered.

- External price referencing: Thailand and India, which have similar income status as the Philippines, are included in the basket for external price referencing, largely referencing prices of Thailand. Price data of UK NHS, PBAC, WHO/UNICEF for EPI vaccines are employed.

- Internal price referencing: In general, for essential drugs with sufficient competition (i.e., drugs with four or more manufacturers), DPRI is set at the median price based on prices collected from the purchase orders of public hospitals in the previous year for each molecule and strength. For medicines with limited market competition (three or less manufacturers) the DOH may

set the DPRI at the lowest winning bid price achieved for this product for the previous year plus an allowable margin to consider inflationary cost (i.e., 2%). The Philippine DPRI does not yet apply reference groups in the setting of the reference prices. The DPRI is updated annually based on prevailing procurement prices of medicines in government health facilities.

- Cost-plus pricing: For DOH public tenders of essential medicines, the cost components are usually applied above the acquisition cost of the medicine, such as warehousing and distribution (5%), cold-chain (3%).

2.1.4.5 Discounts / rebates

In Korea, discount is granted. Under the market-based actual pricing (or incentive system for purchasing low price medicines), a financial incentive is provided for hospitals to purchase medicines at a price lower than the maximum allowable price, which motivate providers to actively negotiate on the price of pharmaceuticals. However, rebate provided by manufacturers and distributors is illegal.

In the Philippines, all medicines are subject to a mandatory 20% discount for senior citizens and persons with disability. There is burden sharing of the discount among manufacturers, distributors and retail pharmacies. Any type of rebates are not allowed.

2.1.4.6 Price composition

□ Mark-up

Table 15. Mark-up

	Wholesale mark-up			Pharmacy mark-up			Hospital mark-up		
	Regulation	Content	Scope*	Regulation	Content	Scope*	Regulation	Content	Scope*
Korea	No			Yes	No mark-up	Reimbursable medicines	Yes	No mark-up	Reimbursable medicines

□ Taxes and others

In Korea, dispensing fee is charged for filling a prescription depending on the number of prescribed days. 10% of VAT rate is applied for only OTC drugs. In the Philippines, 12% of VAT is consistently applied for all medicines. It is being proposed to remove the 12% VAT for the government purchasing of medicines.

2.1.5 Reimbursement

2.1.5.1 Reimbursement policies (Overview)

□ Korea

NHIS operates a national positive list system for the general reimbursement scheme, which includes 17,798 medicines as of July, 2015. The reimbursement list is monthly updated. Not every drug, which is approved by MFDS as being safe, can be listed for reimbursement. Pharmaceutical companies submit their product list to be reimbursed by national health insurance on a voluntary basis. When a pharmaceutical company submits an application for a new drug or new molecular entity to HIRA (Health Insurance Review and Assessment Service), the manufacturer performs an economic evaluation. Then HIRA reviews submitted evidence and assesses the appropriateness of benefit coverage of the drug. The reimbursement rates are not different across medicines, but different across specific groups of population (e.g., cancer, rare disease, et al.)

□ Philippines

The list of drugs funded by the public scheme should conform with the Philippine National Formulary. The Philippine National Formulary lists drugs according to their international nonproprietary name (INN). There are currently 648 drugs in the national formulary. The list is regularly updated (i.e., quarterly) as soon as approvals are granted by the Secretary of Health as

recommended by the Formulary Executive Committee (FEC).

Currently, essential medicines are reimbursed on an inpatient basis as part of the All Case Rates Policy of the Philhealth. The "All Case Rate Policy" was introduced by the Philhealth in January 2014, shifting from the previous Fee-for-Service scheme to encourage greater efficiency and quality of care. Drugs are generally bundled with the current case rates of Philhealth, which consider the total package of care for each disease or medical/surgical procedure covering all inputs such as diagnostics, professional fees, hospitals days, etc. Philhealth also has begun to use the drug price reference index as a basis for costing catastrophic benefit packages and the outpatient drug benefit scheme, which will be launched in 2016

2.1.5.2 Reference pricing

□ There is no reference pricing system in Korea.

□ Drug price reference index of the Philippines

The Department of Health in the Philippines has developed the Drug Price Reference Index (DPRI) which serves as a ceiling price for procurement to guide all national and local government health facilities. It was implemented in 2014 to lessen the wide variations of procurement prices of medicines observed across DOH hospitals nationwide. It also aims to improve the efficiency and good governance in the pricing and procurement of medicines in the public sector through establishing a transparent and publicly available reference price for affordable and quality medicines.

The DPRI is now being referenced by the PhilHealth in costing benefit packages and setting reimbursement caps for medicines. The DPRI is also being targeted to be implemented mandatorily in 2016 across all government health facilities. The DPRI includes all medicines listed in Philippine National Formulary (PNF) for all formulations and strengths. Both locally manufactured and internationally sourced essential medicines are included in the database.

2.1.5.3 Risk-sharing scheme

Risk-sharing scheme was introduced in 2013 and is applied to expensive cancer treatment and orphan drugs for treating rare disease without any alternatives (ex: Evoltra, Revlimid, Erbitux) in Korea. There is no risk-sharing scheme in the Philippines.

2.1.5.4 Decision making tools (pharmaco-economic analysis)

The results of systematic review of clinical evidence and economic evaluation are the criteria used in the decision making regarding medicines pricing and reimbursement for both countries.

In Korea, a formal pharmaco-economic evaluation has been applied since 2007. Pharmaceutical company performs pharmaco-economic evaluation, which is mandatory for the process of reimbursement. The guidelines were firstly developed and published in 2006 and then were revised in 2011. In addition, Heath Technology Assessment (HTA) is performed.

In the Philippines, pharmaco-economic evaluation is employed for the selection of drugs in the national formulary. New drugs can be included in the national formulary when they are cost-effective over existing standards. Currently, a methods guide is being drafted to standardize the process of pharmaco-economic evaluation and will be publicly available in 2016. Pharmaco-economic evaluation is being commissioned to the academe (e.g., for rotavirus vaccine) and also done in-house for high priority products (e.g., for HPV, PCV vaccines)

2.1.5.5 Out-of-pocket payments on medicines

□ Korea

OOP payment for medicines is based on the mixed system of percentage payment and fixed co-payment. Generally, co-payment rates are 20% and 30% respectively for inpatient and outpatient. However, patients pay 40~50 %

copayment for outpatient prescription issued by general or tertiary hospital for their not severe diseases. In addition, patients with cancer and rare disease pay respectively 5% and 10% of cost. There is ceiling on total copayments for a given time period, and there are seven ceiling levels linked to income (i.e., higher ceilings for high-income people).

Table 16. Out-of-pocket payments for medicines, 2015

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	1200 won (Elderly aged 65 and over pay 1200 won if the cost less than 10000 won) - outpatient	500 won (people under medical assistance program) - outpatient
Percentage payments	30%(outpatient), 20%(inpatient)	Patients with cancer and rare disease pay respectively 5% and 10% of cost.

□ The Philippines

At present, there is high out-of-pocket spending for medicines because of the lack of an outpatient drug benefit scheme. Medicines constitute around 46.5% of total out-of-pocket spending. Special discounts (i.e. 20%) are given to the elderly and persons with disability when purchasing medicines from drugstores.

2.1.5.6 Reimbursement policies in hospitals

In Korea, all hospitals are covered for medicines reimbursed by the national health insurance system based on the national reimbursement list. Financing/reimbursement in the in-patient sector is not different from the out-patient sector.

In the Philippines, inpatient drugs are covered both by social health insurance (SHI) and hospital budgets in the public sector. There is full reimbursement of the total package of care through the "all case rate policy" for indigent patients while there is copayment for the total package of care for non-poor patients. In the private sector, there is also partial coverage by the SHI scheme although there may be a fixed co-payment.

2.1.5.7 Hospital pharmaceutical formularies and pharmaceutical and therapeutic committees (P&T committee)

In Korea, pharmaceutical and therapeutic committees which are usually composed of hospital pharmacists and medical doctors review cases regarding (1) purchase of medicines and/or inclusion of medicines in the formulary (2) efficacy of medicines or adverse drug reactions (3) standard prescription or hospital formularies (4) providing or gathering drug information, and so on. However, these roles are different from hospitals to hospitals and not all hospitals have P&T committees.

In the Philippines, each hospital is encouraged to create their own formularies reflecting their own drug needs but based on the Philippine National Formulary. Hospitals develop their formularies through their Pharmacy and Therapeutics Committee. Hospital pharmacists serve as the secretary of the Pharmacy and Therapeutics Committee and are involved in the selection and decision making process of the Committee.

2.1.6 Rational use of medicines

2.1.6.1 Overview

□ Both Korea and the Philippines have legal provisions governing the licensing and prescribing practices of prescribers.

□ Both Korea and the Philippines have legal provisions governing the dispensing practices of pharmaceutical personnel.

□ Both Korea and the Philippines have National Standard Treatment Guidelines (STGs). Specifically, the Philippines has STGs for TB, malaria, HIV/AIDS, dengue, IMCI, hypertension and diabetes.

□ Both Korea and the Philippines have national medicines information center.

2.1.6.2 Monitoring and evaluation

□ Price monitoring

In Korea, the government reviews the prices of prescription medicines for all pharmacies and hospitals using market transaction data since Sep 2014. Based on these prices, maximum reimbursable price will be adjusted from 2016

In the Philippines, an electronic drug price monitoring system (EDPMS) is currently being implemented by the DOH to actively monitor drug prices among hospital pharmacies and public and private drug outlets. Furthermore, the Cheaper Medicines Act mandates the DOH to monitor and publicize retail prices of medicines. This is being done through quarterly dissemination of price information in major newspapers and the social media. In 2015, a web-based consumer platform will be launched by the DOH to allow for more accessible price information to the public.

□ Prescription monitoring

Prescription guidelines have been developed by professional academic association in Korea. Most of prescription guidelines are included in clinical standard medical guidelines. As of November 2013, 115 clinical medical guidelines have been developed. While Korean Medical Guideline Information Center, which is funded by MOHW and KCDC, is certifying developed guidelines and trying to disseminate them to hospitals, there is no official monitoring for prescription guideline. As one of tools for hospital's quality assessment, HIRA regularly monitors and assesses the prescribing behaviors of providers for prophylactic antibiotic use for surgery, prescription for hypertension/diabetes, antibiotics use for acute respiratory infection, the number of drugs in a prescription, etc.

In the Philippines, there are legal provisions regarding prescription guidelines. The government (DOH and FDA) is in charge of the implementation. However, there are no specific indicators and written evaluation of the policies.

□ Pharmaceutical consumption monitoring

From 2008, official statistics on pharmaceutical consumption have been produced in Korea, which follow the OECD criteria. HIRA is in charge of monitoring the consumption of reimbursed drugs. MOHW releases annual report for the monitoring of pharmaceutical consumption including reimbursed and non-reimbursed medicines. Furthermore, DUR (Drug Utilization Review) system was introduced in 2010, which provides drug safety and duplication information to physicians and pharmacists in real-time at the stage of prescribing and dispensing. HIRA runs the DUR using all information on the prescription and dispensing of reimbursement medicines.

In the Philippines, pharmaceutical consumption has been monitored for the different access programs of the DOH since 2011. The overall market sales are also being monitored through the IMS health Data since 2011. There are no computerized tracking systems for prescriptions.

□ Generic Promotion

In Korea, generic substitution is allowed from 2000, but it is not mandatory. The substituted product must be bio-equivalent. If a pharmacist substitute prescribed medicines with lower priced medicines, financial incentive amounting to 30 percent of the price difference is provided to the pharmacist. Physicians can prescribe by the International Non-proprietary Name (INN)) or brand name.

In the Philippines, the Generics Act of 1988 mandates pharmacists to substitute lower priced generic products. Pharmacists are mandated to offer a generic menu card to consumers and substitute medicines following patient's opinion. All physicians are mandated by law to prescribe in generics (INN) although the specification of brand names is allowed for private physicians. There are administrative/legal sanctions based on the generics Act for violation. There has been steadily growing acceptance of generic medicines in the Philippines over the past five years. Generics now account for 65 percent of the total pharmaceutical market, largely branded generics, with an annual growth of 6 percent since 2010. Recent data of IMS health shows that among Asia-Pacific countries with comparable GDPs, the Philippines has a higher

utilization rate of lower-cost generics. The generic prescription rate among physicians has increased from 66% in June 2011 to 73% in June 2014.

□ Medicines advertising and promotion

In Korea, MFDS has the authority to regulate the promotion and advertisement for medicines. Direct advertising of prescription medicines to the public is prohibited. Pre-approval of medicines advertising and promotional materials are required,. and there are guidelines and regulations on advertising and promotion of non-prescription medicines. In the Philippines, the FDA is responsible for regulating the promotion and/or advertising of medicines.

□ Education and training

Continuing education is mandatory for physicians, nurses, or pharmacists in Korea while it is not mandatory in the Philippines. In Korea, core training includes the details of national essential medicines list, standard treatment guidelines, pharmaco-vigilance, clinical pharmacology and drug information for physicians and pharmacists as well as the details of medicines supply management and rational use of medicines for pharmacists.

□ Pharmaco-vigilance

In both Korea and the Philippines, adverse drug reactions (ADRs) are monitored at institution, regional and national levels.

2.1.7 Intellectual property laws and medicines

□ Patent for pharmaceuticals

Korea and the Philippines are members of the World Trade Organization (WTO) and have legal provisions for patent for pharmaceuticals

□ TRIPS Agreement

National legislation has been modified to implement the TRIPS (Trade Related Intellectual Properties) Agreement in both of Korea and the Philippines. Current laws also contain TRIPS flexibilities and safeguards including bolar exception and compulsory licensing provisions in both countries. Korean law does not specifically prohibit parallel imports. However, the parallel import of medicinal products is not allowed in Korea, but allowed in the Philippines. There are legal provisions for patent extension for pharmaceuticals, data exclusivity and linkage between patent status and marketing authorization in Korea, but not in the Philippines.

2.2 General information and health

2.2.1 Population structure

As of 2013, total population is 50,220 thousand in Korea and 98,993 thousand in the Philippines. Over the last decade, the proportion of people aged more than 65 has been largely increasing from 7 percent to 12 percent in Korea, whereas it has not changed in the Philippines showing about 4 percent.

