Pharmaceutical Policy and Financing in Asia-Pacific Countries

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List of abbreviations

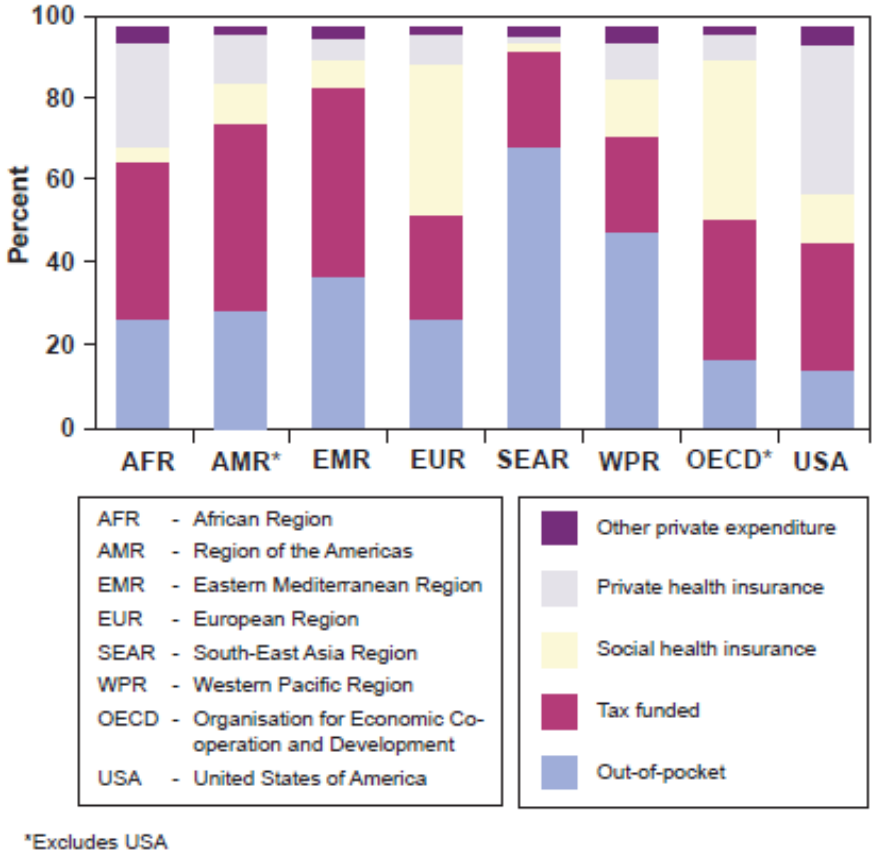
APCNMP	Asia Pacific Conference On National Medicines Policies
ATC	ATC Anatomical, Therapeutic, Chemical (Drug Classification)
BFAD	the Bureau of Food and Drugs
BFAD	the Bureau of Food and Drugs
BnB	Botika Ng Barangay
BP	British Pharmacopoeia
BPP	Better Prescribing Project
BPS	Bulk Purchase Scheme
CDPHI	Cambodia Department of Planning & Health Information
CHI	Compulsory Health Insurance
COBAC	Central Office Bids And Awards Committee
CPGs	Clinical Practice Guidelines
CSMBS	The Civil Servant Medical Benefit Scheme
DOH	The Department Of Health
DPRI	Drug Price Reference Index
DRG	Diagnosis- Related Group
DTC	Drug And Therapeutic Committees
DUR	Drug Utilization Review
ED	Essential Drug
EML	Essential Medicines List
EPI	Expanded Program On Immunization
FDA	Food And Drug Administration
GDP	Gross Domestic Product
GMAP	government mediated access prices
GMP	Good Manufacturing Practice
GPO	the Government Pharmaceutical Organization
HIRA	Health Insurance Review And Assessment)
HTA	Health Technology Assessment
INN	International Non-Proprietary Name
LGU	Local Government Units
MOC	The Ministry Of Commerce
MOHRSS	The Ministry Of Human Resources And Social Security
MOHW	The Ministry Of Health And Welfare
MOPH	The Ministry Of Public Health
MSH	Management Sciences For Health

NDRC	The National Development And Reform Commission
NDRC	National Development Reform Commissions
NDRL	The National Drug Reimbursement List
NFC	the National Formulary Committee
NHIP	The National Health Insurance Program
NHIS	National Health Insurance Service
NICE	The National Institute For Health And Clinical Excellence
NLED	National List Of Essential Drugs
NPPA	The National Pharmaceutical Pricing Authority
OECD	The Organisation For Economic Co-Operation And Development
OOP	Out-Of-Pocket
OPCI	Outpatient Prescribing Costliness Index
OTC	Over-The-Counter
PBS	The Pharmaceutical Benefits Scheme
PCO	Price Control Order
PEA	Pharmaco-Economic Assessment
PHI	Private Health Insurance
PHIC	the Philippine Health Insurance Corporation
PIB	Prices And Income Board
PICs	Pacific Island countries
PITC	Philippine International Trading Corporation
PNDF	Philippine National Drug Formulary
PNDF	Philippine National Drug Formulary
PPP	Purchasing Power Parity
RDFs	Revolving Drug Funds
RHU	Rural Health Unit
SAGPA	Swedish Agency For Growth Policy Analysis
SHI	Social Health Insurance
SSO	The Social Security Office
SSS	The Social Security Scheme
STG	Standard Treatment Guidelines
TCM	Traditional Chinese Medicines
UCS	Universal Coverage Scheme
USP	United States Pharmacopoeia
VAT	Value-Added Tax
VHI	Voluntary Health Insurance
WADP	The Weighted Average Disclosed Price

Chapter 1. Introduction

The Asia-Pacific region is very diverse, characterized by a wide range of inherent cultural traditions, political systems, level of economic development, and the size of population. Health systems in the region also face various challenges (Eggleston 2009). People in the region experience heavy financial burden due to health care cost despite impressive economic development. The portion of out-of-pocket (OOP) payment in total health expenditures is much higher in the Asia Pacific region than in other regions, making up over 40% in the Western Pacific Region and over 60% in the South-East Asia Region (WHO 2009a)(Figure 1). This 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 THE (Total Health Expenditure) is one of the key features of Asia Pacific countries (Teh-Wei 2004). High (public and private) spending on medicines causes financial hardship in households and/or threatens the financial sustainability of health system as well as prohibits the appropriate use of medicines (WHO 2009a).

Figure 1. Sources of health expenditure by region (2005)



Source: WHO (2009a)

While many countries are examining the way to reduce financial burden due to healthcare cost as well as guarantee timely access to health services, universal health coverage is considered as a 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 covered topics related with the use of medicines. On the other hand, most discussions associated with pharmaceutical policy are focused on topics about manufacturing, distribution, efficacy, etc.

Pharmaceutical policy and financing is an important policy issue to be dealt with in the context of universal health coverage. Issues related with whether/which medicines are covered, how medicine prices are decided and whether/how systems guarantee the appropriate use of medicines need to be discussed. Furthermore, health insurance/financing systems need to be designed to reduce OOP expenditures due to medicines and improve the cost-effective use of medicines through active management strategies involving medicine selection, purchasing, and contracting and utilization management.

This study reviews current issues and challenges as well as situations of pharmaceutical system and policy in Asia-Pacific countries. Furthermore, we will seek ways on how Asia-Pacific countries collaborate in developing pharmaceutical policies and conducting research in this sector. First, we will examine the role of pharmaceutical sector in the health system. Second, we will investigate the situation of medicines use and key issues in the pharmaceutical sector and current pharmaceutical policy, including pricing and reimbursement in Asia-Pacific and OECD countries. Third, we will examine pharmaceutical financing system and current policies to guarantee access to and appropriate use of medicine as well as health care system in selected Asia-Pacific countries. Finally, we will propose to establish a network on pharmaceutical policy and financing in the Asia-Pacific region, which reviews, compares discusses the current trend in the use of medicines and pharmaceutical policy and financing in Asia-Pacific countries.

Chapter 2. The characteristics and importance of pharmaceutical policy in the health care system

Pharmaceutical cost is one of major expenditure in the health care sector. 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, the drug policy plays an important role in determining the economic burden of payers in health care system (Roberts and Reich 2011). Even though medicines can improve the level of population health, the inappropriate use of drugs or spending can have a negative impact on patient's health or influence on catastrophic expenditure. Therefore, policy intervention is crucial in the pharmaceutical sector.

Pharmaceutical system can include eight sub-systems: (1) research and development, (2) clinical trials (3) national drug registration (4) drugs manufacturing (5) procurement of products (6) supply chain (7) preparations and selling, and (8) patient utilization of drugs (Roberts and Reich 2011). Specific features or process of pharmaceutical policy varies from countries to countries due to different institutional and socioeconomic backgrounds. Geographically large countries, such as United States, India, and China, also have variations within the countries (Roberts and Reich 2011). Therefore, the drug policy are all conscious efforts affecting the function of the sub-systems that related to the pharmaceutical sector (Lilja, Salek et al. 2008).

In the demand side, the role of prescribing providers is important because of information asymmetry and moral hazard in health insurance. Prescribing behavior of health care providers vary depending on the education and training as well as

marketing of drug companies. There are also difference between prescription drugs and non-prescription drugs in financing, pricing, reimbursement, advertising, regulations, etc. Sometimes consumers prefer more expensive originator drugs and do not adhere to the recommendation of pharmacists (Roberts and Reich 2011).

In the supply side, the pharmaceutical industry is high-technology one, affected by economies of scale in R&D and marketing, and there are market segmentation or competition between originator and generic drugs. There are high entry barriers because of legal patent, R&D and marketing costs, and brand loyalty of providers and consumers (Kwon, 2008). Sometimes health care providers and vendors may seek economic gains, including the prescribing of original high-profit drugs as well as profits in the different stages of distribution channel. In low and middle-income countries, public sector doctors often reduce work hours in public hospitals and increase their time in the private sector. As a result, patients may not receive a proper prescription or the prescription can be duplicated (Roberts and Reich 2011).

Pharmaceutical policy decisions are made at various times by the various departments in the country, which makes it difficult to predict the effectiveness of government intervention. The benefits of pharmaceutical policies will increase along with investment in or taking advantage of financial resources more wisely and the effective implementation of quality management policies, registration systems, drug price controls, proper subsidies, educational campaigns, or supply chain management (Roberts and Reich 2011).

Country's pharmaceutical policy can be different among low/middle-income and high-income countries. In low and middle-income countries, the government’s role includes medicines registration, permits for production, selection of essential

medicines list (EML), supply of public sector procurement, and management of drug stocks in public facilities. Low and middle-income countries also need regulations, such as price control, production audit, qualification for wholesalers, drug quality monitoring, collecting taxes, personnel training, campaign for patients although the enforcement is an issue (Roberts and Reich 2011). On the other hand, high-income countries need to determine whether support or oppose the merger of the pharmaceutical industry, manage export activities of local manufacturers, or have to consider the issue of public-private financing/investment of pharmaceutical sectors (Roberts and Reich 2011).

Whereas pharmaceutical policy is usually formed at the national level, the cooperation across countries is growing in the establishment of the policy. For example, European countries jointly share legal acts through the Official Journal of European Community, and medicines can be authorized through the centralized authorization procedure by the European Medicines Agency, which would encourage pharmaceutical markets to become more and more integrated across EU countries (Lilja, Salek et al. 2008). In addition, European countries established network for pricing and reimbursement of pharmaceutical products in 2005, and this network is rooted in the projects of Europe's PPRI (Pharmaceutical Pricing and Reimbursement Information) and PHIS (Pharmaceutical Health Information System). The network is sharing information and experience of drug pricing and policy among the Member States. Based on the WHO Collaborating Centre (WHO CC) for Pharmaceutical Pricing and Reimbursement Policies, they have meeting twice a year to maintain and publish a variety of data and reports and support activities for research, data accumulation, and related policies (WHOCC 2014).

Chapter 3. Current trends in pharmaceutical system and financing

Ⅰ. Pharmaceutical financing and expenditure

1. Overview

1) Total pharmaceutical expenditure by income level of country

17.6% of the world's population in low income countries accounted for only 1% of global pharmaceutical expenditure. However, poor countries spend a greater proportion of their total health expenditure on medicines than high income countries do (WHO 2011c).

Table 1. Total pharmaceutical expenditure per capita by country's income level, 2005/2006

WB Income group	N	Population (000s)	Absolute amount (million US$)	Per capita (US$)
High	46/48	1 011 957 (16.0%)	$674 011(78.5%)	$434.7
Up-mid	37/42	812 489 (12.9%)	$87 862.8 (10.2%)	$88
Low-mid	44/54	3 379 873 (53.5%)	$88 745.6(10.3%)	$34
Low	34/49	1 114 890 (17.6%)	$8 594.7 (1.0%)	$7.7
Total	**161/193**	**6 319 210 (100.0%)**	**$859 214.1 (100%)**	**$155**

Note: N is number of countries

Source: WHO NHA database, 2005/2006

Table 2. Share of pharmaceutical expenditure in total health expenditure, 2006(%)

Income group	N	Population (thousands)	Mean[a] (%)	Median (%)	Minimum (%)	Maximum (%)
High	46	1 011 957	19.7	18.2	8.7	32.4
Upper-middle	37	812 489	23.1	22.0	10.4	36.8
Lower-middle	44	3 379 873	27.6	26.6	9.8	67.6
Low	34	1 114 890	30.4	29.5	7.7	62.9
All countries	161	6 319 210	24.9	23.1	7.7	67.6

[a] Weighted mean by population.
Source: WHO NHA database

2) Expenditure on medicines by public and private sectors

Countries with lower income level tend to depend on private financing for pharmaceuticals. OOP expenditure is the major source of pharmaceutical payment in all but high-income countries (WHO 2011c).

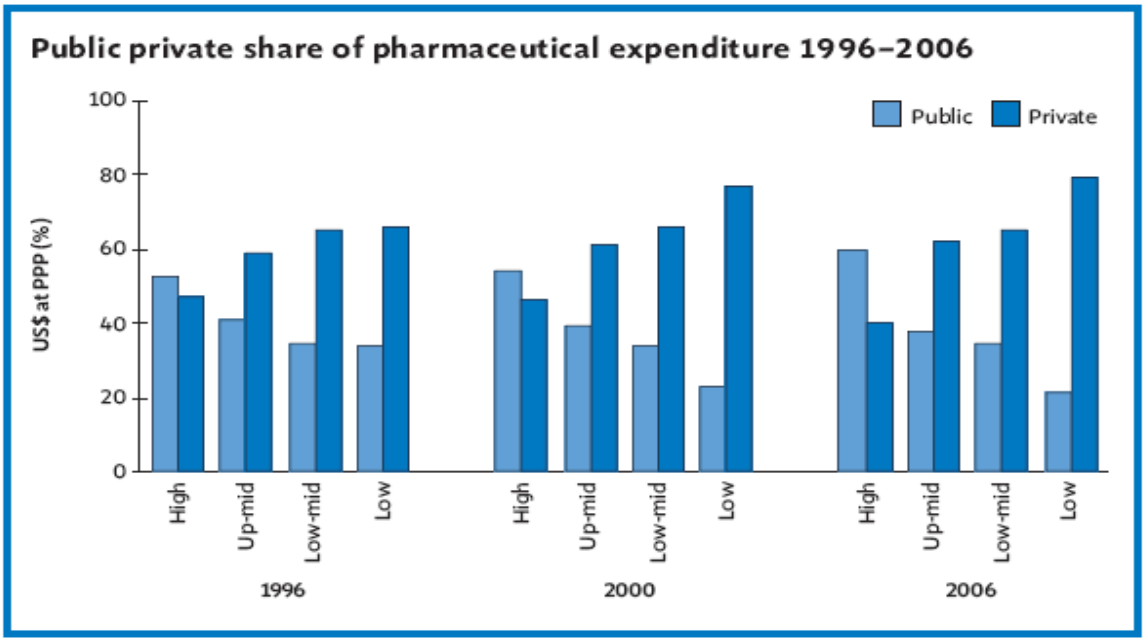
Table 3. Composition of per capita total pharmaceutical expenditure by income group, 2006(in US$ at exchange rate values)

	Total pharmaceutical expenditure						Total expenditure on health			
		Public		Private		Total	Public	Private	Total	
Income group	N	US$	%	US$	%	US$	US$	US$	US$	N
High	42	264.4	61.3	167.2	38.7	431.6	2473.6	1597.6	4071.4	49
Upper middle	31	32.6	38.8	51.5	61.2	84.1	214.7	184.1	398.8	54
Lower middle	34	10.5	33.5	20.8	66.5	31.3	27.5	38.6	66.1	47
Low	27	1.76	23.1	5.85	76.9	7.61	19.2	3.7	22.9	41

Source: World Medicines Situation 2011

Between 1996 and 2006, both public and private spending on medicines steadily increased in all countries. The public share of pharmaceutical expenditure has increased substantially in high income countries, whereas the private share of pharmaceutical expenditure has increased in low income countries (WHO 2011c).

Figure 2. Public/private share of pharmaceutical expenditure 1996-2006



Source: World Medicines Situation 2011

Table 4. Health insurance and medicines coverage by country income level

	Low(48)			Middle (73)			High (35)		
	# yes	Resp. countries	% yes	# yes	Resp. countries	% yes	# yes	Resp. countries	% yes
Health insured population - public sector									
All	1	38	3	18	65	28	22	31	71
Some	25	38	66	37	65	57	7	31	23
None	12	38	32	10	65	15	2	31	6
Medicines covered by health insurance - public sector									
All	1	41	3	10	62	14	15	33	61
Some	25	41	85	38	62	83	13	33	39
None	15	41	12	14	62	3	5	33	0

Source: WHO level 1 data 2007 (Indicators for monitoring country pharmaceutical situation)

3) Trends in pharmaceutical expenditures

Overall, per capita expenditure on medicines has increased by approximately 50% over the period of 1995-2006. The gap in per capita spending between the high- and low-income countries has continued to grow. The largest increases in the proportion of GDP spent on pharmaceuticals have occurred in low-income countries. The biggest growth in the share of total pharmaceutical expenditure in total health expenditure has also occurred in low-income countries, specifically in the WP region (WHO 2011c).

Table 5. Mean per capita total pharmaceutical expenditure by income group, 1995-2006 (ppp US$2005)

Year	High income (N=43–46)	Upper middle income (N=32–37)	Lower middle income (N=36–44)	Low income (N=20–33)	All countries (N=135–148)
1995	275.8	87.9	39.5	12.2	122.1
1996	284.8	90.9	39.9	13.0	126.0
1997	306.0	100.2	40.7	13.3	134.4
1998	319.6	111.4	42.7	14.7	140.6
1999	341.4	112.8	43.1	15.6	149.3
2000	352.0	119.4	46.1	15.4	149.6
2001	380.6	122.0	51.1	15.4	162.9
2002	397.4	122.7	54.5	16.6	178.4
2003	400.5	130.9	64.1	20.1	179.0
2004	407.6	137.7	68.3	19.8	182.5
2005	426.5	143.8	72.1	21.4	193.4
2006	425.9	152.0	71.9	20.3	181.5

N – number of countries. Note that the number of countries reporting data varies from year to year.
Source: WHO NHA database

Table 6. Total pharmaceutical expenditure as a share of GDP by income group, 1995-2006(%)

Year	High income (N=43–46)	Upper middle income (N=32–37)	Lower middle income (N=36–44)	Low income (N=20–33)	All countries (N=135–148)
1995	1.19	1.19	1.31	1.12	1.22
1996	1.20	1.17	1.26	1.19	1.21
1997	1.23	1.25	1.29	1.16	1.24
1998	1.26	1.32	1.34	1.26	1.30
1999	1.31	1.34	1.33	1.41	1.33
2000	1.33	1.39	1.38	1.40	1.37
2001	1.35	1.42	1.45	1.36	1.39
2002	1.40	1.43	1.49	1.46	1.44
2003	1.45	1.46	1.65	1.60	1.53
2004	1.43	1.46	1.68	1.60	1.54
2005	1.46	1.45	1.70	1.65	1.55
2006	1.41	1.45	1.63	1.62	1.52

N – number of countries. Note that the number of countries reporting data varies from year to year.
Source: WHO NHA database

Table 7. Total pharmaceutical expenditure as a share of total health expenditure by income group, 1995-2006 (%)

Year	High-income	Up-mid-income	Low-mid-income	Low income	WHO Member states
1995	17.9	21.7	28.5	27.0	23.3
1996	17.7	21.3	26.3	27.6	22.6
1997	18.3	21.6	26.4	27.3	22.9
1998	18.7	21.6	25.7	29.4	23.2
1999	19.1	22.2	26.1	31.9	23.9
2000	19.7	22.7	25.4	31.1	24.1
2001	19.5	22.7	25.3	30.2	23.8
2002	19.6	22.2	27.0	28.2	23.6
2003	19.7	23.1	29.3	33.2	25.4
2004	19.7	23.3	29.4	32.8	25.5
2005	20.3	23.1	29.2	33.8	25.6
2006	19.7	23.1	27.6	30.4	24.9

Source: World Medicines Situation 2011

Table 8. Total pharmaceutical expenditure as a share of total health expenditure by region, 1995-2006 (%)

Year	AFR	AMR	EMR	EUR	SEAR	WPR	Total
1995	29.1	22.3	31.5	19.2	32.0	22.8	23.3
1996	27.7	22.2	22.8	19.1	32.9	22.6	22.6
1997	27.1	22.9	24.4	19.5	32.6	22.1	22.9
1998	26.5	23.1	25.3	20.0	31.5	22.5	23.2
1999	30.7	23.1	23.7	20.4	32.8	23.6	23.9
2000	29.8	23.4	25.1	20.6	32.8	23.6	24.1
2001	28.2	23.1	25.7	21.3	32.7	22.4	23.8
2002	26.1	23.3	24.0	21.2	31.7	23.7	22..6
2003	26.8	23.8	28.4	23.9	32.5	26.0	25.4
2004	25.5	24.5	26.9	23.7	33.4	27.2	25.5
2005	25.4	24.5	27.3	23.8	33.1	28.0	25.6
2006	24.9	24.1	26.8	23.1	31.8	26.5	24.9

Source: World Medicines Situation 2011

2. OECD countries

1) pharmaceutical expenditure

Pharmaceutical expenditure comprises the third largest component of all health expenditure after inpatient and outpatient care in OECD countries. Across OECD countries, 16.4% of total health expenditure on average was spent on pharmaceuticals in 2011. The share ranges from 6.8 percent in Denmark and Norway to more than 50% in Hungary (Table 9).

While average pharmaceutical expenditure per capita was around USD 495 in 2011, the spending varies from country to country. Chile had relatively low spending at about USD 200, whereas the United States spent as much as USD 1000 on pharmaceuticals in 2011, on a per capita basis. Public financing accounted for 57.6 %, on average, of total pharmaceutical spending. There are wide variations in the public share of pharmaceutical spending from less than 10% in Chile to more

than 80% in United Kingdom and Luxembourg (Table 9)(Figure 3).

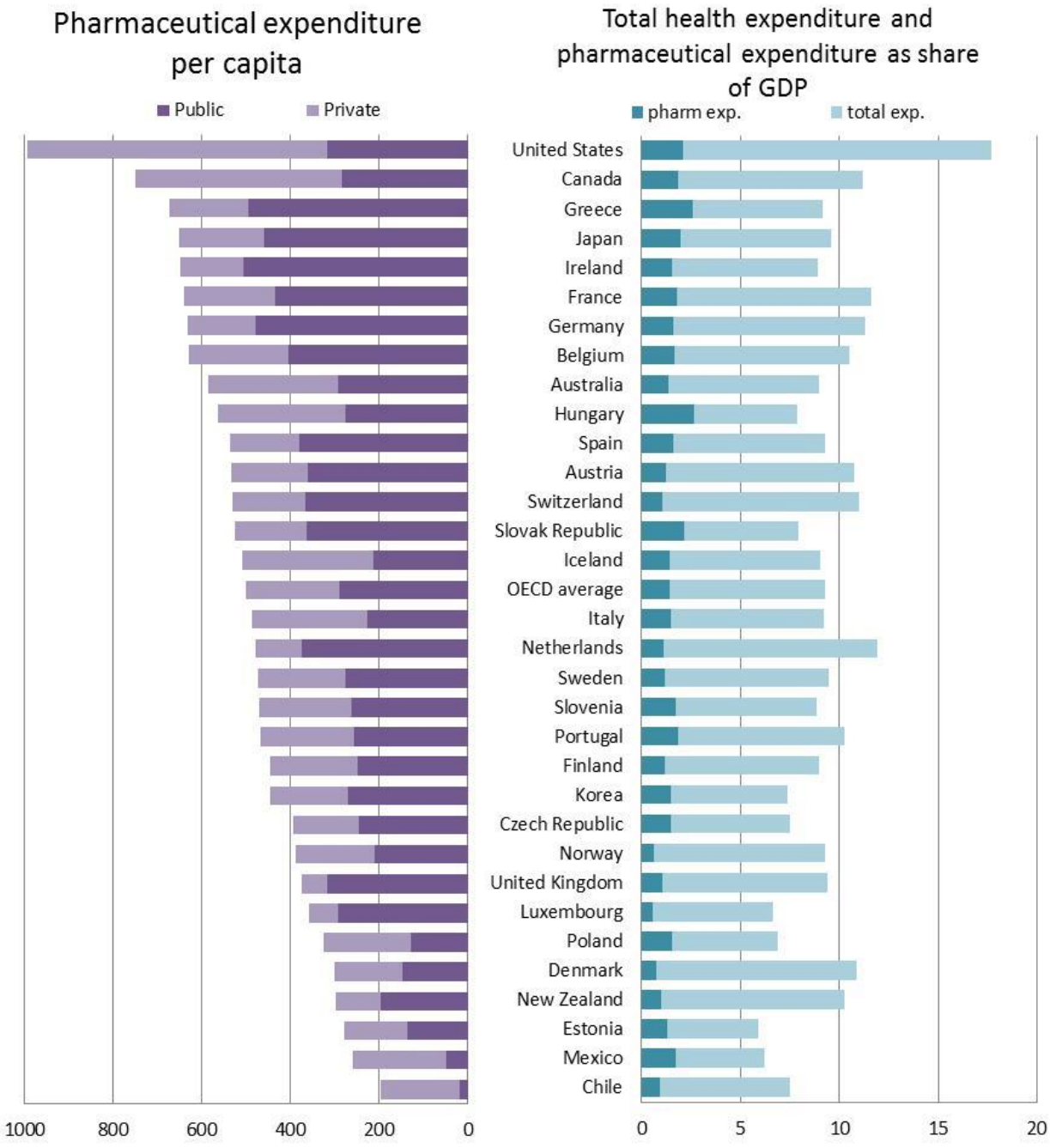
Pharmaceutical expenditure accounted for 1.4 % of GDP on average across OECD countries. The share of pharmaceutical spending in GDP ranges from less than 1 % in Luxembourg, Norway, Denmark, Chile, and New Zealand, to more than 2 % in Hungary, Greece, Slovak Republic, and United States (Table 9)(Figure 3). Public spending on pharmaceuticals accounted for 13.3% of public spending on health on average across OECD countries. Whereas Greece spent more than 30% of public spending on health for pharmaceuticals, Chile spent less than 3% (Table 9)(Figure 4).

Table 9. Pharmaceutical expenditure per capita, as percentages of GDP and total health expenditure, public share of pharmaceutical spending, and medicines share in public health expenditure

	per capita (USD PPP)	% of GDP (%)	% of total health expenditure (%)	public share of pharmaceutical spending (%)	Medicines share in government spending on health (%)
Australia	587.1	1.4	15.4	50.0	12.0
Austria	533.1	1.3	11.7	67.6	10.8
Belgium	630.9	1.6	15.5	64.3	13.2
Canada	751.5	1.9	16.6	37.8	9.5
Chile	197.4	0.9	12.6	9.9	2.9
Czech Republic	394.2	1.5	20.0	62.5	15.2
Denmark	300.4	0.7	6.8	49.2	4.1
Estonia	279.8	1.3	21.5	48.5	13.2
Finland	446.2	1.2	13.2	55.9	10.3
France	641.1	1.8	15.6	68.0	14.2
Germany	632.6	1.6	14.1	75.6	14.3
Greece	673.4	2.6	28.5	73.7	32.3
Hungary	564.0	2.6	33.4	49.0	26.1
Iceland	508.3	1.4	15.4	42.1	8.1
Ireland	647.7	1.6	17.5	78.0	21.0
Italy	487.3	1.5	16.2	46.6	9.9
Japan	651.6	1.9	20.3	70.7	-
Korea	444.9	1.5	20.2	60.8	22.8
Luxembourg	359.5	0.6	8.4	81.7	8.9
Mexico	259.0	1.7	27.1	18.9	11.6
Netherlands	479.3	1.1	9.4	78.4	9.3
New Zealand	298.0	1.0	9.4	65.6	7.4
Norway	387.7	0.6	6.8	54.3	4.5
Poland	326.3	1.5	22.5	39.4	13.4
Portugal	469.0	1.8	17.9	55.1	15.9
Slovak Republic	525.0	2.2	27.4	69.4	27.0
Slovenia	471.3	1.7	19.5	55.9	15.4
Spain	535.8	1.6	17.4	71.0	17.3
Sweden	474.0	1.1	12.1	58.3	9.2
Switzerland	530.7	1.0	9.4	68.9	10.0
United Kingdom	374.6	1.0	11.4	84.7	-
United States	995.0	2.1	11.7	31.9	8.0
OECD AVERAGE	495.5	1.4	16.4	57.6	13.3

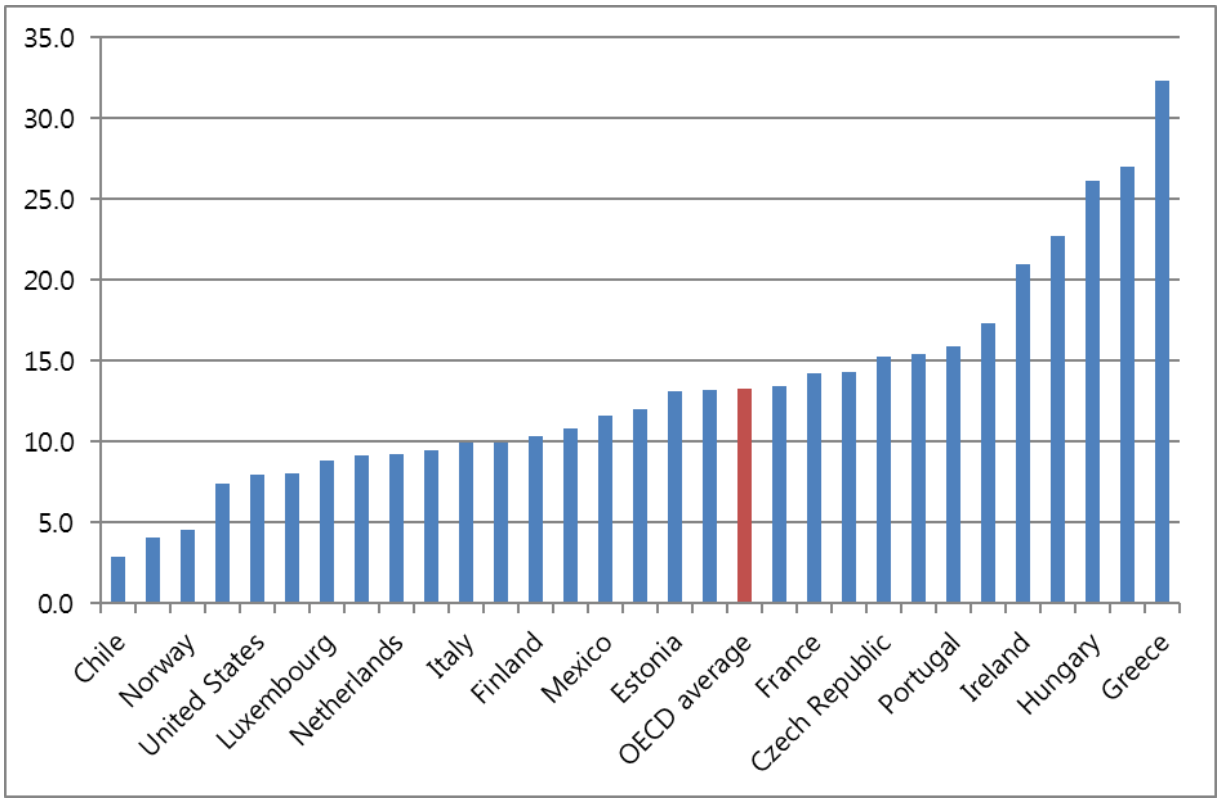
Source: OECD health statistics 2013

Figure 3. Pharmaceutical expenditure, total health expenditure and pharmaceutical expenditure as share of GDP