Table 17. Population structure in Korea

	2000	2005	2009	2010	2011	2012	2013
Total population [1), 2)] (In thousands)	46,316	48,138	49,182	48,580	49,779	50,004	50,220
Population aged 0-14 [3)] (% of total)	21	19	17	16	16	15	15
Population aged 15-64 [4)] (% of total)	72	72	72	73	73	73	73
Population aged ≥ 65 [5)] (% of total)	7	9	11	11	11	12	12

1) World Bank data: http://data.worldbank.org/indicator/SP.POP.TOTL
2) Ministry of Security and Public Administration http://rcps.egov.go.kr:8081/jsp/stat/ppl_stat_jf.jsp
3) World Bank data http://data.worldbank.org/indicator/SP.POP.0014.TO.ZS?page=2
4) World Bank data http://data.worldbank.org/indicator/SP.POP.1564.TO.ZS?page=2
5) World Bank data http://data.worldbank.org/indicator/SP.POP.65UP.TO.ZS
All data was accessed on 11 June 2015

Table 18. Population structure in the Philippines

	2000	2005	2009	2010	2011	2012	2013
Total population (In thousands)	76,504	85,821	91,886	93,444	95,053	96,706	98,393
Population aged 0-14 (% of total)	37.0	37	36	35	35	35	34
Population aged 15-64 (% of total)	59.2	59	61	61	61	62	62
Population aged ≥ 65 (% of total)	3.8	3	4	4	4	4	4

Ref: Philippines Statistics Authority. Accessed at: http://www.nscb.gov.ph/secstat/d_popnProj.asp

2.2.2 Socioeconomic statistics

The GDP per capita is over $25,000 in Korea, which is about 10 times more than in the Philippines. The proportion of people that live in urban area is 84 percent in Korea, while it is 44 percent in the Philippines. When it is measured with poverty head count ratio at $1.25 a day, the poverty rate is 19% in the Philippines. Both countries showed the similar level of literacy rate.

Table 19. GDP per capita

		2000	2005	2009	2010	2011	2012	2013
GDP per capita	Korea	11,948	18,657	18,339	22,151	24,156	24,454	25,977
	Philippines	1,043.5	1,201.0	1,832.0	2,135.9	2,358.1	2,587.6	2,843.1 (2014)
World Bank data								

Table 20. Urban population, poverty rate and literacy rate in Korea

		Year	Source	Notes
Urban population (% of total population)	84	2013	Ref 8	
Poverty headcount ratio at $1.25 a day (PPP) (% of population)	NA			
Literacy rate, adult total (% of people ages 15 and above)	97.9	2002	Ref 9	
Ref 8: World Bank data Ref 9: Central Intelligence Agency All data was accessed on 11 June 2015.				

Table 21. Urban population, poverty rate and literacy rate in the Philippines

		Year	Source
Urban population (% of total population)	44	2014	PSA https://psa.gov.ph/content/urban-barangays-philippines-based-2010-cph
Poverty headcount ratio at $1.25 a day (PPP) (% of population)	19.0	2012	World Bank data
Literacy rate, adult total (% of people ages 15 and above)	97.5%	2010	NSO's 2010 Census of Population and Housing (CPH) http://www.philstar.com/business/2013/12/31/1273515/phl-literacy-rate-improves-97.5-nso

2.2.3 Health

Korea and the Philippines shows the big difference in life expectancy, fertility rate, and mortality. Life expectancy at birth is 81 years in Korea and 68.8 years in the Philippines, respectively. The mortality rate is also much lower in Korea than in the Philippines regardless of its cause. Total fertility rate is 1.3 in Korea and 2.9 in the Philippines.

Table 22. Life expectancy, fertility and mortality in Korea

		Year	Source	Notes
Life expectancy				
Life expectancy at birth, total (Years)	81	2013	Ref 10	
- Male (Years)	78	2013	Ref 11	
- Female (Years)	85	2013	Ref 12	
Life expectancy at age 60, total (Years)	24	2013	Ref 13	
- Male (Years)	22	2013	Ref 13	
- Female (Years)	27	2013	Ref 13	
Fertility				
Fertility rate, total (births per woman)	1.3	2013	Ref 13	
Mortality				
Mortality rate, infant (per 1,000 live births)	3.2	2013	Ref 13	
Mortality rate, under-5 (per 1,000 live births)	3.7	2013	Ref 13	
Mortality by causes				
Age-standardized mortality rates by causes: Communicable (per 100,000 population)	34	2012	Ref 13	
Age-standardized mortality rates by causes: Non-communicable (per 100,000 population)	302	2012	Ref 13	
Age-standardized mortality rates by causes: Injuries (per 100,000 population)	53	2012	Ref 13	
Ref 10: World Bank Ref 11: World Bank data Ref 12: World Bank data Ref 13: WHO World Health Statistics. 2015. All data was accessed on 5 June 2015.				

Table 23. Life expectancy, fertility and mortality in the Philippines

		Year	Source	Notes
Life expectancy				
Life expectancy at birth, total (Years)	68.81	2015	PSA https://psa.gov.ph/content/philippines-figures-0	
- Male (Years)	68.81	2015	PSA	
- Female (Years)	74.34	2015	PSA	
Life expectancy at age 60, total (Years)	17.6	2002	NSCB http://www.nscb.gov.ph/ncs/10thNCS/papers/invited%20papers/ips-26/ips26-01.pdf	
- Male (Years)	16.8	2002	NSCB	
- Female (Years)	19.3	2002	NSCB	
Fertility				
Fertility rate, total (births per woman)	2.96	2015	PSA	
Mortality				
Mortality rate, infant (per 1,000 live births)	23.5	2013	Philippines National Demographic and Health Survey https://dhsprogram.com/pubs/pdf/FR294/FR294.pdf	
Mortality rate, under-5 (per 1,000 live births)	26	2013	Philippines National Demographic and Health Survey	
Mortality by causes				
Age-standardized mortality rates by causes: Communicable (per 100,000 population)	227	2012	WHO World Health Statistics. 2015 http://apps.who.int/iris/bitstream/10665/170250/1/9789240694439_eng.pdf	
Age-standardized mortality rates by causes: Non-communicable (per 100,000 population)	720	2012	WHO World Health Statistics. 2015	
Age-standardized mortality rates by causes: Injuries (per 100,000 population)	54	2012	WHO World Health Statistics. 2015	

2.2.4 Health care delivery

Regarding health care facilities and health care human resources, the Philippines has much poorer infrastructure than Korea. As of 2013, the number of hospitals per 100,000 population is 3.4 in Korea and 1.8 in the Philippines, while the number of hospital beds per 1,000 population is 10.3 and 1.2, respectively. Total number of physician is 109,563 in Korea and 25,865 in the Philippines.

Table 24. Health care facilities and health care utilization in Korea

Health care facilities				
Hospitals (per 100,000 population)	3.4	2013	Ref 13	
Hospital beds (per 1,000 population)	10.3	2012	Ref 14	
Health care utilization				
No. of physician consultations per capita	14.6	2013	Ref 14	
Ref 13: WHO World Health Statistics 2015 Ref 14: Health at a Glance Asia/Pacific 2014				

Table 25. Health care facilities and health care utilization in the Philippines

Health care facilities				
Hospitals (per 100,000 population)	1.8	2013	WHO World Health Statistics. 2015 http://apps.who.int/iris/bitstream/10665/170250/1/9789240694439_eng.pdf	
Hospital beds (per 1,000 population)	1.2	2013	PSA PIF 2015 https://psa.gov.ph/content/philippines-figures-0	
Health care utilization				
No. of physician consultations per capita	-			NA

Table 26. Human resource in Korea

		Year	Source	Notes
No. of physicians, total	109,563	2013	Ref 15	Registered physicians only. The number of dentists is not included (27,409).
No. of pharmacists, total	63,292	2013	Ref 15	Registered pharmacists
No. of traditional doctors, total	21,355	2013	Ref 15	Registered oriental medical doctors
No. of nursing and midwifery personnel, total	316,219	2012	Ref 15	Registered midwives (8,422) and nurses (307,797)
No. of schools of pharmacy, total	35	2015	Ref 16	
No. of graduates of schools of pharmacy per year	1,695	2015	Ref 17	Number of new pharmacists who passed the exam

Ref 15: Ministry of Health and Welfare, Yearbook of Health and Welfare Statistics. 2014
Ref 16: Pharmacy Education Eligibility Test
Ref 17: National Health Personnel Licensing Examination Board. All data was accessed on 8 June 2015

Table 27. Human resource in the Philippines

		Year	Source	Notes
No. of physicians, total	25,865	2014	Department of Health - Health Human Resource Development Bureau http://ndhrhis.com/system.rcall.page.php?xcrs=RPA0001.php&prm=year=2014^seqn=03^title=As%20of%20December%2031%202014	
No. of pharmacists, total	3,753	2014	Department of Health - Health Human Resource Development Bureau	
No. of traditional doctors, total			This should be requested to PMA	
No. of nursing and midwifery personnel, total	60,143	2014	Department of Health - Health Human Resource Development Bureau This should be requested to PRC	
No. of schools of pharmacy, total			This should be requested to CHED	
No. of graduates of schools of pharmacy per year			This should be requested to CHED	

2.2.5 Health care financing and expenditure

Total health expenditure as % of GDP has been rapidly increasing in Korea from 4.3% in 2000 to 7.5% in 2012. It is 4.6% in the Philippines as of 2013.

Table 28. Total health expenditure in Korea

	2000	2005	2009	2010	2011	2012
Total health expenditure (In NCU = Trillion KRW [1)]	26.8	48.9	76.6	86.1	91.7	97.1
Total health expenditure per capita (In NCU = Current USD [2)]	491	988	1,204	1,498	1,652	1,703
Total health expenditure (% of GDP)[3)]	4.3	5.6	7.1	7.3	7.4	7.5
1): Statistics Korea. http://www.index.go.kr/potal/stts/idxMain/selectPoSttsIdxSearch.do?idx_cd=1431&clas_div=&idx_sys_cd=694&idx_clas_cd=1 2) World Bank data 3) World Bank data All data was accessed on 8 June 2015						

Table 29. Total health expenditure in the Philippines

	2005	2009	2010	2011	2012	2013
Total health expenditure (In million pesos, at current prices)[1)]		342,164	380,826	431,047	471,100	526,342
Total health expenditure per capita (in pesos, at current prices)[1)]		3,759	4,112	4,577	4,881	5,360
Total health expenditure (% of GDP)[2)]	3.9	4.3	4.3	4.3	4.5	4.6
1) NSCB 2) World Bank data http://data.worldbank.org/indicator/SH.XPD.PCAP						

The reliance on private funding source to finance health expenditure is bigger in the Philippines than in Korea. The public share as percent of total health expenditure is about 55% in Korea, while it is about 30% in the philippines. The major funding source of health expenditure in the Philippines is out-of-pocket payment, which composes 56.3% of total health expenditure as of 2013. The largest portion of OOP is used for purchasing pharmaceuticals and medical goods.

Table 30. Structure of health expenditure in Korea

Total health expenditure (THE)				
- Public share of THE (%)	54.5	2012	Ref 13	Total percentages should be 100%
- Private share of THE (%)	45.5	2012	Ref 13	
General government expenditure on health as % of total government expenditure	11.7	2012	Ref 13	
Composition of total health expenditure				
General governmental expenditure (%)	12.1	2012	Ref 13 Ref 17	Total percentages should be 100%
Social health insurance (Social security) (%)	42.4	2012	Ref 13 Ref 17	
Private prepaid plans (%)	5.5	2012	Ref 13 Ref 17	
Out-of-pocket (%)	35.9	2012	Ref 13 Ref 17	
Others (%): specify (e.g., international aids)	4.1	2012	Ref 13 Ref 17	
Structure of out-of-pocket payment				
In-patient expenses (%)	NA			Total percentages should be 100%
Out-patient expenses (%)	NA			
Long-term care (%)	NA			
Pharmaceuticals and medical goods (%)	NA			
Collective services (%)	NA			

Ref 13: WHO World Health Statistics 2015
Ref 15: Ministry of Health and Welfare, Yearbook of Health and Welfare Statistics. 2014
Ref 16: OECD Stat Extracts http://stats.oecd.org/
Ref 17: Korean National Health Accounts and Total Health Expenditure in 2012
http://stat.mw.go.kr/front/include/download.jsp?bbsSeq=11&nttSeq=21379&atchSeq=3955

Table 31. Structure of health expenditure in the Philippines

Total health expenditure (THE)				
- Public share of THE (%)	30.4	2013	NSCB	Government: 18.9 Social insurance: 11.5%
- Private share of THE (%)	68.2	2013	NSCB	
General government expenditure on health as % of total government expenditure	4.9	2013	NSCB	
Composition of total health expenditure				
General governmental expenditure (%)	30.4	2013	NSCB	Total percentages should be 100%
Social health insurance (Social security) (%)	11.5	2013	NSCB	
Private prepaid plans (%)	8.7	2013	NSCB	
Out-of-pocket (%)	56.3	2013	NSCB	
Others (%): specify (e.g., international aids)	3.1	2013	NSCB	
Structure of out-of-pocket payment				
In-patient expenses (%)	29	2012	1)	Total percentages should be 100%
Out-patient expenses (%)	14.9	2012	1)	
Long-term care (%)	---			
Pharmaceuticals and medical goods (%)	46.9	2012	1)	
Collective services (%)				
1) Philippine National Health Accounts 2012				

2.3 Pharmaceutical system

2.3.1 Pharmaceutical financing and expenditure

The proportion of pharmaceutical expenditure in GDP is higher in the Philippines than in Korea. In 2012, it accounted for 1.51% in Korea and 2.01% in the Philippines. Pharmaceutical expenditure as % of total health expenditure is also higher in the Philippines than in Korea, which are 43.96% and 19.8%, respectively.

Table 32. Pharmaceutical expenditure in Korea

	2000	2005	2009	2010	2011	2012
Pharmaceutical expenditure (In NCU = Trillion KRW	7.18	10.95	16.85	18.5	19.5	19.2
Pharmaceutical expenditure per capita (In NCU = Current USD	131.6	287	391	427	444.9	445
Pharmaceutical expenditure (% of GDP)	1.02	1.34	1.58	1.58	1.58	1.51
Pharmaceutical expenditure (% of Total health expenditure)	26.8**	22.4	22.0	21.5	21.3	19.8
OECD Health Data: Health expenditure and financing: OECD Health Statistics (database). All data was accessed on 12 June 2015						

Table 33. Pharmaceutical expenditure in the Philippines

	2005	2009	2010	2011	2012	2013
Pharmaceutical expenditure (in thousand pesos)					203,000,000	
Pharmaceutical expenditure per capita					2,103.60	
Pharmaceutical expenditure (% of GDP)					2.01%	
Pharmaceutical expenditure (% of Total health expenditure)					43.6%	

Private share of pharmaceutical expenditure is more than twice higher in the Philippines (87.6%) than in Korea (40%). Share of prescription-only medicines in total market is similar in the two countries although it is slightly higher in Korea than in the Philippines.

Table 34. Structure of pharmaceutical expenditure in Korea

		Year	Source	Notes
Pharmaceutical expenditure (PE)				
- Public share of PE (%)	60	2011	Ref 23	Total percentages should be 100%
- Private share of PE (%)	40	2011	Ref 23	
Prescription-only medicines				
Shares of prescription-only medicines in total market (%)	79.55	2011	Ref 24	
Over-the-counter medicines				
Shares of over-the-counter medicines in total market (%)	20.45	2011	Ref 24	
Over-the-counter medicines (expenditure per capita)	91	2011	Ref 24	
Alternative medicines & Herbal medicines				
Alternative medicines & Herbal medicines (expenditure per capita)	NA			
Ref 23: OECD iLibrary Ref 24: OECD Health at a glance 2013 All data was accessed on 12 June 2015				

Table 35. Structure of pharmaceutical expenditure in the Philippines

		Year	Source	Notes
Pharmaceutical expenditure (PE)				
- Public share of PE (%)	12.4	2013	PNHA 2013	Total percentages should be 100%
- Private share of PE (%)	87.6	2013	PNHA 2013	
Prescription-only medicines				
Shares of prescription-only medicines in total market (%)	73%	2013	IMS Health	
Over-the-counter medicines				
Shares of over-the-counter medicines in total market (%)	27%	2013	IMS Health	
Over-the-counter medicines (expenditure per capita)			Ref 24	
Alternative medicines & Herbal medicines				
Alternative medicines & Herbal medicines (expenditure per capita)			Ref 25	

2.3.2 Availability and access

The number of authorized (or licensed) prescription-only medicines available in the market is similar in the two countries. However, the number of authorized (or licensed) medicines available in the market is higher in Korea than in the Philippines because of difference in the number of authorized (or licensed) over-the-counter medicines available in the market.

Table 36. Number of pharmaceutical products in Korea

Medicines				
No. of authorized (or licensed) medicines available in the market, total	39,847	2013	Ref 25	Criteria: the number of products
Prescription-only medicines				
No. of authorized (or licensed) prescription-only medicines available in the market	23,282	2013	Ref 25	Criteria: the number of products
Over-the-counter medicines				
No. of authorized (or licensed) over-the-counter medicines available in the market	16,565	2013	Ref 25	Criteria: the number of products
New molecular entities				
No. of new molecular entities (NMEs) launched per year	27	2014	Ref 25	No. of authorized medicines
Ref 25: Ministry of Food and Drug Safety, Food & Drug Statistical Yearbook 2014 http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=18082&cmd=v Ref 26: Ministry of Drug and Food Safety. National institute of food and drug safety evaluation. Pharmaceutical approval report. 2015. http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=19225&cmd=v All data was accessed on 1 July 2015				

Table 37. Number of pharmaceutical products the Philippines

Medicines				
No. of authorized (or licensed) medicines available in the market, total	24,917	2015	CDRR Database	This excludes vaccines / biologics and veterinary pharmaceuticals
Prescription-only medicines				
No. of authorized (or	21,144	2015	CDRR Database	

licensed) prescription-only medicines available in the market				
Over-the-counter medicines				
No. of authorized (or licensed) over-the-counter medicines available in the market	3,773	2015	CDRR Database	
New molecular entities				
No. of new molecular entities (NMEs)		2015	ICTMD	

Whereas MOHW releases medicines list for drug shortage prevention program (e.g., low-priced medicines) in Korea, National Medicines List (EML) exists in the Philippines. In the Philippines, 649 medicines are listed as essential medicines, and median availability in public sector was 53.6%.

Table 38. Essential medicines in Korea

Essential Medicines				
National Essential Medicines List (EML) exists? (yes/no)	Not applicable			MOHW releases medicines list for drug shortage prevention program. (e.g., low-priced medicines)
No. of Essential Medicines, total				
Availability of essential medicines				
Median availability of selected generic medicines, public (%)	NA			
Median availability of selected generic medicines, private (%)	NA			
Price of essential medicines				
Median consumer price ratio of selected generic medicines, public	NA			
Median consumer price ratio of selected generic medicines, private	NA			

Table 39. Essential medicines in the Philippines

		Year	Source	Notes
Essential Medicines				
National Medicines List (EML) exists? (yes/no)	Yes	2015	DOH	
No. of Essential Medicines, total	649	2015	DOH	
Availability of essential medicines				
Median availability of selected generic medicines, public (%)	53.6	2013	DOH Drug Availability Study 2013	Primary care units 65.9 Hospitals 41.3
Median availability of selected generic medicines, private (%)				
Price of essential medicines				
Median consumer price ratio of selected generic medicines, public	0.65 -8.75	2015	DOH	
Median consumer price ratio of selected generic medicines, private	0.42 -69.26	2015	DOH	

2.3.3 Pharmaceutical prescription and consumption

In both Korea and the Philippines, separation of prescribing (e.g., physicians) and dispensing (e.g., pharmacists) is mandatory. Only physicians are allowed to prescribe medicines and only pharmacists can dispense medicines.

Table 40. Separation of prescribing and dispensing in Korea

	Yes/No	Year	Source	Notes
Separation policy				
Separation of prescribing (e.g., physicians) and dispensing (e.g., pharmacists1) exists?	yes	2013	Ref 28	
If yes, is it mandatory or voluntary?	mandatory	2013	Ref 28	
Who is allowed to prescribe medicines?				
Physicians	Yes	2015	Ref 28	
Nurses	No	2015	Ref 28	
Pharmacists1	No	2015	Ref 28	
Others– specify: (e.g., Community health workers)	No	2015	Ref 28	
Who is allowed to dispense medicines?				
Physicians	No	2015	Ref 28	
Nurses	No	2015	Ref 28	
Pharmacists	Yes	2015	Ref 28	
Others– specify: (e.g., Community health workers)	No	2015	Ref 28	
Ref 28: Pharmaceutical affairs act. SECTION 2 Preparation of Drugs Article 23 (Preparation of Drugs (May 2015))				

Table 41. Separation of prescribing and dispensing in the Philippines

	Yes/No	Year	Source
Separation policy			
Separation of prescribing (e.g., physicians) and dispensing (e.g., pharmacists1) exists?	Yes	1969	An Act Regulating the Practice of Pharmacy and Setting Standards of Pharmaceutical Education in the Philippines and for Other Purposes. http://www.lawphil.net/statutes/repacts/ra1969/ra_5921_1969.html
If yes, is it mandatory or voluntary?	Yes	1959	The Medical Act of 1959 http://www.lawphil.net/statutes/repacts/ra1959/ra_2382_1959.html
Who is allowed to prescribe medicines?			
Physicians	YES	1959	The Medical Act of 1959 http://www.lawphil.net/statutes/repacts/ra1959/ra_2382_1959.html
Nurses	NO		Philippine Nursing Act of 2002 http://www.lawphil.net/statutes/repacts/ra1959/ra_2382_1959.html The Medical Act of 1959
Pharmacists	NO		The Medical Act of 1959 http://www.lawphil.net/statutes/repacts/ra1959/ra_2382_1959.html
Others – specify: (e.g., Community health workers)	No		
Who is allowed to dispense medicines?			
Physicians	No		
Nurses	No	2002	Philippine Nursing Act of 2002
Pharmacists	Yes		An Act Regulating the Practice of Pharmacy and Setting Standards of Pharmaceutical Education in the Philippines and for Other Purposes http://www.lawphil.net/statutes/repacts/ra1969/ra_5921_1969.html
Others – specify: (e.g., Community health workers)	no		

Table 42. Pharmaceutical consumption in Korea

Consumption(In DDD)				
Hypertension drugs	148	2011	Ref 19	DDD, per 1000 people per day
Anticholesterols	34	2011	Ref 19	
Antidiabetics	62	2011	Ref 19	
Antidepressants	13	2011	Ref 19	
Ref 19: OECD Health at a Glance 2013				

Generic market share is much higher in the Philippines than in Korea; in Korea and the Philippines, 44% and 77 % respectively in terms of volume, and 41% and 61% respectively in value.

Table 43. Generic market share in Korea

Generic shares in % of total market				
In volume	44	2007	Ref 29	
In value	41	2007	Ref 29	
Generic shares in % of total out-patient market				
In volume	42.6	2012	Ref 30	Including reimbursement medicines and per oral medicine only.
In value	41.7	2012	Ref 30	Including reimbursement medicines and per oral medicine only
Generic shares in % of the in-patient market				
In volume	44.3	2012	Ref 30	
In value	34.3	2012	Ref 30	
Ref 29: Yoon (2008). Issues on Drug Pricing and Reimbursement in Korea. Korean Development Institute. Ref 30: Korea Institute for Health and Social Affairs, Statistics for pharmaceutical consumption and sales – in-depth analysis 2013 (accessed on 14 June 2015)				

Table 44. Generic market share in the Philippines

Generic shares in % of total market				
In volume	77%	2013	IMS Health 2013	
In value	61%	2013	IMS Health 2013	
Generic shares in % of total out-patient market				
In volume				
In value				
Generic shares in % of the in-patient market				
In volume				
In value				

2.3.4 Pharmaceutical industry

The number of domestic pharmaceutical manufacturers is 684 in Korea and 67 in the Philippines. Approximately 73% and 90% of domestic pharmaceutical manufacturers are GMP certified in the Philippines and Korea, respectively.

Table 45. Pharmaceutical manufacturers in the Philippines

		Year	Source	Notes
No. of domestic pharmaceutical manufacturers, total	67	2015	Database	Ethical manufacturers as of 9 Sept 2015
No. of active domestic pharmaceutical manufacturers in production	65	2015	Database	-Do-
No. of domestic manufacturers that are GMP certified	49	2015	Database	-Do-

Table 46. Pharmaceutical manufacturers in Korea

		Year	Source	Notes
No. of domestic pharmaceutical manufacturers, total	684	2013	Ref 25	Sum of domestic and international pharmaceutical manufacturers in Korea.
No. of active domestic pharmaceutical manufacturers in production	616	2013	Ref 15	Except the number of herbal medicine manufacturers.
No. of domestic manufacturers that are GMP certified	616+	2013	Ref 25	All pharmaceutical manufacturers which manufacture medicines in Korea should be approved the KGMP by the MFDS. But it is not easy to track the exact number of GMP certified pharmaceutical manufacturers as the number of manufacturers change over time.
Ref 25: Ministry of Food and Drug Safety, Food & Drug Statistical Yearbook 2014 http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=18082&cmd=v Ref 15: Ministry of Health and Welfare, Yearbook of Health and Welfare Statistics. 2014 (assessed on 15 June, 2015)				

The number of wholesalers is 2,393 in Korea and 4,700 in the Philippines. In both countries, private wholesalers have a dominant position in the market. (In Korea, there is no public wholesalers.) The number of community pharmacies is 20,886 and 23,767 in Korea and the Philippines, respectively. Most of them are private in both countries.

Table 47. Pharmaceutical distributors in Korea

		Year	Source	Notes
Wholesalers				
No. of wholesalers, total	2,393	2013	Ref 25	
- thereof of public wholesalers (%)	0	2013	Ref 25	Total percentages should be 100%
- thereof of private wholesalers (%)	100	2013	Ref 25	
Retailers				
No. of community pharmacies, total	20,886	2013	Ref 25	
-thereof of public pharmacies (%)	0.005	2013	Ref 25	There is one public pharmacy in Korea, which deals with orphan drugs only. (Korea Orphan Drug Center)
-thereof of private pharmacies (%)	99.995	2013	Ref 25	
Ref 25: Ministry of Food and Drug Safety, Food & Drug Statistical Yearbook 2014 http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=18082&cmd=v (accessed on 20 June 2015)				

Table 48. Pharmaceutical distributors in the Philippines

		Year	Source	Notes
Wholesalers				
No. of wholesalers, total	4,700	2015	CDRR licensing database	
- thereof of public wholesalers (%)	0.26 %	2015		Total percentages should be 100%
- thereof of private wholesalers (%)	99.74%	2015		
Retailers				
No. of community pharmacies, total	23,767	2015		
-thereof of public pharmacies (%)	0.48 %	2015		Total percentages should be 100%
-thereof of private pharmacies (%)	99.52 %	2015		
Ref 25: Ministry of Food and Drug Safety, Food & Drug Statistical Yearbook 2014 http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=18082&cmd=v (accessed on 20June 2015)				

III. Survey on feedback for long-version pharma country profile

1. Results

A total of 10 countries (Brunei Darussalam, New Zealand, Cambodia, China, Indonesia, Lao PDR, Malaysia, Singapore, Viet Nam, Thailand, and the Philippines) and 18 experts responded to survey during the meeting (The 2nd Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region (in Seoul on 17-18 Sep 2015)). Most of respondents appreciated the importance of sharing information on pharmaceutical policies in each country (on average 4.43/5). However, they evaluated that the level of information availability is not that high (on average 3.35/5). Full survey results in each item is listed in Appendix 2.

1.1 Importance of sharing information

The importance of sharing information on pharmaceutical policies in the Asia-Pacific region was rated in the range of 3.8 to 4.94 with little deviation. Pharmaceutical experts in the Asia-Pacific countries agreed that sharing information on pharmaceutical policies and status is highly valuable.

Respondents scored the highest in (1) Pharmaceutical Expenditure, PE per capita, PE as % of THE, (2) Procurement agency (if applicable) and Purchasing policies (tender, price negotiations) in the public sector with identification of the national price setting institutions and mechanisms (if applicable) (on average 4.94/5). Experts also highly agreed on the necessity for sharing information on (3) pricing policies or any regulations (on average 4.94/5) and (4) pricing monitoring (4.89/5).

On the contrary, respondent score the lowest in terms of the necessity of information sharing in the areas of (1) legal provision on patent linkage to market authorization (3.8/5) and (2) pharmaceutical consumption of selected

medicines in DDD (Defined Daily Dose) (3.94/5). Some respondents gave feedback that they are not familiar with the concept of DDD or ATC (Anatomical Therapeutic Chemical) Classification System, which are already utilized in developed countries. Except for two items, respondents rated the importance of sharing information at least 4 or more.