Source: OECD health statistics 2013

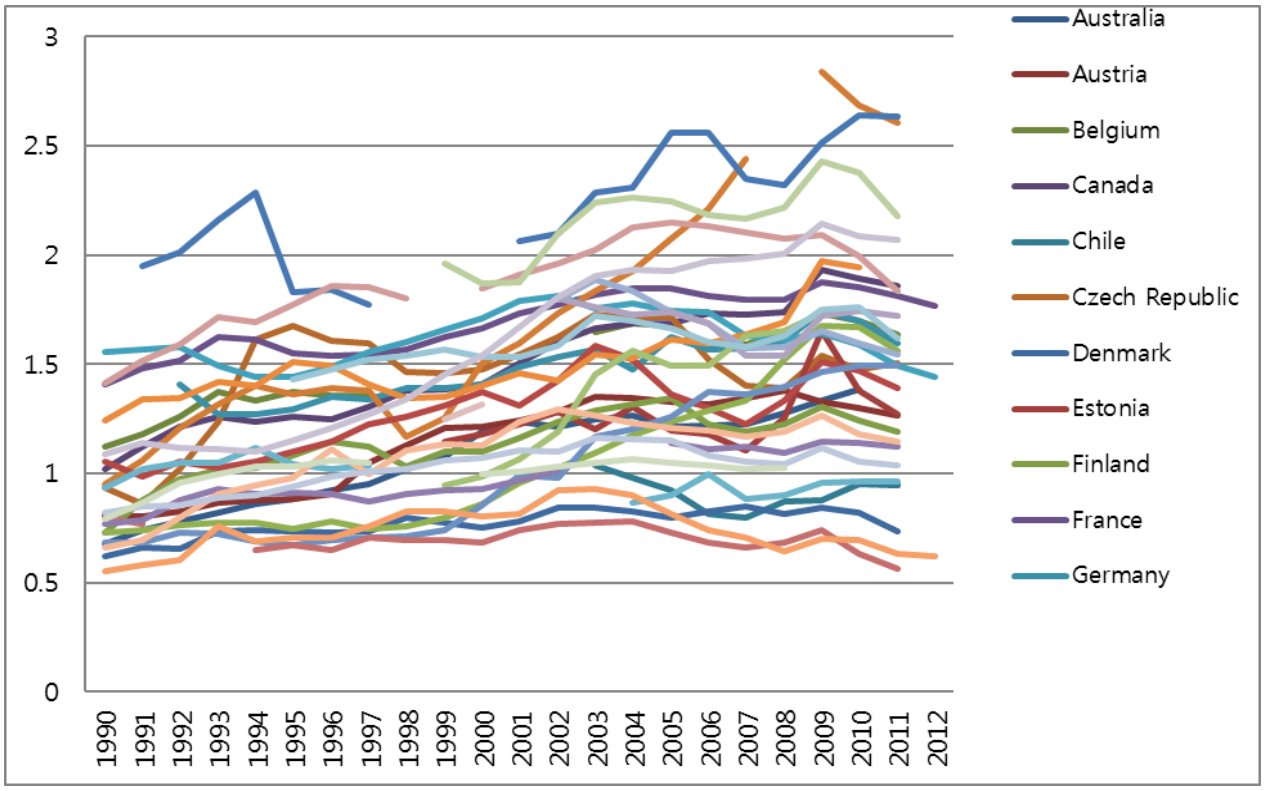
Figure 4. Medicines share in government spending on health (%)



Source: OECD health statistics 2013

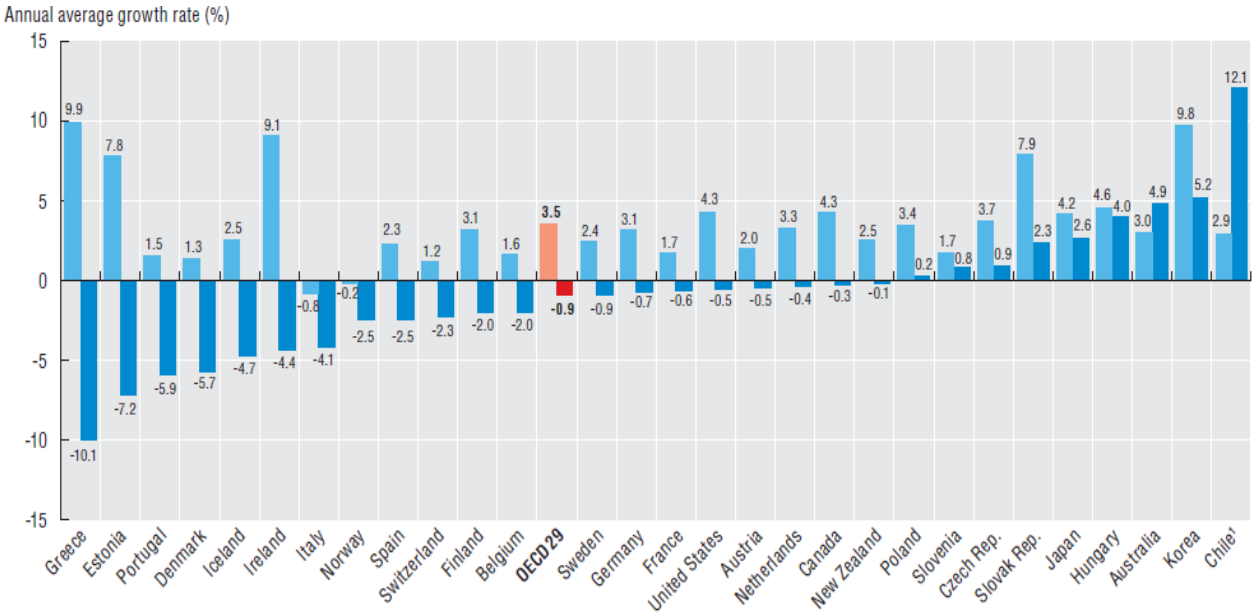
The share of pharmaceutical expenditure in GDP decreased across many OECD countries around 2009 (Figure 5). Whereas pharmaceutical expenditure per capita has increased by 3.5% on average between 2000 and 2009 in 29 OECD countries, the average growth rate decreased to -0.9% between 2009 and 2011. Particularly, growth rate showed a significant reduction in Greece, which were affected by economic crisis around 2009(OECD, 2013) (Figure 6).

Figure 5. Pharmaceutical spending as a share of GDP



Source: OECD health statistics 2013

Figure 6. Average annual growth in pharmaceutical expenditure per capita, in real terms, 2000 to 2011 (or nearest year)

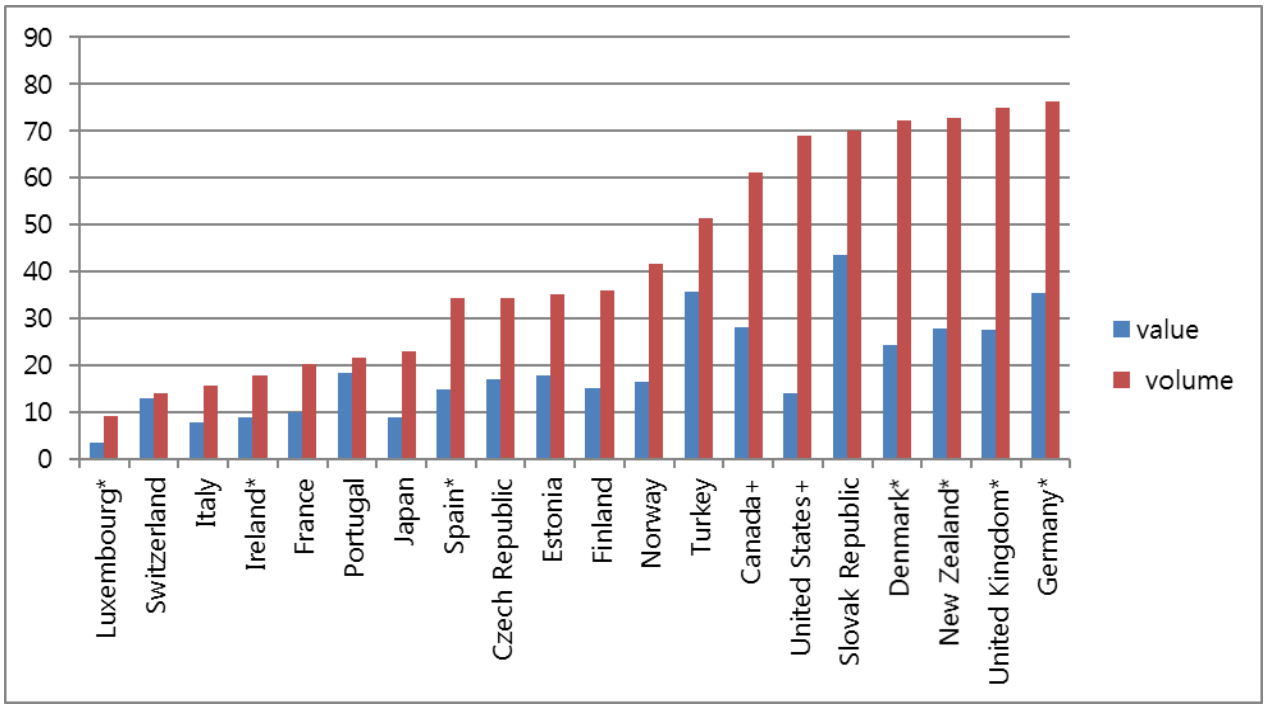


Source: OECD health data at a glance (2013)

2) Shares of generic and OTC medicines

Generic market share differ from country to country. Generics accounted for about three-quarters of pharmaceutical market in Germany, United Kingdom, New Zealand and Denmark while they represented less than one-quarter of the market in Luxembourg, Switzerland, Italy, Ireland, France, Portugal, and Japan in terms of volume (Figure 7).

Figure 7. Generic market share

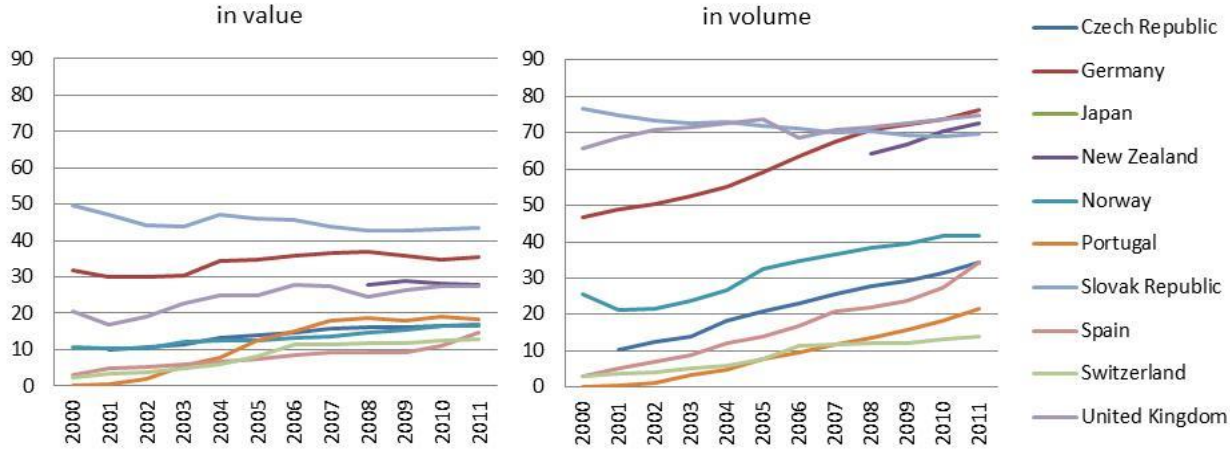


*Reimbursed pharmaceutical market
Source: OECD health statistics 2013 ;+IMS health (2010)

In 10 OECD countries with available information on generic market share, the share of the generic market showed an increasing trend over the past decade except Slovak Republic. Generic market share increased more remarkably in terms of volume than value. Particularly, the generic market in Portugal with low generic market share in 2000 grew from zero to 25% in volume and to 17 % in value in 2011. In Spain, the generic market share increased from less than 3 % in 2000 to

34% in volume and 15% in value in 2011. In Japan, the generic market share increased from 17% to 23% in volume and from 6% to 9% in value between 2005 and 2011. In Germany, United Kingdom, and New Zealand with high generic market share, the generic market share increased in volume whereas generic market share slightly decreased in Slovak Republic (Figure 8).

Figure 8. Trend in generic share in the pharmaceutical market, selected countries, 2000 to 2011

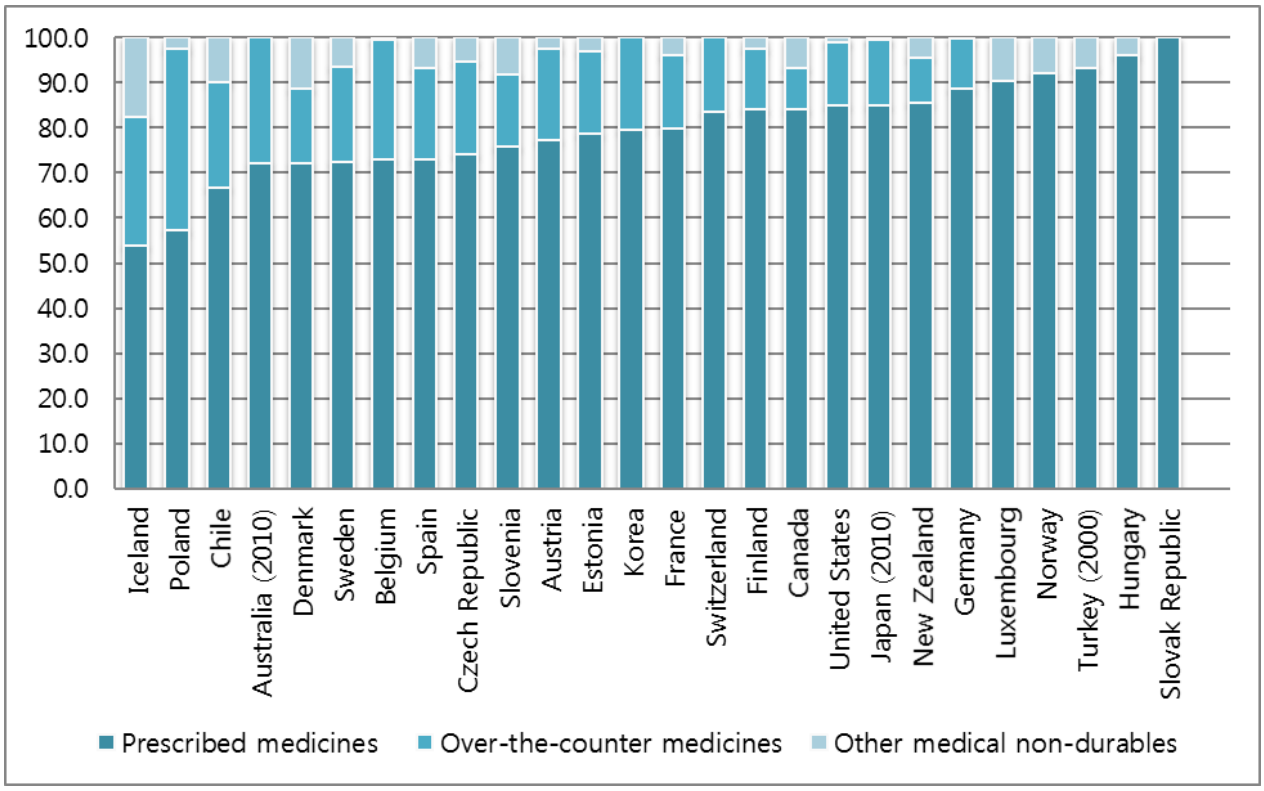


Source: OECD health statistics 2013

The share of prescription medicines in total pharmaceutical expenditure in 26 countries with available information is higher than 50%. On average, prescription medicines accounted for approximately 80% of total pharmaceutical expenditure whereas over-the-counter (OTC) drugs represented 19%. In Poland, the share of OTC products is the greatest at 40% of total pharmaceutical expenditure (

Figure 9).

Figure 9. Share of prescription and over-the-counter (OTC) drugs in total pharmaceutical expenditure, 2011 or nearest year



Source: OECD health statistics 2013

3. Non-OECD Asia-Pacific countries

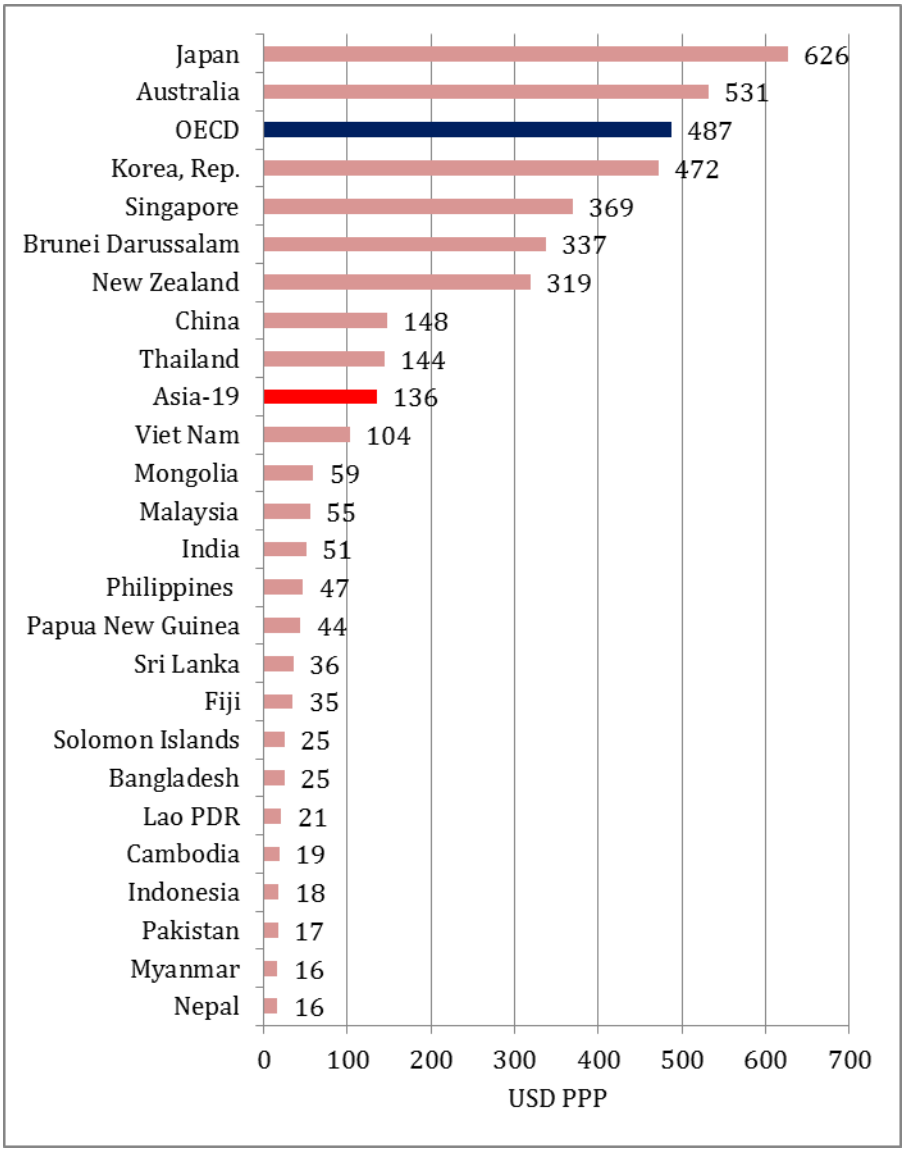
1) Pharmaceutical expenditure

Per capita pharmaceutical spending varies greatly among Asia-Pacific countries. In 2009, a large number of countries spend below ppp $ 60 per capita, while it is less than ppp $ 20 per capita for Cambodia, Indonesia, Myanmar and Nepal. On average, OECD countries spend more than three times as much as Asian countries (ppp $ 487 *vs.* 136). However, the average share of pharmaceutical spending in health expenditure of Asian countries is twice that of OECD countries (29.7% *vs.* 15.6%) (OECD/WHO 2012). This share varies from Papua New Guinea and Viet Nam, which report the largest proportion of total health spending on pharmaceuticals (51.4% and 50.9%) to Malaysia and Solomon Islands with the lowest (8.8% and 10.9%). This is partly due to important differences in the dispensing of pharmaceuticals as well as how expenditures are currently classified. In many countries (*e.g.*, Sri Lanka, Thailand, Hong Kong, China), physicians dispense medicines as part of their overall delivery of medical care, and the cost of the dispensed medication is not charged to the patient, but is included as part of the diagnostic or consultation fee. In this case, the amounts that are distributed through retail channels and reported as dispensing of medical goods can be low (OECD/WHO 2012).

The annual average growth rate of real per capita pharmaceutical expenditure in Asian countries almost doubled that of the OECD countries from 2000-09: 6.3% versus 3.5%. Importantly, pharmaceutical spending increased at a higher rate than total health spending in Asia (5.6%), while health spending increased at a higher rate in OECD countries (4%) compared to pharmaceutical spending. Mongolia, Lao

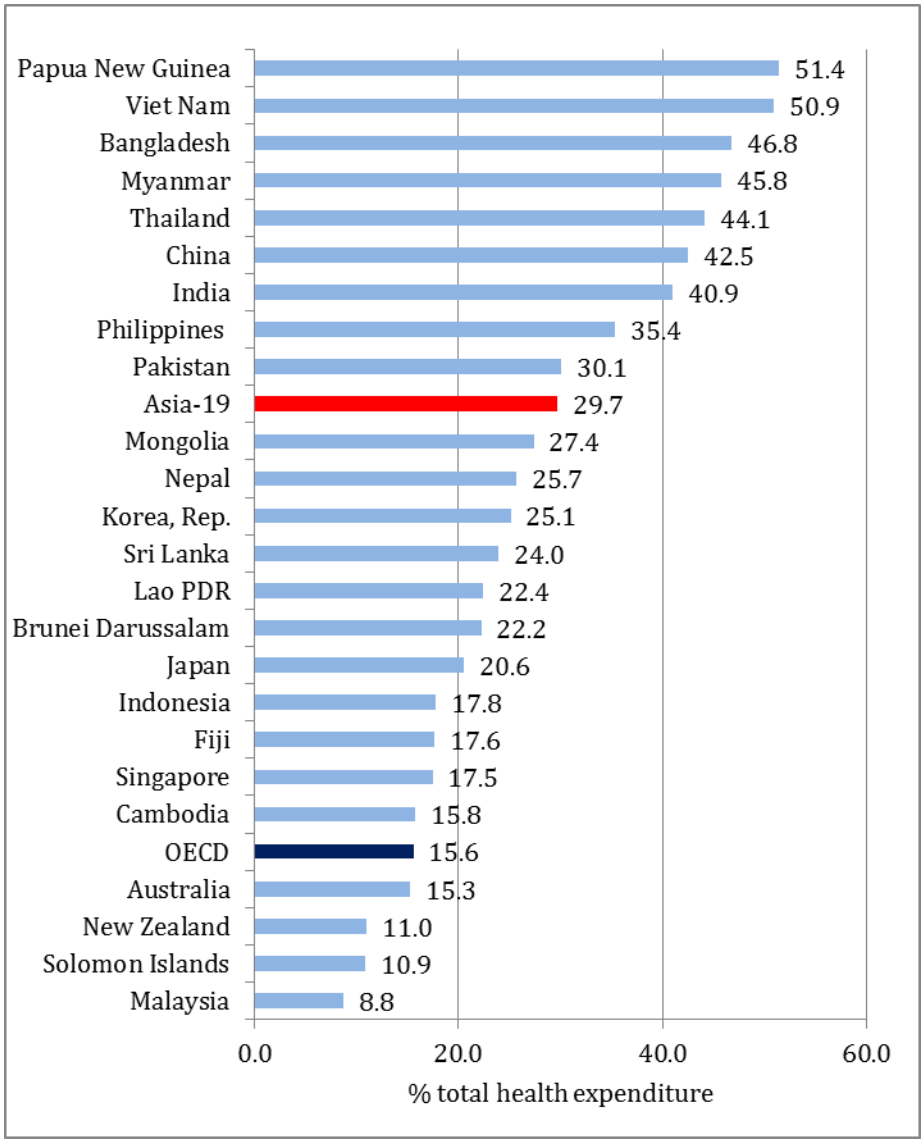
PDR, Myanmar and Viet Nam reported an annual average growth of more than 10%, while Pakistan is the only country that showed a decrease over the same period (–3.1%) (OECD/WHO 2012).

Figure 10. Pharmaceutical expenditure per capita, 2009



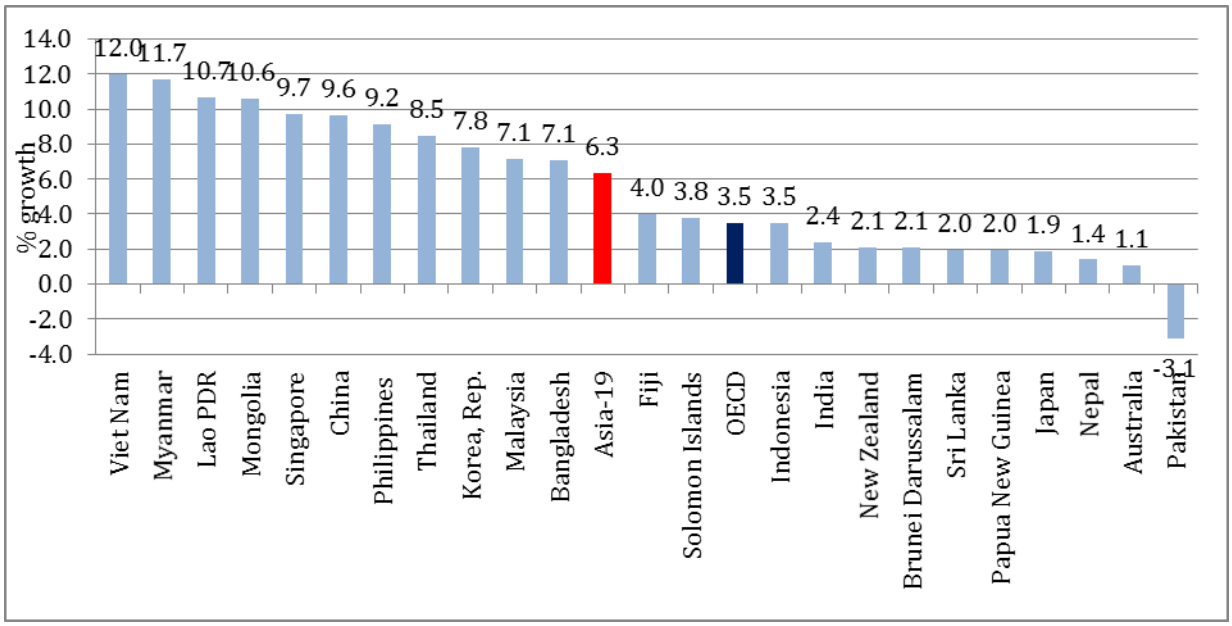
Source: OECD/WHO (2012)

Figure 11. Pharmaceutical expenditure as a share of total health expenditure, 2009



Source: OECD/WHO (2012)

Figure 12. Annual average growth rate of pharmaceutical expenditure per capita, 2000-09



Source: OECD/WHO (2012)

Table 10. Total pharmaceutical expenditure in Asia-Pacific countries (2006)

Country	TPE as % of GDP	TPE as % of THE	TPE per capita(2005, ppp$)	Private share of TPE(%)
Bangladesh	1.5	46.1	16.6	89.4
Bhutan	0.4	10.8	14.7	38.6
India	2	56.5	47.3	96
Indonesia	0.7	28.3	22.6	94
Maldives	1.3	15.9	61.9	23.1
Myanmar	0.9	39.6	10.1	95.7
Nepal	1.4	28.2	14.1	81
Sri Lanka	0.8	18.1	29.9	88.2
Thailand	1.5	42.9	110.3	12.3
Cambodia	1.8	30.9	28.7	86.3
China	1.7	36.2	77.6	73.5
Cook Islands	0.4	10.4	81.9	31.2
Fiji	0.6	17.1	27.9	54.7
Laos	1.6	40.1	30.5	97.8
Mongolia	0.7	11.9	18.9	28.5
Papua New Guinea	1.6	50.3	30.8	24.8
Philippines	1.6	41.1	47.7	90.1
Samoa	0.8	16.8	31.8	17.7
Viet Nam	3.2	49.3	72.2	87.7

TPE: total pharmaceutical expenditure
THE: total health expenditure
Source: World Medicines Situation 2011

According to World Health Survey 2002-2003, most of household OOP for health were paid for purchasing medicines and distributed un-proportionally by household income level, specifically high burden on low income household.

Table 11. Structure of OOP health payment by household income level (%)

	China			Lao PDR			Malaysia		
Income quintile	Inpt	Outpt	Drugs	Inpt	Outpt	Drugs	Inpt	Outpt	Drugs
1(poor)	1.0	17.0	64.6	4.8	19.9	61.5	11.7	16.9	42.5
2	0.5	27.7	60.9	8.2	12.3	63.2	5.4	22.0	40.8
3	0.4	47.0	47.7	7.8	10.4	65.5	4.1	21.7	40.3
4	2.2	62.3	28.0	9.9	18.1	57.6	4.3	16.4	37.4
5(rich)	55.0	19.8	15.2	32.0	8.0	42.3	34.5	11.3	21.9
Total	43.1	25.9	21.3	25.2	10.1	47.8	22.7	14.3	28.8

	Philippines			**Vietnam**		
Income quintile	**Inpt**	**Outpt**	**Drugs**	**Inpt**	**Outpt**	**Drugs**
1 (poor)	6.0	9.4	**65.9**	4.7	30.8	**56.2**
2	5.0	11.6	**68.8**	6.9	30.1	**54.4**
3	9.1	10.1	**64.1**	7.4	31.6	**51.4**
4	11.2	10.5	**61.2**	12.0	27.7	**51.1**
5(rich)	30.5	9.6	**44.9**	36.7	17.9	**29.0**
Total	24.4	9.8	**50.2**	27.2	21.9	**37.0**

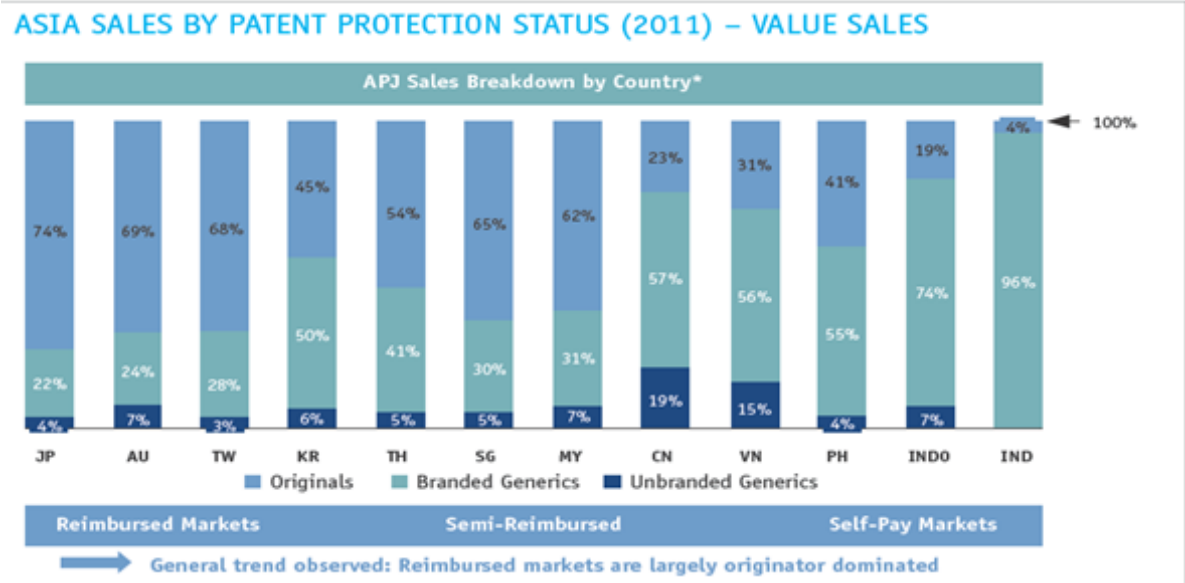
Source: Author's calculation using World Health Survey 2002-2003

2) Market structure

A. Generic market share

Most of developed Asian countries show that originator drug dominated the market while developing countries have relatively high market share of generic medicines (IMS Health 2013).