Table 49. Top 5 and bottom 5 items for importance of sharing information

Top 5 items	Avg. score	Bottom 5 items	Avg. score
Procurement agency (if applicable) and Purchasing policies (tender, price negotiations) in public sector with identification of the national price setting institutions and mechanisms (if applicable)	4.94	Legal provision on patent linkage to market authorization	3.80
Table on Pharmaceutical Expenditure, PE per capita, PE as % of THE	4.94	Table on pharmaceutical consumption of selected medicines in DDD	3.94
Pricing policies or any regulations (free, statutory, negotiations, rules of rebates /discounts) in tabular format	4.89	Table on % of urban population, poverty headcount ratio, literacy rate	4.06
Price monitoring	4.78	Generic promotion substitution (mandatory or voluntary, allowed, public perception, incentives) INN prescribing (mandatory, evaluation of prescribing habits)	4.06
Table on Total Health Expenditure, THE per capita, THE as % of GDP over several years	4.76	Table on human resources (Number of physicians, pharmacists, traditional doctors, nurses, midwives, number of school of pharmacy, number of pharmacy graduates per year)	4.11

1 = not important, 5 = very important to know

1.2 Information availability

Experts evaluated information availability lower than their perception of the importance of sharing information (min 2.39/5 Max. 4.69/5). Deviation is also found to be bigger in information availability than in the importance of sharing information. Pharmaceutical experts in the Asia-Pacific countries highly appreciated the value of sharing information on pharmaceutical policies and status. However, they evaluated that data to assess and/or compare pharmaceutical policies is not readily available.

Respondents thought that (1) description of pharmaceutical system: legal basis is the most available information (4.69/5), followed by (2) population trends over several years (4.33/5) and (3) GDP, GDP per capita over several years (4.23/5). Information for (2) and (3) are already provided by World Bank, WHO, and OECD, however, score is lower than we expected.

Respondents evaluated that (1) pharmaceutical consumption of selected medicines in DDD is the least available information (2.39/5). Pharmaceutical experts in Asia-Pacific countries evaluated that this item has low priority in terms of both data availability and need for sharing information. They also scored that it is difficult to get data on (2) Out-of-pocket payment on medicines(2.5/5), and (3) generic market share in outpatient and inpatient (2.61/5). Some respondents gave feedback that some items are not relevant in their country context. For example, they do not have enough resource to develop a system to follow-up and gather data. Therefore, they need technical supports from WHO and/or experts from other developed countries.

Table 50. Top 5 and bottom 5 items for information availability

Top 5 items	Avg. score	Bottom 5 items	Avg. score
Description of Pharmaceutical system – legal basis	4.69	Table on pharmaceutical consumption of selected medicines in DDD	2.39
Table on population trends over several years	4.33	Out-of-pocket payment on medicines – fixed co-payments, percentage payments, deductibles in place in tabular format	2.50

Top 5 items	Avg. score	Bottom 5 items	Avg. score
Table on GDP, GDP per capita over several years	4.28	Table on generic market share in outpatient and inpatient	2.61
Table on life expectancy, fertility, mortality, mortality by causes	4.06	Table Structure of pharmaceutical expenditure (PE, prescription medicine, OTC, alternative and herbal medicines)	2.71
Tabular information on respective authorities responsible for medicines regulation (registration, supply chain regulation, vigilance), procurement and distribution pricing control, reimbursement, medicines promotion, as applicable	4.06	Pharmaceutical consumption monitoring	2.72

1= very difficult to collect, 5= always available

1.3 Comparison for importance of information sharing and information availability

Items with high importance for sharing information but with low score in terms of data availability were compared. Respondents answered that information on OOP payment on medicines are of high priority to be shared among Asia-Pacific countries, however, information availability is limited. In addition, pharmaceutical experts agreed that information on monitoring of pharmaceutical consumption, prescription pattern, medicines price should be shared with each other although their access to available data is limited for analysis and comparison.

Table 51. Item comparison with high importance for sharing information and low availability of information

Top 5 items	Importance of sharing information	information availability
Out-of-pocket payment on medicines – fixed co-payments, percentage payments, deductibles in	4.72	2.50

Top 5 items	Importance of sharing information	information availability
place in tabular format		
Pharmaceutical consumption monitoring	4.56	2.72
Prescription pattern monitoring	4.61	2.78
Price monitoring	4.78	3.06
Table Structure of pharmaceutical expenditure (PE, prescription medicine, OTC, alternative and herbal medicines)	4.39	2.71

IV. Discussion and Conclusion

1. Overview on pharmaceutical policies and financing in Asia-Pacific countries

The Asia-Pacific region is very diverse in health care system, financing and expenditure as well as in socioeconomic condition. Australia reported the largest health expenditure per capita ($6,109) while Lao PDR, Cambodia, and Papua New Guinea showed the lowest spending less than $100. The public share of total health expenditure varied from Cambodia, which reported the lowest proportion of total health expenditure (25%) to Brunei with the highest (91.8%). The private share of total health expenditure was the highest in Cambodia (75.3%), followed by Singapore, the Philippines, and Indonesia (62.4%, 62.3% and 60.4%, respectively).

The level of pharmaceutical spending also varied greatly among Asia-Pacific countries. Pharmaceutical expenditure per capita is the largest in Japan and Australia, while it was the lowest in Lao PDR, Cambodia, Indonesia, and the Philippines ($20.4, $34.3, $42.3 and $49.8, respectively). Thailand, Brunei and Japan reported the highest public share of pharmaceutical expenditure (90.4%, 87% and 74.1%, respectively), while the private share of pharmaceutical spendings is high in the Philippines (87.9%) and Indonesia (84.8%).

Compared with the structure of total health expenditure, the private share was higher in the pharmaceutical expenditure. The generic share of pharmaceutical expenditure varied from 26% to 81% among countries.

The results of pilot (long-version) survey for Korea and the Philippines provide in-depth information on the current status of pharmaceutical system and financing in both countries. They are quite different in pharmaceutical pricing, purchasing, procurement and generic policy, et al. While the price of prescription medicines is set through the negotiation between NHIS and pharmaceutical company in Korea, it is set freely in the Philippines although there is a drug price reference index to set a cap on procurement of essential medicines in national hospitals. This price reference is to be implemented

government-wide by 2016 to cover all government agencies and public health facilities in the Philippines.

In Korea, there is no procurement at national or local leve,l and providers purchase medicines directly. However, public hospitals and hospitals with over 300 beds are recommended to purchase medicines through bidding process. In the Philippines, tendering is the default mechanism of procurement of essential medicines in the public sector, especially for multi-source products, but there is free pricing and wide variations of drug prices for the outpatient sector. NHIS operates national positive list system for the general reimbursement scheme, which includes 17,798 medicines in Korea, whereas the Philippine National Formulary lists include 648 drugs according to their international nonproprietary name (INN).

Generic substitution is allowed for both countries. It is not mandatory, and physicians can prescribe by the International Non-proprietary Name (INN)) or brand name in Korea. However, it is mandatory for pharmacists to substitute lower price generic products in the Philippines. It is also mandatory for physicians to prescribe in generics in the public sector. Among Asia-Pacific countries with comparable GDPs, the Philippines has the highest utilization rate of lower-cost generics.

2. Evaluation of the pharma country profile

This study planed to conduct a pilot (long-version) survey for 4 countries including Australia, Japan, Korea, and the Philippines. However, Australia and Japan did not participating in the survey.

On the feedback survey on the pharma country profile template, most of the respondents appreciated the importance of sharing information on pharmaceutical policies with other countries, while they are concerned about limited availability of data and information.

The highest scores in terms of the need for sharing information were reported in pharmaceutical expenditure, procurement and purchasing policies, pricing policies or any regulations. On the contrary, scores were the lowest in

the areas of intellectual property and pharmaceutical consumption of selected medicines in DDD (Defined Daily Dose). Pharmaceutical consumption of selected medicines in DDD has low priority in terms of both data availability and the value of sharing information. They also evaluated that it is difficult to get detailed information on OOP payment on medicines and the market share of generics.

3. Future of Asia-Pacific network on pharmaceutical policy and financing

Asia Pacific countries face common challenges in health system. The portion of out-of-pocket (OOP) payment in total health expenditures is much higher in the Asia Pacific region than in other regions, and particularly, OOP expenditure is the major source of pharmaceutical payment in low- and middle-income Asian countries. Since high spending on medicines causes financial hardship in households and prohibits the appropriate use of medicines (WHO, 2009), many Asia-Pacific countries are attempting various kinds of policies for medicines.

Pharmaceutical pricing and reimbursement mechanism is one of the key mechanisms in enhancing access to and appropriate use of medicines. However, these policies are not well developed in Asian low- and middle-income countries due to political barrier as well as capacity problems (Kwon et al., 2014). The need and demand for evidence-based policy decision are now increasing, and comparison of pharmaceutical system performance across countries is very important to improve policies and systems. This need for collaboration to develop evidence-based policies led to the launching of regional network on access to medicines for UHC in Asia-Pacific countries.

However, the Asia Pacific network for pharmaceutical financing and policies is just the first step toward achieving desirable collaboration and policy learning. It is necessary to build a network capacity for sharing information through regular network meetings, workshops, and other suitable communication forum. The network should develop the methodological

framework for indicators to systematically measure the performance of pharmaceutical systme and compare each country's pharmaceutical policies. The results of our pilot survey using detailed version of pharma template as well as the feedback on the template will help the network further develop and refine the indicators and survey tools for more fruitful collaboration.

Once the methodological framework is established, it is necessary to develop national reporting systems on pharmaceutical pricing and reimbursement information. Based on this reporting, the network will be able to provide scientific advice and technical assistance to member countries on interpreting and understanding the results of survey for improving the performance of pharmaceutical system.

In the face-to-face annual meeting, there will be brief presentations on the recent major developments and changes in pharmaceutical policy in each country. The meeting will also select a few key topics of pharmaceutical policy, which are of common policy interest for participating countries, and have deep discussions. Best practice examples can be presented followed by active discussions on some key issues, such as and essential medicines list, health technology assessment (HTA), pharmaceutical pricing and reimbursement, benefits package decisions for medicines, etc. When the members of the network get back to their own countries, they can provide the experience of successful policies of other countries in the region (success factors, implementation strategy, impacts of the policy, etc.) in order to improve their own pharmaceutical system.

As the official members of the network are officers of government ministry or health insurance agency, communication among members should follow a formal line communication. As a result, it has taken longer time to communicate and get response to the survey. Another challenge is to encourage more (middle- or high-income) countries to participate in the long survey. As it takes time and requires high level of expertise to fill the long survey, government officers need to collaborate with researchers in their countries to complete the survey. In other word, the members of the network (or officers of the government) are expected to play the role of the focal point rather than complete the survey themselves.

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Therapeutic Goods Administration. https://www.tga.gov.au/
Pharmaceutical Benefits Scheme http://www.pbs.gov.au/pbs/home
Department of Health, Pharmaceutical Benefits Advisory Committee http://www.pbs.gov.au/info/industry/listing/participants/pbac

Brunei Darussalam

Ministry of Health, Medicines Control Authority
http://www.moh.gov.bn/Theme/Home.aspx

Cambodia

Ministry of Health http://www.hiscambodia.org/public/homepage_en.php
Department of Drug and Food, Ministry of Health http://www.ddfcambodia.com/

China

National Health and Family Planning Commistion of th PRC http://en.nhfpc.gov.cn/
China Food and Drug Administration http://eng.cfda.gov.cn/WS03/CL0755/

Indonesia

Ministry of Health http://www.depkes.go.id/index.php?lg=LN02
indonesia National Agency for Drug and Food Control
http://www.pom.go.id/index.php/home/en

Japan

Ministry of Health, Labour and Welfare http://www.mhlw.go.jp/english/
Pharmaceuticals and Medical Devices Agency http://www.pmda.go.jp/english/

Lao PDR

National Institute of Public Health, Ministry of Health http://www.nioph.gov.la/
Food and Drug Department, Ministry of Health
http://www.fdd.gov.la/showContent_en.php?contID=37

Malaysia

Ministry of Health Malaysia http://www.moh.gov.my/english.php
National Pharmaceutical Control Bureau http://portal.bpfk.gov.my/
Ministry of Domestic Trade, Cooperatives and consumerism
http://www.kpdnkk.gov.my/kpdnkkv3/index.php?lang=en
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Mongolia

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New Zealand

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Medicines and Medical Devices Safety Authority http://www.medsafe.govt.nz/

Pharmaceutical Management Agency http://www.pharmac.health.nz/

Philippines

Department of Health http://www.doh.gov.ph/

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http://www.hira.or.kr/main.do

Singapore

Ministry of Health https://www.moh.gov.sg/index.html

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Thailand

Ministry of Public Health http://eng.moph.go.th/

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Viet Nam

Ministry of Health http://www.moh.gov.vn/sites/en-us/pages/home.aspx

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Appendices

Appendix 1. Long pharma country profile

WHO Collaborating Centre for Health System and Financing

Pharmaceutical System and Financing Country Profile (DRAFT)

Country 2015

Please do not distribute.

SNU Health
Graduate School of Public Health
Seoul National University

Pharmaceutical System and Financing Country Profile

Template

Update: April 2015

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Acknowledgements

Please add text.

This template was prepared on the basis of the following two main sources.

- Vogler, S., Zimmermann, N., Leopold, C. : PPRI/PHIS Pharma Profile Template (long version) (Accessible at: http://whocc.goeg.at/Literaturliste/Dokumente/MethodologyTemplate/PPRI_PHIS_Pharma_Profile_template_May'13.docx)
- World Health Organization, The Global Fund, Pharmaceutical Sector Country Profile Questionnaire. (Accessible at: http://www.who.int/medicines/areas/coordination/Empty_English_Questionnaire.pdf)

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Part I. Pharmaceutical policy and financing

Part II. General information and health

Part III. Pharmaceutical system

List of abbreviations

Please add abbreviations used in this profile and delete those you did not use.

ATC	Anatomic therapeutic chemical classification
INN	International Non-proprietary Name
GDP	Gross domestic product
HTA	Health technology assessment
HE	Health expenditure
NCU	National currency unit
NHS	National health service
NMEs	New molecular entities
OECD	Organization for Economic Co-operation and Development
OOP	Out-of-pocket payment
OTC	Over-the-counter medicine
PE	Pharmaceutical expenditure
POM	Prescription-only medicine
PPP	Purchasing power parities
SHI	Social health insurance
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
WHO	World Health Organization

Part I. Pharmaceutical policy and financing

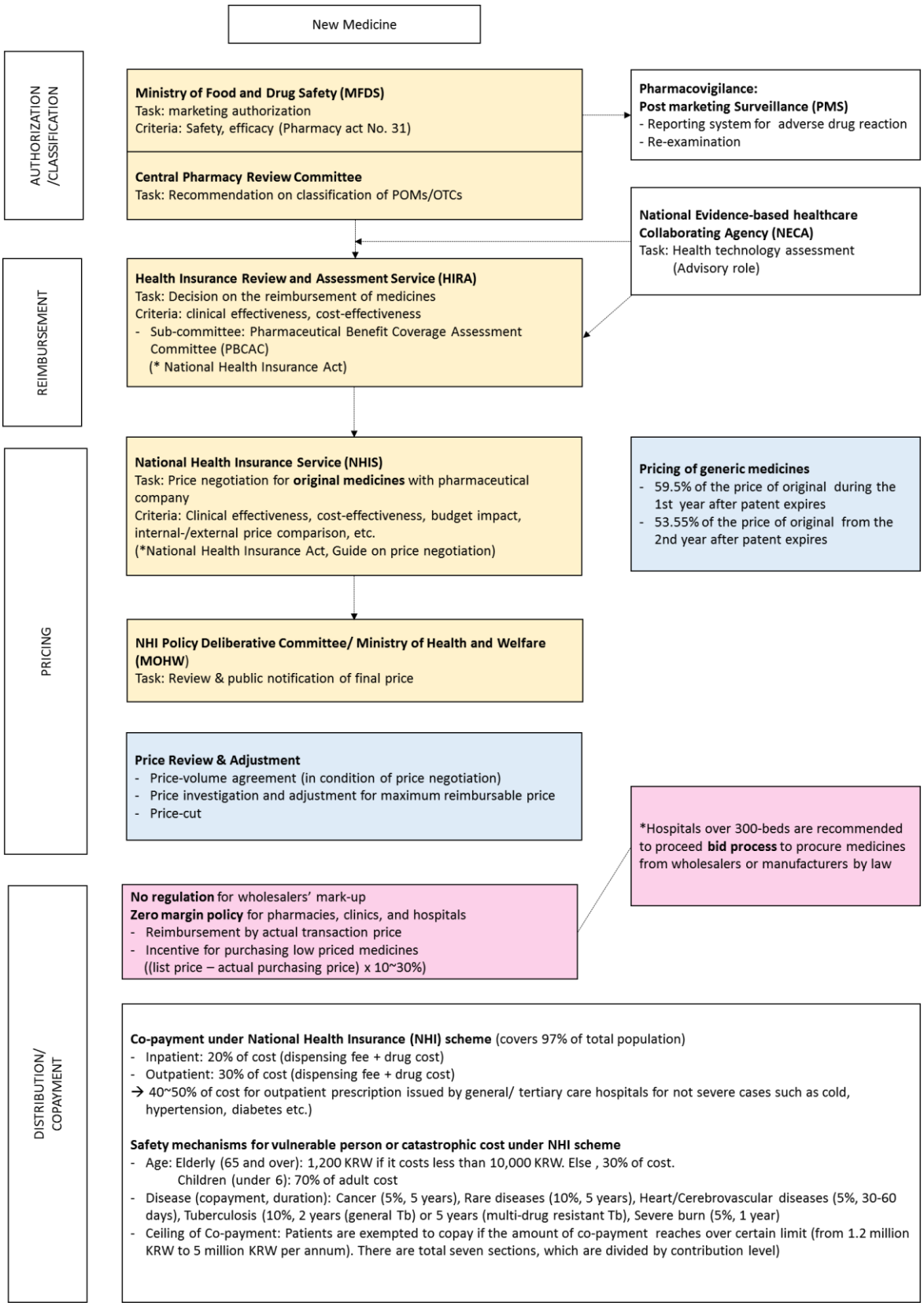
1 Organization of the pharmaceutical system (Overview)

- Please describe key characteristics of your major public financing mechanism for health care (e.g., National Health Service, Social Health Insurance, etc.). If your country has social health insurance, please provide information on the population coverage.

- Please describe the pharmaceutical system in your country as of 2015 and briefly explain the medicines' policy in the prescription-only medicines and the over-the-counter medicines. Please provide a flowchart of the pharmaceutical system following the model provided in Figure 1 *[from PPRI / PHIS Pharma Profile Template]*

- Briefly explain the most important changes in the out-patient and the in-patient sectors as well as the foreseen pharmaceutical reforms in your country. Please describe systemic changes currently implemented and those still under discussion. *[from PPRI / PHIS Pharma Profile Template]*

Figure 1: ***South Korea – Flowchart of the pharmaceutical system (sample for South Korea)***



Source: Adapted from S. Kim (2011) Pharmaceutical system in South Korea in the in-and out-patient sector. PPRI conference.

- Please fill out Table 1 to provide information on relevant authorities and key regulatory actors (including committees, boards, etc.), third party payers as well as market actors and their interest group as of 2015. *[from PPRI / PHIS Pharma Profile Template]*

Table 1: Country – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2015

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest group in English (local name, local abbreviation)
Market authorisation	e.g., Pharmaceutical Affairs Act	e.g., In- and out-patient sector	e.g., Ministry of Food & Drug Safety	e.g., Responsible for marketing authorisation of medicinal products in Korea and reviewing of the safety, and efficacy of pharmaceuticals.	e.g., pharmaceutical companies Interest group: KPMA (Korea Pharmaceutical Manufacturers Association),
Pricing / Purchasing					
Reimbursement					
Promotion					
Distribution					
Vigilance					

Source:

- Please comment on the table. *[from PPRI / PHIS Pharma Profile Template]*

2 Market authorization

2.1 Licensing and inspection

- Please fill out Table 2 to provide information on licensing where pharmaceutical activities are performed *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

Table 2: Country - Legal basis of market authorization

	Legal provision (Yes/No)	Legal basis	Name of authorities (in English)	Activities (ex. inspection as a pre-requisite)
Manufacturers(public/private)				
Importers(public/private)				
Wholesalers and distributors(public/private)				
Pharmacies (public/private)				
Dispensing points of health facilities (public/private)				
Others: specify_____ [1]				

[1] Other places not in the table where pharmaceutical activities are performed.

- Do legal provisions require a marketing authorization (registration) for all pharmaceutical products on the market? *[from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Is an expert committee involved in the marketing authorization process? Please describe the primary criteria and the process of a marketing authorization (registration). [adapted *from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Do the legal provisions require a declaration of potential conflict of interest from the experts involved in the assessment and decision making of registration? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Do the legal provisions allow applicants to appeal against medicines regulatory authority decisions? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Is there a Good Manufacturing Practices (GMP) document or guideline? Who publishes it? Do domestic and international manufacturers have to comply with it? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Is there a Good Distribution Practices (GDP) document or guideline? Who publishes it? Do wholesalers and distributors have to comply with it? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there National Good Pharmacy Practice guidelines? Who publishes it? Do pharmacies have to comply with it? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Please fill out Table 3 to provide information on inspecting practices for places where pharmaceutical activities are performed *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

Table 3: Country - Legal basis related with pharmaceutical inspection practices

	Legal provision (Yes/No)	Legal basis	Name of authorities (In English)	Activities (ex. Frequency)
Manufacturers (public/private)				
Importers (public/private)				
Wholesalers and distributors (public/private)				
Pharmacists (or pharmaceutical personnel) (public/private)				
Dispensing points of health facilities (public/private)				
Others:_____ [1]				

[1] Other places not in the table where pharmaceutical inspection activities are performed

3 Quality assurance

3.1 Quality of medicines

- Is there an officially defined protocol for ensuring the quality of medicines, including testing of medicines to be registered, collection and testing of samples for monitoring, reporting of results, corrective actions taken when poor results are found and preventative measures to be taken to reduce future incidence of poor results? *[adapted from WHO operational package for assessing, monitoring and evaluating country pharmaceutical situations]*

  - Medicines samples tested
    - ✓ For medicines registration (Yes/No)
    - ✓ For post-marketing surveillance (Yes/No)

  - In which of the following laboratories are samples tested?
    - ✓ Government quality control laboratory (Yes/No)
    - ✓ Local academic institutions (Yes/No)
    - ✓ Private laboratory (Yes/No)
    - ✓ Mini laboratories (district, regional) (Yes/No)
    - ✓ Quality control laboratory in another country (Yes/No)

  - Total number of sample(s) tested in 2013: ( )
  - Total number of sample(s) failed to meet quality standards in 2013: ( )
  - How are results reported when poor results are found
  - What kind of corrective actions are taken when poor results are found
  - Please describe legal procedures for the recall and disposal of defective products

- Are there any laws, regulations, programmes or procedures for detecting and combating counterfeit medicines including active regular surveillance, official agreement with police authorities, involvement in national or international networks, etc.? *[from WHO operational package for assessing, monitoring and evaluating country pharmaceutical situations]*

- What sources of information are used to detect and combat counterfeit medicines? *[from WHO operational package for assessing, monitoring and evaluating country pharmaceutical situations]*

  · Reports from national authorities:
  · Reports from specific or ad hoc studies:

- Reports from the pharmaceutical sector:
- Reports from civil society or NGOs:

4 Pricing

4.1 Pricing policies

- Describe the main pricing policies for medicines (free pricing, statutory pricing, price negotiations) in your country – with regard to the different types of medicines (prescription medicines / OTC, hospital medicines, innovative medicines, generics, reimbursable / non-reimbursable medicines, biosimilar medicines). *[from PPRI / PHIS Pharma Profile Template]*

- Please fill out Table 4 and specify for which medicines are pricing policies applicable. Feel free to insert more rows, e.g., on "Price-Volume Agreements" or "Price Notification", if applicable. *[from PPRI / PHIS Pharma Profile Template]*

Table 4: Country – Ways of pricing of medicines at manufacturer level, 2015[1]

Pricing policies		(Non) prescription market		(Non) reimbursement market		Specific groups of medicines		
		POM	OTC	Reimbursable	Non-reimbursable	Generics	Parallel traded	Others, specify: e.g., biosimilars
Free pricing								
Price control	Statutory pricing							
	Price negotiations							
	Tendering							
	Others – specify: (e.g., Price-Volume Agreements)							

POM = prescription-only medicines, OTC = over-the-counter medicines

[1] Please fill with "Yes" or "No", if this policy is applied. Feel free to add further specifications (e.g., POM – yes, but only if reimbursable)

Source:

4.2 Purchasing policies

- Please describe respectively the major purchasing policies (e.g., tendering or negotiations) used in the out-patient and in-patient sector in your country as of 2015. If different purchasing policies are applied in your country (in parallel or in one following the other), please comment on their relevance. Should one purchasing policy follow another (e.g., first central tendering, then direct purchases of hospitals) please describe. *[adapted from PPRI / PHIS Pharma Profile Template]*

- Are there other purchasing policies (besides tendering and negotiations) that play a role in the out-patient and in-patient sector? What are the legal provisions for these? Who is involved and what are the most relevant criteria? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Who is in charge of deciding if and at what price medicines are purchased?

  For
  a) Hospital level
  b) Out-patient sector,

- Are there specific institutions, bodies or persons involved in the process? What is the role of the hospital pharmacists (or pharmaceutical personnel)? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Is the hospital price different from out-patient price? Or is it different across region or between public and private sector? Which price type does the hospital price correspond to (ex-factory, pharmacy purchasing price, pharmacy retail price)? Is there an official price calculation scheme for medicines used in hospitals? *[adapted from PPRI / PHIS Pharma Profile Template]*

4.3 Procurement

- Do (1) hospitals and (2) pharmacies carry out their own procurement or is there joint procurement for a group of facilities? (Please describe for (1) hospitals and (2) pharmacies, respectively) Is there a national / regional procurement agency in your country? *[from PPRI / PHIS Pharma Profile Template]*

- Who is involved in the procurement process? Who has the advisory and the decision making role in the procurement process? What are the most relevant criteria for deciding if a medicines is to be purchased? [from *PPRI / PHIS Pharma Profile Template]*

4.4 Pricing procedure

Basically there are four main pricing procedures:
- External price referencing
- Internal price referencing
- Cost-plus pricing
- (Indirect) profit control
- Others

- Please fill out Table 5 with necessary information (if a pricing procedure applies to in-patient and out-patient sector differently, please describe): *[adapted from PPRI / PHIS Pharma Profile Template]*
    - Which pricing procedures are currently used?
    - Are these enforced by law? Who is involved in the pricing procedure?
    - Have there been major changes in the pricing procedures in the past few years?

Table 5: Country – Pricing procedures, 2015

Pricing procedure	In use: (yes / no)	Price type[1]	Scope[2]
External price referencing			
Internal price referencing			
Cost-plus pricing			
(Indirect) profit control			
Risk/cost sharing			
Price/volume agreements			
Others, specify: _____			

[1] Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

[2] Scope = a pricing procedure does not always refer to all medicines: e.g., a pricing procedure could only refer to reimbursable medicines, whereas for Over-The-Counter medicines there is free pricing.

Source:

- List the criteria which are taken into account in the pricing decision? Are there laws or other regulations for the different pricing procedures? *[from PPRI / PHIS Pharma Profile Template]*

- If possible, please explain pricing procedures in detail e.g.,: *[from PPRI / PHIS Pharma Profile Template]*

    - External price referencing:

        - Which countries are included in the basket for external price referencing? Why were these countries chosen? Are there alternative countries in case there are no data from the selected countries? What happens if there are no data from the selected countries?

        - How are prices set? Please, explain the methodological background on how are prices set (at the average of all prices, the lowest price of the basket). Have there been changes in the methodology?

        - Who provides the country price information? How is the data provided and in what way? In case a manufacturer provides the information, how does the authority check the information?

        - What happens if the price in one of the reference countries changes?

    - Internal price referencing:

        - Are there formal rules (e.g., methodology) or laws / decrees for internal price referencing? If yes, please explain.

        - At which level (ATC 5 or below) are prices compared? Are there therapeutic referencing in your country? Have there been any changes in the methodology recently or in the past few years?

- Cost-plus pricing
    - Are there formal rules (e.g., on methodology) or laws / decrees on cost-plus pricing? If yes, please explain.
    - What evidence / information are required from the industry for the pricing procedure? (e.g., information on production cost, expected sales, price of the medicines in other countries, the therapeutic value, cost effectiveness analysis, any other information)
- (Indirect) profit control
    - Are there formal rules (e.g., on methodology) or laws / decrees on cost-plus pricing? If yes, please explain.
- Others
    - If there are other pricing procedures, please describe.

4.5 Discounts / rebates

Please write about discounts and rebates granted by public payer, medicines purchaser and so on, including the following points (if in-patient and out-patient sector have different characteristics, please describe): *[from PPRI / PHIS Pharma Profile Template]*

- Are all types of discounts / rebates allowed (or only cash discounts or discounts in kind)?

- Are there specific rules (e.g., limitations) regarding commercial discounts / rebates (e.g., maximum limits for specific medicines, for specific actors)?

- For commercial discounts, please give the average for the different segments.

- Are discounts/rebates granted along with managed entry, risk sharing, price-volume agreement, etc.?

- Are there mandatory discounts in your country?
    - If yes, for which medicines (e.g., medicines in the public interest)?
    - Who are obliged to grant the mandatory discounts (e.g., manufacturers, distributors, and other actors)?
    - To whom (e.g., Social Insurance) have mandatory discounts to be granted?
    - What is/are the legal basis for granting mandatory discounts?
    - Please state the amount or percentage of mandatory discounts (for different segments, actors, and medicines) granted?