Figure 13. Pharmaceutical market structure in selected Asia countries (sales %)



Source: IMS Health 2013

B. OTC drug market

OTC drug sales in the Asia-Pacific region (excluding Japan) have significantly outpaced the growth of global OTC drug market for three consecutive years. According to the 2012 IMS OTC Global Analysis, the market grew by 16% over 2011, which is 14 percentage points higher than the growth in the global OTC drug market. Moreover, as of September 2012, OTC drug sales in the Asia-Pacific region account for 21% of global OTC drug sales (IMS Health 2013).

In countries with developed OTC drug markets, such as Australia, Japan, Singapore and the Philippines, self-medication is established as a norm and is reinforced by advertising messages. Products are highly accessible, and consumers are clear in their preference at the point of sale (IMS Health 2013). In countries with developing OTC drug markets, such as India, China, Vietnam, Indonesia, Thailand, Malaysia and South Korea, self-medication exists but it is constrained by advertising regulations and government reimbursement. (IMS Health 2013).

Ⅱ. Pharmaceutical system and policy

1. Pharmaceutical policy: types and issues

1) Financing mechanism

Pharmaceutical financing system is related to a nation's financing of overall health care system. The public funding mechanism is affected by various factors: level of economic development, a nation's tax system, and choice for budgetary and expenditure, etc. (Roberts and Reich 2011). There are several financing options for a nation's health system and its pharmaceutical sector (Kwon, 2011).

A. General tax revenue

Allocation of general revenue to the health sector depends on political bargaining, so sometimes pharmaceutical financing can be insecure because of competing sectors, economic difficulties, and political pressures. As a result, tax revenue can affect the availability of medicines in the public sector (Roberts and Reich, 2011). A tax-based system for health care has the benefit of rapid extension to the informal sector, such as the case of Thailand (Tangcharoensathien, Wibulpholprasert et al. 2004). If tax-based financing is based on income tax, it can be more progressive than social health insurance, of which contribution is usually proportional to income, while consumption tax is regressive.

B. Social insurance

Social insurance fund have the advantage of earmarking, i.e., less affected by political situations. Social Health Insurance (SHI) agency, separate from public

delivery system, can improve its purchasing function, such as benefit packages and provider payment system (Kwon, 2011). Even in the SHI system, the poor cannot afford to pay contribution, and government subsidy is essential to provide coverage for them.

C. Private insurance

Premiums of private health insurance (PHI) is determined by the risk or expected expenditure of the enrollee. As a result, private insurance market suffers from adverse selection and cream skimming (preferred risk selection by the insurer). The role of private insurance is not big in low- and middle-income countries due to their limited purchasing power.

D. Community financing

Community financing, e.g., community-based health insurance (CBHI), has a limited capacity of risk pooling and purchasing. Poor people in the community cannot afford to contribute even a small amount. Although community financing has a potential to improve the awareness about prepaid financing scheme for health care, the voluntary enrollment makes community financing vulnerable to adverse selection (Kwon, 2011).

E. OOP payment

In low- and middle-income countries, OOP payment is a major source of pharmaceutical financing. OOP can be a payment for public sector or private sector, and many of low-income countries supply medicines and receive payment in forms of cash at the time of service delivery (Roberts and Reich, 2011).

2) Pricing

Pharmaceutical price regulation is important because of inadequate competition in the pharmaceutical market. Competition in the pharmaceutical market is limited due to information asymmetry and separated responsibility for the purchasing decision makers (physicians and prescribers) and those who bear the cost (patients and third party payers). Without price regulation, pharmaceutical manufacturers can benefit from relatively inelastic demand by pricing at high levels using their monopolistic power (OECD 2008). Pharmaceutical pricing matters especially in countries with weak pharmaceutical systems. In those countries, price affects affordability and access to medicines directly as the majority of pharmaceutical spending is through OOP pay, and the availability of medicines in public facilities is very low.

A. Free or market based pricing

There are only three OECD countries (the United States, Germany, and the United Kingdom) where manufacturers can set list prices for new products freely at market entry. On the other hand, it is allowed only for those drugs that are not reimbursed by the universal coverage scheme in other countries. In most OECD countries, this constitutes a relatively small minority of the drugs authorized for sale in the market by prescription, given the importance of coverage for drug sales (OECD 2008).

B. External price benchmarking (External reference pricing)

External benchmarking of pharmaceutical prices is the most widely used measure to limit prices or reimbursement prices in OECD countries. It uses the prices of medicines in other countries to set or negotiate the price of medicines in a

country. It is perceived by public authorities as a means to assure the fairness or appropriateness of the proposed (or actual) price in relation to what is paid in other countries (OECD 2008). External price benchmarking is simple and straight forward in terms of information and capacity requirements, although information on "real" prices in other countries is very difficult to get. However, it has weak theoretical foundation because it simply assumes that price in other countries is optimal (Espin, Rovira et al. 2010).

Countries use external referencing in different ways. For example, the Slovak Republic sets its price cap at 10% above the average price in the three lowest-priced countries among those referenced. Switzerland is flexible in how the comparator prices are taken into account, disregarding outliers and bringing in alternative countries for consideration when few prices are available (OECD 2008). External benchmarking in Japan is used to adjust the price of a new drug if it differs significantly from the average of the drug's price in France, Germany, the United Kingdom and the United States. If the price of a new drug with no therapeutic comparators or a new drug with a significant therapeutic added-value over therapeutic comparators is three-quarters that of the average overseas price, the price will be increased. If, on the other hand, the price of a new drug, with or without therapeutic comparators, is found to be 1.5 times greater than the average overseas price, then the price will be lowered (Inajumi 2008).

C. Internal reference pricing

Internal reference pricing is a method that drugs are priced based on a comparison with similar existing medicines, most often generic drugs and, less commonly, therapeutic alternatives. At least four OECD countries (Canada, France, Japan and Switzerland) consider the prices of similar products already in the

market as a guide to pricing new products that have therapeutic comparators. Several OECD countries use internal reference pricing to regulate the price of generic entrants at the time of inclusion in the positive list. Through this practice, known as generic price linkage, the generic is priced at market entry at a discount by reference to the price of the original product (OECD 2008).

D. Value-based pricing

It is the price decisions based on benefits or effectiveness of new drugs over those currently available. Cost-effectiveness analysis and other methods of pharmaco-economic assessment (PEA) are used to compare the (incremental) cost of a medicine with its (incremental) potential benefit in terms of relevant health outcomes *(e.g.,* improvements in patient health or reductions in disability). Since the introduction of the systematic use of PEA in the reimbursement process in Australia in 1993, most OECD countries use PEA in their pricing and reimbursement decisions (Dickson, Hurst et al. 2003, Sorenson, Drummond et al. 2008). When therapeutic alternatives are available, incremental cost-effectiveness is usually used to make decisions as to whether the new product can be considered "worth" the additional cost. On the other hand, when no therapeutic alternative is available, an implicit or explicit definition of a cost-effectiveness threshold is required (Eichler, Kong et al. 2004).

E. Other pricing methods

Profit control: The United Kingdom uses indirect price control by limiting pharmaceutical companies' profits. Manufacturers are free to set the price at market entry but further increases are limited by the PPRS. If a company's rate of profit exceeds the authorized level, it must reduce the general price level of its

products to pay back excessive returns to the NHS, but it can decide on which products will see price adjustments (OECD 2008).

Cost-plus pricing: In some OECD countries, the reimbursement pricing scheme takes production costs into account to set or negotiate prices for certain pharmaceuticals – usually generic versions of original products. For example, Slovak Republic limits the ex-manufacturer price charged by producers based domestically (exclusively generic manufacturers). Spain uses a cost-plus approach, in which the ex-factory price of a listed drug is determined by production costs plus a standard rate of return set at 10 to 12% (OECD 2008).

Price-volume agreements: Purchasers may have price-volume agreements at a product level in order to obtain price reductions when volume increases. Given the low marginal cost of production, pharmaceutical firms may be willing to negotiate based on the total value of sales, rather than on a per-unit price basis. This prospectively offers lower-income countries a way to provide some access to medicines without potentially compromising the value of manufacturers' sales elsewhere, but there is a need to make sure that products are not diverted to other markets (OECD 2008).

3) Reimbursement (coverage decision)

Reimbursement is usually applied to prescription drugs as non-prescription drugs are seldom reimbursed. It may also depend on the indication, for which the drug is prescribed. In most countries, the list defining the drugs eligible for reimbursement is the first economic tool that public insurance uses to influence demand. Therefore, how the list is defined and updated is a crucial aspect of

pharmaceutical policy. Reimbursement in most countries is differentiated by type of drug, type of beneficiary or both (Jacobzone 2000).

4) Procurement & service delivery

Many low- and middle- income countries have been able to use competitive public procurement to achieve low prices for multi-source generic medicines. But in countries with decentralized health systems, competitive and transparent procurement of medicines by all local governments and individual health facilities is difficult because of their weak financial and procurement capacity and poor governance. For example, a study of pharmaceutical procurement by national and decentralized health facilities in the Philippines found higher average procurement prices at local municipality level than at province level and lowest average prices at national level (WHO/HAI 2011).

In addition, public purchasing is susceptible to corruption, and the purchasing cycle in the public sector is often fragmented and technically demanding, which results in delay and rigidity of purchasing. It is not unusual that it takes more than six months between a decision to purchase and the arrival of medicines in low income countries. To overcome these problems, many countries tried a few strategies such as changing the unit being purchased from a particular stock of medicines to a combination of technical advice, transaction management, and a series of medicines deliveries (Roberts and Reich, 2011).

Some low-income countries consider contracting out those functions because of the difficulty of creating reliable organizations with the necessary technical expertise within their civil services (ex. Zambia). Governments in low- and middle-

income countries have also sought ongoing relationships with an international NGO or government-sponsored suppliers in order to purchase from more reliable sources. Countries with the most limited expertise in international markets may have to rely on intermediaries to facilitate their purchasing activities. In particular, a tender board in low-income countries is not likely to know, or be in contact with, all the potential suppliers of various generic medicines to purchase (Roberts and Reich, 2011).

5) Cost containment strategies (mainly volume control)

Governments and insurers employ various measures to manage the volume and mix of pharmaceuticals consumption. Some of those policies are aimed towards physicians and pharmacists, and a few directly address patient demand.

A. Policies directed towards physicians

① Budgeting

Introducing prescribing budgets for doctors can be a strong economic incentive to change the prescribing behavior of physicians. For example, Germany introduced collective prescribing budgets in 1993 for all general practitioners to control rising drug expenditure. A collective penalty was applied if the budget was overspent. In the years after the introduction of the system, the number of prescriptions, as well as sickness funds' expenditure on medicines, decreased (OECD 2008). In the Slovak Republic, insurance companies also introduced soft budgets because physicians resisted hard budgets, but results show little to no effect on prescribing behavior. Physicians face a different budget target for each

insurer, which dilutes the importance of any of the individual budget targets (Kaló, Docteur et al. 2008).

② Clinical practice guideline (CPG)

CPGs are often developed by medical specialists as a guide to physician decision making. Within these guidelines, the overall management of a condition, including best prescribing practice, is proposed. In Mexico, the government produced 42 practice guidelines for common diseases, which are not directly aimed at prescribing patterns but emphasize the use of generics (Moïse and Docteur 2007a).

③ Other initiatives to influence physician prescribing

Practice profiling or benchmarking is used in many countries to assess performance of a provider in comparison with a panel of similar providers. Educational strategies, especially outreach by experts, and mechanisms involving visits and counselling, have proven to be most effective in terms of changing prescribing behaviour (Cantillon and Jones 1999, Grol and Grimshaw 2003).

B. Policies directed towards pharmacists (Generic substitution)

Many countries have tried to increase the use of generics by allowing pharmacists to substitute generic drugs for prescribed brand-name ones when the patient agrees and the physician does not object. In Hungary, pharmacists are obliged to propose generic substitution, and the proposed substitute must be the cheapest available generic, but the patient has the right to refuse the substitution (PPRI 2007a). Sweden took a step further by mandating substitution by

pharmacists of the lowest-cost substitutable product (generic or parallel import) unless a prescription is specified by a physician as "substitution not allowed". Germany also has mandatory substitution, except when expressly forbidden in writing by the prescribing physician, when the price differential between prescribed product and generic alternative exceeds a certain threshold (OECD 2008). The policy seems to have been effective in generating price competition in the off-patent market and in increasing the market share of generics as well as has reduced the average level of co-payments for prescribed medicines (Moïse and Docteur 2007b).

C. Policies directed towards patients (Cost-sharing)

The most commonly used approach to influence patient demand is the cost-sharing such as deductibles and co-payments. These are sometimes set at one level for all reimbursed products but are more commonly differentiated in order to avoid the reduced use of essential pharmaceuticals. For example, the Belgian social insurance system defines five categories of medicines, each with a different reimbursement rate. Those products considered "vital", such as treatments for cancer, are reimbursed at 100% of the price. Products considered "therapeutically important", such as antibiotics, are reimbursed at 75% (except for certain vulnerable patients who are eligible for an exceptional 85% reimbursement rate). Pharmaceuticals that are used to treat symptoms are reimbursed at a 50% rate (OECD 2008).

2. Pharmaceutical Policy in OECD countries

1) Financing mechanism

Most OECD countries provide coverage for basic health needs to (almost) all residents through a tax-funded national health system or mandatory SHI. As coverage for pharmaceutical care is included in the basic benefit package, people in OECD countries typically pay much less than half the cost of their pharmaceutical consumption (OECD 2010).

The public sector is the primary source of funding for pharmaceuticals and its funding represented on average 58% of total pharmaceutical expenditure across OECD countries in 2011. Nevertheless, it is lower than the share of public sector funding in total health expenditure, 72% in 2011. For example, as Table 12 shows, the private sector plays a bigger role in financing pharmaceutical expenditure than any other type of services in ten of seventeen countries (OECD 2008). In addition, the share of public spending in total health expenditure varies across OECD countries. Whereas public expenditure accounts for around 80% of pharmaceutical spending in Germany, Ireland, the Netherlands, Luxembourg and the United Kingdom, it represented less than 40% in Chile, Mexico, the United States, Canada and Poland (Figure 14).

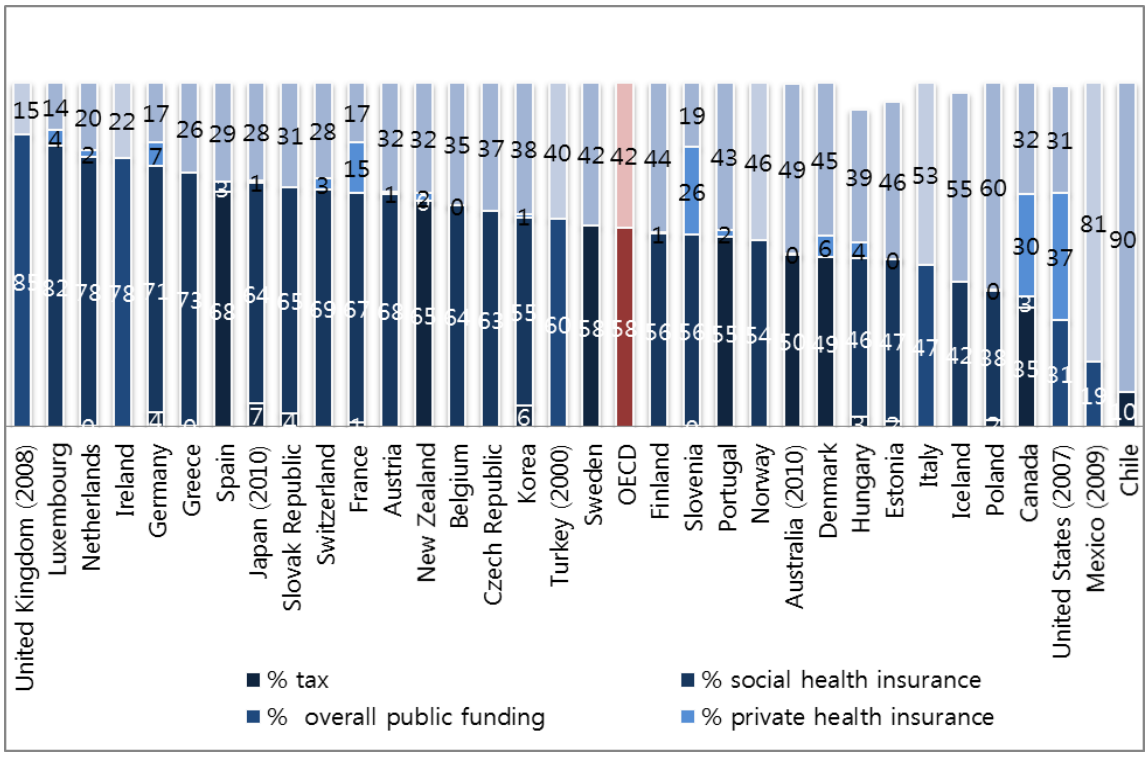
Table 12. Private sector and OOP expenditure as a percentage of total expenditure, by healthcare function, 2005

Healthcare function	In-patient curative and rehabilitative care		Out-patient curative and rehabilitative care		Services of long-term nursing care		Pharmaceutical and other medical non-durables		Total current expenditure	
Financing agent	OOP	Other private	OOP	Other private	OOP	Other private	OOP	Other private	OOP	Other private
Australia[1]	6%	19%	23%	10%	20%	0%	41%	1%	21%	11%
Canada	2	7	17	20	17	1	32	29	15	15
Czech Republic	2	1	10	0	n.a.	n.a.	24	0	11	1
Denmark	5	0	20	3	11	0	39	5	15	2
France	3	4	13	20	n.a.	n.a.	13	18	7	14
Germany	2	9	16	14	25	3	20	6	12	10
Japan[1]	5	4	19	1	8	5	30	0	16	3
Korea	25	10	46	6	19	8	49	0	40	5
Luxembourg	2	4	10	3	0	0	14	2	7	3
Netherlands[1]	5[2]	29[2]	(2)	(2)	0	7	26[3]	23[3]	8[4]	26[4]
Norway[1]	1	0	36	0	12	0	40	0	17	0
Poland	2	2	36	7	1	8	61	1	28	4
Portugal	n.a.	n.a.	n.a.	n.a.	46	1	39	4	23	5
Slovak Republic	1	0	36	0	n.a.	n.a.	26	0	24	1
Spain	3	6	33	11	22	0	27	0	22	7
Switzerland	5	14	43	8	57	3	30	3	31	10
United States	n.a.	n.a.	n.a.	n.a.	26	11	35	41	13	41

Note: Private financing includes all private sources of financing except out-of-pocket (OOP) payments.
n.a.: not available.
1. 2004 (2004/05 fiscal year for Australia).
2. There is no distinction between in-patient and out-patient curative and rehabilitative care.
3. Medical goods dispensed to out-patients.
4. Total current expenditure (does not include capital formation of health care provider institutions).
Source: 2006 and 2007 Joint OECD-Eurostat-WHO Health Accounts (SHA) Data Collection.

Source: re-cited from OECD (2008)

Figure 14. Pharmaceutical spending, by funding sources, 2011 or nearest year



Source: OECD health statistics 2013

Public sector finances much of outpatient pharmaceuticals in OECD countries except Italy, Iceland, Canada, Poland, the United States and Mexico. Particularly, in several countries, PHI plays a significant role; for example, PHI represented 20~30 % in the financing of outpatient medicines in the United States (30%), Canada (30%), Slovenia (26%) and France (17%) (OECD 2010). In addition, prescribed pharmaceuticals in outpatient sector are covered by multiple schemes, and benefits coverage varies across the schemes in Canada, Chile, Mexico and the United States (OECD 2010).

The role of PHI varies across countries. In Canada, whereas drugs in inpatient sector are fully covered through public scheme, prescription drugs in outpatient sector are covered through different schemes (OECD 2010); for example, about one-third of Canadian residents are covered by public programs, and PHI is the

main source of coverage for pharmaceuticals, covering more than the rest of the population and spending 30% of total pharmaceutical expenditure [1] (Paris and Docteur 2006). In the United States, people obtain drug coverage through employer-sponsored private plans, individually-purchased private plans, Medicare Part D plans (voluntary program for the elderly), Medicaid (for the poor) and so on (OECD 2010). In France, PHI only covers copayment from public insurance.

Table 13. Health systems characteristics and pharmaceutical coverage in several OECD countries

	Coverage for basic health needs and for pharmaceutical care
Australia	All residents are covered by the national health system Medicare, which includes the pharmaceutical Benefits Scheme (PBS). The PBS covers drugs dispensed in community pharmacies or in private hospitals, as well as some highly specialized drugs in public hospitals. States finance most medicines used in public hospitals.
Austria	All residents are covered by multiple insurers, which include pharmaceutical coverage.
Belgium	Almost all residents (99%) are covered by SHI, which includes coverage for pharmaceutical care.
Canada	All residents are covered by the national health system Medicare. Medicare covers pharmaceutical used in inpatient care, but not those used in outpatient care. Pharmaceutical coverage for outpatient care is obtained through PHI for about 2/3 of residents, and by public drug plans for the remaining 1/3. All residents over 65 years are covered by provincial plans as well as all residents in Manitoba and Saskatchewan once deductibles have been exceeded.
Chile	About 87% are covered by the National Health Fund (FONASA)(80%) or the private health system (ISAPRES) (17%), which includes pharmaceutical coverage but there is no publicly-funded insurance for prescription drugs.
Czech Republic	All residents are covered by multiple insurers, which include pharmaceutical coverage.
Denmark	All residents are covered by the national health system, which includes pharmaceutical coverage.
Estonia	About 93% are covered by mandatory health insurance and the others are covered by voluntary coverage, which include pharmaceutical coverage.
Finland	All residents are covered by local health services, which include pharmaceutical coverage.
France	All residents are covered by SHI, which includes pharmaceutical coverage.
Germany	All residents are covered either by SHI (89% of the population) or by PHI (11%). In both cases, the basic benefit package includes pharmaceuticals.
Greece	All residents are covered by multiple insurers, which include pharmaceutical coverage.
Hungary	All residents are covered by national health services, which include

[1] Publicly financed schemes operated by provinces and territories and the federal government provide coverage to only certain populations (seniors, social assistance beneficiaries, indigenous persons, veterans, etc.).

	pharmaceutical coverage.
Iceland	All residents are covered by national health services, which include pharmaceutical coverage.
Italy	All residents are covered by the national health system (Servizio Sanitario Nazionale, SSN), which includes pharmaceutical coverage. Prescription drugs are divided into three tiers according to clinical effectiveness and, in part, cost-effectiveness. The first tier is covered in all cases, but the second tier is covered only in hospitals, and the third is not covered.
Japan	Almost all residents are covered by SHI and the remaining (about 1%) by public assistance. Both include pharmaceutical coverage.
Korea	All residents are covered, either by national health insurance (97%) or by a tax-funded program (Medical Aid).
Luxembourg	Almost all residents (97%) are covered by SHI, which includes pharmaceutical coverage.
Mexico	More than half of the population is covered through labor-market based social security; around 45% by the Seguro Popular (a publicly-subsidized voluntary scheme targeting the poor population); 1% by voluntary private coverage. These schemes provide coverage for outpatient prescription drugs but the range of benefits covered is not uniform
Netherlands	All residents are covered by mandatory health insurance, which includes pharmaceutical coverage.
Norway	All residents are covered by national health insurance, which includes pharmaceutical coverage.
Poland	About 97% are covered by SHI, which includes pharmaceutical coverage.
Portugal	All residents are covered by national health services, which include pharmaceutical coverage.
Slovak Republic	About 95% are covered by multiple insurers, which include pharmaceutical coverage.
Slovenia	All residents are covered by social insurance system based on a single insurer, which includes pharmaceutical coverage.
Spain	Almost all residents (99%) are covered by the national health system and the remaining (about 1%) by private health coverage, which includes pharmaceutical coverage.
Sweden	All residents are covered by the national health system, which includes pharmaceutical coverage.
Switzerland	All residents are covered by “sickness funds” or commercial insurance companies, which includes pharmaceutical coverage.
Turkey	All residents are covered by SHI, which includes pharmaceutical coverage.
United Kingdom	All residents are covered by national health systems.
United States	No universal coverage (public program: 32%, private insurance: 53%)

Source: Albreht (2009); Knaul, González-Pier et al. (2012); Koppel (2008); Missoni and Solimano (2010); OECD/WHO (2011); OECD (2013); Paris and Belloni (2013); Paris, Devaux et al. (2010)

2) Pricing

In general, whereas the prices of OTC medicines, which is not included in the coverage of health insurance, are not regulated, the prices or reimbursement prices of out-patient prescription drugs covered by health insurance are subject to regulation (OECD 2010). There are however several exceptions; for example, the prices of all patented medicines are regulated in Canada and Mexico even if those are not covered by health insurance. Canada sets maximum ex-factory prices while Mexico regulates retail prices paid by patients without social insurance coverage (OECD 2010).

Manufacturers can freely set their prices at market entry for outpatient prescription drugs in Denmark, the United Kingdom and the United States.[2] However, there are other mechanisms to control price; for example, the coverage of a medicine is decided based on its price in Denmark (PPRI 2008, OECD 2010); companies should change the price of their products in the United Kingdom if their profit exceeds the annual cap imposed by the Pharmaceutical Pricing Regulation Scheme. In addition, price increases are subject to authorization and must be justified in the United Kingdom.[3] Furthermore, the National Institute for Health and

[2] In the United States, Prices of drugs purchased by federal authorities or Medicaid program are regulated (OECD 2010). Germany allowed manufacturers set their prices but implemented a regulation for maximum reimbursement prices in 2011 (Paris and Belloni 2013)

[3] In the United Kingdom, the government and the industry have agreed on the principle of "flexible pricing" so that companies are able to increase the price of their products after market entry if new evidence has been produced about the benefits of their drug (OECD 2010).

Clinical Excellence (NICE) decides whether the NHS cover the medicine, based on the cost effectiveness of medicines, budget impact, etc. (OECD 2010).

A. External price benchmarking (international benchmarking)

Most OECD countries except Sweden and UK employ international benchmarking (OECD 2010). In Japan, external benchmarking is used to adjust the price of any new drug (Inajumi 2008, Docteur and Paris 2009). In Canada, the federal Patented Medicine Prices Review Board (PMPRB) uses international benchmarking to ensure that the prices of patented medicines are not excessive (regardless of reimbursement) and set the manufacturer's maximum selling price (Paris and Belloni 2013).

Generally, the price level is set as a function of the average price in the benchmarked countries. Mexico refers to the prices paid in the six countries with the highest market share for the product considered (OECD 2010). Greece recently implemented international benchmarking, and the three lowest prices in the European Union are used as benchmark for price (OECD 2010). In Switzerland, the prices of reimbursed medicines were re-examined referring to the prices periodically in six countries (Austria, Denmark, France, Germany, the Netherlands and the United Kingdom) (OECD 2010). Although the introduction of external price benchmarking might be expected to achieve cost-containment, the impacts are not consistent across countries (Docteur and Paris 2009, Carone, Schwierz et al. 2012).

B. Internal (or therapeutic) reference pricing

Internal reference pricing decides drug costs based on therapeutic comparators. Reference price policies have been adopted in OECD countries except Austria, Luxembourg, Sweden and the United Kingdom (Docteur and Paris 2009, OECD 2010). A few countries such as Canada, Belgium, France, Italy, Japan and Switzerland use internal reference pricing for non-innovative drugs (Docteur and Paris 2009, OECD 2010).

A reference price is set for all drugs within a cluster, which is generally defined based on bioequivalent, pharmacologically equivalent or therapeutically equivalent products. For example, Belgium, Denmark, Finland, France, Portugal and Spain defined clusters of bioequivalent products (with the same active ingredients or combination of active ingredients, administered in the same way, ATC (Anatomical Therapeutic Chemical)-5 level) (OECD 2010). Countries including Australia, the Netherlands and New Zealand define clusters of pharmacologically equivalent products although they are chemically different active ingredients (ATC-4). Countries sometimes define wider groups with pharmacological difference, but therapeutic equivalence (ATC-3). Countries such as Canada, Germany, Hungary and Czech Republic set clusters based on various levels (GaBI online 2011). When comparable products are not available, clusters are defined more broadly in the Netherlands and Germany (Carone, Schwierz et al. 2012).

Different methods are used to calculate the reference price across OECD countries with therapeutic reference pricing. The price is set based on the lowest price within the cluster in several countries such as Australia, Czech Republic,

France, Hungary and Italy, the average of lowest several prices in Denmark, Portugal and Spain, the average price in the Netherlands, and by a regression model using prices of drugs within a cluster in Germany (Carone, Schwierz et al. 2012, GaBI online 2011).

Generic price linkage is a specific form of internal reference pricing; the generic is priced at a rate of original drug price. For instance, generic drugs must be priced at least 50% below the price of the off-patent originator in France, and at least 30% below in Switzerland (Docteur and Paris 2009). In Greece that recently implemented a stepped-price model, generic prices were set at 90% of the original medicines prices (OECD 2010, Vogler, Zimmermann et al. 2011).

C. Price review and adjustment

In 2007, Australia implemented "price disclosure"; the weighted average disclosed price (WADP) is regularly computed for drugs subsidized by the Pharmaceutical Benefits Scheme (PBS); if the gap between the current PBS ex-factory price and the WADP is 10% or more, the PBS price would be adjusted to the new calculated price. In Japan, the drug prices are regularly investigated by the government and adjusted closer to actual market prices (OECD 2010). In Greece, dynamic pricing was applied after market entry. The frequency of price reviews followed by price cuts increased from one to three times a year for medicines having entered the market during the past four years (OECD 2010, Vogler, Zimmermann et al. 2011).

Table 14. Regulation of prices or reimbursement prices of medicines in OECD countries

Country	price regulation	ERP	IRP
Australia	Maximum ex-factory price is set for listed medicines.	-	0
Austria	All covered medicines	0	-
Belgium	Maximum ex-factory price is set for listed medicines.	0	0
Canada	At Federal level: Maximum ex-factory price for all patented Medicines. Provinces and Territories level: Maximum prices set for drugs covered by public drug plans.	0	0
Czech republic	Maximum reimbursement price is set for listed medicines.	0	0
Denmark	No price regulation at market entry, but periodically price cap agreements between the MOH and the association of pharmaceutical companies.	0	0
Finland	All covered medicines	0	0
France	Maximum statutory price for medicines listed for outpatient care and for a list of expensive hospital medicines, set at the time of listing	0	0
Germany	Since 2011: Statutory price negotiated after market entry	0	0
Greece	All covered medicines	0	-
Hungary	Maximum reimbursement price is set for listed medicines.	0	0
Iceland	Maximum reimbursement price is set for listed medicines.	0	
Ireland	All covered medicines.	0	-
Italy	Maximum statutory ex-factory price for outpatient reimbursed medicines and for expensive hospital medicines, set at the time of listing.	*	0
Japan	Reimbursement price for medicines included in the positive list.	0	0
Korea	Maximum reimbursement price for listed medicines.	*	-
Luxembourg	(drugs imported at prices set in other countries)	0	-
Mexico	All patented medicines	0	
Netherlands	Maximum wholesale price for outpatient prescription-only medicines (listed or not) and expensive hospital drugs.	0	0
New Zealand	All covered medicines. Maximum reimbursement price is set for some clusters of products	†	0
Norway	Maximum pharmacy purchase price set for all prescription- only medicines, at the time of market entry	0	0
Poland	All covered medicines. Maximum reimbursement price is set for some clusters of products	0	0
Portugal	Maximum reimbursement price is set for some clusters of products	0	0
Slovak republic	All covered medicines. Maximum reimbursement price is set for some clusters of products	0	0
Spain	Maximum ex-factory prices for reimbursed medicines	0	0
Sweden	In order to be reimbursed, the manufacturer must propose a price at which the drug will be considered cost-effective. Purchase and retail prices are regulated.	-	-
Switzerland	All covered medicines	0	0

Turkey	All medicines. Maximum reimbursement price is set for some clusters of products	0	0
United Kingdom	No direct price control, but possible price agreement following NICE negative recommendation based on economic assessment.	-	-

Note: ERP: external reference pricing; IRP: internal reference pricing; * as a supportive tool; †informal
Source: Carone, Schwierz et al. (2012); Leopold, Vogler et al. (2012); Paris and Belloni (2013); Paris, Devaux et al. (2010)

3) Reimbursement and benefit package

A. Centralized and decentralized decision

In all countries other than Canada and the United Kingdom, the pharmaceutical benefit is defined at the central level. In Canada, each drug plan designs its own benefit package for prescribed medicines through drug formularies. The United Kingdom, England and Scotland define the covered benefit package for pharmaceuticals (OECD 2010, Paris and Belloni 2013). In countries with decentralized system in the sectors other than pharmaceuticals, such as Australia, Italy, Spain and Sweden, the benefit package is generally defined at the central level and is mostly identical or similar. In addition, autonomous communities can offer additional benefits in Spain (Paris and Belloni 2013).

In Germany and the Netherlands, where competing insurers are allowed to deviate from the centrally defined benefit package, health insurance are required to cover all active substances in the pharmaceutical benefit package, but not necessarily all products. In addition, they can cover drugs that are not included in the national benefit basket (Paris and Belloni 2013). In Mexico with pluralistic system of coverage, whereas positive list is defined for public institutions at the central level, public providers are not obliged to purchase all medications included in this list and usually design their own formularies (Paris, Devaux et al. 2010).

B. Negative and positive list

OECD countries establish a list of drugs funded by public scheme in positive list and/or negative list. Positive list defines the list of medicines eligible for reimbursement, and negative list does medicines excluded. Public schemes in most OECD countries employ positive list defined at the central level; for example, whereas provincial and federal drug plans cover medication with positive list, private insurers established negative list in Canada (Paris, Devaux et al. 2010).

Several countries have both lists. The Czech Republic, the Slovak Republic and Iceland establish both positive and negative lists at the central level. On the other hand, Greece had been the only country with no positive or negative lists for pharmaceuticals but implemented positive list and negative list in 2010 (Paris, Devaux et al. 2010, Vogler, Zimmermann et al. 2011). Unlike most OECD countries, medicines are covered based on negative list in Germany and the United Kingdom (OECD 2010). That is, every product marketed is covered by default unless it belongs to the list of medicines excluded from reimbursement by law or policy.

Table 15. Definition of the health benefit basket

Country	Definition of the benefit basket for medical procedures:						Definition of the benefit basket for pharmaceuticals:					
	A positive list is established at the central level	A negative list is established at the central level	Individual health insurance funds establish their own positive lists	Individual health insurance funds establish their own negative lists	Constraints established their own positive lists at the local level	The benefit basket is not defined	A positive list is established at the central level	A negative list is established at the central level	Individual health insurance funds establish their own positive lists	Individual health insurance funds establish their own negative lists	Constraints established their own positive lists at the local level	The benefit basket is not defined
Australia	X						X					
Austria						X	X					
Belgium	X						X					
Canada						X			X			
Czech Republic		X					X	X				
Denmark						X	X					
Finland						X	X					
France	X						X					
Germany		X						X				
Greece			X				X	X				
Hungary						X	X					
Iceland						X	X	X				X
Ireland						X	X					
Italy	X						X					
Japan	X						X					
Korea	X						X					
Luxembourg	X						X					
Mexico	X					X	X		X			
Netherlands	X						X					
New Zealand						X	X					
Norway						X	X					
Poland	X						X					
Portugal						X	X					
Slovak Republic	X						X	X				
Spain	X						X					
Sweden						X	X					
Switzerland		X					X					
Turkey						X	X					
United Kingdom		X						X				

Source: Paris and Belloni (2013); Paris, Devaux et al. (2010)

C. Criteria for positive and negative list

Reimbursements are decided based on pre-defined criteria if products obtain a marketing authorization. Under positive list, new drugs (or new indications of existing products) that apply for reimbursement status are assessed systematically before market entry. Although most OECD countries take into account pharmaco-economic assessment (PEA) to determine reimbursement status, only several countries such as Australia, the Netherlands, New Zealand and Sweden employ it systematically for all products applying for the reimbursement (OECD 2010).

Negative list is likely to encourage the rapid adoption of new technologies and lead to high health care spending compared to positive list. In the United Kingdom and Germany employing negative list, budget impact are considered and PEA are used. For example, reimbursement for products with high costs, high budget impact and/or a high level of uncertain effectiveness are decided based on PEA in the United Kingdom. In Germany, although products with new therapeutic value enter the market at manufacturers' prices, they are assessed three months after market entry (Paris and Belloni 2013).

PEA was implemented recently in France and Germany. From October 2013, newly launched innovative drugs are required to undergo an economic assessment in France (Furet, Marinoni et al. 2013). In January 2011, Germany introduced an early benefit assessment for new chemical entities, and the methodology is currently in its discussion phase (Riedel, Repschlager et al. 2013). Korea recently introduced PEA in the decision for positive listing (OECD 2010). In addition, cost-effectiveness studies are sometimes used in Italy and Spain to inform price

negotiations (Paris and Belloni 2013).

D. Cost sharing

Drug coverage schemes in most OECD countries require prescription fees, co-insurance rates or/and deductibles for medicines. In general, national regulations define the benefits covered (or excluded) and the level of cost sharing regardless of a single or multiple payers in most OECD countries (Docteur and Paris 2009).

In the majority of OECD countries, outpatient pharmaceuticals are mostly included in the standard benefit package of public schemes. However, six countries such as Canada, Chile, Estonia, Israel, Mexico and the United States, do not provide publicly funded prescription drug coverage for all citizens. In Chile, there is no publicly-funded prescription drug scheme. Seguro Popular in Mexico covers the poor who are unable to get private insurance. Medicare part D in the United States is available to US citizens aged 65 or over, and those with disability or with end-stage renal disease on dialysis under the age of 65 are also eligible. In Canada and Israel, the type of drug schemes depends on regions or health funds. Although there are a variety of prescription drug insurances across age and employment status in Estonia, it covers around 95% of the population (Barnieh, Clement et al. 2014). In Ireland, the government pays for approximately 80% of all medicines; there are 4 principal schemes, which determine whether people get free or subsidized medicines (PPRI 2007b).[4] In the United Kingdom, England and Scotland have

[4] · General Medical Services Scheme (GMS and known as medical cards) provides free of charge medication to people who have low affordability, including elderly aged 70 years and over.

· Drug Payment Scheme (DPS) is for ordinarily residents and can require patients to pay a maximum of €85/month for medicines for themselves or their families. People must register to get benefit under this scheme.

different systems for prescription drug coverage: e.g., copayment system exists in England but not in Scotland (Barnieh, Clement et al. 2014). In addition, cost-sharing levels differ according to regions in Italy (OECD 2008).

Pharmaceutical coverage generally entails user charges although the payment is waved for some parts of the population and categories of drugs (OECD 2010). Some OECD countries (such as Belgium, Czech Republic, Denmark, England, Estonia, Greece, Finland, Hungary, Ireland, Italy, Luxembourg, New Zealand, Norway, Poland, Slovenia, South Korea, Spain, and Turkey) reduce or waive copayments for those with certain conditions like chronic diseases (Barnieh, Clement et al. 2014). For example, those certified as having one of several designated long-term illnesses are exempt from cost-sharing requirements for covered medicines in Ireland (PPRI 2007b).

In several OECD countries, copayments vary depending on the type of drug or its indication. For example, copayment depends on the essential nature of the medicine or class of medications in Portugal; there are no copayments for insulin in Greece and Sweden. In Iceland and Slovakia, all pharmaceuticals deemed vital by the scheme are fully reimbursed (Barnieh, Clement et al. 2014). In the Slovak Republic, coinsurance rates in social insurance vary depending on different categories of products, ranging from 0% to 20% (Kaló, Docteur et al. 2008). In Belgium, coinsurance rate varies by type of drug, including 0% for vital pharmaceuticals but 80% for contraceptive medicines. In France, 35-, 70- or 85-

· Long Term Illness Scheme (LTI) provides necessary medicines to patients with specific conditions (e.g. diabetes, epilepsy) free of charge irrespective of their income.

· Hi-Tech Medicinal Products (HTMP) Scheme provides high-tech medicines such as anti-rejection drugs for transplant patients and chemotherapy. A charge depends on schemes that patients are enrolled in (PPRI 2007b).

percent coinsurance rates are applied depending on drug categories with fixed copayment, whereas some drugs are reimbursed fully (Paris and Belloni 2013).

Copayments vary by socio-economic status, either income or employment status, or with age in some countries such as Australia, Belgium, Czech Republic, England, Estonia, Greece, Hungary, Italy, Japan, New Zealand, Norway, Slovenia, South Korea, Spain, and Turkey (Barnieh, Clement et al. 2014). In addition, co-insurance rate decreases in Norway and Sweden as cumulative spending of patients increases (Paris and Belloni 2013). Patients have to pay a deductible before getting any reimbursement in several countries; for example, this deductible only applies to pharmaceutical spending in Denmark and Sweden, but to all health care services in the Netherlands (Paris and Belloni 2013, Barnieh, Clement et al. 2014). In the Netherlands, there is no copayment or reimbursement until annual expense reaches 170 euros. In Denmark and Sweden, the copayment percentage decreases throughout the year based on consumption. In addition, Medicare part D in USA has deductible, which varies according to plan and income (Barnieh, Clement et al. 2014).

In Australia, Austria, Czech Republic, Italy, England New Zealand, patients pay a fixed charge for prescription drug (Paris and Belloni 2013, Barnieh, Clement et al. 2014). For example, patients pay € 4.7 as the prescription fee for medicines reimbursed by the social insurance scheme, without any other percentage co-payment and deductibles in Austria (Leopold and Habl 2008). In Denmark, Estonia, France, Germany, Norway, Poland and Slovakia, both fixed and percentage copayments were employed (Barnieh, Clement et al. 2014). In Canada, the nature and extent of co-payments vary widely across drug plans (Paris and Belloni 2013). In addition to these copayments, a few OECD countries implemented a therapeutic

reference pricing, in which patients should pay any difference between the reference price and the retail price of the drug (Barnieh, Clement et al. 2014).

E. Product-specific reimbursement and pricing agreements

In several OECD countries, payers and pharmaceutical companies have developed product-specific pricing agreements on medicines with high costs or high budget impact. OECD countries, except Denmark, Norway and Spain, use product-specific agreements (Paris and Belloni 2013). These agreements include extracting a part of the revenue for medicine's sale beyond an agreed level or cut its price, limiting the amount of public funding, and sharing the risks of uncertain benefits (OECD 2010).

Volume-price agreements require companies to pay back the share of revenue to payer (or insurer) or decrease the price of their product depending on the agreement, which links the unit price of a product to volumes sold (OECD 2010). In several OECD countries such as France, Australia, Italy and Belgium, these agreements are signed between public payer and pharmaceutical company. These agreements usually take the form of confidential discounts or rebates although agreements are sometimes public in Italy (Paris and Belloni 2013).

Agreements to limit budget impact aims to prevent public payers from spending more than a fixed amount per patient. Public payers spend certain amount of cost while companies cover fully the rest of the cost. In several countries such as UK and Sweden, this agreements are employed for several medicines (Paris and Belloni 2013).

Risk-sharing agreements are signed when medicine's benefit claimed by company is uncertain. Payer (or insurer) agrees to pay for the new treatment but will ask the company to refund if claimed benefits fail to appear (OECD 2010). In England, France and Italy, these agreements have been signed between the public payer and manufacturers (OECD 2010).

Coverage with evidence development schemes has been adopted in Italy, the United Kingdom, the United States, Sweden and Australia (Carlson, Sullivan et al. 2010). These schemes are adopted to improve knowledge about product's impact on health when there is a high level of uncertainty in the clinical evidence produced by the manufacturer. For example, CED schemes provide coverage only for patients included in clinical trials in the UK, and this agreement is used to identify the long-term effect of a medicine in Sweden (OECD 2010).

4) Quality assurance of medicine use

Drug utilization review (DUR) is a quality assurance program based on the need for review and control of the prescribing and utilization of drugs. It involves a comprehensive review of patients' prescription and medication data before, during and after dispensing, to ensure the appropriate and effective use of medications (Wertheimer 1988).

In the US and Sweden, DUR program has been developed mainly in outpatient sector such as pharmacy. In the US, prospective and retrospective DUR are conducted for Medicare patients. All pharmacies are required to perform prospective DUR based on electronic system, and problems involving drug choice, dosing and drug interaction are monitored. Prospective and retrospective

medication reviews are also conducted whenever an outpatient prescription is dispensed to a Medicaid recipient (Navarro 2008). In Sweden, DUR program was implemented in 2010 at the national level. Information on the appropriate use of drugs based on patient's medical history is provided to the pharmacist. In Canada, DUR programs are performed based on "Pharmacy Network", which provides information on the appropriate use of medicines to pharmacy almost instantly. The programs vary from state to state (Kim et al. 2010). In European and Scandinavian countries, a sort of retrospective DURs have been performed, which compare medicine consumption across regions or countries. In addition, prescribing indicators and training programs have been developed to change physicians' prescription behavior in these countries (Choi and Park 2010).

5) cost containment

A. Toward physicians

Prescribing behavior

Most OECD countries enforce guideline-based prescribing to improve quality and performance of prescribing. Physician prescriptions are monitored in more than half of the countries, including Austria, Finland, Japan and South Korea, and in several of these countries, the patterns and volume of physician prescribing were compared to others (Austria, Belgium, Denmark, England, Estonia, Finland, Hungary, and Slovenia). Incentives such as rewards and/or sanctions for over-prescribing are used in several countries (Austria, Belgium, England, Luxembourg and Spain) (Barnieh, Clement et al. 2014). For example, if physician's prescription patterns are seriously different from others', they may be forced to pay back the

difference in Austria, although it is very rare (Leopold and Habl 2008). In Belgium, agreements are signed based on consensus between some insurers and doctors, which require insurers to pay bonus to doctors or doctors to pay a fine (Barnieh, Clement et al. 2014).

Generic prescription

Allowing physicians to prescribe medicines with International Non-proprietary Names (INN) aims to promote the use of the cheapest medicine with the same active ingredient (Carone, Schwierz et al. 2012). In the United Kingdom, prescribing in INN is high at 79% of all prescribed medicines compared to other OECD countries, which may be affected by several measures, including medical school teaching and the use of computer software suggesting generic alternatives to branded medicines (Barnieh, Clement et al. 2014). In France, primary care doctors may make an agreement voluntarily with public payer, which links bonus and penalty to targets such as the share of generic prescription (Carone, Schwierz et al. 2012). Physicians may also be required to follow prescription quotas, asking them to prescribe a certain share of cheap pharmaceuticals in several countries, including Belgium, Germany, Spain and Slovak Republic (Carone, Schwierz et al. 2012).

B. Towards pharmacists

Pharmaceutical companies often offer discounts or rebates to pharmacists. Countries such as the UK and the Netherlands have introduced 'claw back' systems to pull back these discounts to third party payers (Rietveld and Haaijer-Ruskamp 2002). The design of mark-ups for distributors of pharmaceuticals may also affect dispensing behavior. Pharmacists' mark-ups, which can be linear, regressive, a

fixed-fee (Netherlands) or fee-for-service (UK), are regulated by law (Carone, Schwierz et al. 2012).

Whereas prescription in INN or generic substitution is not allowed in pharmacies in Greece, it is mandatory for pharmacists to substitute generics in Denmark and Sweden. However, this does not seem to be a necessary condition to ensure the high use of generics as generics have high market shares in several countries without mandatory substitution, including Poland and the United Kingdom (OECD 2010). As pharmacists' margins are set in relation to the price of medicines and therefore may be higher (in absolute terms) for more expensive products, pharmacists are less willing to substitute a generic for a more expensive drug. In Switzerland, pharmacists receive a fee for generic substitution. In several countries such as Hungary, Norway and Poland, pharmacists have the obligation to inform patients about the possibility of a cheaper alternative, which acts as a non-financial mechanism to encourage generic substitution (OECD 2010).

C. Toward manufacturers

Manufacturers should pay back a part of their revenue in several countries if a pre-specified budget ceiling is exceeded. For example, in France, parliament decides target increase, "k-rates", for each category of expenditure every year by voting. When the increase in pharmaceutical expenditure exceeds the k-rate, the manufacturer must pay back a certain amount via a rebate scheme (Sauvage 2008). Italy negotiates individual caps for each pharmaceutical company on revenues drawn from NHS sales (OECD 2010). In the UK, the profit of pharmaceutical companies is set through a negotiation between the Department of Health (DOH) and the Association of the British Pharmaceutical Industry; although companies

within the scheme are free to set their market entry prices, if profits exceed specified levels, companies should return the excess or reduce prices (UK Government Department of Health 2012).

Tendering can be considered as a specific type of volume-price agreement as manufacturers set their bidding price depending on a specified volume of sales. A tendering procedure is often used in case of public procurement such as public hospitals and financing schemes (Nguyen, Knight et al. 2014). For example, in New Zealand, an international competitive tendering system is used for prescription medicines that are distributed through private-sector pharmaceutical supply chains but financed publicly (Hawkins 2011). Currently, the Netherlands and Germany are known to use public tendering (Carone, Schwierz et al. 2012).

D. Toward patients

Incentives for patients depend on OOP payments. Patients have a financial incentive to choose cheaper drugs when the co-payment is a percentage of the price. Some countries have supplemented existing incentives to encourage the use of generic medicines. For instance, the co-insurance rate for brand-name drugs when cheaper generics are available increased from 10 to 20% in Switzerland in 2006. Patients had to pay in advance for their drugs and be reimbursed later when they refuse generic substitution in France in 2008 (OECD 2010).

Table 16. Policies to promote the use of generic drugs

Countries	Prescription in INN			Generic substitution		
	Not allowed	Allowed	Mandatory	Not allowed	Allowed	Mandatory
Australia		X			X	
Austria	X			X		
Belgium			X[1]		X[1]	
Canada[2]		X	X		X	X
Chile			X[3]		X	
Czech Republic	X				X	
Denmark	X					X
Finland		X				X
France		X			X	
Germany		X				X
Greece	X[4]					X[4]
Hungary		X			X	
Iceland					X	
Ireland		X			X[5]	
Italy		X			X	
Japan		X			X	
Korea		X			X	
Luxembourg		X		X		
Mexico			X		X	
Netherlands		X			X	
New Zealand		X			X[6]	
Norway		X			X	
Poland		X			X	
Portugal			X			X[7]
Slovak Republic		X				X
Spain		X				X [8]
Sweden		X				X
Switzerland		X			X	
Turkey	X				X	
United Kingdom		X		X		
United States[9]						

Notes: 1. To be implemented; Antonissen (2012)
2. In Canada, the regulation of prescription and generic substitution differ across provinces and territories.
3. Only in the public sector.
4. To be implemented; Meick (2012)
5. To be implemented.
6. If the pharmacist has a substitution arrangement with the prescriber
7. GaBI online (2013)

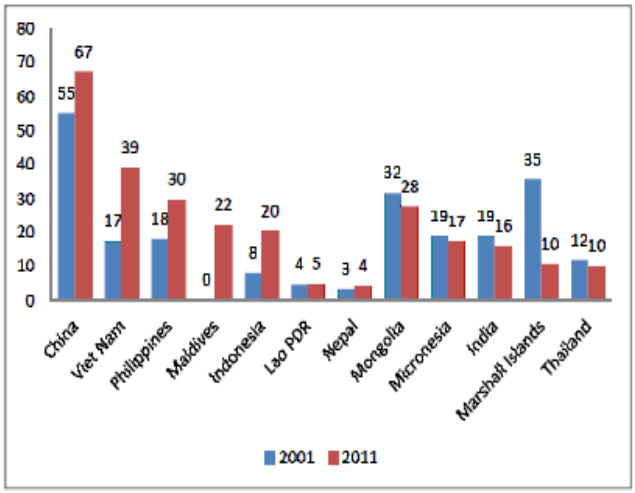
8. Rada (2011)
9. Legislation on prescription in INN and substitution is not uniform across states.
Source: various sources identified by footnotes and OECD (2010)

3. Pharmaceutical Policy in Non-OECD Asia-pacific countries

1) Financing mechanism

In the Asia-Pacific region, most low- and middle-income countries rely mainly on tax-financing, and some middle income countries have SHI element. The funding from taxation and private sector (direct payment by households) are relatively larger in the AP region than global averages. Even though the SHI share of government health spending remains smaller in the Asia-Pacific region than the average of international middle or high income countries, the SHI funding has been expanded in the Asia-Pacific middle income countries from 2001 to 2011 (Whitaker 2013). Government subsidies for the poor or informal sector workers can be effective in the extension of coverage in the Asia-Pacific region (Kwon 2011).

Figure 15. Share of government health spending via social insurance



Source: WHO NHA data. Note that SHI expenditure may be rising in absolute terms even as it declines as share of government spending, and that national classifications of funding may differ.

Public health care financing can best be analysed by looking at three elements: the risk pools involved; benefit packages offered; and the purchase of care. Decentralization is also relevant in the regional context (see Box 1).

Source: Whitaker (2013)

Examples of financing mechanisms for the pharmaceutical sector in Asia-Pacific region

Here are some examples of financing for the pharmaceutical sector in the Asia-pacific region. The countries can be categorized into tax-based system (e.g., Nepal, Fiji, Malaysia) and social insurance based system (e.g., China, Philippines), and using revolving drugs funds (e.g., Lao PDR) for financing pharmaceuticals.

In Nepal, under the National Free Healthcare Services Programme, services are provided free of charge to citizens although the type/extent of services covered may not be sufficient. There are 321 medicines in National List of Essential Medicines, and 22 to 45 medicines of different dosage forms are listed for free health care at various health facilities levels (WHO/Nepal MOH 2011). All public

health facilities are subsidized by government, using general tax revenue, particularly to provide health services for the poor (HSRSP 2010). Therefore, copayments or fees for medicines are not imposed but paid by government. Revenue from the sales of medicines is not used for paying the salaries or the income supplement of public health personnel in the same facility (WHO/ Nepal MOH 2011)

In Fiji, provision of health care in the public sector is free or at very low cost for all citizens, and therefore, all pharmaceuticals provided in public health facilities are free (WHO 2011a). Public health system provide free medicines for particular conditions, such as malaria, tuberculosis, sexually transmitted diseases, HIV-related disease, and Expanded Program on Immunization (EPI) vaccines for children (WHO/Fiji MOH 2013). Revenue from the sales of medicines is not used for paying the salaries or the income supplement of public health personnel in the same facility, like Nepal (WHO/Fiji MOH 2013). Private providers charge higher user fees than the public facilities, and the fees are not regulated by the government (WHO 2011a).

In Malaysia, main sources of health expenditure consisted of the Ministry of Health (MOH) (46%) and household OOP expenditure (34%) in 2009. Even though public sector health services are offered to the whole population, consultations and medicines are paid by OOP payment (WHO 2012). Due to high mark-ups by dispensing doctors and private retail pharmacies, people had to pay high amount of OOP payment (e.g., about an average of one week's wages for peptic ulcers) to purchase medicines (Babar, Ibrahim et al. 2007).

In Cambodia, there are three sources of health financing: (i) the government health budget, (ii) aid from donors and other health partners and (iii) OOP pay by

households. The country has a low level of public funding (less than 40%) for the health service delivery, high dependence on donor funding for health care (reaching US$ 103 million or US$7 per capita per year in 2007), and high level of OOP household spending (67% of THE in 2005). It is reported that OOP payments are caused by the direct purchase of medicines from pharmacies and drug sellers, user fees to public and private providers, and payments to government staff working privately (CDPHI and WHO 2008).

In Thailand, there are three main public schemes: the Universal Coverage Scheme (UCS), the Social Security Scheme (SSS), and the Civil Servant Medical Benefit Scheme (CSMBS). In UCS, pharmaceutical benefit in the National List of Essential Drugs (NLED) is fully covered in capitation fee for ambulatory care and in case base payment for inpatient services (Hanvoravongchai 2013). In SHI, drug benefit is based on National ED list, and payment for medicines is included in the inclusive capitation for ambulatory and inpatient services. In CSMBS, drug benefit is also based on National ED list, and fee for services is applied for drugs in ambulatory care, and Diagnosis-Related Group (DRG) based payment to inpatient care.

In China, through the health care reform since 2009, the coverage of basic health insurance and the availability of benefit package expanded to reduce OOP health expenditure. According to the summary of activities under the National Health Care Reform of 2009–2011 and directions for 2012, essential medicines list (EML) for primary level care was issued at central and provincial levels. All government–run primary care facilities in urban and rural areas provide essential medicines at cost (zero profit/mark–up), and the zero mark-up will be expanded to village clinics, non–government run primary care facilities, and pilot county hospitals. In 2012, there was a comprehensive financing reform to replace earnings

from medicines sales with funding for operating costs in government–run primary care facilities. One of the main activities is provider payment reform, such as DRGs and case based payments, clinical pathways, setting fixed prescription fees, and establishing independent pharmaceutical distribution networks (Barber, Huang et al. 2013).

In the Philippines, public insurer (PhilHealth) provides coverage for the Philippine National Drug Formulary (PNDF) for inpatients, but not for outpatients (WHO 2011b, WHO/Philippines MOH 2012). In 2007, the reimbursements by PhilHealth for medicines were 32%, and these were mostly for inpatient benefits. The reimbursements for medicines by PhilHealth comprised about 5% of the total national medicines expenditure (Thatte, Hussain et al. 2009). There is a cap schedule for inpatient medicines: the range of cap is from case A, which is 2,700 Philippines Peso for a primary hospital, up to case D, which is 40,000 Philippines Peso for a tertiary hospital. OOP payment is charged if the fee is above the cap (WHO/Philippines MOH 2012). Until recently, OOP payment for drugs is very high, accounting for almost 70% of total household OOP payments (WHO 2011b). The revenue from medicines sales can be used for paying the salaries of public health personnel or income supplement in the same facility (WHO/Philippines MOH 2012).

In India, there is a paradox in the pharmaceutical system. India is the third largest medicines producer in the world by volume, but at the same time, the country also has more than 650 million people without access to essential medicines. Heavy reliance on OOP payment is one of the main causes of the problem. Public expenditure on health care is low (25% of THE), and more than 75% of OOP health care expense is used to purchase medicines. Moreover, more than 80% of medicines (in volume) is consumed in retail sales (APCNMP 2013).

In Lao PDR, Revolving drug funds (RDFs) were established in 1997, based on the Decree No. 230. RDFs charged drugs at cost plus 25%, and the government awarded license to private pharmacies to improve the availability of essential medicines at the primary health care level (WHO 2014a). RDFs is operated as follows: the initial capital investment and operational costs are covered by government or donor funding. Then drug supplies are replenished by collecting monies from the sales of drugs (Ali 2009). As the mark-up (e.g., 40%) is used to cover overhead costs, drug prices vary widely and medicines expenditure became one of the major burden on households (WHO 2014a). At the SHI level, inpatient medicines (mostly generic medicines) are covered, but its population coverage is very limited.

In Indonesia, there are several social insurance schemes: Askeskin/Jamkesmas for the poor and near poor; Askes, which is compulsory SHI for civil servants and their dependents, civil service retirees, and military; Jamsostek as a compulsory SHI for private formal sector employees and their dependents; Jamkesda, which is 242 district local governments-running insurance (Rokx 2009, Holloway 2011). Pharmaceutical expenditure accounts for over one-third of total health expenditure (Hawkins 2008). OOP payment is a main component of pharmaceutical spending, and most private purchases are for high-price branded generics or some innovator originators. Almost half of essential medicines for public primary care come from the central government budget, and district spending varies widely. For budget allocation purposes, MOH advocates that primary care essential medicines should meet the WHO indicative target (US$2 per capita per year) (Rokx 2009).

In Vietnam, the list of reimbursement drugs covered by the SHI is issued by the MOH (Tien, Phuong et al. 2011). The drug list for health insurance members

consisted of 750 medicines and 237 traditional herbal medicines, and 54 drugs for children have been added to the list (Tien, Phuong et al. 2011). Despite the SHI reimbursement drug list, there are high OOP payments for medicines, and insured patients have to buy many of their drugs in private pharmacies because hospitals frequently suffer from temporary shortages of drugs (Tien, Phuong et al. 2011).

Implications of financing mechanisms of non-OECD countries in the Asia-Pacific region

In non-OECD countries from the Asia and Pacific region, OOP payment is the major source of financing in the pharmaceutical sector. Although many countries try to improve access to health care through universal health coverage, pharmaceutical sector still relies on OOP payment or the coverage is very limited. Many countries have essential medicines list, and government covers the medicines in the EDL by general tax revenues and/or SHI. However, direct purchase in private pharmacies or uncovered drugs by physician's prescribing make people spend a large portion of their total health expenditure on purchasing medicines.

Table 17. Summary of financing mechanisms for the pharmaceutical sector in non-OECD countries in the Asia-Pacific region

Countries (year)	Overall financing scheme	% Population enrolled	Scope of benefits on health care sector	Financing system for the pharmaceutical sector
Nepal (2011)	Tax		Public health facilities	Copayments or fees for medicines are not imposed in public health facilities
Fiji (2011)	Tax		public health facilities	All pharmaceuticals provided in public health facilities are free. Private providers charge high user fees, which are not regulated by the government.