4.6 Price composition

4.6.1 Remuneration of wholesalers, pharmacists and hospitals

- Describe how wholesalers, pharmacists (or pharmaceutical personnel), and hospitals are remunerated (mark-ups / fee-for service). Are these regulated by law? If mark-ups are applied, are these linear, regressive, or other? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Does the mark-up/mark-up regulation cover all medicines, or only the prescription / reimbursable segment? Is it regulated only for public sector? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Please fill out Table 6 and provide an overview of how wholesalers and pharmacists (or pharmaceutical personnel) are remunerated. [from *PPRI / PHIS Pharma Profile Template]*

Table 6: Country – Regulation of wholesale, pharmacy and hospital mark-ups, 2015

	Wholesale mark-up			Pharmacy mark-up			Hospital mark-up		
	Regulation	**Content**	**Scope***	**Regulation**	**Content**	**Scope***	**Regulation**	**Content**	**Scope***
Ex)South Korea	*No*			*Yes*	*No mark-up*	*Reimbursable medicines*	*Yes*	*No mark-up*	*Reimbursable medicines*

* Regulations concerning mark-ups do not always apply to all medicines, it may only target POMs or reimbursable medicines

Source:

4.6.2 Taxes

- What is the Value added tax (VAT) rate for medicines (if it is different in the in-patient and out-patient sector, please describe respectively)? *[from PPRI / PHIS Pharma Profile Template]*

- Is this the standard VAT rate or does the VAT applied to medicines different from the normal VAT? Please indicate the relevant VAT rates for medicines in 2015 (Standard VAT/VAT on medicines). [from *PPRI / PHIS Pharma Profile Template]*

- Please specify if the VAT refers only to a group of medicines and/or if there are split rates for different medicines (e.g., reimbursable / non-reimbursable). *[from PPRI / PHIS Pharma Profile Template]*

- Please, provide information with regards to changes in VAT rates in the last few years (plus the reason for that) and on possible planned changes. *[from PPRI / PHIS Pharma Profile Template]*

- Are there, as of 2015, <u>further taxes / fees</u> applied on medicines (e.g., a pharmacy fee per medicines dispensed or a general pharmacy tax)? *[from PPRI / PHIS Pharma Profile Template]*

5 Reimbursement

5.1 Reimbursement policies (Overview)

- Is there a national reimbursement medicines list? Or is it defined at state/province level? *[from WHO operational package for assessing, monitoring and evaluating country pharmaceutical situations]*

- Describe the legal framework for the reimbursement policies. Who are the main actors in deciding for the reimbursement of medicines, and what is/are their role? What medicines (scope, e.g., also OTC products) are included in the reimbursement scheme? [from *PPRI / PHIS Pharma Profile Template]*

- Please describe the general reimbursement scheme in your country and in case there are some specific schemes (e.g., for specific patient groups or expensive medicines). Please provide answers to the following points: What is the name of the current scheme? When was it introduced? What is/are the legal framework for this scheme? Who is covered by this scheme (coverage of population)? Who is excluded from this scheme (e.g., asylum seekers)? *[from PPRI / PHIS Pharma Profile Template]*

5.2 Reimbursement procedure

Please describe in this section how medicines are financed in your country as of 2015. Specify if the financing / reimbursement system is applied in the in-patient sector and/or out-patient sector and/or country-wide or for a majority of hospitals (e.g., public hospitals). [from *PPRI / PHIS Pharma Profile Template]*

- How is/are the reimbursement procedure linked to pricing of medicines (e.g., pricing policy is applied to only reimbursable medicines)? *[from PPRI / PHIS Pharma Profile Template]*

- Is the list of drugs funded by public scheme defined in positive list (list of medicines eligible for reimbursement) and/or negative list (medicines excluded)? How is this administered? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Do(es) the list(s) contain information on active ingredients or medicines by trade name? How many active ingredients or medicines are included in the list(s)? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Are the list(s) published? If yes, please indicate the source. How often is (are) the list(s) updated? How often are changes in the list(s) made? *[adapted from PPRI / PHIS Pharma Profile Template]*

- How are these changes communicated to physicians, pharmacists (or pharmaceutical personnel), and patients? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Which evaluations are undertaken? Please describe respectively if there is any difference between in-patient and out-patient sector. *[adapted from PPRI / PHIS Pharma Profile Template]*

- Please explain the role and the composition of the responsible body for reimbursement decisions. Who decides on the inclusion of medicines for reimbursement? Describe the criteria / factors that determine whether or not a pharmaceutical is eligible for reimbursement. *[from PPRI / PHIS Pharma Profile Template]*

- Describe the relevant reimbursement categories and the reimbursement rates in your country. Who is in charge of defining these categories and which laws define and enforce these schemes? When are the regulation implemented? [from *PPRI / PHIS Pharma Profile Template]*

5.3 Reference pricing system

Please describe in this section the reference pricing system in your country. Specify if the system is applied to the in-patient and/or out-patient sector or both.

- Is there a reference pricing system in your country? When was the reference pricing system implemented? *[from PPRI / PHIS Pharma Profile Template]*

- What is the scope of the reference pricing system (covering all products, limited range) in your country? Which products are covered? How many active substances and brands are included? Are parallel traded medicines included in reference groups? *[from PPRI / PHIS Pharma Profile Template]*

- What criteria are used to group medicines in categories (e.g., ATC 5 level, ATC 4 level, indication / disease)? Please explain in detail at what price type of medicines are compared? *[from PPRI / PHIS Pharma Profile Template]*

- How many reference groups are included? How often is/are the reference price groups reviewed/updated and evaluated? *[from PPRI / PHIS Pharma Profile Template]*

- What happens if there are no matching medicines to compare what is/are available in your country? *[from PPRI / PHIS Pharma Profile Template]*

- How is the reference price calculated? *[from PPRI / PHIS Pharma Profile Template]*
    - Lowest priced medicines in a group, the average, the average plus 10%, or as something else?
    - How is the “dose-equivalency” determined?

- Does your country have a reference pricing system where the reimbursement rate for all interchangeable substances (e.g., statins) is calculated from the lowest price or a computed price (like e.g., the average of the two cheapest medicines, etc.)? *[from PPRI / PHIS Pharma Profile Template]*

- What happens if a physician prescribes medicines above the reference price? Does the patient have to pay the difference between the actual price and the reference price? *[from PPRI / PHIS Pharma Profile Template]*

- Have there been any major changes in the reference pricing system in your country recently? *[from PPRI / PHIS Pharma Profile Template]*

5.4 Risk-sharing schemes / Managed entry agreements

Please elaborate on the developments and trends regarding risk-sharing schemes / managed entry agreements in your country as of 2015:

- Is such a system in place in your country? If yes, please explain (type of scheme). When was it introduced? What is/are the legal basis? [from *PPRI / PHIS Pharma Profile Template]*

- Which actors / active ingredients / products /sectors (in-patient, out-patient, or both?) are covered? Are results / evaluations available? [from *PPRI / PHIS Pharma Profile Template]*

5.5 Decision making tools

Please describe briefly the tools that are used in the decision-making process regarding medicines in your country as of 2015. Please consider the following points:

- What tool(s) is/are used in the decision making process regarding medicines pricing and reimbursement? *[from PPRI / PHIS Pharma Profile Template]*

- Describe use of pharmaco-economic analysis (e.g., is this mandatory for the process of market authorization, pricing, reimbursement, or others? Who performs them?). Please state the legal / national source for pharmaco-economic analyses. *[from PPRI / PHIS Pharma Profile Template]*

- Are pharmaco-economic evaluations necessary for types of medicines (all, POM, OTC)? Are there any differences? *[from PPRI / PHIS Pharma Profile Template]*

- Since when are pharmaco-economic analyses applied? Who performs them? *[from PPRI / PHIS Pharma Profile Template]*

- Is the provision necessary for obtaining market authorisation/ pricing decision to obtain reimbursement? *[from PPRI / PHIS Pharma Profile Template]*

- Evaluation of pharmaco-economic guidelines: *[from PPRI / PHIS Pharma Profile Template]*
    - Please provide an overview of the content of the pharmaco-economic guidelines used in your country.
    - How often are the pharmaco-economic guidelines updated / revised?
    - Who is in charge of evaluating the pharmaco-economic guidelines?

- Is Heath Technology Assessment (HTA) performed in your country? Are they used as basis for decision making? *[from PPRI / PHIS Pharma Profile Template]*

- Are external audit reports available? *[from PPRI / PHIS Pharma Profile Template]*

5.6 Out-of-pocket payments on medicines

- Please describe the situation on private pharmaceutical expenses. What type of out-of-pocket payments (fixed co-payments, percentage payments, deductibles, etc.) is/are applicable in your country? Explain which mechanisms and exemptions are in place for the vulnerable groups. *[from PPRI / PHIS Pharma Profile Template]*

- If applicable, please add a table showing the system for out-of-pocket payment in your country as shown in Table 7. Please describe respectively if there are any difference between in-patient and out-patient sector. *[from PPRI / PHIS Pharma Profile Template]*

Table 7: Country – Out-of-pocket payments for medicines, 2015

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments		
Percentage payments		
Deductibles		
Reference pricing system		

Source:

5.7 Reimbursement policies in hospitals

Please describe if financing/reimbursement in the in-patient sector is different from the out-patient sector

- What legal provision(s) (e.g., Social Insurance Law) is/are relevant for reimbursement in the hospital sector? *[from PPRI / PHIS Pharma Profile Template]*

- Who is the main "payer" of medicines in hospitals (e.g., NHS / SHI, state, owner of hospital, community / region)? Is funding for medicines covered by hospital budgets? Which budget(s) cover reimbursement for medicines in in-patient sector? *[from PPRI / PHIS Pharma Profile Template]*

- At what level are medicines covered by hospital budget(s) for in-patient care (full / partial reimbursement)? *[from PPRI / PHIS Pharma Profile Template]*

- Do patients have to co-pay for medicines received during the treatment in hospitals if medicines are partly reimbursed? *[from PPRI / PHIS Pharma Profile Template]*

- Is the criteria for funding medicines in the hospital sector different from other sectors such as clinic and pharmacies? *[from PPRI / PHIS Pharma Profile Template]*

5.7.1 Hospital pharmaceutical formularies

Please describe if there are hospital pharmaceutical formularies in your country as of 2015. In describing the system, please consider the following points:

- Is there a separate hospital pharmaceutical formularies for each hospital? Or are they different by state/province level *[adapted from PPRI / PHIS Pharma Profile Template]*

- Do hospitals (which? – all public hospitals? hospitals of the same owner?) have joint hospital pharmaceutical formularies? *[from PPRI / PHIS Pharma Profile Template]*

- Are there national hospital and/or regional hospital pharmaceutical formularies, accompanied by individual hospital formularies? *[from PPRI / PHIS Pharma Profile Template]*

5.7.2 Pharmaceutical and therapeutic committees

- What is the role of (1) the hospital pharmacists (or pharmaceutical personnel) and (2) the pharmaceutical and therapeutic committees – advisory or decision making for purchase of medicines and/or inclusion of medicines on the formulary? Please describe for (1) the hospital pharmacists (or pharmaceutical personnel) and (2) the pharmaceutical and therapeutic committees, respectively *[from PPRI / PHIS Pharma Profile Template]*

6 Rational use of medicines

6.1 General information

- Are there legal provisions governing the licensing and prescribing practices of prescribers? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there legal provisions governing the dispensing practices of pharmaceutical personnel? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there National Standard Treatment Guidelines (STGs) for most common illnesses, which are produced/endorsed by the Ministry of health? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there public or independently funded national medicines information centre, which provides information on medicines to prescribers, dispensers, and consumers? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

6.2 Monitoring and evaluation

- Briefly describe the methods used to evaluate the pharmaceutical prices, expenditure, prescriptions and consumption in the out-patient and in-patient sectors. If applicable, were these tools implemented? Who is in charge of the monitoring process and at what frequency? Are there any written evaluation(s) available? *[from PPRI / PHIS Pharma Profile Template]*

6.2.1 Price monitoring

- Does the government run an active national medicines price monitoring system for retail prices? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there regulations/mandates that requires publication of retail medicines price information? If yes, please explain how the information is made publicly available. *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

6.2.2 Prescription monitoring

Please describe the developments and trends related to prescription monitoring in your country as of 2015:

- Are there prescription guidelines to encourage rational use of medicines in your country? For what kind of diseases are guidelines implemented for? When was this measure implemented? [adapted *from PPRI / PHIS Pharma Profile Template]*

- Which authority / institution is in charge of the implementation? (e.g., government, universities, third party payers, research institutions, private industry / professional association research institutions? Are many of these produce annual reports? Please provide the corresponding websites). [adapted *from PPRI / PHIS Pharma Profile Template]*

- How often are these monitored and measured? Are the results published? Please provide the link. *[from PPRI / PHIS Pharma Profile Template]*

- Are there any specific indicators used? Please provide details and examples. *[from PPRI / PHIS Pharma Profile Template]*

- Has there been any written evaluation of the policies? If yes, are the reports publicly available? If so, please provide the link to the publication and information of the institution who made the publication. *[from PPRI / PHIS Pharma Profile Template]*

6.2.3 Pharmaceutical consumption monitoring

Please describe the developments and trends regarding the monitoring of pharmaceutical consumption in your country as of 2015:

- Is pharmaceutical consumption monitored in your country (e.g., per region, per patient, per diagnosis)? When was this measure implemented? *[from PPRI / PHIS Pharma Profile Template]*

- Which authority / institution is in charge of monitoring pharmaceutical consumption? (e.g., government, universities, third party payers, research institutions, private industry / professional association research institutions? Many of these often produce annual reports, please provide the corresponding websites). *[from PPRI / PHIS Pharma Profile Template]*

- How often are these monitored and measured? Are the results published? Please provide the link. *[from PPRI / PHIS Pharma Profile Template]*

- What are the specific indicators used? Please, comment and provide examples. *[from PPRI / PHIS Pharma Profile Template]*

- Has there been any written evaluations of the policies? If yes, are the reports publicly available? If so, please provide the link to the publication and information of the institution who made the publication. *[from PPRI / PHIS Pharma Profile Template]*

- Are there computerized tracking systems in place for prescriptions? *[adapted from PPRI / PHIS Pharma Profile Template]*

- Is adherence to treatments monitored by looking at the share of medicines dispensed in actual? Is there any system that reviews patients' prescription and medication data before, during and after dispensing to ensure appropriate and effective use of medicines? *[adapted from PPRI / PHIS Pharma Profile Template]*

6.3 Generic Promotion

6.3.1 Generic substitution

Please elaborate on the developments and trends regarding generic substitution in your country as of 2015:

- Is generic substitution allowed in your country? Since when is generic substitution allowed in your country? *[from PPRI / PHIS Pharma Profile Template]*

- Is generic substitution mandatory or voluntary? In case it is mandatory, please state the legal regulations for generic substitution. *[from PPRI / PHIS Pharma Profile Template]*

- How is the public perception about generics in your country? *[from PPRI / PHIS Pharma Profile Template]*

- Are physicians allowed to exclude generic substitution? If yes, under what situation? *[from PPRI / PHIS Pharma Profile Template]*

- Are pharmacists (or pharmaceutical personnel) allowed to substitute branded medicines (e.g., the originator) with a generic? Please explain situations where pharmacists (or pharmaceutical personnel) substitute (e.g., it is mandatory or only allowed when the physicians has written the prescription with its International Non-proprietary Name (INN)). *[from PPRI / PHIS Pharma Profile Template]*

- Are there incentives for generic substitution? If yes, please explain what incentives are in place (e.g., financial incentives).