Malaysia (2012)	Tax		comprehe nsive for public sector services	Even though the whole population have access to public sector health services with very low OOP pay, OOP pay for medicines can be high due to high mark-ups by dispensing doctors and private retail pharmacies.
Cambodia (2012)	Tax, community based health insurance		inpatient, pilot outpatient	Direct purchase of medicines from pharmacies and drug sellers is one of the reasons for the high OOP.
Thailand (2012)	Universal Coverage Scheme (UCS), Social Security Scheme (SSS) for private employees, Civil Servant Medical Benefit Scheme (CSMBS)		comprehe nsive	UCS: Essential Drug (ED) List is fully covered in capitation fee for ambulatory care and global budget + case based payment for inpatient services. SSS: Drug benefit referred to National ED lists. Drug payment is included in the inclusive capitation for ambulatory and inpatient services. CSMBS: Drug benefit referred to National ED lists. Fee for services for drugs in ambulatory care, and DRG for inpatient care.
China (2013)	SHI: Urban employee basic medical insurance (UEBMI), Urban resident basic medical insurance (URBMI), Rural cooperative medical system (RCMS)	93%	mainly inpatient, partially outpatient	All government–run primary care facilities in urban and rural areas provide essential medicines at cost (zero profit mark–up).
Philippines (2012)	SHI: PhilHealth	76%	mainly inpatient, outpatient for the low-income populatio n	PhilHealth provides coverage for the Philippine National Drug Formulary (PNDF) for the inpatient sector.
India (2012)	SHI: RSBY	8%	inpatient, pilot outpatient	Public expenditure on health care is low (e.g., 25% of THE), and OOP expenses is high. More than 75% of OOP healthcare expenses are used on medicines.
Lao PDR (2014)	Social Security Organization (SSO) for salaried private employees; State Authority for Social Security (SASS) for civil	19.6%	Limited coverage	Revolving drug funds (RDFs) are operating to improve the availability of essential medicines at the primary health care level.

	servants; Community-Based Health Insurance (CBHI) for non-poor workers in the informal sector; Health Equity Fund (HEF) for the poor			
Indonesia (2012)	Askeskin/ Jamkesmas (SHI for the poor), Askes (Compulsory SHI for civil servants and their dependents), Jamsostek (Compulsory SHI, opt-out option for private sector employees), JAMKESDA (district local governments-running insurance)	63%	Comprehensive	Pharmaceuticals account for over one-third of THE, and most medicines are purchased by out of pocket pay. Privately purchased medicines supplied through private pharmacies or drug sellers, which account for a large percentage of total drug spending. Almost half of public spending on essential medicines for public primary care came from the central government budget.
Vietnam (2012)	Social health insurance	41%	Comprehensive	Despite SHI reimbursement covered drug list, OOP payment for medicines is high as people have to buy many drugs in private pharmacies.

source:

1. % of population coverage data for each country (year) : Whitaker (2013) or other sources as below
2. Nepal: HSRSP (2010); WHO/Nepal MOH (2011)
3. Fiji: WHO (2011); WHO/Fiji MOH (2013)
4. Malaysia: Babar, Ibrahim et al. (2007); WHO (2012)
5. Cambodia: CDPHI and WHO (2008)
6. Thailand : Thai working group on Observatory of Health and Policy (2010); Hanvoravongchai (2013)
7. China: APCNMP (2013); SAGPA (2013); Barber, Huang et al. (2013)
8. The Philippines: Thatte, Hussain et al. (2009); WHO/Philippines MOH (2012); WHO (2011)
9. India: APCNMP (2013)
10. Lao PDR: WHO (2014)
11. Indonesia: Rokx (2009); Holloway (2011)
12. Vietnam: Tien, Phuong et al. (2011); Ekman, Liem et al. (2008)

2) Procurement and service delivery

The Organization for Economic Co-operation and Development (OECD) noted that "Effective and efficient public sector procurement systems are essential to the

achievement of the Millennium Development Goals and the promotion of sustainable development" (OECD 2005). To improve the efficiency in procurement for the public or private sector, drug policies can be important (WHO 2001, Sharpe, Levin et al. 2013). Procurement method is determined by various factors: national procurement policies, regulations, funder requirements, procurement expertise, management capacity, quality assurance capacity, and product price (WHO 2011c). Competitive bidding applies standardized public sector procedures for high-financial-value transactions when there is more than one potential supplier. Small-scale competition is used for low-financial-value transactions and also considered as shopping and direct procurement. In a sole-source procurement, the contracts are issued without competition.

According to "The World Medicines Situation 2011," there are significant trends over the past 5 to 10 years in developing countries. The most significant change is the increase in country-level procurement rather than direct support from the donors. Therefore, the responsibility for national procurement also increased, requesting the important role of national regulatory authorities. Moreover, medicine quality assurance also calls for an effective regulatory system accompanying appropriate testing capacities (WHO 2011c). However, the public sector procurement often experiences the lack of capacities because of limited financial resources, low transparency or lack of understanding of complex process (WHO 2011c).

Another important issue is service delivery and the rational use of medicines. In low- and middle-income counties, even in formal shops, many medicines sellers are not registered or regulated. There are disparities even within a country, and central urban areas usually have less informal supplies but peri-urban or rural areas are dominated by informal supplies. There are serious problems of overuse

and misuse of medicines, but enforcement of regulations is difficult (Roberts and Reich 2011). To improve the rational use of medicines, several policies can be implemented, such as regular monitoring of drug use, periodic updating of clinical guidelines, operating a medicine information center for prescribers or drug committees, and education programs for providers and consumers (WHO 2011c).

There are various characteristics in medicines procurement and service delivery among countries according to their political and economic context, capacities for drug manufacturing, and history of regulatory authorities, health care infrastructure and distribution channels. This report will describe each country's procurement system, the current state of national regulatory authority for the pharmaceutical sector and service delivery, and rational use of medicines.

Examples of procurement and service delivery mechanisms of the pharmaceutical sector in non-OECD countries in the Asia-Pacific region.

A. Procurement of medicines

In China, before the reforms, procurement was carried out in the facility level, relying on many small–scale fragmented distribution systems with high mark–ups. Through the national health care reform, the government-led bidding platforms were set up in all districts, and online purchasing was implemented in the majority of counties at the end of 2010. The government reported that the average price of essential medicines decreased by 16.9% between 2009 and 2011, to which larger volume purchasing and management efficiencies of provincial procurement have contributed. The emphasis on the lowest price, rather than quality or supplier performance, has led manufacturers to submit commercial bids lower than cost.

Moreover, the provincial EMLs are not procured in some regions due to lack of suppliers, sole-source manufacturers, and non–acceptance of the tendering price by firms. The central government encouraged the "two–envelope" to make sure minimum quality standards under the tendering system, however, the procurement process and logistics capacity, specifications, and criteria are not uniform across the provinces (Barber, Huang et al. 2013). [5]

In the Philippines, there were 471 registered pharmaceutical companies, and among them, almost 50% are foreign-owned as of 2007. Most of locally owned pharmaceutical manufacturers produce generic medicines (Ball and Tisocki 2009). Procurement of medicines in the public sector is done by government. Vaccines and medicines for vertical programs or special initiatives are procured by DOH at central level, but retained hospitals, provinces, cities, municipalities and barangays procure medicines by themselves (WHO/Philippines MOH, 2012). National guidelines on Good Distribution Practices (GDP) are drafted recently, but the list of GDP certified warehouses or distributors in the public sector does not exist (WHO/Philippines MOH, 2012). Drugstores have the greatest market share (80.1%): 62.7% in chains and 17.4% in independent stores. Market share of others are as follows: clinics account for 10.2% (NGOs 9.9%, government agencies 0.3%) and hospitals 9.7% (government hospitals 2.3%, private hospitals 7.4%) (WHO 2011b).

In Nepal, procurement of medicines in the public sector is centralized under the Ministry of Health and Population, and there are Public Procurement Act

[5] Two envelop: "the first document set represents the compliance of quality and performance standards by suppliers. After the suppliers meet the quality standards, in the second step, commercial bid can be evaluated" (Barber, Huang et al. 2013).

[Public Procurement Act, 2063 (2007). Available at: www.lawcommission.gov.np] and Public Procurement Regulations [Public Procurement Rules, 2064 (2007). Available at: www.lawcommission.gov.np] for the public sector. Regional health directorate has been allocated 10% budget and the districts have been allocated 20% budget for maintaining the buffer stock of medicines or preparing for the shortage of stocks (WHO/Nepal MOH 2011). The public supply system has a Central Medical Store at National Level (Logistics Management Division), and there are 5 public warehouses. But national guideline on Good Distribution Practices (GDP) does not exist. In the private sector, there are legal provisions for licensing wholesalers and distributors, but they are not GDP certified (WHO/Nepal MOH 2011).

In Fiji, procurement of medicines in the public sector is under the responsibility of Fiji Pharmaceuticals and Biomedical Services Centre, which is a part of the MOH. There is Central Medical Store at National Level and one public warehouse, which is based on a Divisional Hospital. Even though Good Distribution Practices (GDP) licenses do not exist, GDP is addressed in the National Medicinal Products Policy 2012. In the private sector, there are legal provisions for licensing wholesalers and distributors, and there is a list of GDP certified wholesalers and distributors (WHO/Fiji MOH 2013). Private sector doctors and pharmacists are legally allowed to import medicines when medicine labels are in compliance with either the British Pharmacopoeia（BP) or United States Pharmacopoeia (USP) standards, except for narcotics and other restricted substances (WHO 2011a).

Indonesia has a decentralized medicines management system. Through the introduction of Indonesian National Medicines Policy (revised version) in 2006, all public health facilities procure generic essential medicines (APCNMP 2013). Under

the Indonesian MOH No.68 of 2010, hospitals have to manage pharmaceutical supply chain and inventory by themselves since 2010 (Rachmania and Basri 2013). The new regulation makes hospitals operate all main activities by themselves. Therefore, there are no economies of scale in medicines procurement because all districts and hospitals individually purchase their own medicines. Many districts have no electronic inventory system for drug management, manual stock control is common, and management of quantities of medicines are determined by past consumption (Holloway, 2011).

In Lao PDR, domestic manufacturers and importers obtain market authorization. Therefore, not only private pharmacies and clinics, but also retailers, health centres, and public hospitals get medicines from wholesalers. In public hospitals, the pharmaceutical department has responsibility for drug supply management and dispensing to outpatients and inpatients (WHO 2014a).

In Malaysia, health facilities can purchase pharmaceutical products and medical supplies in mainly three ways. First, they purchase medicines in Pharmaniaga Logistics Sdn. Bhd (the current concession holder company). As a major supplier, Pharmaniaga Logistics accounts for about 45% of the total MOH drug budget by supplying and managing 571 items. Second, if the purchasing amount is above RM 500,000, they can use central tender. Third, if they purchase lower-cost products, they can use local purchasing (WHO 2012). If the MOH purchases from local concession companies and tenders, it is 60% cheaper than from the private sector because doctors and private retail pharmacies set high mark-ups. But the public sector price is still 1.3 times higher than the International Reference Price. Price control and the increased utilization of generic medicines are required to obtain affordable medicines in the Malaysian public sector (Babar, Ibrahim et al. 2007).

Table 18. Summary of procurement of medicines in non-OECD countries in the Asia-Pacific region

Countries	Characteristics of Medicines Procurement
China	- After Chinese national health care reform, the government-led bidding platforms were set up in all districts, and online purchasing was implemented in the majority of counties at the end of 2010. - The provincial EMLs are not procured in some regions, for lack of suppliers, sole source manufacturers, and non–acceptance of tendering price by firms.
The Philippines	- Procurement of medicines in the public sector is done by government. Other retained hospitals, provinces, cities, municipalities and barangays procure medicines by themselves.
Nepal	- Procurement of medicines in the public sector is centralized under the Ministry of Health and Population. - Regional health directorate has been allocated 10% budget, and the districts has been allocated 20% budget for maintaining the buffer stock of medicines or preparing the shortage of stocks.
Fiji	- Procurement of medicines in the public sector is under the responsibility of Pharmaceuticals and Biomedical Services Centre. - Private sector doctors and pharmacists are legally allowed to import medicine, if medicines label comply with either the BP or United States Pharmacopoeia standards.
Indonesia	- In a decentralized medicines management system, hospitals have to manage pharmaceutical supply chain and inventory by themselves, so there are no economies of scale in medicines procurement. - Many districts have no electronic inventory system for drug management.
Lao PDR	- Domestic manufacturers and importers obtain market authorization. - Wholesalers provide medicines to public hospitals, private pharmacies and clinics, retailers, and health centres.
Malaysia	- Health facilities can purchase pharmaceutical products and medical supplies mainly three ways: Pharmaniaga Logistics Sdn. Bhd (a major supplier), central tender, or local purchasing.

Sources:

1. China: Barber, Huang et al. (2013)
2. the Philippines: Ball and Tisocki (2009); PHAP (2008); WHO (2011); WHO (2012); WHO/Philippines MOH (2012)
3. Nepal: WHO/Nepal MOH (2011)
4. Fiji: WHO (2011); WHO/Fiji MOH (2013)
5. Indonesia: APCNMP (2013) ; Holloway, (2011); Rachmania and Basri (2013)
6. Lao PDR: WHO (2014)
7. Malaysia: Babar, Ibrahim et al. (2007); WHO (2012)

B. National regulatory authority for pharmaceutical sector

In the Philippines, the PNDF as EML is under the DOH regulation and serves as a base for government drug procurement and for PhilHealth reimbursement. Moreover, through the revised Generics Act of 2008 (RA 9502), compulsory licensing, parallel importation, price controls and generic substitution were conducted to improve the provision/accessibility of quality and low-cost medicines (WHO 2011b).

In Indonesia, National Agency of Drug and Food Control is responsible for a central quality assurance system. The national government has imposed regulations, standards, and enforcement activities for pharmaceutical quality control. Effective quality assurance has been one of the important factors for securing the accessibility and affordability of good quality medicines in the decentralized system (APCNMP 2013).

In Bhutan, the national drug policy was in place 1987, and the first standard treatment guideline (STG) was implemented in 1989. A national formulary was in place in 1994, and the revised national drug policy was developed in 2007. The Bhutan Government established the Essential Medicines and Technology Division in 2008, which is responsible for providing systematic, evidenced-based information to the MOH. The evidence area includes new technologies, assessment for use of medical supplies, rational prescribing, good storage and dispensing practices (Roughead, Lhazeen et al. 2013).

In Laos, The Food and Drug Department (FDD) of the MOH is the national regulatory authority. The FDD administers the quality of pharmaceutical products by monitoring the wholesalers to ensure the drug storage conditions (by means of random quality checks). There are guidelines dealing with rational drug use and

clinical practice, and the standards have been distributed throughout the country. However, there are many challenges until now, especially in the enforcement of law and regulations by the drug regulatory authority, reinforcement of the quality assurance system, and enhancement of the rational use of medicines (APCNMP 2013, WHO 2014a).

In Fiji, the Fiji Pharmacy and Poisons Board approves the drugs importation based on whether the drugs meet the British/ United States standards or not. The Fiji Procurement Office oversees the tendering process (WHO 2011a). The public sector has a quality assurance process for pre-qualification of products and suppliers. There are also explicit criteria and procedures for supplier's pre-qualification and a list of pre-qualified suppliers and products (WHO/Fiji MOH 2013).

In Malaysia, the MOH Pharmaceutical Services Division (PSD) sets National Medicines Policy (DUNAS). The PSD works to protect consumers from hazardous medicines and misleading advertisements. In accordance with international conventions, the government supervises the importation/exportation of narcotics, psychotropic substances and precursor chemicals. Pharmacies, medical clinics, wholesalers and industries have been audited under the steering of PSD enforcement officers (WHO 2012). Drug abuse of designer drugs is an emerging problem. For example, the industries commonly use illicit manufacturing (e.g., amphetamine type stimulants from chemicals) and pharmaceutical products containing precursors (e.g., ephedrine, pseudoephedrine). Therefore, PSD enforcement officers conduct audits in pharmacies, medical clinics, wholesalers and industries to control the drug abuse (WHO 2012).

In China, the Provincial and National Development Reform Commissions (NDRC) regulate broad aspects of essential medicines system. There is an emphasis on improving quality of medicines under the reform, including quality standards for the national EML (307 drugs). Since 2009, at provincial level, all essential medicines (EML) have to undergo quality sampling and testing annually, and at central level, the testing is performed every three years. And greater attention is warranted to the highest risk products. The strengthened systems to reduce adverse drug effects include not only routine sampling and testing but also electronic bar codes on packages (Barber, Huang et al. 2013).

C. Service delivery and rational use of medicines

In Indonesia, the MOH implemented the revised national medicines policy in 2006. The government supported the rational use of medicine as one of the three main objectives of the policy. The program for the rational use of medicines includes the implementation of educational, regulatory, managerial strategies and monitoring medicines utilization especially at the primary health care level throughout the country. WHO indicators for National Drug Policies were used for the collection of data, which produced yearly indicators to assess national performance and variation by province in medicines use. Results from 27 provinces showed that the utilization of antimicrobial decreased for non-pneumonia upper respiratory tract infections (from 60.02% to 41.36%) and nonspecific diarrhea (from 62.33% to 36.88%) between 2010 and 2011. An indicator of polypharmacy decreased from 3.59 to 3.47, and the percentage of patients receiving an injection for myalgia increased from 3.72% to 3.96%. Human resource deficiencies in primary health-care units seem to interrupt the monitoring system (Roughead,

Lhazeen et al. 2013).

In Bhutan, the Essential Medicines and Technology Division uses the World Health Indicators for monitoring medicines policy. To assess drug consumption and prescribing patterns, utilization reports are collected every 6 months. To assess rational use of medicines, a monthly prescription survey is performed. Monitoring includes whether drugs belong to the national essential medicines list as well as the number of medicines per prescription. However, whether medicines were given in the correct dose or under-utilized are not monitored (Roughead, Lhazeen et al. 2013).

In China, for rational medicines utilization, clinical treatment guidelines and hospital essential medicines formulary were developed and issued, and prescription monitoring systems were launched (Barber, Huang et al. 2013).

In the Philippines, there are disparities among urban areas and remote areas in medicines supply. Drugs availability depends on prescribing doctors and drug stores or pharmacies in the area. In urban areas, such as National Capital Region or Region III, many government health professionals are working. But in remote areas, such as Autonomous Region for Muslim Mindanao, there are only few government doctors are working. Moreover, many drug stores are distributed in NCR or other urban areas, so remote areas experience the shortage of drug supply. Some clinics, Rural Health Unit (RHU), government hospitals and Botika ng Barangay (BnB), which is DOH-led community based pharmacies, health workers dispense drugs in their own clinics without pharmacies. In this circumstance, even though there is a law for separating prescribing and dispensing, its implementation is difficult (WHO 2011b).

In Fiji, all GPs are allowed to stock a small amount of pharmaceuticals for emergency situations. Some GPs are also allowed to dispense pharmaceuticals if he/she live more than five kilometers from a pharmacy. Other entities are not allowed to dispense pharmaceuticals. The Fiji Pharmaceutical Service is linked with three divisional hospitals by the Epicor computerized inventory system. Through the system, stock levels, distribution, ordering, and reporting management-related information are monitored. On the other hands, in the private sector, pharmaceutical suppliers consist of one manufacturer, nine wholesalers that sell prescription medicines, the Suva Private Hospital with its own private pharmacy, and 45 private pharmacies and 125 GPs. The private sector is not monitored for their quality of medicines delivery (WHO 2011c). In Fiji, several methods are applied to monitor the rational drug use, such as prescribing, dispensing and patient compliance surveys, and the comparison of epidemiological data with drug purchasing data (WHO 2011a).

In Malaysia, over 1,760 private retail pharmacies are operating mainly in urban areas. In government hospitals and larger government health clinics, pharmacists and assistant pharmacists are employed. Assistant pharmacy officers can work for dispensaries and dispense medicines under the supervision of district pharmacists. In smaller health clinics, assistant pharmacists or dispensers are employed, and in rural clinics, paramedics, assistant medical officers and community nurses are employed for dispensing (WHO 2012). Private sector doctors can prescribe and dispense drugs without regulations on indications or frequency. Private sector doctors usually prescribe brand drugs, and over-prescribing by them is a major problem. The National Medicines Policy states that 'to improve the quality use of medicines, prescribing and dispensing functions must be separated' but it has not been implemented due to private sector physicians

(WHO 2012). The Malaysian government has recently progressed pharmacy practice from a product-oriented to a more patient-oriented service. Patients can get a counselling to improve understanding of medication, pharmacists become a part of health care team as an expert in drug safety, and pharmacists offer drugs and poison information in major hospitals (WHO 2012). Moreover, in order to empower consumers with proper information on medicines use, strategies on educational intervention for consumers were implemented (Roughead, Lhazeen et al. 2013). A national study of medicine utilization in 2008 showed that 56% of consumers did not understand the right use of their drugs, 51% did not know their trade name, and 56% did not know common side-effects (Bahri, Othman et al. 2009).

D. Availability and Affordability of Medicines in Asia-Pacific region[6]

Cameron et al. (2009) showed the results of medicines availability, price, affordability in developing countries using the WHO/HAI methodology (Cameron, Ewen et al. 2009).

[6] The part D is based on Cameron et al. (2009)'s study and extracted the case of Asia-Pacific region countries and restructured the prior study.

Table 19. Survey countries by Cameron et al.'s study (2009)

Country(survey date)	WHO region	World Bank Income Group(2007/08)
China, Shandong Province(10/2004)	Western Pacific	lower-middle
China, Shanghai Province(09/2004)	Western Pacific	lower-middle
Fiji(09/2004)†	Western Pacific	lower-middle
Malaysia(10/2004)	Western Pacific	upper-middle
Mongolia (11/2004)	Western Pacific	low
Philippines (02/2005)	Western Pacific	lower-middle
India, Chennai State(01/2004)	South-East Asia	low
India, Haryana State(10/2004)	South-East Asia	low
India, Karnataka State(11/2004)	South-East Asia	low
India,MaharashtraState,12districts(10/2004)	South-East Asia	low
India,MaharashtraState,4regions(01/2005)	South-East Asia	low
India, Rajasthan State(06/2003)	South-East Asia	low
India, West Bengal State(12/2004)	South-East Asia	low
Indonesia(08/2004)	South-East Asia	lower-middle
Sri Lanka (09/2001)*,†,‡, §	South-East Asia	lower-middle

*Pilot studies. †Did not survey public sector medicine outlets. ‡Did not survey public sector procurement prices. §Private sector data on lowest-priced generic medicines excluded since they were not surveyed using the current WHO/HAI methodology.
Source: Cameron, Ewen et al (2009)

(1) Availability

According to Cameron et al.'s study, "availability" was measured as follows: if a medicine was located on the day of the survey in medicine outlets, the % of medicine outlets was assumed as availability. Management Sciences for Health (MSH) median international reference price was used for reference standard, "actual procurement prices for medicines offered by non-profit suppliers and international tender prices in low-income and middle- income countries." According to Table below, mean "availability" of the basket of 15 generic medicines in the public sector was 38.8% in southeast Asia region and 43% in western Pacific. Mean availability of the 15 generic medicines in the private sector was ranging from 50.1% in the western Pacific to 75.1% in southeast Asia. The study said that the private sector availability of generics was high in

India (91.8%) but low in the Philippines (33.6%) and China (34.6% in Shandong and 38.3% in Shanghai) (Cameron, Ewen et al. 2009).

(2) Median price ratio

"Median price ratios" of 15 generic medicines in public sector procurement price to the MSH international reference price for lowest-priced generics are shown in line <3> in the table. Generic medicine prices in public sector procurements for the basket of 15 medicines were close to or lower than international reference prices in the southeast Asia, whereas 44% more than international reference prices in western Pacific region countries. Line <4-6> in the table shows that even though medicines are free in the public sector, "availability" is often not sufficient. For example, public sector patients pay for medicines 6.84 times more than the international reference price in southeast Asia countries and 11.95 times in western Pacific countries, even for lowest-priced generics. Moreover, the prices in the private sector are higher than the public sector in southeast Asia. When it comes to originator brands drugs, prices in the private sector were much higher than the international reference price (Cameron, Ewen et al. 2009).

Table 20. Mean availability, median price ratio in southeast Asia and western Pacific countries

	SEAR	WPR
<1> Mean availability of the basket of 15 generic medicines (range)-public sector (%)	38.3 (n=8*) (16.3, 57.9)	43 (n=5**) (22.2, 79.2)
<2> Mean availability of the basket of 15 generic medicines (range)-private sector (%)	75.1 (n=8) (64.3, 91.8)	50.1 (n=6) (33.6, 77.6)
<3> Median price ratios of 15 generic medicines in public sector procurement price to the MSH international reference price for lowest-priced generics	0.63 (n=8) (0.27, 1.72)	1.44 (n=6) (0.59, 2.94)
<4> Median price ratios of the median final (patient) price of lowest-priced generics in the public sector to the MSH international reference price	6.84 (n=1)	11.95 (n=4)
<5> Median price ratios of the median final (patient) price of lowest-priced generics in the private sector to the MSH international reference price	9.61 (n=8)	11.25 (n=6)
<6> Median price ratios of the median final (patient) price of originator brands in the private sector to the MSH international reference price	21.28 (n=9)	34.21 (n=5)

Data are mean (number of surveys) (range), WHO Region: SEAR=southeast Asia. WPR=western Pacific. *No availability data for SriLanka (pilot). **Fiji did not survey the public sector.
Source Cameron, Ewen et al (2009)

(3) Affordability

"Affordability" is measured by the number of days' wages of the lowest-paid unskilled government worker's salary to purchase courses of treatment for common conditions. For example, for treating Ulcer by Ranitidine for 30 days, unskilled government worker's salary ranged 0.5 days (for private sector lowest priced generics) to 5.5 days (for private sector original brand drugs). However, even when the public sector provides free medicines or at a low cost, many drugs were not available in the public sector consistently. Therefore, patients might have to purchase medicines from the private sector, which is much more expensive (Cameron, Ewen et al. 2009).

Table 21. Mean number of day's wages of the lowest-paid unskilled government worker needed to purchase a course of treatment, by WHO Region

		SEAR	WPR
Adult respiratory infection Amoxicillin 250mg capsule/ tablet, three per day for 7 days	Private sector OB	1.2 (n=4)	0.5 (n=2)
	Private sector LPG	0.6 (n=8)	0.4 (n=4)
	Public sector LPG	0.4 (n=1)	0.4 (n=3)
Diabetes Glibenclamide 5mg capsule/tablet, two per day for 30 days*	Private sector OB	1.3 (n=8)	1.6 (n=3)
	Private sector LPG	0.4 (n=8)	0.7 (n=4)
	Public sector LPG	0.6 (n=1)	0.7 (n=1)
Asthma Salbutamol 0.1 mg/dose inhaler, 200 doses	Private sector OB	1.2 (n=9)	1.4 (n=5)
	Private sector LPG	0.6 (n=7)	0.7 (n=6)
	Public sector LPG	---	1.1 (n=2)
Ulcer Ranitidine 150 mg capsule/ tablet, two per day for 30 days*	Private sector OB	2.7 (n=9)	5.5 (n=3)
	Private sector LPG	0.5 (n=8)	1.7 (n=6)
	Public sector LPG	2.2 (n=1)	1.2 (n=4)

*One month has been used as the course of treatment for chronic diseases. WHO Region: SEAR=southeast Asia. WPR=western Pacific
OB: originator brands, LPG: lowest-priced generics
Source: Cameron, Ewen et al. (2009)

Implications from Procurement/Service delivery mechanisms of non-OECD countries in the Asia-Pacific region

The documents show that many countries are trying to set up efficient procurement system at their national level, but these efforts are limited to the public sector. Recently, many countries also established or reformed their national regulatory authorities, but their enforcement power or management capabilities are not yet sufficient. There are disparities in service delivery of medicines even within a country, between urban and rural areas, in the supply of professional pharmacists. Many people use private sector medicines, but effective regulations on this area is scarce. There are several efforts to improve rational use of medicines, but the implementation is at an early stage in Asia-Pacific countries.

According to Cameron et al.'s (2009) study, availability of medicines in the public sector was not sufficient, which may be due to funding difficulties, shortage of stocks, problems of inaccurate forecasting, weak distribution systems, or private resale by medicines leakage. Therefore, although public sector medicines are free or at low cost, people's access to medicines can be limited by low availability. High price of generic medicines in public sector procurement relative to the MSH international reference price indicates the need to improve the efficiency in procurement. In the private sector, average percentage of availability was higher than the public sector, but expensive price is a barrier to accessibility.

3) Pricing & Reimbursement

A. Overview of each country's pricing and reimbursement system

In Thailand, the Ministry of Public Health (MOPH) developed the NLED, which includes drugs, vaccines, radioactive substances, and disinfection agents that are necessary for prevention as well as major health problems, and set a "medium price" or "reference price" of each drug in the NLED. All public healthcare facilities are required to procure the drugs using government budget based on the NLED and within the medium price. The three public health insurance schemes reimburse medicines based on the NLED (Jirawattanapisal, Kingkaew et al. 2009). In Thailand, several mechanisms have been used to control medicine prices. The price of OTC drugs must be labeled under the control of MOC and companies are required to submit information on cost structure and international prices used in setting the price of OTC drugs. On the other hand, the "Medicine Price Ceiling" is employed to control the prices of non-OTC drugs in the NLED. The authority collects information

on purchasing prices of drugs from all public hospitals and set the maximum prices for each drug that sellers can charge public hospitals. Public hospitals use this information and negotiate medicine price when they purchase medicines from pharmaceutical companies (Jirawattanapisal, Kingkaew et al. 2009).

In China, drugs on the national drug reimbursement list (NDRL) are reimbursable under the three insurance schemes: Urban Employment Basic Medical Insurance, New Rural Cooperative Medical Insurance, and Urban Resident Basic Medical Insurance. The NDRL, managed by the MHRSS (Ministry of Human Resource and Social Security), has covered 1,140 Western drugs and 987 traditional Chinese medicines (TCMs) since the revision of the list in 2009. It is separated into two parts: list A of clinically necessary and effective and lower price, and list B of clinically selective and effective and premium priced. List A consists of 349 Western drugs and 154 TCM, and List B of 791 Western drugs and 833 TCM. Whereas A list mainly includes local generics with 100% reimbursement, B list does branded products and some imported drugs with 10% to 30% patient copayment. B list can be adjusted partially by province and municipalities, depending on their health care needs and economic conditions. The NDRC are responsible for the pricing of all medicines covered by public nsurance programs and work jointly at both national and provincial levels, whereas the prices of other products are not regulated (Liu, Fukuda et al. 2009). Pricing procedure primarily is divided into two types, 1) “uniform pricing ceiling” for most generics and 2) “independent pricing policy” for specified medicines such as patented medicines, off-patent originators, domestic primary generics, and subsequent generics of obviously superior quality. In 2001, the NDRC announced that independent pricing can be applied for drugs with a better treatment effect at a low cost compared with

similar drugs (Liu, Fukuda et al. 2009).

India has a strong price control mechanism through the National Pharmaceutical Pricing Authority (NPPA). The NPPA revises medicine prices and the list of medicines subject to price regulation on the basis of established criteria. The Authority also collects data on pharmaceutical market such as production, exports and imports, monitors the availability of drugs, and takes remedial steps. Furthermore, the authority monitors the prices of de-controlled drugs set by manufacturers, through various methods such as scrutiny of price lists submitted by manufacturers, analysis of monthly "retail store audit reports" published by ORG-IMS, and information collected from official and nonofficial sources (Thatte, Hussain et al. 2009).

In the Philippines, the Essential Drug Price Monitoring System oversees monthly prices of 37 essential drugs related with leading causes of morbidity and mortality across the country. The "Universally Accessible Cheaper and Quality Medicines Act of 2008", which imposes the price ceiling for certain drugs, was implemented in order to reduce medicine cost. In addition, the drug prices are annually compared with international prices. PhilHealth uses a Drug Price Reference Index (DPRI) for reimbursement of medicines, which is a list of reference prices implemented as the maximum reimbursable price of certain medicines (Thatte, Hussain et al. 2009).

In Malaysia, whereas the MOH negotiates the prices of new technologies with companies through a central purchasing system in the public sector, medicine prices are not regulated in the private sector (Thatte, Hussain et al. 2009). In Pakistan, the Drug Registration Board is in charge of the registration and pricing of new medicines. The regulation system has been recently developed; the medicines

were priced on a case-to-case basis until the mid-1990s; the government established a Price Advisory Committee in 2008, which is responsible for controlling the prices of the most commonly used molecules and the essential medicines recommended by the WHO (Thatte, Hussain et al. 2009).

B. The use of Health Technology Assessment (pharmaco-economic evaluation)

Although Health Technology Assessment (HTA) and economic evaluation have been well established in all developed countries, it has not been actively adopted in developing countries of the Asia Pacific region. There are two broad categories of countries in the region: Australia, Malaysia, Singapore, New Zealand, China, Philippines, Korea, Thailand, and Taiwan implemented HTA programs formally; Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Laos, Maldives, Mongolia, Nepal, Pakistan, Sri Lanka, and Vietnam have those mechanisms informally or perform other related activities (Sivalal 2009).

Economic evidence, including budget impact and pharmacoeconomic evaluation, has also been very important for reimbursement decision-making in Thailand, China and South Korea. This evidence is sometimes used in price negotiation and to lower pharmaceutical expenditures. However, economic evaluation is used in the early stages of development in China and Thailand. Several common barriers, for example, human capacity and data availability for obtaining economic evidence, still exist (Ngorsuraches, Meng et al. 2012).

4) Cost containment

A. Overview

Due to the fast growth of pharmaceutical expenditure and its rising impact on total health budget, many Asia-Pacific countries have focused on pharmaceutical cost containment. Countries with mature pharmaceutical market, which include Japan, Australia, South Korea, Taiwan and Singapore, have been taking more diverse approach, relying on price controls, drug volume controls and budget controls (IMS Health 2012).

In Taiwan, for example, the BNHI (Bureau of National Health Insurance) has introduced many strategies to control health expenditure. These strategies include price adjustment based on the prices of international products, existing products (inter-brands comparison) or market price, and volume survey; delegation of financial responsibility to regional bureaus; co-payment for outpatient drugs; generic grouping (a reference pricing scheme based on chemical equivalence); a global budget payment system for clinics and hospitals; and reduction of flat daily payment rate of drugs for clinics (IMS Health 2012).

Pharmaceutical market is less mature in other Asian countries, and Philippines, Malaysia, Vietnam and Indonesia have mostly focused on price-oriented controls such as mandatory price cuts (IMS Health 2012). For example, the Philippines introduced the cheaper Medicines Act in 2008 and announced maximum retail prices (Thatte, Hussain et al. 2009). In China the NDRC has instituted 27 mandatory retail price cuts for over 2000 chemical compounds and 300 TCMs since 1998. On average, the price reduction across therapeutic categories is around 20%. Nevertheless, the excessive pricing cuts were not successful in accomplishing the

intended goal of reducing the total OOP spending in recent years. This is primarily because a uniform pricing cut was not followed by a comprehensive reform in the rational use of medicines, insurance coverage policy, and the FDA approval policy for "new" drugs. For example, manufacturers launched new medicines, such as branded generics with changed name, formula, or packaging, in response to price cut and pulled previous drugs from the market because of low profit margins (Meng, Cheng et al. 2005, Liu, Fukuda et al. 2009).

B. Generic medicines policy

Across many developed markets, generics growth significantly outperforms overall pharmaceutical market growth—a trend that is expected to continue. Few countries in the Asia-Pacific region employ generic substitution policy. At its most aggressive form, generic substitution targets are set by pharmacy associations and payers, and patients who seek the brand should pay out of pocket. In many places, pharmacists are legally required to inform patients of the availability of lower-cost substitutions. In Thailand, some hospitals as well as some insurance schemes implemented generic substitution policy (WHO/HAI, 2011). The evaluation of this policy reported that it would yield a significant cost saving if extended to other settings (i.e. outpatient settings) (Kaojarern and Pattanaprateep 2012).

In addition, the Thai MOPH endorsed the use of generic forms of seven patented drugs for public non-commercial purposes under article 51 of the Thai Patent Act B.E.2535 (1992), which complies with article 31(b) of the World Trade Organization Agreement on TRIPS and the Doha Declaration on Intellectual Properties and Public Health. These consisted of efavirenz, lopinavir/ritonavir,

clopidogrel, imatinib, docetaxel, erlotinib, and letrozole. The policy led to a significant price reduction in these drugs, encouraging the Government Pharmaceutical Organization (GPO) to import generic products from India and also to produce them locally (Jirawattanapisal, Kingkaew et al. 2009).

C. Budget control

Thailand, China, Japan, and Taiwan have recently put forward a variety of capping provisions to contain costs. Taiwan and Thailand have introduced DRG-based reimbursement to cap heath care spending, and introducing a similar type of measures has been discussed in Indonesia. At the hospital level, China and Thailand are capping expensive drug use to limit the number of prescriptions written and filled for them (IMS Health 2012). Thailand has also enacted capping programs for nine diseases that are considered to have above-average branded drug use. To control overall cost, spending caps can be employed in the way of either limiting the amount of spending for the treatment of each patient or for all patients in a therapeutic area (IMS Health 2012).

Chapter 4. Country cases on pharmaceutical system and financing in Asia-Pacific region

Ⅰ. China[7]

1. Description of health care system

1) Financing & health care delivery system

China's health system has experienced dramatic changes in the past decades since the 1978 economic reforms. Reliance on state funding decreased and public health services were decentralized (Hsiao 2007). In addition, the collapse of China's community financing institutions in rural areas and limited risk-pooling in urban areas produced a dramatic fall in health insurance coverage. Health insurance coverage for Chinese population dropped from about 70 percent in 1981 to 20 percent by 1993, and rebounded only since the 2003 implementation of new insurance scheme (Yu, Li et al. 2010).

There are three main non-competing health insurance schemes in China, which have different administration bureaus and target populations. Urban employees are covered by the employment-based basic medical insurance scheme, which was established in 1998. Since it covered only 27 percent of urban residents in 2006, an urban resident scheme started in 2007 for the rest of the urban population who were not covered by other schemes, including children, students, the unemployed, etc. In rural areas, a new cooperative medical scheme began in 2003, which covers 86 percent of the total rural population by the end of 2007 (Yu, Li et al. 2010).

Despite the Chinese government's effort to expand health insurance coverage, the coverage is still not universal in China, which makes patient OOP payment a non-trivial source of financing for health care. As a share of total health expenditure,

[7] Comments by Zhao Kun are appreciated.

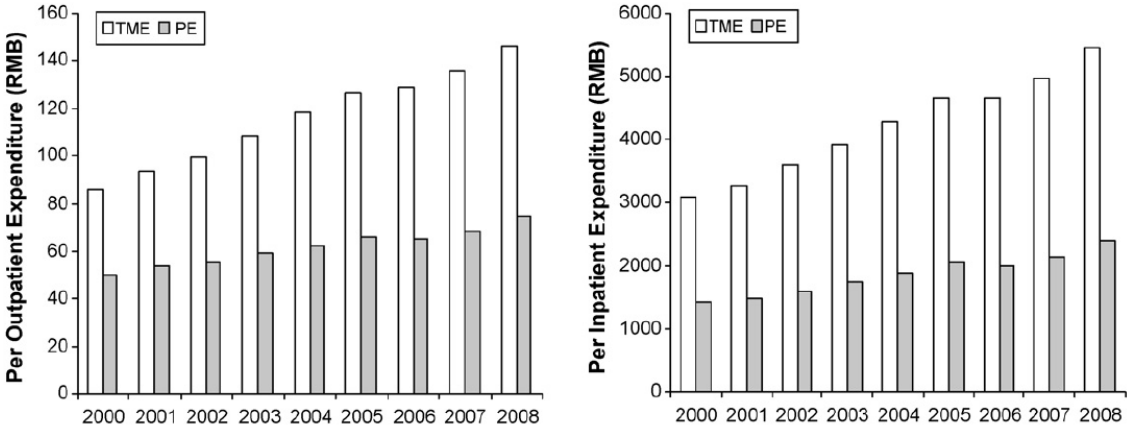
OOP payments increased from 20 percent in 1978 to 60 percent in 2001, falling to 49 percent in 2006(Blumenthal and Hsiao 2005, Yu, Li et al. 2010).

The health delivery system in China is highly dominated by the state-owned providers, accounting for 90% of total hospitals nationwide. The Chinese government continues regulating health service prices tightly by imposing a ceiling on prices charged for routine services and surgeries in order to ensure that basic services are accessible for the general population (Blumenthal and Hsiao 2005). With a major dilemma to balance providing low-priced services with the reduced public funds, public hospitals are left with little options but to seek revenues by supplying more profitable services such as pharmaceuticals. As a result, pharmaceutical consumption accounts for about 50% of the total health expenditures (Liu, Fukuda et al. 2009).

2) The role of pharmaceutical sector in health system

Partly due to the strictly regulated price of health service and mark-up pricing pattern, physicians have incentives to over-prescribe medicines to patents, which have contributed to the escalation of pharmaceutical expenditure. The share of pharmaceuticals in total health expenditure was higher than that in the United States and the European Countries (Chen and Schweitzer 2008). Figure 16 shows that the percentage of pharmaceutical expenditure in per-patient medical expenditure has always been maintained at a high level (Yu, Li et al. 2010). Spending on medicines accounted for 41.9% of total health expenditures or 2.1% of GDP in 2010 (Figure 17) (Chen and Schweitzer 2008).

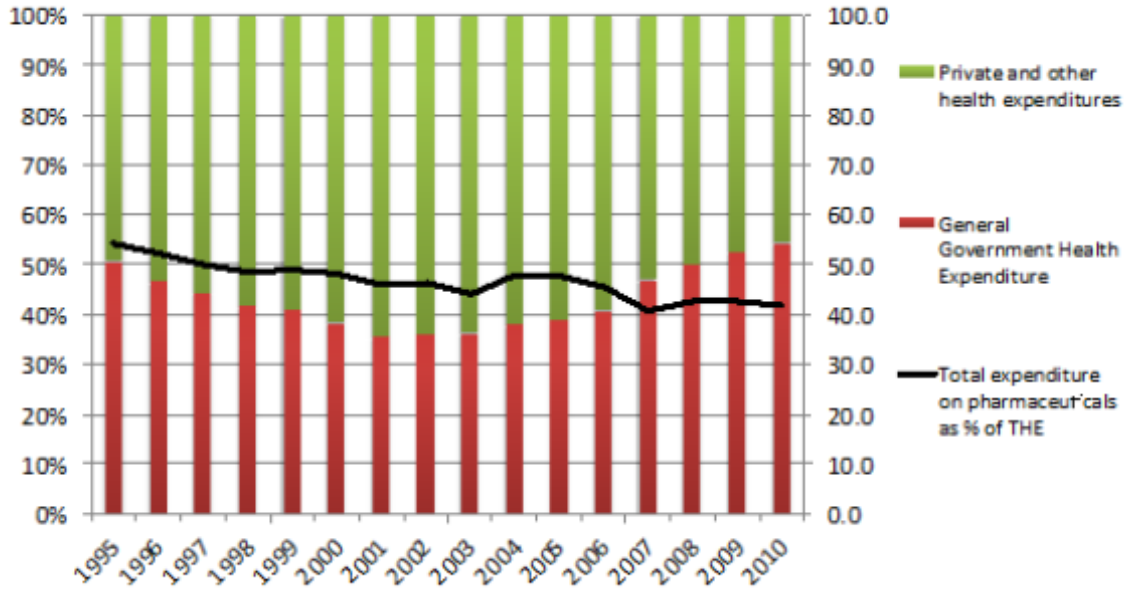
Figure 16. Per patient expenditure in China since 2000



TME: Total medical expenditure, PE: pharmaceutical expenditure, RMB: Chinese currency

Source: Yu et al. (2010)

Figure 17. Private and general government health expenditures, and pharmaceutical spending as % of total health expenditure, 1995-2010



Source: China national Health Economics Institute (2012)

As drug expenditure accounts for the largest share of national health expenditures in China, pharmaceutical cost containment is an especially important

issue in China. China has attempted a number of measures to control pharmaceutical expenditure, including the use of drug formularies, regulating the prices of pharmaceuticals and markups, capping the annual growth rate of incomes of hospitals (Chen and Schweitzer 2008).

2. Reimbursement & pricing process

1) Reimbursement

Chinese government introduced the current reimbursement system in the 1990s to contain pharmaceutical expenditure and to improve the rational use of medicines by limiting the scope of drugs that doctors can prescribe. The NDRL, maintained by the Ministry of Human Resources and Social Security (MOHRSS), covers about 2,000 medicines. Drugs on the NDRL are reimbursable under the three insurance schemes. The NDRL consists of two parts: A list and B list. All medicines in the EML are in the list A, and drugs in the list A are considered more basic and require lower price. Most of them are local generics with 100% reimbursement, while the B list includes branded products and some imported medicine with 10% to 30% patient copayment (Liu, Fukuda et al. 2009). The formulary is distributed to provincial governments, which cannot change drugs in category A and have limited authority to determine category B. Central guidelines indicate that the provincial government can adjust up to 15% of medicines on the list B to meet their own health needs. The MOHRSS plans to revise the central reimbursement list every four years (Barber, Huang et al. 2013)

There is a time lag between product launch and gaining reimbursement, an average of 3 years, longer the an average of 6 months for the US and France and 3

months for Japan(Liu, Fukuda et al. 2009). Until 2009, the EML was not used in financing and insurance reimbursement. After health care reform in 2009, the government issued a revision of the first part of the EML for primary care facilities. This EML is composed of 307 medicines, which are available at cost (no mark-up) at primary care facilities. All medicines in the EML are included in the central reimbursement list (Barber, Huang et al. 2013).

2) Pricing

Pharmaceutical prices have long been regulated in China. The NDRC is responsible for pricing medicines that are included in the category A of the NDRL. NDRC mainly sets ceiling prices based on the average production cost multiplied by some markups to account for profits and R&D costs (maximum retail prices). Manufacturers' prices are based on the production cost reported by manufacturers plus a 5 percent mark-up, to which a 15 percent mark-up is added for the wholesale price, and an addition of further 15 percent mark-up constituted the retail price (Yu, Li et al. 2010). However, higher mark-ups are given to specified pharmaceutical products, largely patented medicines, off-patent originators, and domestic primary generics that can demonstrate significant higher quality and efficacy benefits to encourage innovations ("independent pricing")(Sun, Santoro et al. 2008).

In cases of drugs classified as category B, their price ceilings are determined by provincial governments. In 2005, the responsibility for price regulation for OTC drugs on the formulary was delegated from the NDRC to provincial pricing bureaus that can set prices according to local health care priorities and requirements. Price of other drugs not covered in the drug formularies can be determined freely by

market forces (Liu, Fukuda et al. 2009).

3. Pharmaceutical cost containment strategy

1) Price cut

Pharmaceutical cost containment policies in China have focused mainly on price regulation. Since 1998, the NDRC has introduced extensive and substantive price reductions on over 2,000 medicines. On average, the price reduction across therapeutic categories is around 20%. To some extent, expected effects were achieved; however, the excessive price cuts appear to have had limited effect on health spending growth because manufacturers responded for each price cut with replacing "old" drugs with "new" drugs, which are usually more profitable branded generics with "a little change" (Meng, Cheng et al. 2005, Liu, Fukuda et al. 2009). Furthermore, health care providers have less incentive to be price sensitive because they rely on profits from pharmaceutical sales to cover operating deficits, and the markup is usually higher for expensive, brand-name products than for cheap local products. Therefore, they continued to prescribe expensive products.

2) Pharmaco-economic evaluation

China has a formal HTA program in the development of the drug formulary. Pharmacoeconomic analysis compares the benefits and costs of drugs and examines the impact of these drugs on the funds of medical insurance. Only those with pharmacoeconomic advantages and optimal impact on the funds are selected. After a preliminary formulary is formed, the next step is voting, which is deployed

at both national and provincial levels. On the basis of voting results, consultation experts bring forward the suggestions for payment limitation to some drugs, which are expensive and abused easily (Ngorsuraches, Meng et al. 2012).

Even though the increasing number of pharmaco-economic and pharmaceutical outcome research studies has had some impact on policy making, the use of pharmaco-economic evaluation is still in its early stages in China. Pharmaceutical companies are not required to provide PE evidence such as comparative clinical evidence, pharmaco-economic data, and reimbursement decisions in other countries. Similar to many countries in the Asia-Pacific region, China needs to overcome some barriers to strengthen PE, including the limited number of pharmaco-economic experts, comprehensive and valid database of drug price information, professional agencies, and training (Ngorsuraches, Meng et al. 2012). However, the new health reforms (October 2008) mentioned that health economic studies will be gradually requested when drug companies apply for new drug approval from 2012 (Oortwijn, Mathijssen et al. 2010).

3) Procurement

By the 2010, centralized drug procurement processes at the municipal level were established in all regions. The new tendering system, which is called as "the Anhui model" because of its initial test-run in that province, entails a two-part bidding process for companies that want to provide pharmaceuticals. In the first round, manufacturers have to prove their technical proficiencies and volume capabilities to supply the region adequately. Then, those that pass the first round and submit the lowest price bid win the contract ("two-envelope" tendering

system). Before the reforms, procurement was made at facility level, which contributed to higher mark-ups for medicines with many small-scale fragmented distribution systems and large numbers of wholesalers and distributors. After reform, provincial procurement has contributed to improved efficiencies in management, which resulted in reductions in medicines prices. The government reported that the price of essential medicines decreased on average by 16.9% between 2009 and 2011(Barber, Huang et al. 2013).

However, even though the original intention of this system was to guarantee a drug supply that is both affordable and high-quality, the reality seemed to be unsatisfactory (Sun, Santoro et al. 2008). The bidding tends to result in one manufacturer winning the tender for one product. Generally, over-reliance on single-source suppliers may decrease competition for certain products (Barber, Huang et al. 2013). In addition, it is reported that many companies with low quality and questionable manufacturing processes can slip through the first round and then easily outbid companies that focus on higher quality despite their higher costs. [8]

4) Zero mark-up policy

The government has implemented comprehensive health care reforms nationwide in 2009, specifically focusing on the reform of the essential medicines system. To reduce the cost of medicines, essential medicines are provided at cost (zero profit mark-up) at all government-run primary care facilities in urban and

[8] http://www.cuttingedgeinfo.com/2012/china-anhui-drug-pricing/

rural areas. This policy has delinked prescribing and physician remuneration in many primary care facilities, thus reducing the incentive for over-prescription. The share of government subsidies for hospital revenue has increased steadily after the reform since local governments are mainly responsible for compensating for the revenue lost through the zero mark-up policy (Barber, Huang et al. 2013). Chinese government plans to expand this zero mark-up policy for essential medicines to village clinics, non-government run primary care facilities, and pilot county hospitals (Barber, Huang et al. 2013).

4. Service delivery (distribution)

In China, there is no separation between prescribing and dispensing, and most patients typically fill their prescriptions in the hospital's pharmacy. They prefer hospital pharmacies to retail drug stores for its convenience, physician recommendation, non-standardized prescription, and greater assurance of medicines quality. Hospitals account for roughly four-fifths of all retail pharmaceutical sales. Thus, hospitals strongly influence the supply chain in the pharmaceutical distribution system. In addition, physicians working in Chinese hospitals have strong incentives to over-prescribe medications as well as to prescribe based on profit margin rather than clinical efficacy because they are often paid bonuses linked to hospital revenue. The severity of irrational use of medicines such as unnecessary prescribing of antibiotics in China is caused partly by distorted provider incentives as well as the historical legacy of combined prescribing and dispensing in societies with herbal medicine traditions. During the health care reform 2009 in China, much debate has focused on separating physician's

prescribing and dispensing functions and its potential impact on drug spending (Sun Q et al., 2008).

5. Key challenges

1) The problem of current pricing system – higher price means higher profit

Prices paid to pharmaceutical manufacturers are principally based on manufacturer's self-reported production cost because the government lacks the capacity to estimate actual production costs. Furthermore, since government-regulated mark-ups for both wholesalers and retailers are a fixed percentage of price, expensive drugs were preferred by both, and manufacturers have incentives to inflate self-reported costs to increase both their own margins and those of their primary customers (Sun, Santoro et al. 2008). "New drug" registrations were also pursued to obtain eligibility of higher prices, while they were not "new" in reality, usually with "a little change". Under this system, drug prices are set to be high, and low-price medicines are less available (Yu, Li et al. 2010).

2) Low incentives for efficient pharmaceutical utilization: distorted price schedule

Government financial support to public hospitals constituted about 60 percent of hospital revenue in the beginning of the 1980s, but it had dropped to 8.2 percent by 2003(Sun, Santoro et al. 2008). The remaining revenue comes from fee-for-service activities under a government controlled price schedule, which is usually

below costs for basic health care but is above costs for high tech diagnostic services and assures a 15 percent profit margin on drugs. This price-setting system creates an incentive for providers to introduce high tech services and prescribe more and expensive drugs than would be optimal for patients because the profit from them functions as a cross-subsidy for the revenue shortfall. This cross-subsidization shifts the cost from the government to the patients (Yu, Li et al. 2010).

According to Meng et al(2005), drug expenditures for all patients in two public hospitals still increased rapidly after the implementation of price cut policy. They concluded that utilization, more than price, determined the drug expenditures in these two hospitals. Thus, strategies to control pharmaceutical quantity as well as retail prices need to be implemented to contain hospital drug expenditure. The use of appropriate reimbursement mechanisms and the introduction of a prospective payment system would be effective strategies to achieve them (Chen and Schweitzer 2008).

3) Lack of authoritative drug formulary

The health insurance authorities have adopted drug formularies to contain drug expenditure and to improve the rational use of drugs. They consider clinical efficacy, safety, and affordable price as the criteria of the selection of drug formularies. However, the decision to list an item on the formulary is not transparent and is not monitored well enough to assure the drugs are selected by the criteria. The selection process for the EMLs and the pharmaceutical reimbursement lists relies mainly on expert opinion rather than objective evidence, which often lacks credibility and acceptability among other experts (Barber, Huang

et al. 2013).

4) Lack of the formal HTA system for drug pricing and formulary

The health insurance authorities and pricing decision bodies have adopted some HTA works, but it is not mandatory for manufacturers to submit the evidence of clinical effectiveness and cost effectiveness in the decision process of pricing and selecting drug formularies. Due to the lack of valuable comparators, the drug with high cost-effectiveness may not be included in the formularies, and the price of selected drug is too high.

Ⅱ. Fiji

1. Description of health care system[9]

1) Financing & health delivery system

Fiji's health system is predominantly financed by general taxation. The other main source of financing are OOP payments, while smaller amounts are derived from PHI and donor organizations. There are no compulsory social insurance schemes. In 2008, government health expenditure accounts for 68% of the total health expenditure, while private health expenditure has remained around 25% in recent years even though OOP pay has risen in association with the expansion of private health sector. External sources of funding, including contributions from multilateral and bilateral development agencies and non-government organizations, represent 6% of total health expenditure (WHO, 2011).

Table 22. Trends in health expenditure in Fiji

Expenditure	1995	2000	2005	2007	2008
Total health expenditure in $PPP per capita (1995 prices)	178.0	245.0	271.0	-	-
Total health expenditure as % of GDP	3.9	4.7	4.1	4.3	4.2
Public expenditure on health as % of total expenditure on health	58.2	69.0	72.0	71.2	69.6
OOP payments as % of total expenditure on health	-	-	11.9	15.4	15.5
Mean annual real growth rate in GDP	-	-1.7	3.6	-6.6	0.2
Government health spending as % of GDP	3.0	3.5	3.2	3.3	2.9

Source: WHO (2011)

Public provision of health care is free or at very low cost. User fees are charged for some basic and selected services, with exemption for certain population groups.

[9] Mainly based on WHO (2011c)"

Private providers charge user fees, which are often substantially higher than those in public facilities and are not regulated by the government. Most of health services are provided by the government. A small private sector is mainly located in urban areas and used mainly by those in the formal employment. Private GPs receive a fee-for-service payment, and some are contracted to private organizations to provide employee health care (WHO, 2011c).

2) The role of pharmaceutical sector in health system

The share of pharmaceuticals in overall health spending in Fiji (10.88%) is below average of OECD countries. It is also in the mid-range of developing country expenditure, especially the lowest among five Pacific island countries. However, patient's OOP payments are mostly for prescriptions, OTC drugs and outpatient services. The public/private share of pharmaceutical expenditure was 53.3%/46.7% (WHO 2009b).

Table 23. Pharmaceutical expenditure by source of funds, Fiji, 2005

Source of Funds	% of TPE
Public Pharmaceutical Expenditure	53.3% of TPE
Government-sourced funds(tax funded)	53.24
Social security health insurance	-
External (i.e., donor)	0.06
Private Pharmaceutical Expenditure	46.7
OOP to private sector plus pre-paid plans (PHI)	46.55
OOP to public sector	0.15
TPE	US$ 10,663,153.22 (10.88% of THE)

TPE: Total Pharmaceutical Expenditure
THE: Total Health Expenditure
Source: Fiji Pharmacy Service, MOH (2006)

2. Reimbursement & pricing process

1) Reimbursement

All products on the EDL are available free of charge at public health facilities, but there is no public reimbursement for products for the private sector. The EDL consists of 430 drugs available in the public sector, including 61 vital medicines. It indicates the type of drugs that can be supplied at the different levels of health services. Fiji's National EDL is a part of the Essential Medicines Formulary. The National Medicines and Therapeutic Committee requires evidence-based research to justify cost-effectiveness of a recommended item (WHO 2011a).

There are two main PHI companies in Fiji. One insurer covers drug therapy for acute illnesses only and reimburses the pharmacist to the level of generic drug cost. The copayment is one dollar per prescription. The other insurer operates a capitation scheme with medical practitioners, which covers prescription drugs for outpatient visits and does not cover medication for inpatient use. There is a patient co-payment of $1 (Bailey 2002).

2) Pricing

Pharmaceuticals are subject to direct price control under the Counter Inflation Act. Retail pharmacies are allowed a maximum mark-up of 35% on prescription medicines (plus a 45% dispensing fee) and 30% on OTC medicines. There is no value-added tax (VAT) on prescribed medicines but this tax is payable on OTC medicines. The Fiji Prices and Income Board (PIB) controls prices in the market by setting percentage markups for both wholesalers and retailers (Consumer Council

of Fiji 2010). The PIB also sets maximum retail prices for certain common household medicines (Bailey 2004).

All pharmaceuticals are imported by the government-funded Fiji Pharmaceutical Services and supplied to government health facilities. Private pharmacies can purchase from the Fiji Pharmaceutical Services with allowable wholesale and retail markups set by the Fiji PIB (WHO 2011a). According to HAI survey, medicines are purchased by the government for prices considerably lower than the international comparator prices in the public sector.[10]

3. Pharmaceutical cost containment strategy

Medicine prices are monitored by the PIB (now merged with the Commerce Commission). The PIB (Commerce Commission) is also responsible for the control of compliance of wholesalers and retailers in pharmaceutical products. The problem is that PIB has not reviewed the Price Control Order (PCO) on medicines and nor produced formal monitoring report for judging compliance of wholesalers and retailers since 1992. Therefore, in response to Fiji's increasing health care cost, the Fiji government needs to review and revise the PCO, which is about 20 years out of date. There is a trend to alleviate the constraint on state-funded services and facilities by adopting private health care or a user-pay system (Consumer Council of Fiji 2011).

[10] http://www.haiweb.org/medicineprices/surveys/200409FJ/survey_report.pdf

4. Service delivery (distribution)[11]

Public sector procurement is through international competitive tender from pre-approved suppliers utilizing the WHO Certificate of Compliance for pharmaceutical items. There is no drug registration system in Fiji, but quality of medicines in the public sector is controlled through monthly retrospective analysis. There is currently no such control over quality of medicines procured in the private sector, and doctors and pharmacists are legally entitled to import any medicines, which comply with either BP or USP standard, except narcotics and other restricted substances. All products entering Fiji need to be registered in their country of manufacture. Some pharmacists and medical practitioners have been illegally importing drugs of Indian Pharmacopoeia standard, most of which are not equivalent with products of BP or USP standard.

Retail pharmacists can also purchase medicines from the Fiji Pharmaceutical Services revolving fund bulk purchase scheme (BPS), which was established in 1981. This method is used by the government to lower prices for essential medicines in the private sector as pharmacists and doctors can purchase requirements at cost plus a lower-than-usual mark-up (20%). This saving is then passed on to the patient. Private GPs are legally entitled to dispense and supply medicines if they are not located within five kilometers of a retail pharmacy. Private sector pharmaceutical suppliers consist of one manufacturer, nine wholesalers selling prescription medicines, the Suva Private Hospital with its own private pharmacy, 45 private pharmacies, and 125 GPs (WHO 2011a).

[11] Mainly based on

'http://www.haiweb.org/medicineprices/surveys/200409FJ/survey_report.pdf'

All public health facilities dispense pharmaceuticals, which are provided free of charge. Out-of-stock medicines are monitored monthly by the MOH. Prescribing in the public sector is primarily by generic name, while both brand and generic names are used in the private sector based on prescriber's preference. A private sector pharmacy, when substituting a generic drug for a prescribed one, must inform both patient and prescriber that the substitution has been made (WHO 2011a).

5. Key challenges

1) Control of medicines quality

Some pharmacists and medical practitioners have been illegally importing drugs of Indian Pharmacopoeia standard. The result of the illegal importation has been the compromise of public health in Fiji and the provision of unfair price competition. In addition, it has been reported that some medicines supplied by dispensing medical practitioners have been unlabeled or merely wrapped in paper (Bailey 2002).

2) Need for action of PIB (Commerce Commission) for cost containment

It was mentioned that the PIB has not reviewed the PCO on medicines and has not produced formal monitoring report for compliance of wholesalers and retailers since 1992. Therefore, the PCO is about 20 years out of date. The PIB needs to revise the PCO and report compliance status of wholesalers and retailers when health system faces increasing health care expenditure (Consumer Council of Fiji 2011).

III. Indonesia[12]

1. Description of health care system

1) Financing & health care delivery system

Historically, private health expenditure was a main source in overall health financing, but the public health spending has increased since 2005-06, under the government's effort for universal coverage by Social Security Law in 2004. As a new health program for the poor, Asuransi Kesehatan Masyarakat Miskin or Askeskin was introduced. The population coverage rate increased with the expansion of Jamkesmas (Jaminan Kesehatan Masyarakat), which is the program for the near poor people. The estimated health insurance coverage is about 48 percent of the population in 2008 (Rokx 2009).

The major health financing programs (SHI model) are described in Figure below. Askeskin/Jamkesmas, which is SHI for identified poor and near poor and funded from general revenue, covered 76.4 million people. Since 2008, the MOH have been in charge of the major administrative functions, and the MOH takes responsibilities for provider payment (Rokx 2009). Askes (Asuransi Kesehatan), which is compulsory SHI for civil servants and their dependents, civil service retirees, and military, covered 14 million people. Askes is funded by government employee contribution (2 percent premium) and government (2 percent premium). Askes program is administered by P.T Askes, which is a for-profit state enterprise.

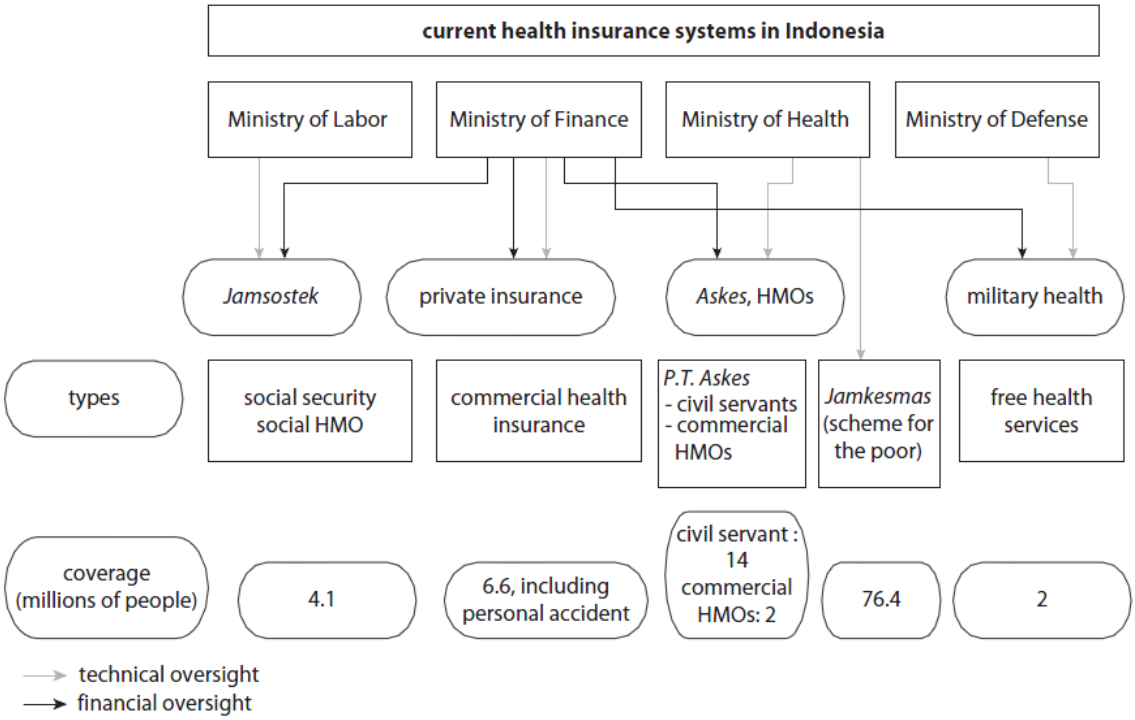
[12] Comments by Suryawati Sri are appreciated.