- In case of non-adherence, are there sanctions? Are pharmacists (or pharmaceutical personnel) allowed to substitute therapeutically (i.e. dispense a pharmaceutical with equal therapeutic benefits (~ analogous substitution)? Is this type of substitution obligatory? *[from PPRI / PHIS Pharma Profile Template]*

- Are pharmacists (or pharmaceutical personnel) allowed to substitute parallel imported medicines? Is this type of substitution obligatory? *[from PPRI / PHIS Pharma Profile Template]*

6.3.2 INN prescribing

Please elaborate on the developments and trends regarding INN prescribing in your country as of 2015:

- Are physicians allowed to prescribe generics? Do physicians receive an evaluation of their prescribing habits? Is it mandatory? (i.e. Do physicians have to prescribe by the International Non-proprietary Name (INN))? What happens if a physician opposes to this? *[from PPRI / PHIS Pharma Profile Template]*

6.3.3 Other generic promotion

Please elaborate on the developments and trends regarding other generic promotion policies in your country as of 2015:

- Is the use of generic medicines promoted (e.g., among patients, physicians, pharmacists (or pharmaceutical personnel))? If yes, how and what measures are implemented (e.g., information campaigns). *[from PPRI / PHIS Pharma Profile Template]*

- Are there special activities promoting the use of generics such as lower prescription fees for generics or fast track pricing and reimbursement decision or faster launch? *[from PPRI / PHIS Pharma Profile Template]*

- What is the reason for promoting generic medicines? (Reasons for this could be to ensure access of patients to a greater variety of medicines, to enhance local generic manufacturers or for cost-containment reasons). *[from PPRI / PHIS Pharma Profile Template]*

6.4 Medicines advertising and promotion

- Are there legal provisions controlling the promotion and/or advertising of prescription medicines? Who is responsible for regulating promotion and/or advertising of medicines? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there legal provisions prohibiting direct advertising of prescription medicines to the public? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there legal provisions requiring pre-approval of medicines advertising and promotional materials? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are there guidelines/regulations on advertising and promotion of non-prescription medicines? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

6.5 Education and training

6.5.1 Continuing education

- Is mandatory continuing education, which includes pharmaceutical issues, required for physicians, nurses, or paramedical staff? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

6.5.2 Physicians

- Does core training of physicians include a component on the national essential medicines list? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of physicians include a component on the use of standard treatment guidelines? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of physicians include a component on the pharmacovigilance? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of physicians include a component on the problem-based pharmacotherapy? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

6.5.3 Pharmaceutical personnel

- Does core training of pharmaceutical personnel include details of the national essential medicines list? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of pharmaceutical personnel include details of the use of standard treatment guidelines? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of pharmaceutical personnel include details of the pharmacovigilance? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of pharmaceutical personnel include details of the drug information? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of pharmaceutical personnel include details of the clinical pharmacology? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Does core training of pharmaceutical personnel include details of the medicines supply management? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Is mandatory continuing education, which includes rational use of medicines, required for pharmaceutical personnel? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

6.6 Pharmacovigilance

- Are adverse drug reactions (ADRs) monitored? *[from WHO operational package for assessing, monitoring and evaluating country pharmaceutical situations]*

- If yes, at which of these health system levels are adverse drug reactions (ADRs) monitored: *[from WHO operational package for assessing, monitoring and evaluating country pharmaceutical situations]*

  - Local level:
  - Regional level:
  - Central level:

7 Intellectual property laws and medicines

- Is your country a member of the World Trade Organization (WTO)? *[from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

    - If yes, do legal provisions about patent for pharmaceuticals exist?

- Please provide the name and address of the institution responsible for managing and enforcing intellectual property rights. *[from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

    - Please provide URL if it exists.

- National legislation has been modified to implement the TRIPS Agreement? *[adapted from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

    - If yes, are current laws contain TRIPS flexibilities and safeguards?

        - ✓ If yes, is a compulsory licensing provisions that can be applied for reasons of public health present in the national law? Please describe under which conditions it is available and the cases granted.

        - ✓ If yes, is bolar exception present in the national law?

- Is your country eligible for the transitional period to 216 (the exemption on pharmaceutical patent protection for least developed country as agreed in the Doha Declaration on TRIPS and Public Health)? *[from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Are parallel importing provisions present in the national law? [from *WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Do legal provisions about data exclusivity exist for pharmaceuticals? *[from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Do legal provisions for patent extension exist for pharmaceuticals? *[from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

- Do legal provisions for linkage between patent status and marketing authorization exist? *[from WHO/Global Fund Pharmaceutical Sector Country Profile Questionnaire]*

Part II. General information and health

Part II gives a brief introduction of the demographic and socio-economic situation of the country as well as overall health care system.

1 Population structure

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters).

1.1 Population

	2000	2005	2009	2010	2011	2012	2013
Total population (In thousands)							
Population aged 0-14 (% of total)							
Population aged 15-64 (% of total)							
Population aged ≥ 65 (% of total)							
Ref 1: World Bank data: http://data.worldbank.org/indicator/SP.POP.TOTL Ref 2: Ministry of Security and Public Administration http://rcps.egov.go.kr:8081/jsp/stat/ppl_stat_jf.jsp Ref 3: World Bank data http://data.worldbank.org/indicator/SP.POP.0014.TO.ZS?page=2 Ref 4: World Bank data http://data.worldbank.org/indicator/SP.POP.1564.TO.ZS?page=2 Ref 5: World Bank data http://data.worldbank.org/indicator/SP.POP.65UP.TO.ZS All data was accessed on 11 June 2015							

2 Socioeconomic statistics

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

2.1 Economy

In NCU = _____[1]	2000	2005	2009	2010	2011	2012	2013
GDP (In thousands)							
GDP per capita							
Exchange rate (NCU per USD)							
Ref 6: World Bank data: http://data.worldbank.org/indicator/NY.GDP.MKTP.CD/countries Ref 7: World Bank data http://data.worldbank.org/indicator/NY.GDP.PCAP.CD?page=1 All data was accessed on 11 June 2015.							

[1] Please indicate in which currency the data is provided. (e.g., U.S. Dollar (USD))

NCU = national currency unit, GDP = gross domestic product

2.2 General

		Year	Source	Notes
Urban population (% of total population)			Ref 9	
Poverty headcount ratio at $1.25 a day (PPP) (% of population)			Ref 10	
Literacy rate, adult total (% of people ages 15 and above)			Ref 11	
Ref 9: World Bank data http://data.worldbank.org/indicator/SP.URB.TOTL.IN.ZS Ref 10: World Bank data http://data.worldbank.org/indicator/SI.POV.DDAY Ref 11: Central Intelligence Agency https://www.cia.gov/library/publications/the-world-factbook/fields/2103.html All data was accessed on 11 June 2015				

3 Health

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

		Year	Source	Notes
Life expectancy				
Life expectancy at birth, total (Years)			Ref 10	
- Male (Years)			Ref 11	
- Female (Years)			Ref 12	
Life expectancy at age 60, total (Years)			Ref 13	
- Male (Years)			Ref 13	
- Female (Years)			Ref 13	
Fertility				
Fertility rate, total (births per woman)			Ref 13	
Mortality				
Mortality rate, infant (per 1,000 live births)			Ref 13	
Mortality rate, under-5 (per 1,000 live births)			Ref 13	
Mortality by causes				
Age-standardized mortality rates by causes: Communicable (per 100,000 population)			Ref 13	
Age-standardized mortality rates by causes: Non-communicable (per 100,000 population)			Ref 13	
Age-standardized mortality rates by causes: Injuries (per 100,000 population)			Ref 13	

Ref 10: World Bank http://data.worldbank.org/indicator/SP.DYN.LE00.IN
Ref 11: World Bank data http://data.worldbank.org/indicator/SP.DYN.LE00.MA.IN
Ref 12: World Bank data http://data.worldbank.org/indicator/SP.DYN.LE00.FE.IN
Ref 13: WHO World Health Statistics. 2015.
All data was accessed on 5 June 2015.

4 Health care delivery

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

4.1 Health care facilities and utilization

		Year	Source	Notes
Health care facilities				
Hospitals (per 100,000 population)			Ref 13	
Hospital beds (per 1,000 population)			Ref 14	
Health care utilization				
No. of physician consultations per capita			Ref 14	
Ref 13: WHO World Health Statistics 2015 Ref 14: Health at a Glance Asia/Pacific 2014				

4.2 Human resource

		Year	Source	Notes
No. of physicians, total			Ref 15	
No. of pharmacists, total[1]			Ref 15	
No. of traditional doctors, total			Ref 15	
No. of nursing and midwifery personnel, total			Ref 15	
No. of schools of pharmacy, total			Ref 16	
No. of graduates of schools of pharmacy per year			Ref 17	
Ref 15: Ministry of Health and Welfare, Yearbook of Health and Welfare Statistics. 2014 http://stat.mw.go.kr/front/include/download.jsp?bbsSeq=1&nttSeq=21531&atchSeq=4003 Ref 16: Pharmacy Education Eligibility Test http://www.kpeet.or.kr/pds/college_info.html Ref 17: National Health Personnel Licensing Examination Board. http://www.kuksiwon.or.kr/Publicity/ExamStatistic.aspx?SiteGnb=5&SiteLnb=2 All data was accessed on 8 June 2015				

[1] If statistics are not available, please provide aggregated value (i.e. pharmaceutical personnel) along with the details in the notes section.

5 Health care financing and expenditure

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

5.1 Total health expenditure

	2000	2005	2009	2010	2011	2012
Total health expenditure (In NCU = _____[1])						
Total health expenditure per capita (In NCU = _____[1])						
Total health expenditure (% of GDP)						
Ref 18: Statistics Korea. http://www.index.go.kr/potal/stts/idxMain/selectPoSttsIdxSearch.do?idx_cd=1431&clas_div=&idx_sys_cd=694&idx_clas_cd=1 Ref 19: World Bank data http://data.worldbank.org/indicator/SH.XPD.PCAP Ref 20: World Bank data http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS All data was accessed on 8 June 2015						

[1] Please indicate in which currency the data is provided. (e.g., U.S. Dollar (USD))

NCU = national currency unit, GDP = gross domestic product

5.2 Structure of health expenditure

		Year	Source	Notes
Total health expenditure (THE)				
- Public share of THE (%)			Ref 13	*Total percentages should be 100%*
- Private share of THE (%)			Ref 13	
General government expenditure on health as % of total government expenditure			Ref 13	
Composition of total health expenditure				
General governmental expenditure (%)			Ref 13	*Total percentages should be 100%*
Social health insurance (Social security) (%)			Ref 13	
Private prepaid plans (%)			Ref 13	
Out-of-pocket (%)			Ref 13	
Others (%): specify (e.g., international aids) _____			Ref 13	
Structure of out-of-pocket payment				
In-patient expenses (%)			Ref 17	*Total percentages should be 100%*
Out-patient expenses (%)			Ref 17	
Long-term care (%)			Ref 17	
Pharmaceuticals and medical goods (%)			Ref 17	
Collective services (%)			Ref 17	

Ref 13: WHO World Health Statistics 2015
Ref 15: Ministry of Health and Welfare, Yearbook of Health and Welfare Statistics. 2014
http://stat.mw.go.kr/front/include/download.jsp?bbsSeq=1&nttSeq=21531&atchSeq=4003
Ref 16: OECD Stat Extracts http://stats.oecd.org/
Ref 17: Korean National Health Accounts and Total Health Expenditure in 2012
http://stat.mw.go.kr/front/include/download.jsp?bbsSeq=11&nttSeq=21379&atchSeq=3955

[1] If statistics are not available, please provide the total value (in-patients + out-patients or thereof public + thereof private)

[2] Please indicate in which currency the data is provided. (e.g., U.S. Dollar (USD))

NCU = national currency unit, OOP = Out-of-pocket

Part III. Pharmaceutical system

Part III gives a brief introduction to the pharmaceutical system of the country including expenditure, access to medicines, prescription, and consumption as well as pharmaceutical industries.

1 Pharmaceutical financing and expenditure

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

1.1 Total pharmaceutical expenditure

	2000	2005	2009	2010	2011	2012
Total pharmaceutical expenditure (In NCU =_____[1])						
Total pharmaceutical expenditure per capita* (In NCU =_____[1])						
Total pharmaceutical expenditure (% of GDP)						
Total pharmaceutical expenditure (% of Total health expenditure)						

Ref 18: OECD Health Data: Health expenditure and financing: OECD Health Statistics (database). http://www.oecd-ilibrary.org/docserver/download/190800231e1t007.pdf?expires=1434443763&id=id&accname=guest&checksum=68680F92199BE7CBE63285BB92F2A883
Ref 19: OECD Health at a Glance 2013 http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf
Ref 20: OECD data https://data.oecd.org/healthres/pharmaceutical-spending.htm
Ref 21: OECD iLibrary http://www.oecd-ilibrary.org/social-issues-migration-health/pharmaceutical-expenditure_pharmexp-table-en
Ref 22: OECD iLibrary http://www.oecd-ilibrary.org/docserver/download/190800221e1t007.pdf?expires=1434443757&id=id&accname=guest&checksum=F44C2154505AA10CA411DCF0866D127F
All data was accessed on 12 June 2015

[1] Please indicate in which currency the data is provided. (e.g., U.S. Dollar (USD))

NCU = national currency unit, GDP = gross domestic product

1.2 Structure of pharmaceutical expenditure

		Year	Source	Notes
Total pharmaceutical expenditure (TPE)				
- Public share of TPE (%)			Ref 23	*Total percentages should be 100%*
- Private share of TPE (%)			Ref 23	
Prescription-only medicines				
Shares of prescription-only medicines in total market (%)			Ref 24	
Over-the-counter medicines				
Shares of over-the-counter medicines in total market (%)			Ref 24	
Over-the-counter medicines (expenditure per capita) (In NCU = _____[2])			Ref 24	
Alternative medicines & Herbal medicines				
Alternative medicines & Herbal medicines (expenditure per capita) (In NCU = _____[2])			Ref 25	

Ref 23: OECD iLibrary http://www.oecd-ilibrary.org/public-share-of-pharmaceutical-expenditure-2010_5jxsslws7fzt.xls?contentType=%2fns%2fGraph%2c%2fns%2fTable%2c%2fns%2fStatisticalPublication&itemId=%2fcontent%2fgraph%2fhealth_glance_ap-2014-graph104-en&mimeType=application%2fvnd.ms-excel&containerItemId=%2fcontent%2fbook%2fhealth_glance_ap-2014-en&accessItemIds=
Ref 24: OECD Health at a glance 2013 http://dx.doi.org/10.1787/888932918966
All data was accessed on 12 June 2015

[1] If statistics are not available, please provide the total value (in-patients + out-patients or thereof public + thereof private).