Local governments run JAMKESDA insurance with their distinct premiums and benefit packages.

Jamsostek (Jaminan Sosial Tenaga Kerja), which is SHI for private formal sector employees (companies with 10 or more employees) and their dependents, covered 4.1 million people. Jamsostek is funded by the employer, which is a 3 percent (6 percent for families) payroll contribution (up to Rp 1 million [US$110] per month ceiling). It is managed by a for-profit state enterprise, and employers can opt-out, if they want self-insuring or private insurance for employees. Recently, under President Decree No. 111/2013, Indonesian Government has issued a new comprehensive social security scheme. All health insurance schemes are merged into a single payer BPJS Ketenagakerjaan. Others, such as PHI, JPKM (Jaminan Pemeliharaan Kesehatan Masyarakat, Community Health Insurance Scheme), are not compulsory, but based on voluntary participation, also covered more than 6.6 million (Rokx 2009).

The differences in benefit package among the programs have resulted in significant differences in health expenditures and utilization among the programs, such as high OOP costs for Jamsostek and Askes (about 40%) and restrictions on the utilization of private sector under Askes and Askeskin/Jamkesmas (Rokx 2009). Under those health financing system, OOP payment is still large in total health expenditure. Even though the percentage of government expenditure on health has increased from 28.8% (2005) to 39.6% (2012), private expenditure (60.4% in 2012) and OOP expenditure as a percentage of private expenditure (75.1% in 2012) on health are still high, and government's role for risk-pooling mechanism is one of the challenging issue (WHO 2014b).

Figure 18. Current health insurance systems in Indonesia (Type and Coverage)



Source: Rokx (2009)

Table 24. Health expenditure in Indonesia

	2005	2006	2007	2008	2009	2010	2011	2012
Total expenditure on health as a percentage of gross domestic product (%)	2.8	2.9	3.1	2.8	2.8	2.9	2.9	3
General government expenditure on health as a percentage of total expenditure on health (%)	28.8	31.4	36.4	35.9	36.1	37.7	37.9	39.6
Private expenditure on health as a percentage of total expenditure on health (%)	71.2	68.6	63.7	64.2	63.9	62.3	62.1	60.4
OOP expenditure as a percentage of private expenditure on health (%)	76.7	76.3	77.2	76.5	76.7	75.8	76.4	75.1

Source: WHO (2014b) South-East Asia Region: Indonesia statistics summary (2005 - 2012)

Local governments at the district level have responsibility for the delivery of health services. Under decentralized system since 2000, province-level health

offices are in charge of the supervision of provincial hospitals as well as training or coordination, however, they are not fully in charge of resource allocation. Districts have accountability for health services delivery and resource allocation. District-level hospitals usually provide curative care services, and Puskesmas (health centers) provide primary care services at the sub-district level (Rokx 2009).

There are four types of hospitals for curative services. District-level hospitals provide all main services and have referrals systems for more complicated cases to higher level hospitals, and the highest level is teaching hospitals in major cities. In public health facilities and hospitals officially owned by local governments, salaries and operational costs are funded by central subsidies in theory. But public hospitals and later Puskesmas have become reliant on user fees because they were urged to apply self-governing (Swadana) principle. The private sector was promoted to have a more significant role in delivering health services since 1990s. Therefore, the number of private hospitals and emergency-trained midwives increased, and they charged for their services by fee for service (Rokx 2009).

2) The role of pharmaceutical sector in health system

Indonesia's pharmaceutical expenditure per capita is 18 USD PPP, which is relatively small compared with 136 USD PPP in Asian 19 nations and 487 USD PPP in OECD countries in 2009 (OECD/WHO 2012). However, pharmaceutical expenditure as a share of total health expenditure was 17.8% in Indonesia, which is higher than OECD countries of 15.6% in 2009 (OECD/WHO 2012). Therefore, pharmaceutical is one of the critical areas of health expenditure in Indonesia. Almost half of public spending on EDL for primary care came from the central

government budget, even though district spending varies widely. Availability of public sector low-priced generics may contribute to lower pharmaceutical expenditure per capita (18 USD PPP) compared with other Asia-pacific countries like Vietnam (104 USD PPP), Malaysia (55 USD PPP), Philippines (47 USD PPP), and Fiji (35 USD PPP).

However, people purchase most branded generics or some innovator brands by OOP payment in the private sector, and those drugs are more expensive than the lowest-priced generics. This is related to financial incentives for dispensing doctors or drug sellers to prescribe or sell higher-priced, higher-margin branded medicines (Rokx 2009). Public health insurance programs, such as Askeskin program, also experienced a rapid increase in expenditure for hospital drugs since 2006–07 because of difficulties in controlling membership and outside-formulary prescribing (Rokx 2009).

2. Reimbursement & pricing process

1) Reimbursement

Indonesia has a national EML updated every 3 years. However, MOH only partially follow, public hospitals/ government insurance/ provinces/ districts poorly follow, and private sector have not followed the EML. All insurance agencies, whether public or private, have their own reimbursement drug lists, which cover more medicines than the EML. For example, the EML contains 323 chemical entities, but ASKES has its own list of 1035 items and about 400 chemical entities (Holloway 2011). With a recent progress toward universal health coverage along with a single payer, compliance with the EML is likely to increase.

Government social insurances (ASKES, JAMKESMAS and JAMKESDA), which cover more than 40% of population, reimburse directly to pharmacist or health facility. About 2% of people is covered by PHI, and the main private insurance is JAMSOSTEK (Holloway 2011). Basic Benefits Packages are different across the insurance schemes, especially for drug benefits. For example, Askes and Askeskin/Jamkesmas provide services largely in the public sector, on the other hands, Jamsostek provide services in the private sector, and Jamkesmas has different formularies or generic requirements (Rokx 2009). For example, patient are allowed to utilize public health facility (puskesmas or hospital) or approved private doctors, and patient are allowed to use the ASKES –listed medicines and get a maximum 3 drugs per one prescription (Holloway 2011). P.T. Askes spends about 25 % of its health expenditure on medicines and has made efforts to control medicines spending. The coverage of Jamkesmas is very limited with the formulary including only unbranded generic medicines. But Jamkesmas does not control off-formulary prescribing, nor has capacity to monitor the availability of discounted drugs. Jamsostek spend about 40 percent of its health expenditure on medicines (Rokx 2009).

2) Pricing

WHO/HAI reported that unbranded generics have low public procurement prices, and branded generics and original brand drugs have high prices in hospitals and private pharmacies (Diack, Seiter et al. 2010). MOH fixed prices of generic medicines annually, but there are no fixed price for branded generic medicines or branded originator drugs. It is reported that copayments do not work as a tool for cost containment because there is no fixed price for branded generic medicines and

pharmaceutical manufacturers set price of all medicines except generics (Holloway 2011).

3. Pharmaceutical cost containment strategy: SHI scheme's control for pharmaceutical expenditure

The Askes, has been evaluated as a "good practice" for drug expenditure management system. The P.T. Askes has specific strategy for pharmaceutical sector management as follows (Diack, Seiter et al. 2010):

"(i) a formulary based on independent, scientific advice; (ii) priorities linked to budget availability; (iii) prescribing protocols for high-cost drugs; (iv) competition to obtain discounted prices for drugs listed in its Daftar Dan Plafon Harga Obat (drugs price list); (v) publication of the price list; and (vi) paying pharmacists fixed fees and declining margins instead of a percentage mark-up (Rokx 2009)."

However, expansion or application of PT ASKES medicines system to other social insurances requires a well-planed system to deal with the larger number of members and different management circumstances (Diack, Seiter et al. 2010).

4. Service delivery (distribution)

Indonesian national medicines policy was established in 1983 and revised in 2006. Based on this revised decentralization policy, authority of providing health services was delegated to local governments (Roughead, Lhazeen et al. 2013). Central government provides a budget for medicines, and the District Health Office

procures or distributes medicines for all primary care facilities (so called puskesmas). Among the MOH generic medicines list (453 items), less than 50% are on the national EML. Local governments provide a budget for hospitals to procure their own medicines. All provinces, districts and hospitals have developed or made their own formularies, which usually include more drugs than the EML (Holloway, 2011).

Indonesian MOH No.68 of 2010 implemented a new regulation that hospitals must operate all main activities by their own. Since 2010, hospitals have to manage pharmaceutical supply chain and inventory by themselves (Rachmania, 2013). Therefore, there are no economies of scale in medicines procurement because all districts and hospitals individually purchase their own medicines. Moreover, many districts have no electronic inventory system for drug management. Manual stock control is common and management of quantities of medicines are often determined by past consumption (Holloway, 2011)

5. Key challenges

1) Lack of centralized national and local government's management of pharmaceutical budgeting

Even though price of unbranded generics in public procurement are low, there are still high hidden costs. These problems may come from, for example, the lack of centralized planning, budgeting, procurement, and coordination with the local level. In the public procurement, large variation in procurement regulations and very low price ceilings for unbranded generic drugs have interrupted competition, which

resulted in monopolistic supply by state-owned companies and the lack of bidding in rural areas associated with high transport costs and small volumes. At the same time, too little budget were allocated to essential medicines for primary care by some district governments. Therefore, they experienced shortage of medicines in primary care level as well as difficulties of procurement and logistics management of medicines (Diack, Seiter et al. 2010). It was also pointed out that some traditional medicines were included in the EML without scientific basis

2) Increase in pharmaceutical expenditure

Since Indonesia expanded SHI coverage, the country experienced the increase in pharmaceutical expenditure, especially in the early phase of implementation. Indonesia's social insurance scheme (such as ASKES for civil service) tried to reduce doctor's prescribing of out-of-formulary or high cost medicines, but has not been effective (Diack, Seiter et al. 2010). Moreover, patients do not have to pay copayment and have no incentive to choose less costly generic medicines (Holloway 2011).

IV. The Philippines[13]

1. Description of health care system

1) Financing & health care delivery system

Under the National Health Insurance Act (RA 7875), the Philippines instituted the National Health Insurance Program (NHIP) in 1995. The law paved the way for the creation of the Philippine Health Insurance Corporation (PHIC), known as PhilHealth (PhilHealth Homepage 2014)[14]. The Philippine government had new health sector plan of achieving universal health care as the main goal in 2010. It had goals to increase the poor people's enrollment in PhilHealth and improve benefits package of the outpatient and inpatient. Alongside the universal health coverage plan, the government offered full subsidy to the poor (who is under 20% of the population), and the central and local government units (LGUs) paid premiums for the second poorest 20% people (WHO 2011b).

The main four types of financing mechanisms in the Philippines are (1) OOP payments by households, (2) premium contributions or prepayment by households and firms to PhilHealth, HMOs, private insurance, (3) government budget for public health care facilities and PhilHealth. Among the insurance mechanism, the PhilHealth is the largest programme in terms of coverage and benefit payments. In recent years, private insurance and HMO sector has grown but these account for less than 7% of total health spending (WHO 2011b).

[13] Comments by Noel Juban are appreciated.

[14] http://www.philhealth.gov.ph/about_us/history.htm

However, a big portion of increasing health care expenditure comes from OOP payments by private households, even though PhilHealth covers more than 70% of population. For example, private expenditure on health accounts for 62.3% in total health expenditure, and OOP expenditure represents 83.5% of private expenditure on health in 2012 (WHO 2014c).

Table 25. Health expenditure in the Philippines

	2005	2006	2007	2008	2009	2010	2011	2012
Total expenditure on health as a percentage of gross domestic product (%)	3.9	4	3.9	3.8	4.3	4.2	4.4	4.6
General government expenditure on health as a percentage of total expenditure on health (%)	38.4	36.8	35.1	31.7	36.3	37.2	36.9	37.7
Private expenditure on health as a percentage of total expenditure on health (%)	61.6	63.3	64.9	68.3	63.7	62.8	63.1	62.3
OOP expenditure as a percentage of private expenditure on health (%)	84.3	85.3	85	84.7	83.7	83.6	83.5	83.5

Source: WHO (2014c) Western Pacific Region: Philippines statistics summary (2005 - 2012)

Health care delivery system in the Philippines consists of small public sector and large private sector. The delivery system is decentralized, the DOH acting as the governing agency, and communities and individuals are provided services by LGUs and the private sector. The DOH suggests national policy direction and provides technical standards or guidelines on health. LGUs have autonomy and responsibility for health services, under the guidance from the DOH. Secondary hospitals provide services mostly at the provincial level. Primary care (including maternal and child care, nutrition services, and direct service functions) provide services at city and municipal administrations. Every municipality in the country has RHUs since 1950s

(WHO 2011b). A substantial portion of Philippine health care is provided by the private sector, which has larger manpower and financial and technical resources. The private sector consists of for-profit and non-profit providers. DOH and PHIC regulates the private health sector, but information on private providers is usually not reported to the DOH information system (WHO 2011b).

2) **The role of pharmaceutical sector in health system**

About half of household health spending are on drugs. Reimbursements of PhilHealth accounts for 30 percent of total spending on drugs, and large unmet need for drugs remains (Picazo 2012). Many government hospitals experience the absence of drugs, so households are forced to buy their drugs in the private sector pharmacies by means of OOP spending (Picazo 2012). About 68% of household OOP health payments are used for medicines (WHO 2011b).

The price of medicines is high in the Philippines. According to previous studies (BIZCLIR 2009; Lavado 2011), the price of medicines is higher than in India and Pakistan, even for similar brand names of similar manufacturers. The ratio of median prices to international reference prices are 30.23 for originator brand drugs in the public sector, and 37.1 in the private sector in 2008/09, and the ratios of Philippine price has increased compared to 2005 (Picazo 2012). Therefore, the government tries to implement "the Cheaper Medicines Program" policy (Picazo 2012).

Table 26. Median medicine price ratios for innovator brands and their generic equivalents in the Philippines

Type	Sector	2005	2008/09
Innovator (originator) Brand	Public	15.31	30.23
	Private	17.28	37.1
Generic Equivalent	Public	6.4	9.78
	Private	5.64	10.76

Source: Picazo. (2012.)

2. Reimbursement & pricing process

1) Reimbursement

The Philippine medicines policy has a list of essential medicines, so called the PNDF. All government procurement of medicines and the Philippine Health Insurance Corporation's reimbursement of drugs are based on PNDF (NCPAM 2014)[15]. There are 1,509 medicines in the EML, which was lastly updated in 2008 (WHO/Philippines MOH 2012). The DOH organized the National Formulary Committee (NFC), which worked to formulate the EDL PNDF Volume I. The PNDF became the basic component of the National Drug Policy and acts as the basic concept of EDs (NFC 2008).

PHIC used PNDF as the basis for claim reimbursements for drugs and medicines since 1999. PhilHealth's benefit package for inpatient care provides reimbursement for PNDF medicines up to specified ceilings (WHO 2011b). PhilHealth's benefit does not provide coverage for outpatient medicines

[15] http://www.ncpam.doh.gov.ph/index.php/major-program?id=44#1-1-what-is-pndf

(WHO/Philippines MOH 2012) although PhilHealth has been pilot-testing initiatives like Primary Care Benefit Packages that provides coverage for outpatient care. Reimbursements are limited to prescriptions that contain the corresponding covered generic drugs. Medicines that can be covered are purchased only from hospital pharmacies in theory (NFC 2008). Reimbursement for medications bought from outside pharmacies are allowed as some medicines are out of stock with hospital pharmacies although the major limiting factor is the low ceiling for reimbursements (comments by Prof. Noel Juban).

Some non-PNDF drugs are also reimbursed by PhilHealth. PhilHealth maintains a Positive List of 36 medicines, and there are several pathways for making this list: clinical trial results are used for safety and cost-effectiveness tests, and local and international data sources are used for post-marketing surveillance studies and adverse drug reaction reports, and costs data from local retail drugs are also used. PhilHealth included medicines in the Positive List that were lifted from three CPGs, e.g. community acquired pneumonia, hypertension, and urinary tract infection in 2000 (Thatte, Hussain et al. 2009).

2) Pricing

According to "Universally Accessible Cheaper and Quality Medicines Act of 2008", there are price ceilings for certain drugs under the President's authority to impose the price (Republic Act No. 950 2008). Local units of the Bureau of Food and Drugs (BFAD) collect drug prices, including leading government's pharmacies, private hospital's pharmacies, and leading private drugstore chain. The drug price information would be compared with international prices annually (Thatte,

Hussain et al. 2009).

There is DPRI, which is the publication for a range of drug prices of top 185 drugs. PhilHealth and the DOH led this work for the public awareness of the appropriate price of medicines and price transparency. The list of reference prices on DPRI is implemented as the ceiling price for the reimbursement for certain drugs, so PhilHealth will reimburse up to the DPRI price (Thatte, Hussain et al. 2009).

3. Pharmaceutical cost containment strategy

The major policies to control the price of medicines are the Generics Act, Parallel Drug Importation, and Cheaper Medicines Law.

1) The Generics Act

According to the Generics Act of 1988 and associated regulations, all public facilities have to procure medicines by generic name. However, medicine prices have remained high because of intensive marketing by dominant manufacturers and importers of originator brands, and 'branded-generics' contributed to the existing market imbalances and failures (Ball and Tisocki 2009).

2) Parallel Drug Importation

The DOH started parallel drug importation as an innovative strategy to reduce costs of medicines in 2000. PDI allows the importation of a patented drug from a third country, mostly from India and Pakistan, without the authorization of the

patent holder. After the Philippine International Trading Corporation (PITC) imported PDI medicines, the DOH distributed them to their DOH-retained hospitals (72 hospitals) and three LGU hospitals. The distribution was processed under the Pharmaceutical Management Unit-50 Program (so called GMA 50: Gamot na Mabisa at Abot Kaya), with the 50 relating to 50% cheaper medicines. The PDI fulfilled an estimated average of 60.9 % price reduction of drugs in 2004, which was higher than the targeted 50% reduction by 2010 (David and Geronimo 2008).

LGUs can also purchase PDI medicines directly, and BnB became a primary retailer of PDI drugs in the mid-2000s. The BnB is a community-based supplier of OTC medicines as well as a short list of essential prescription medicines. However, the amount of PDI procurement has been very small compared with the Philippines total pharmaceutical sales (Picazo 2012).

3) Cheaper medicines law

The President has the authority to regulate the price of medicines and the DOH Secretary was empowered to establish a drug price monitoring and regulation system under the "Cheaper Medicines Act". This Act allowed the President to issue Executive Order (E.O.) 821 for the maximum retail prices of prescription drugs, which is known as government mediated access prices (GMAP) for selected medicines related to common causes of morbidity and mortality in the Philippines (effective since August 2009) (Picazo 2012).

4. Service delivery (distribution)

In the Philippines, the private sector dominates (more than 90 percent) the pharmaceutical market. According to PHAP, the medicines sales are distributed as follows: drug stores (about 80%), hospitals (10%), and other retail outlets (10%). In more detail, a major pharmaceutical chain accounts for 63%, other small independent pharmacies 17%, private hospitals 7%, public hospitals 3%, and other private outlets 10% (Ball and Tisocki 2009). The BnBs are allowed to sell low-priced generic OTC drugs and 2 prescription drugs (amoxicillin and cotrimoxazole). These days, up to 40 essential OTC drugs and 8 prescription drugs are sold by BnBs. Until 2010, 16,350 BnBs had been established in the Philippines, leading to 1 BnB per 3 barangays (Picazo 2012).

Even though there is legal basis for separation of prescribing (physicians) and dispensing (pharmacists), many clinics and RHUs dispense medicines without pharmacies, and BnBs run their pharmacies without pharmacist (WHO 2011b). There is also a regional variation between urban and rural areas because most government health professionals work in urban areas. Therefore, rural/remote areas are experiencing shortage of drug supply (WHO 2011b).

The government has P100 program, which distributes designated packs of selected essential medicines for a price of P100 or less inclusive of any mark-ups since 2008 (Higuchi 2008). However, this program has a limited impact due to limited number of access points because only DOH hospitals and a limited number of LGU hospitals are dispensing with P100 packs.

5. Key challenges

1) High medicines price and high retailer markups

Similar brand name drugs in the Philippines are 5 to 30 times more expensive than India and Pakistan (BIZCLIR 2009, Lavado 2011). At the retail and distributor level, high markups are assigned. Markups ranged from 5–355% at the retailer level and 18–117% at the distributor level for generic medicines. Markups were 5-8% at private retail pharmacies and 2-60% at large chain pharmacy for originator brand medicines (Ball and Tisocki 2009, Picazo 2012). Government policies were not effective because public facilities suffer from the shortage of medicines inventories and people have to pay high price for medicines at private retail pharmacies.

2) High OOP payment burden for the poor

In the Philippines, coverage of PhilHealth is still not sufficient (in terms of population and benefits coverage), e.g., limited coverage for outpatient drugs. As a result, poorer households spend larger share of their health care costs for medicines than richer households do. According to an analysis of Family Income and Expenditures Survey 2006, the poorest households (the lowest income 10 percentile) spent 59% of their medical care costs on drugs. But the richest households (the highest income 10 percentile) spent 41% of their medical care costs on drugs (Picazo 2012).

3) Dominance of originator brands among the richer – market segmentation

Pharmaceutical market is highly segmented in the Philippines. The richer Filipinos tend to use originator brands and 'branded-generics' at private drug stores or hospitals. Middle classes tend to follow the richer group, but they use some of public facilities. The poor tend to get their medicines from public facilities, community outlets and drugstores, and the poor usually use cheaper generics (Kanavos, Lim et al. 2002). Market segmentation and dominance of expensive originator brands or 'branded-generics' are associated with insufficient quality assurance of generic drugs by BFAD (Kanavos, Lim et al. 2002, Ball and Tisocki 2009). It is also related to marketing (targeted at prescribing physicians) by dominant manufacturers and distributors

4) Parallel drug importation

PITC imported originator brands that are cheaper than locally available originator drugs. Even though the PITC Pharma is procuring low-priced medicines for Filipinos, there are also adverse consequences. The existence of parallel imports can affect generic companies, which may not have incentive to enter the market because the generic companies experience increased uncertainty in terms of market size. Therefore, the policy needs to be closely monitored to ensure that the parallel importation does not disturb the entry of generics to the market (Ball and Tisocki 2009).

V. Thailand[16]

1. Description of Health care system

1) Health care financing & delivery system

The health insurance system has three major schemes, the CSMBS, the SSS and the UCS. The UCS covers about 75% of the country's population while the CSMBS and the SSS cover approximately 22% (Ngorsuraches, Meng et al. 2012). The CSMBS providing health services to government employees, their dependents, and retirees is fully funded by general tax and is run by the Comptroller General's Department, Ministry of Finance. The SSS, a compulsory insurance scheme for employees in the private sector, covers only the employees. Its fund comes from employers, employees and the government and is managed by the Social Security Office (SSO). People who are not eligible for the CSMBS and the SSS are covered by the UC scheme. It is primarily funded by general tax and operated by the National Health Security Office (Ngorsuraches, Meng et al. 2012).

All three insurance schemes have their own benefit package and payment system. The three public health insurance schemes have similar benefit package covering outpatient, inpatient and emergency services, medical and surgical services, and medicines. However, as utilization processes and payment systems are different across three schemes, hospitals confront a mix of financial incentives when managing their service provision (Hirunrassamee and Ratanawijitrasin 2009).

[16] Comments by Supon Limwattananon are appreciated.

CSMBS beneficiaries choose public providers freely without any register process (and can use private-sector admission services for life threatening accidents and emergencies), but since 2007 the Scheme has encouraged the beneficiaries to register with a preferred public hospital. If they do that, they can use outpatient services without paying upfront and being reimbursed later (Thai working group on Observatory of Health and Policy, 2010). The CSMBS uses prospective payment (DRG) for inpatient services under soft budget (that is, spending greater than the annual budget is reimbursed) and fee-for-service type of payment for ambulatory services, which has been regarded as a factor resulting in over-treatment in the CSMBS. The SSS allows its beneficiaries to use health care services at either public or private hospitals. They need to register in preferred provider. While public and private hospitals are competing contractors, private contractors accounts for higher share, around 65% of total SSS beneficiaries. The scheme is based on capitation payment for both inpatient and outpatient services, and hard budget is applied. Additionally, incentives are provided to providers depending on the percentile of utilization (Thai working group on Observatory of Health and Policy, 2010).

As the UC scheme applies capitation type of payment for ambulatory services, beneficiaries need to register with a preferred primary care network in their local districts. Inpatient health services are reimbursed by a DRG type of payment. Although there are some other additional pays for high-cost services, annual budget is allocated to providers in hard budget (it is not allowed to pay beyond what is negotiated and approved) (Thai working group on Observatory of Health and Policy, 2010).

Table 27.Characteristics of public and private health insurance schemes

Insurance scheme	Population coverage		Financing source	Mode of provider payment	Access to service	per capita expenditure
Civil Servant Medical Benefit Scheme	Government employees plus dependents (parents, spouse and up to two children age <20)	9%	General tax, noncontributory scheme	Fee for service, direct disbursement to mostly public providers and DRG for inpatient care	Free choice of public providers, no registration required	US $ 367
Social Health Insurance	Private sector employees, excluding dependents	16%	Tri-partite contribution, equally shared by employer, employee and the government	Inclusive capitation for outpatient and inpatient services plus additional adjusted payments for accident and emergency and high cost care, utilization percentile and high risk adjustment	Registered public and private competing contractors	US $ 71
Universal coverage	The rest of the population not covered by SHI and CSMBS	75%	General tax	Capitation for outpatients and global budget plus DRG for inpatients plus additional payments for accident and emergency and high cost care	Registered contractor provider, notably district health system	US $ 79
Private health insurance	Additional health insurance scheme for those who can afford premiums	2.2 %	Health insurance premiums paid by individuals or households	Retrospective reimbursement	Free choice of health care providers, either public or private providers	-

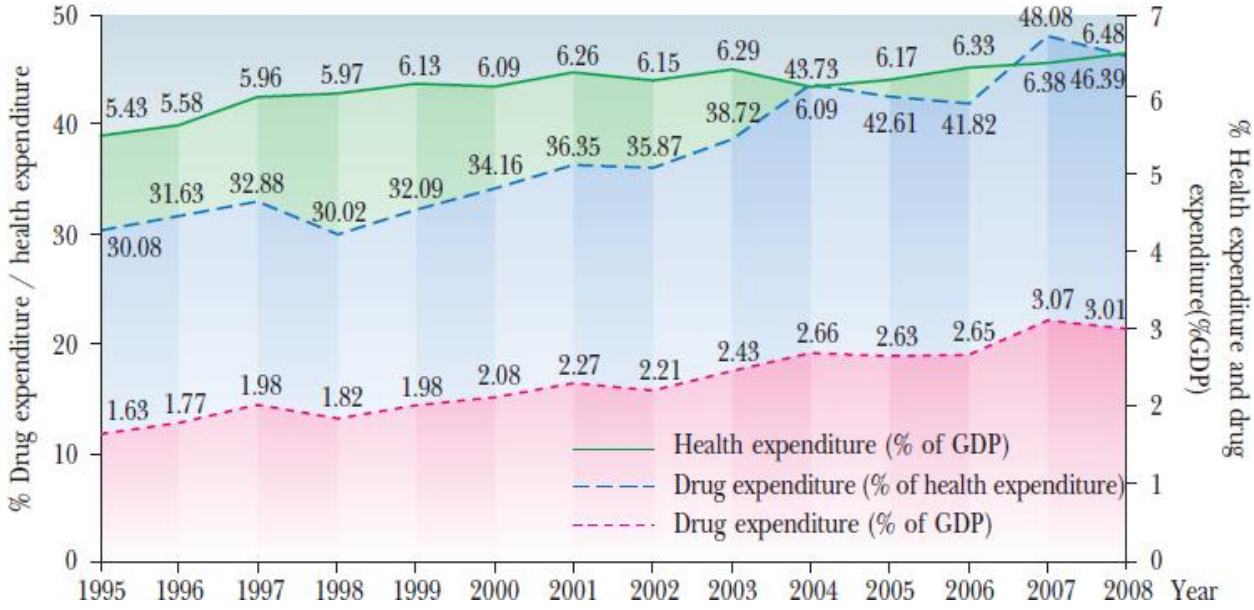
Source: Thai working group on Observatory of Health Systems and Policy (2010); Thailand's Health Insurance System Research Office (2012)

2) The role of pharmaceutical sector in health system

Total pharmaceutical expenditure represented approximately 34.2% in 2000 and increased to 46.4% of the total health expenditure in 2008, which increased at a rate higher than health expense and economic growth (Bureau of Policy and Strategy and

Thailand MOPH 2012). It is much higher than other Asian countries (OECD/WHO 2012). The outpatient services relying on prescription drug use and the fee for service payment of the CSMBS are known to be contributing factors to a rapid increase in drug expenditure (Ngorsuraches, Wanishayakorn et al. 2013).

Figure 19. Trend of pharmaceutical expenditure from 1995 to 2008 in Thailand



Source: Bureau of Policy and Strategy and Thailand MOPH (2012)

2. Reimbursement & pricing process

1) Pricing

The Thai FDA is responsible for the market authorization of drugs, which is decided based on the safety, efficacy, and quality of the products. Costs of non-OTC drugs are regulated through the Medicine Price Ceiling, which sets maximum price for each drug that manufacturers and distributors can charge public hospitals (Jirawattanapisal, Kingkaew et al. 2009). Bulk purchasing at the national and provincial levels is another

mechanism to control medicine price. The MOPH also controls maximum allowable percentage mark-up; for example, hospitals cannot get mark-up greater than 30%. However, this regulation is applied only to government hospitals, but not to other sectors (Anantachoti, Choompon et al. 2004). As regulations are not applied to all health care sectors, medicines are sold at higher prices compared with international reference prices, and the prices varies widely with high mark-up (Anantachoti, Choompon et al. 2004, Cameron, Ewen et al. 2009, Sooksriwong, Yoongthong et al. 2009, Hassali, Alrasheedy et al. 2014).

For OTC drugs, the Ministry of Commerce (MOC) regulated drug costs through mandatory price labelling. Drug manufacturers and importers are required to submit their products' price list and to seek permission from MOC in order to adjust price. Medicine is a product on the watch list monitored monthly (Anantachoti, Choompon et al. 2004). However, the mechanism does not work well. While more than 30,000 branded drug products are registered, only less than 0.1% of them were actually monitored.

2) Reimbursement

The beneficiaries of all three schemes are eligible for pharmaceuticals on the NLED. While the National Drug Committee develops the list, economic evaluation recently became an important element for informed decisions (Ngorsuraches and Kulsomboon 2010). Meanwhile, the beneficiaries of three schemes might receive pharmaceuticals that are not included in the list, with the authorization from a physician. Particularly, the beneficiaries of the CSMBS tend to have more access to the products outside of the NLED due to the fee-for-service payment, whereas hospitals

are discouraged to provide expensive pharmaceuticals for the UC and SSS beneficiaries due to their capitation payment. While the UC beneficiaries pay nothing at the point of health care, the CSMBS and SSS beneficiaries can be charged a mark-up of 10-30% on drugs dispensed and later are reimbursed respectively by MOF and MOL (Holloway 2012).

3. Pharmaceutical cost containment strategy

1) Health technology assessment

As health care utilization has increased rapidly, there is an increasing attention to the use of cost-effective medicines based on HTA. The HTA unit was established in 2002 under the MOPH's Department of Medical Services (Teerawattananon, Tantivess et al. 2009). Pharmacoeconomics (PE) has been applied in the decision process on the reimbursement of drugs listed on the NLEM. Potential drugs that should be evaluated are investigated through various stakeholders including health care providers, academicians, payers, and patient advocacy groups annually. Based on the World Health Organization guideline, average GDP per capita is considered to set a cost-effective threshold. Results of economic evaluation have been used to negotiate drug prices with manufacturers before the drugs are listed on the NLEM (Ngorsuraches, Meng et al. 2012).