[2] Please indicate in which currency the data is provided. (e.g., U.S. Dollar (USD))

NCU = national currency unit, OOP = out-of-pocket, PE = pharmaceutical expenditure

2 Availability and access

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

2.1 Market entry

		Year	Source	Notes
Medicines[1]				
No. of authorized (or licensed) medicines available in the market, total[1]			Ref 25	
Prescription-only medicines[1]				
No. of authorized (or licensed) prescription-only medicines available in the market[1]			Ref 25	
Over-the-counter medicines[2]				
No. of authorized (or licensed) over-the-counter medicines available in the market[1]			Ref 25	
New molecular entities				
No. of new molecular entities (NMEs) launched per year			Ref 26	
Ref 25: Ministry of Food and Drug Safety, Food & Drug Statistical Yearbook 2014 http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=18082&cmd=v Ref 26: Ministry of Drug and Food Safety. National institute of food and drug safety evaluation. Pharmaceutical approval report. 2015. http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=19225&cmd=v All data was accessed on 1 July 2015				

[1] Count total number of unique dosage forms and strengths. Tablets, capsules, injections, elixirs and suppositories should be counted in different strengths. For example, if Paracetamol (Brand X) 250 mg and 500mg have been approved to be marketed, they count as two medicinal products because they have two unique strengths. Paracetamol (Brand Y) 250 mg and 500mg are another two unique products [From WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situation http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/]

[2] If statistics are available, please provide counts of prescription-only medicines and over-the-counter medicines separately.

2.2 Essential medicines

		Year	Source	Notes
Essential Medicines				
National Essential Medicines List (EML) exists? (yes/no)			Ref 22	
No. of Essential Medicines, total			Ref 22	
Availability of essential medicines				
Median availability of selected generic medicines, public (%)			Ref 23	
Median availability of selected generic medicines, private (%)			Ref 23	
Price of essential medicines				
Median consumer price ratio of selected generic medicines, public			Ref 24	
Median consumer price ratio of selected generic medicines, private			Ref 24	

Ref 22: Ministry of Health and Welfare, Yearbook of Health and Welfare Statistics. 2013
http://stat.mw.go.kr/front/include/download.jsp?bbsSeq=1&nttSeq=21132&atchSeq=3888
Ref 23: WHO Global Health Observatory Data Repository, http://apps.who.int/gho/data/node.main.488?lang=en
Ref 24: WHO Global Health Observatory Data Repository, http://apps.who.int/gho/data/node.main.518

3 Pharmaceutical prescription and consumption

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

3.1 Separation of prescribing and dispensing

	Yes/No	Year	Source	Notes
Separation policy				
Separation of prescribing (e.g., physicians) and dispensing (e.g., pharmacists[1]) exists?			Ref 25	
If yes, is it mandatory or voluntary?			Ref 25	
Who is allowed to prescribe medicines?				
Physicians			Ref 25	
Nurses			Ref 25	
Pharmacists[1]			Ref 25	
Others – specify: (e.g., Community health workers)			Ref 25	
Who is allowed to dispense medicines?				
Physicians			Ref 25	
Nurses			Ref 25	
Pharmacists[1]			Ref 25	
Others – specify: (e.g., Community health workers)			Ref 25	
Ref Pharmaceutical affairs act. SECTION 2 Preparation of Drugs Article 23 (Preparation of Drugs (May 2015)				

[1] If statistics are not available, please provide the aggregated value (i.e. pharmaceutical personnel) along with the details in the notes section.

3.2 Pharmaceutical consumption

		Year	Source	Notes
Consumption(In DDD[1, 2])				
Hypertension drugs			Ref 19	
Anticholesterols			Ref 19	
Antidiabetics			Ref 19	
Antidepressants			Ref 19	
Ref 19: OECD Health at a Glance 2013 http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf				

[1] If the unit of DDD is not available, provide another value (i.e. in packs) along with the comments unit used in notes.

[2] Please indicate on the note whether you only included medicines which WHO suggested in the guideline for DDD assignment (Available at: http://www.whocc.no/atc_ddd_index/) or not (e.g., you might include medicines beyond this guideline and applied additional DDD).

DDD = defined daily doses, OTC = over-the-counter medicines

3.3 Generic market share *[from PPRI / PHIS Pharma Profile Template]*

		Year	Source	Notes
Generic shares in % of total market				
In volume[1]			Ref 40	
In value[2]			Ref 40	
Generic shares in % of total out-patient market				
In volume[1]			Ref 39	
In value[2]			Ref 39	
Generic shares in % of the in-patient market				
In volume[1]			Ref 39	
In value[2]			Ref 39	
Ref 40: IMS Health. Generic Medicines http://www.imshealth.com/imshealth/Global/Content/Document/Market_Measurement_TL/Generic_Medicines_GA.pdf (accessed on 10 July 2014) Ref 39: Korea Institute for Health and Social Affairs, Statistics for pharmaceutical consumption and sales – in-depth analysis 2013 http://stat.mw.go.kr/front/include/download.jsp?bbsSeq=11&nttSeq=21194&atchSeq=3855 (accessed on 14 July 2014)				

[1] Expressed in number of prescriptions (if you have another measure for volume e.g., medicines/packs dispensed or sold please specify)

[2] Expressed in expenditure (if you have another measure for value e.g., sales, please specify)

4 Pharmaceutical industry

Please fill out the table and provide the source of information. Some examples of references are provided (in grey letters). If necessary, provide comments in the notes section.

4.1 Pharmaceutical manufacturers

		Year	Source	Notes
No. of domestic pharmaceutical manufacturers, total[1]			Ref 25	
No. of active domestic pharmaceutical manufacturers in production[1]			Ref 15	
No. of domestic manufacturers that are GMP certified			Ref	
Ref 25: Ministry of Food and Drug Safety, Food & Drug Statistical Yearbook 2014 http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=18082&cmd=v Ref 15: Ministry of Health and Welfare, Yearbook of Health and Welfare Statistics. 2014 http://stat.mw.go.kr/front/include/download.jsp?bbsSeq=1&nttSeq=21531&atchSeq=4003 (assessed on 15 June, 2015)				

[1] If statistics are available, you can provide information separately for registered and active (in production) manufacturers.

GMP = good manufacturing practice

4.2 Pharmaceutical distributors

		Year	Source	Notes
Wholesalers				
No. of wholesalers, total			Ref 25	
- thereof of public wholesalers (%)			Ref 25	*Total percentages should be 100%*
- thereof of private wholesalers (%)			Ref 25	
Retailers				
No. of community pharmacies, total			Ref 25	
-thereof of public pharmacies (%)			Ref 25	*Total percentages should be 100%*
-thereof of private pharmacies (%)			Ref 25	
Ref 25: Ministry of Food and Drug Safety, Food & Drug Statistical Yearbook 2014 http://www.mfds.go.kr/index.do?mid=690&pageNo=1&seq=18082&cmd=v (accessed on 20 June 2015)				

Appendix 2. Detailed results of feedback on long pharma country profile (template)

	Information to be shared (1= not important 5= very important to know)		Information availability (1=very difficult to collect, 5= always available)	
	mean	SD	mean	SD
PART I. PHARMACEUTICAL POLICY AND FINANCING				
1. Organization of pharmaceutical system				
1.1 Description of Pharmaceutical system – legal basis	4.62	1.08	4.69	0.61
Tabular information on respective authorities responsible for medicines regulation (registration, supply chain regulation, vigilance), procurement and distribution pricing control, reimbursement, medicines promotion, as applicable	4.33	1.56	4.06	1.72
2. Market Authorization				
2.1 Description of regulations and practices for licensing and inspection manufacturers, importers, wholesalers, distributors, pharmacies, dispensing health facilities (in tabular format)	4.50	0.83	3.83	1.30
3. Quality Assurance				
3.1 Description of Quality Assurance mechanisms in place, Quality Control testing laboratory in place, policies and practices in place for combating SSFFFC medicines	4.22	1.27	3.61	1.21
4. Pricing				
4.1. Pricing policies or any regulations (free, statutory, negotiations, rules of rebates /discounts) in tabular format	4.89	0.31	3.78	1.47
4.2. Procurement agency (if applicable) and Purchasing policies (tender, price negotiations) in public sector with identification of the national price setting institutions and mechanisms (if applicable)	4.94	0.23	3.72	1.52
4.3. Pricing procedures i.e. external referencing, internal referencing, cost-plus, profit control, and other	4.67	0.75	3.17	1.61
4.4. Price Composition due to Mark ups + any	4.28	0.93	2.89	1.52

	Information to be shared (1= not important 5= very important to know)		Information availability (1=very difficult to collect, 5= always available)	
	mean	SD	mean	SD
taxes (VAT) (if regulations exist on mark ups or taxes for medicines) for wholesalers, distributors, retail pharmacy/ pharmacists or hospitals in tabular format				
5. Reimbursement				
5.1. Reimbursement policies and procedures– reimbursement list, decision makers, schemes and legal provision and financing mechanism, negative or positive list, reimbursement decision bodies and process , rates.; risk-sharing schemes and managed entry agreements	4.56	1.01	3.61	1.42
5.2 Decision making tools, Health technology assessment; pharmaco-economic analysis, priority setting procedures	4.33	1.25	2.89	1.59
5.3 Out-of-pocket payment on medicines – fixed co-payments, percentage payments, deductibles in place in tabular format	4.72	0.45	2.50	1.26
5.6. Reimbursement policies in hospitals – payers, level of coverage, copayments, criteria, and legal provision Hospital pharmaceutical formularies – national/regional/facility, role of Pharmaceutical or Drug and Therapeutic Committee	4.28	1.33	2.94	1.58
6. Rational Use of Medicines, Monitoring & Vigilance				
6.1. Legal provisions for licensing of prescribers, dispensers, presence of Standard Treatment Guidelines, presence of national medicines information centre	4.33	1.00	4.06	1.03
6.2. Monitoring and evaluation of drug utilization				
Price monitoring	4.78	0.53	3.06	1.54
Prescription pattern monitoring	4.61	0.68	2.78	1.55
Pharmaceutical consumption monitoring	4.56	0.68	2.72	1.37
6.3. Generic Promotion policies and practices				
Generic promotion substitution (mandatory or voluntary, allowed, public perception, incentives) INN prescribing (mandatory, evaluation of prescribing habits)	4.06	1.47	3.18	1.50
6.4 Medicines advertising and promotion (legal	4.22	1.23	3.61	1.42

	Information to be shared		Information availability	
	(1= not important 5= very important to know)		(1=very difficult to collect, 5= always available)	
	mean	SD	mean	SD
provisions, advertisement of prescription medicines, pre-approval on advertising, guidelines)				
6.5 Education and training				
Mandatory continuing education (doctors, pharmacist other health professionals	4.22	1.51	3.61	1.46
6.6. Pharmacovigilance (ADR monitoring at different levels)	4.28	1.45	3.50	1.54
7. Intellectual Property Rights and medicines				
Legislations in Intellectual Property Rights (provisions for TRIPS flexibilities), WTO membership status, enforcement institution (any trade agreements in place requiring any TRIPS++ provisions)	4.28	1.24	3.39	1.46
Legal provision on patent linkage to market authorization	3.80	1.72	2.94	1.98
PART II. GENERAL INFORMATION ON HEALTH				
1. Population Structure				
Table on population trends over several years	4.61	0.95	4.33	1.15
2.Socioeconomic Statistics				
2.1 Table on GDP, GDP/capita over several years	4.50	1.17	4.28	1.28
2.2 Table on % of urban population, poverty headcount ratio, literacy rate	4.06	1.61	3.50	1.61
3. Health				
Table on life expectancy, fertility, mortality, mortality by causes	4.56	1.17	4.06	1.47
4. Health care delivery				
4.1. Table on Health care facilities and utilization	4.17	1.50	3.78	1.36
4.2. Table on human resources (Number of physicians, pharmacists, traditional doctors, nurses, midwives, number of school of pharmacy, number of pharmacy graduates per year)	4.11	1.52	3.67	1.49
5. Health care financing and expenditure				
5.1 Table on Total Health Expenditure, THE/capita, THE as % of GDP over several years	4.76	0.42	4.00	1.33
5.2 Table on Structure of health expenditure (THE, Composition of THE, Structure of out-of-pocket	4.76	0.42	3.76	1.06

	Information to be shared		Information availability	
	(1= not important 5= very important to know)		(1=very difficult to collect, 5= always available)	
	mean	SD	mean	SD
payment)				
PART III. PHARMACEUTICAL SYSTEM				
1.Pharmaceutical financing and expenditure				
1.1 Table on Pharmaceutical Expenditure, PE/capita, PE as % of THE	4.94	0.23	3.67	1.33
1.2 Table Structure of pharmaceutical expenditure (PE, prescription medicine, OTC, alternative and herbal medicines)	4.39	1.21	2.71	1.64
2. Availability and access				
2.1 Table on market entry (Number of registered medicines, prescription medicines, OTC, New Molecular Entities)	4.61	0.59	3.83	1.30
2.2 Table on essential medicines (Medicines List, number listed, median availability of selected medicines, median consume price ratio of selected generics in public and private	4.67	0.58	3.50	1.42
3. Pharmaceutical prescription and consumption				
3.1 Table on separation of prescribing and dispensing (policy, prescribing authority, dispensing authority)	4.39	0.89	2.89	1.56
3.2 Table on pharmaceutical consumption of selected medicines in DDD	3.94	1.81	2.39	1.60
3.3 Table on generic market share in outpatient and inpatient	4.28	1.24	2.61	1.34
4. Pharmaceutical Industry				
4.1 Table on pharmaceutical manufacturers (number of domestic manufacturers, number of GMP certified manufacturers)	4.22	1.13	3.89	1.20
4.2 Table on pharmaceutical distributors (number of wholesalers, retailers)	4.22	1.18	3.61	1.21
Total	4.43		3.46	