2) Payment system to promote the use of less expensive medicine

In Thailand, generic prescribing in primary care practice is common. A few studies in Thailand have demonstrated that its capitation payment system increased

adherence to hospital-level generic substitution policies and increased prescribing of generics, where hospitals shared risk for medicines costs (WHO/HAI 2011). For example, several measures are implemented at hospital level: setting the maximum drug cost or quantity of drug per prescription, restricting prescription for drugs which are high cost or high risk of irrational use, and imposing mandatory generic substitution. However, the CSMBS beneficiaries have easy access to expensive drugs outside the National List of Essential Medicines. When doctors prescribes the drugs not covered by the NLEM, they get full reimbursements by declaring with written statement one of the 6 reasons for the use of these non-essential medicines. This was not the case of the SSS and UC because of their capitation type of payment (Ngorsuraches, Wanishayakorn et al. 2013). Furthermore, the government can control budget of the schemes; for example, the per-capita budget of the UC scheme is set at 2,755.60 baht for three years from 2012 in order to contain increasing health expenditure (Saengpassa and Sarnsamak 2013).

3) Reimbursement Restriction

Most of non-essential drugs are costly, and their usage was an important factor in high drug expenditure particularly in the CSMBS. To decrease drug expenditure, several measures that restrict the reimbursement are implemented, including the exclusion of specific drugs from coverage, drug utilization evaluation of new drugs or those that are costly or have a risk of irrational use and step therapy or fail-first requirements (a patient has to be treated with ED and if they are unsuccessful, the NLED could be used and covered by the government) (Thaweethamcharoen, Noparatayaporn et al. 2013). For example, the government issued a regulation

controlling expenses for glucosamine sulphate in the CSMBS in 2012 and announced that glucosamine reimbursements decreased from 600 million to 10 million baht (Saengpassa and Sarnsamak 2013). Step therapy or fail-first requirements was also launched particularly for CSMBS scheme patients in 2010, and a study reported the use of non-essential drugs was decreased (Thaweethamcharoen, Noparatayaporn et al. 2013).

4. Service delivery (distribution)

Hospitals purchase more than 80 percent of all pharmaceuticals sold in the country, while drug stores purchase the remaining 20 percent (Gross 2013). Patients tend to use prescribed medicines at hospital pharmacies rather than community pharmacies or drug stores. Pharmacy staff usually dispenses medicines in hospitals (Holloway 2012). While public hospitals have their own hospital drug lists based on the NLED, the regulation requests public hospitals to procure 70-100% essential drug items, costing 60-90% of the government budget (Holloway 2012). Since the regulation applies to only government budget, large public hospitals purchase more non-NLEDs (Yoongthong, Hu et al. 2012). Public facilities also should purchase about 50-70% of their medicines from GPO (Holloway 2012).

Every hospital has a Drug and Therapeutic Committees (DTC) to manage the 3-year procurement plan and drug purchasing and monitor adverse drug effects. Other actions to promote the rational use of medicines are rarely conducted. In addition, community hospitals are responsible four drug distribution to health centers below them. They send medicines to HCs according to their requests. All HCs operate a computer system, which records the diagnosis and drug treatment of each patient,

and these data are used to estimate and negotiate the NHSO budget for the coming year (Holloway 2012).

All medicines are sold OTC except Special Controlled Drugs, which include systemic steroids and oncology drugs and cannot be sold without prescription. Meanwhile, many doctors work in their own private clinics after finishing work in public facilities. They usually dispense medicines as patients are unwilling to pay for consultation without dispensed medicine (Holloway 2012). There are a few national STGs for certain diseases, but hospitals/doctors are not regulated to follow the rules. In addition, prescribing practices in the outpatient sector are known to be inappropriate; for example, prescribing unnecessary medicines for common cold cases, many medicines for aches and pains, and inappropriate medicine for a disease (Holloway 2012). A study investigating the availability of 43 medicines reported that the median availability of lowest priced generics in the public sector was higher at 75% than for originator brands at 10%, whereas the median availability of lowest priced generics and originator brands in the private sector was 29% (Cameron et al. 2011).

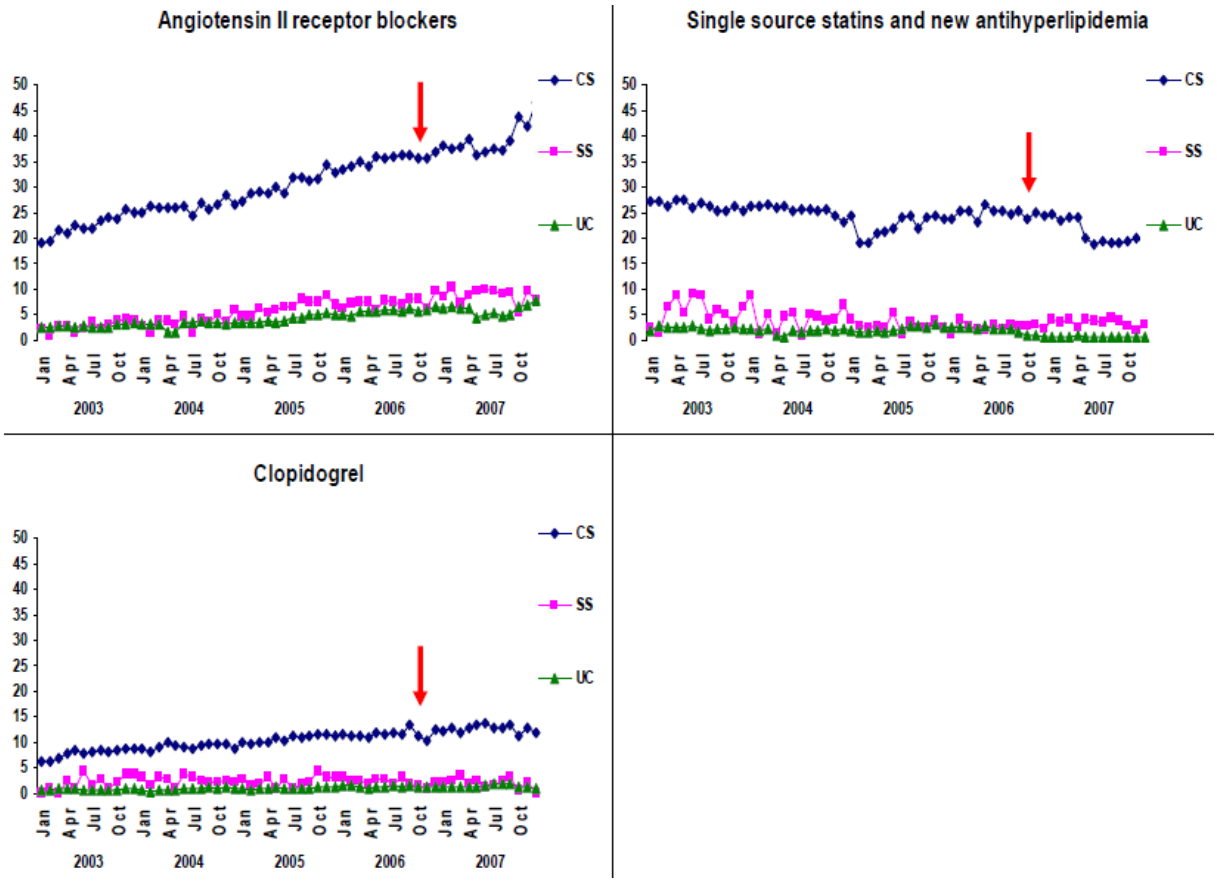
5. Key challenges

1) Access and quality of care in the UC and SSS

Recent studies have found inequities in access to care and the provision of expensive drugs and high-cost procedures across three health insurance schemes. For example, per capita expenditures are different across the three schemes: US $ 71 and US $ 79 respectively in SSS and UC but US $ 367 in CSMBS (Thailand's Health

Insurance System Research Office 2012). Furthermore, a study comparing the monthly prescriptions of innovative drugs reported that widely available lower-cost medicines are not prescribed optimally for CSMBS patients whereas UCS patients with advanced cancer or leukemia may not receive the expensive interventions required to prolong survival (Limwattananon, Limwattananon et al. 2009).

Figure 20.The percent of patients receiving certain drugs by three insurance schemes



Source: Limwattananon, Limwattananon et al. (2009)

As the issues of access and quality of care are major concerns for the UC and SSS beneficiaries, the government implemented several efforts to solve these problems. For example, more payments are sometimes added though capitation in the primary payment type for the UC, and the UC has expanded its coverage for high-cost medicines like anti-retro viral drugs, etc. However, the principle of additional

payment and expansion of coverage is under-developed (Ngorsuraches and Kulsomboon 2010).

2) Cost containment in the CSMBS

There is a concern about a rapid increase in health expenditure, especially under the CSMBS. While there is a big difference in per capita expenditure between the CSMBS and the UC/the SSS as mentioned earlier, policymakers consider that there is an over-spending among CSMBS beneficiaries (Ngorsuraches and Kulsomboon 2010). Particularly, medicine is a major factor contributing to the rapid increase in cost. A report investigating medicines use in 26 hospitals shows that outpatient drug expense in CSMBS account for 66–68% of the hospitals' total drug expense (Kanchanachitra 2010).

Payment mechanisms including direct payment in the CSMBS are pointed out as important factors. The CSMBS has limited capacity to act as an active purchaser as it provides reimbursement directly to health care providers for outpatient bills. In addition, global budget ceiling is not set up for the inpatient sector (Thai working group on Observatory of Health and Policy, 2010). Recently, the government is considering the implementation of several measures such as defining conditions for reimbursement of drugs excluded from the NLED and limiting expenses for outpatient services by using a capitation system (Saengpassa and Sarnsamak 2011).

3) No national pricing policy

There is no national pricing policy in Thailand to regulate medicine prices.

Although public facilities are required to purchase medicines below Medicine Price Ceiling and their mark-up are also regulated, the regulations are not applied to other sectors. Accordingly, different prices for the same medicine as well as high prices for the innovator brand medicines are observed (Sooksriwong, Yoongthong et al. 2009). The price regulation system at every level of drug supply chain should be considered: manufacturers to hospitals/drug stores and hospitals/drug stores to patients. Price regulations, such as maximum selling prices or maximum wholesale/retail mark-ups, should be implemented and enforced (Sooksriwong, Yoongthong et al. 2009).

VI. Viet Nam[17]

1. Description of health care system

1) Health care financing & delivery system

Vietnam had a tax-based financing system and health care services and medicines were provided free of charge in the past. However, "Doi Moi" reform based on market mechanisms was launched in 1986 after it had faced economic crisis in the 1970s. The reform entailed the profound changes in the health care system: user fee was implemented, private practice was legalized; pharmaceutical market was liberalized, etc. Vietnam's financing and delivery system, which had been based on the public sector, were converted into a unregulated private-public mix system after the reforms. Particularly, the reform resulted in the rapid increase in OOP health expenditure, which accounted for 71% and 80% in 1993 and 1998, respectively (Lieberman and Wagstaff 2009).

Health insurance was introduced for civil servants and workers in the formal sector to contain the growth of OOP spending in 1992. Later, it was expanded to cover socially protected people, the poor and children under the 6 years of age (Tien, Phuong et al. 2011). The compulsory part of public health insurance covers around 41% of the population, including the formally employed (9%), the poor (18%), and children under the age of 6 (11%). In addition, about 3% of the population including retirees, dependents of military and police officers, and meritorious people are

[17] Comments by Hong Van are appreciated.

covered by special provisions. The voluntary part of public insurance covers approximately 11% of the population, most of which are students and school children. But the recently revised Health Insurance Law makes (social) health insurance mandatory. According to Vietnam Social Security, SHI covers 59% of population as of 2011.

Table 28. Vietnam Health Insurance System

Programme	Population coverage	Target group(s)	Financing
Social health insurance (SHI)*	9%	Formally employed, retirees, disabled, meritorious people	3% payroll tax (2% employers and 1% employees)
Health care funds for the poor (HCFP)*	18%	The poor, ethnic minorities in mountainous areas, inhabitants in disadvantaged communities	General government revenues (75%) and Provincial resources (25%)
Programme of free health care for children under 6 years of age	11%	All children under 6 years of age	General government revenues
Voluntary health insurance (VHI)	11%	Self-employed, informal sector workers, dependents of CHI-members, students and school children	Private premium contributions based on ability to pay
Total	49%		

Source: Vietnam Social Security (VSS) 2007.
*Formally part of Compulsory Health Insurance (CHI).

Source: Re-cited from Ekman, Liem et al. (2008)

Total health expenditure was 6.9 percent of gross domestic product in Vietnam in 2011, which is higher than 4.3% of other low middle-income countries (WHO/Vietnam MOH, 2012). Per capita health expenditure has grown rapidly, increasing approximately four times over 10 years, from USD 21 in 2000 to USD 76 in 2009 (Moon 2012). Furthermore, the annual growth rate of total health expenditure was higher than that of GDP (9.8% vs. 7.2% between 1998 and 2008) (Tien, Phuong et al. 2011).

As SHI coverage has been expanded, the share of OOP spending in total health

expenditure decreased and the self-medication share of spending has decreased to 34.5% in 2009 (WHO/ Vietnam MOH 2012). However, private expenditure still accounts for approximately 55.4 % of total health expenditure in 2010 (Vietnam MOH and WHO 2010). Especially, OOP expenditure accounts for about 90 percent of total private health expenditure. In addition, health insurance covers only 60% of the population in 2010, and near poverty group and workers of the informal sector are not covered (Matsushima and Yamada 2013).

SHI beneficiaries can use health services in the commune health center or district hospital where they are registered. If they use services in other commune health centers or district hospitals, their payment will be reimbursed later (Tien, Phuong et al. 2011). The SHI benefit package is based on positive list, covering both outpatient and inpatient. Although it covers expensive advanced services, patients would face high copayment and reimbursement ceiling. The prices of medical services are set by the MOH and the Ministry of Finance (WHO/ Vietnam MOH, 2012).

Health care sector has been grown rapidly; for example, the number of private practices and pharmacies increased from 19,836 and 14,182 in 1998 to 30,000 and 21,600 in 2008, respectively (Nguyen 2009). For inpatient care, public hospitals are major providers, accounting for 93.9% of total inpatient admissions in 2010 although the private health sector has expanded rapidly (WHO/ Vietnam MOH, 2012). Whereas private sector accounted for 40 percent of total outpatient visits in 2010, public sector plays a much bigger role in rural areas as private health units are concentrated in big cities (World Bank 2007).

2) The role of pharmaceutical sector in health system

From an input perspective, the increase in medicine prices is a key factor leading to the rapid growth in total health expenditure, accounting for 30 percent of the growth (World Bank 2007). While per capita medicine expenditure is USD $ 104 in Viet Nam, the share of medicine spending in total health expenditure is 50.9 % in 2009, which is higher than other Asian countries (OECD/WHO 2012). The government has implemented several policies to control medicine expenditure, such as improving transparency in licensing, medicine supply and sales, competitive tendering procurement, and a ceiling on the profit margin. Although the impact of these policies is not explicit, the drug consumer price index increased by 5.27% in 2012, which is lower than the increase of consumer price index, 6.81% (Vietnam MOH & Health Partnership Group 2013).

2. Reimbursement & pricing process

1) Pricing

The government allowed local drug sources to design price level differently even within a price bracket set by the MOH in 1989, and the shift to free market pricing for medicines resulted in high medicine prices in Vietnam (Nguyen 2011). The government has implemented several policies to stabilize drug price since 2003 because drug prices increased more rapidly than general inflation. The declaration and publication of price information has been a primary mechanism to stabilize medicine price by improving transparency. Prices are set and declared to the Drug Administration of Vietnam by the manufacturer or importer (Nguyen 2011). Wholesalers and retailers are also required to publish the wholesale and retail prices respectively. Declared prices are published on the website of the Drug Administration

of Vietnam, and medicines cannot be sold at prices higher than their published prices (Nguyen 2011).

2) Reimbursement

The major drug list was issued as a basis for reimbursements for the insured when health insurance was implemented in 1992 (Vietnam MOH & Health Partnership Group 2013). The list of drugs eligible for insurance reimbursement at public facilities in 2010 consisted of 900 active ingredients, 57 radioactive and radio-contrast agents, including 300 herbal traditional medicines and 127 preparations drugs in traditional medicine. To be consistent with the treatment needs and capacity of health workers, the list is more limited for the lower level of the facility, covering 297 active ingredients at the commune level. Whereas the official benefit package is generous, the actual availability of pharmaceuticals depends on individual hospitals and practitioner preferences (WHO/ Vietnam MOH, 2012) as hospitals can design their own drug list based on the national drug list (Tien, Phuong et al. 2011). In addition, the public health insurance scheme does not cover medicines purchased directly at a retail private pharmacy (Nguyen 2011).

There is a concern that the reimbursement drug list has not been developed on the basis of the evidence of cost-effectiveness. As HTA is not implemented, selection of medicine is largely depending on proposals of hospitals rather than on evidence of cost effectiveness (Vietnam MOH & Health Partnership Group 2013). Some drugs that are rarely used in some developed countries are included in the reimbursement list (Tien, Phuong et al. 2011). In addition, the processes for adding new drugs to the list or removing from the list are not well-defined.

3. Pharmaceutical cost containment strategy

1) Price control by improving transparency

The declaration and publication of price information has been a primary mechanism to regulate medicine price by improving transparency. Medicines cannot be sold at prices higher than their published prices, which were reported to the Drug Administration (Nguyen 2011). However, this mechanism does not work as expected. Some medicines are sold higher than the declared price, and the reasonableness of the declared wholesale prices are rarely assessed although the regulation proposes international reference pricing as the evaluation tool.

Figure 21. Pricing mechanism in Viet Nam

Source: WHO Country Office for Vietnam (2010)

2) Procurement

In public hospitals, medicines are purchased through a tendering system, which may be conducted at the individual hospital level or at the provincial government level, which was established in 2006 to achieve economies of scale in tendering

process and to simplify administrative processes and costs. As of 2013, tendering is conducted in 47 out of 63 provinces. The MOH announces periodically the maximum purchasing prices for medicines with the intention of creating a ceiling on tendered prices (Nguyen 2011). However, the procurement system has not been effective. Competitive tendering for procurement of drugs is fragmented, which results in variations in winning bid prices for the same drug across health care providers (Vietnam MOH & Health Partnership Group 2013). It is known that public hospitals purchase lowest-priced generics higher than the international reference price (Nguyen 2011). Furthermore, the bidding price sometimes appeared to be higher than the declared one.

In 2012, Vietnam has made major reforms in drug procurement through changes in regulations for transparent, convenient, increased competition in bidding (Joint Circular No. 01 / 2012 / TTLT-BYT-BTC by Ministry of Health, Ministry of Finance guiding the procurement of medicines in health facilities, Circular 11/2012 / TT-BYT by Ministry of Health guiding dossiers for procurement of medicines in the health facilities).[18] The reforms have had a positive impact on drug price and choice of drugs at health facilities, especially for generic drugs. Drug price decreased, but the impact on the price of original brand-name drugs is negligible. Vietnam social security system has the responsibility to participate in the drug bidding process. The provisions of the new Procurement Law (effective on July 1, 2014) and the decrees guiding new procurement laws provide roadmap for centralized drug procurement (national and provincial level), and by 2016, all provinces have to implement centralized drug procurement.

[18] This paragraph is provided by Hong Van.

3) External reference pricing

Comparative pricing system has been included in the regulation over the past decade as a tool to ensure the reasonableness of declared price. However, there are no explicitly defined methods in terms of the type of prices compared, countries compared, and the standard of comparison. The regulation recently was revised and requires the government to announce the list of countries compared, but the list has not been announced (Nguyen 2011).

4. Service delivery (distribution)

Whereas medicines listed in the health insurance benefit package are reimbursed by the social insurance fund and dispensed by hospitals, patients buy their drugs frequently in private pharmacies because of the lack of medicines in hospitals (WHO /Vietnam MOH, 2012). There is 0.5 retail pharmacy per 1000 population on average. The proportion of essential medicines available in private pharmacies, hospital pharmacies and public facilities were 55.3%, 56.4% and 55.9%, respectively. The mean percentage availability of the sample of 15 lowest-price generics was 34.8% in the public sector and 56.0% in the private sector, similar to the average of country-level availability of medicines across World Bank low income countries. Compared with the Western Pacific Region, Vietnam had lower availability of medicines in the public sector but slightly higher availability in the private sector (Nguyen 2009). Meanwhile, access to medicines is relatively low in remote and rural areas along with regional disparity in access to care (Vietnam MOH & Health Partnership Group 2013).

Besides high drug prices, irrational and unsafe use of medicines, high rates of antibiotic use, and low share of generic medicines in prescriptions result in high drug spending and indirectly impede access to essential medicines (Vietnam MOH & Health Partnership Group 2013). Furthermore, medicines are listed in INN, but providers can prescribe generic and/or brand-name products, which makes providers susceptible to incentive from medicine suppliers and prescribe more expensive drugs. They would prefer prescribing drugs un-covered by SHI as they receive incentives from pharmaceutical companies and suppliers (Tien, Phuong et al. 2011). Furthermore, provider payment based on fee-for-service would also contribute to the inappropriate use of medicines.

Traditional medicine has been integrated into the national health system since the 1950s. It is widely used and particularly important to people with difficulty in accessing primary health care services due to cost or distance. The proportion of consultations relying on traditional medicine appeared to be 25% at the commune level, and 9% at the provincial and district level in 2010 (WHO/ Vietnam MOH, 2012). A national program on traditional medicine proposed in 2010 has a plan to establish or renovate traditional medicine in all provinces/cities (Vietnam MOH & Health Partnership Group 2013).

5. Key challenges

1) Price control mechanism

The declaration and publication of price information as a primary mechanism to regulate medicine price does not work as expected. First, as resources to assess the reasonableness of declared prices are limited, medicine prices declared by

pharmaceutical companies have not been validated. It is possible for companies to declare false prices, higher than the actual prices (Nguyen 2011). In addition, medicines are sold at prices higher than their published prices as monitoring system does not work well. Furthermore, maximum distribution margins were regulated between the year of 2004 and 2006 by the rule, which was expired in 2006 (Nguyen 2011). In 2013, new plan involving a ceiling on the margin has been tried in 9 health facilities for drug procurement of 12 active ingredients (Vietnam MOH & Health Partnership Group 2013). Meanwhile, competitive tendering model for drug procurement has not been developed at national level although fragmented procurement is known to be ineffective in reducing drug cost (Vietnam MOH & Health Partnership Group 2013).

2) Inefficient reimbursement medicine list

There are several concerns about reimbursement list: the list is not developed based on evidence of cost-effectiveness and includes too many medicines without adequate selection mechanism (Tien, Phuong et al. 2011). Without a formal mechanism of technology assessment, the selection of medicines is based on provider's suggestions and less cost-effective medicines are included (Vietnam MOH & Health Partnership Group 2013). For example, the current list includes nearly twice more medicines compared with essential medicines. Inclusion of a wide range of medicines may result in inefficient use of health care resources and limit the purchasing power of the payer in negotiating a better price (Nguyen 2011).

3) Inefficient procurement and inappropriate use of medicine

Fragmented procurement of medicines and procurement not limited to essential medicines is a concern. They lead to high medicine price by diluting the advantage of economies of scale and purchasing power as well as unnecessary duplication and inefficiencies (Nguyen 2011, Tien, Phuong et al. 2011).

Inappropriate profit-driven prescribing behavior is a factor undermining the rational use of medicines and leading to inflated price in Viet Nam, interacting with fee-for-service payment and the lack of the separation of prescribing and dispensing. Physicians' prescribing is often driven by revenue generation, resulting in the overuse of expensive medicines than necessary. As a result, medicine prices at the patient level are more inflated and patient access to medicines decreased (Nguyen 2011).

VII. Republic of Korea

1. Description of health care system

1) Financing & health delivery system[19]

The major mechanism for health care financing in Korea is SHI, covering the entire population. It is a single payer system with uniform contribution rate and benefit package for the insured. Contribution rate is set as the percentage of income (employee) or income & property (self-employed). Coinsurance rate is set as 20% for covered service in inpatient care, but it is differentiated from 30% to 60% in outpatient care, depending on the level of providers with lower cost sharing for primary care. The poor are exempted from paying contribution and coinsurance payment at the point of service. Benefit package of health insurance is explicitly defined and includes most of medical care services, except very new costly technology, but with relatively high cost sharing. For medical services to be included in the benefit package, various criteria are considered such as clinical effectiveness, cost effectiveness, financial burden on patients, fiscal impact on health insurance, etc.

Even though the share of OOP payment has steadily decreased with increasing share of SHI in total health expenditure, it is still higher than OECD average. As of 2011, the share of OOP payment is 35.2%. OOP payment in social insurance consists of coinsurance for covered services and full payment for uncovered

[19] Mainly based on Kwon, S., C. Kim and T. Lee (2014).

services. There are ceilings on cumulative OOP payment for 6 months, whose levels are different according to income levels. The role of PHI in health care financing has been increasing, but its share of total health expenditure is still low (5.5% as of 2011).

Korea has experienced the highest rate of increase in health expenditure among OECD countries. For the last 10 years, the average annual real growth rate of health expenditure has been greater than that of GDP.

Table 29. Trends in health expenditure in Korea, 1995 to 2011

Health expenditure	1995	2000	2005	2011
Total health expenditure per capita in ppp$ (2005)	340	555	1011	1831
Total health expenditure as % of GDP	3.7	4.3	5.6	7.4
Public expenditure on health as % of total expenditure in health	38.6	50.4	53.3	55.3
OOP payment as % of total expenditure on health	51.8	39.4	37.5	35.2
OOP payments as % of private expenditure on health	84.4	79.4	80.3	78.9

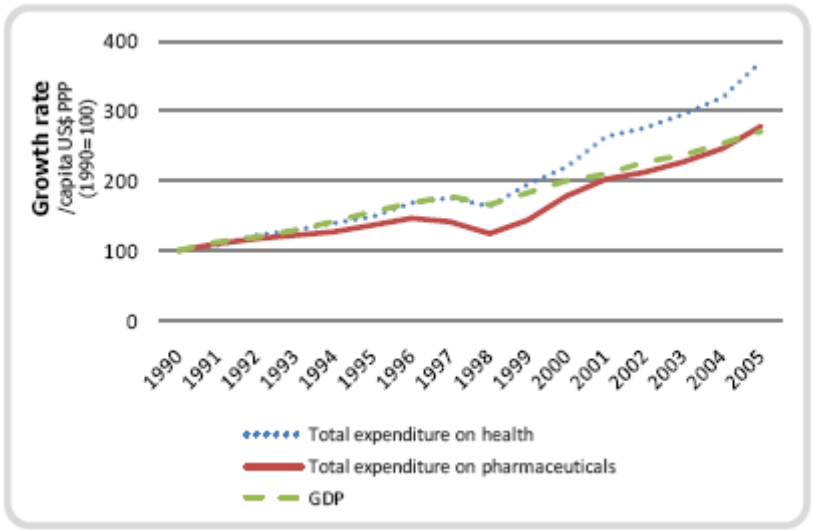
Source: MOHW, Korean National Health Accounts and Total Health Expenditure in 2011, 2012

The majority of health care providers are in the private sector: 94% and 88% out of total hospitals and beds, respectively. All licensed providers are mandated to have the contract with National Health Insurance Service (NHIS). Health insurance pays health care providers based on fee for service, and fee schedule for health care providers is annually negotiated between NHIS and provider associations. There are two exceptions to the fee-for-service payment: DRG-based prospective payments are applied to 7 disease categories since July 2013, and per-diem payment differentiated by 17 disease categories is applied to long-term care hospitals.

2) The role of pharmaceutical sector in health system

Spending on pharmaceuticals has increased sharply since 1998, and the growth rate outpaces that of GDP from 2004. As of 2010, total expenditure on pharmaceuticals as share of total health expenditure is about 20.3% in Korea, which is greater than OECD average (15.6%) (OECD Health Statistics 2012). Because of fast growth of pharmaceutical expenditure and its increasing proportion of national health expenditures in Korea, pharmaceutical cost containment has been an urgent and important issue since 2000. Since then, ROK has experienced several significant changes in the pharmaceutical policy, such as the separation of prescribing and dispensing of drugs, positive listing based on cost effectiveness (Lee 2010).

Figure 22. Trends of pharmaceutical expenditure in comparison with total health expenditure and GDP



Source: OECD Health Statistics

2. Reimbursement & pricing process

1) Reimbursement

In the past, health insurnace reimbursement of pharmaceuticals is based on negative listing, which resulted in too many drugs for reimbursement. As of January 2006, 21,740 were listed for reimbursement (5,411 molecules). Under the negative list system, all drugs that obtained market authorization from the Korean FDA were automatically reimbursable. To contain pharmaceutical expenditure, government introduced the policy of positive listing of reimbursable drugs in December 2006, and drugs that demonstrate cost–effectiveness can be included on the reimbursable (positive) list. The factors that determine whether a product can be reimbursed are based on efficacy, safety and economic evaluation as well as the expected volume of sales.

After implementing the new list system, more than 16,000 out of 22,000 drug items remained on the reimbursement list. From the second half of 2007, a comprehensive review of the cost-effectiveness of each product has been undertaken. Government predicted that the number of items on the benefit list would be reduced to around 5,000 after completing the evaluation. In reality, however, few changes have been seen in the total number of pharmaceuticals in the list (Lee 2010).

The procedure for a pharmaceutical to be added to the list is as follows. Firstly, pharmaceutical companies must pass a series of tests set by the Korean FDA to enter the market. After market authorization, manufacturers submit data to the Pharmaceutical Evaluation Committee of HIRA (Health Insurance Review and Assessment) for cost–effectiveness review of the applicant drug. Lastly, upon

completion of the review process, drug manufacturers begin negotiations with the NHIS (National Health Insurance Service) on the reimbursable price of the drug.

2) Pricing

Whereas the prices of OTC medicines and non-reimbursed medicines are decided by pharmaceutical companies, the maximum reimbursable prices of medicines in the NHI reimbursement list are regulated. Furthermore, the prices of patent medicine and patent-expired medicine are set in a different way.

Previously, the price of new drugs for insurance reimbursement was set as the average price in 7 countries (USA, UK, Germany, France, Italy, Swiss, and Japan), which was called A7 average price system, which is an external reference pricing. More specifically, the price of innovative new drugs was set as the average of manufacturing prices (65% of list price) plus VAT and distribution mark-up. For non-innovative drugs, the price was determined as the average of relative prices of similar domestic medicines or same/similar medicines in 7 countries. The previous pricing mechanism was criticized because the term “innovative“ has never been precisely defined and innovative patent drugs were likely to remain at premium prices in South Korea (Kwon, 2009). In addition, it tended to result in high prices because it depended on the list price rather than real (transaction) price in high-income countries. Considering that Korea is a rather early adopter of new drugs, it was often the case that same/similar medicines are listed in only a limited number of countries, where the price is very high (Kwon 2009).

After pharmaceutical policy change in 2006, price negotiation between manufacturers and the health insurer was employed for all patent drugs with price-

volume consideration. When listing, pharmaceutical manufacturer should submit expected volume. The initial price is re-assessed in the second year according to sales volume during the first year. If a product's consumption is 30% higher than predicted, then the price of the product should be lowered in proportion to the volume increase. From the second year, products with consumption of 60% or greater than the preceding year were the target of re-pricing (Lee 2010). Recently, several changes were implemented as there was a concern that it led to relatively small price reduction for medicines with huge volume increase. The agreement is based on the total expenditure of all products with the same ingredient and same formulation in a company. Furthermore, if the total expenditure of a medicine increases by 10% or more than 5 billion won compared with the previous year, the ingredient with the same formulation will be listed for the agreement. The agreement will be waived if the total expenditure is less than 1.5 billion (Korea MOHW, 2013).

Risk-sharing agreement was implemented in limited areas in 2014. NHIS agrees to fund the new treatment for diseases without alternative treatment such as expensive cancer drug and the new treatment for rare disease, but the company will be asked to refund if it does not meet certain agreed-upon criteria. Pharmaceutical company can select a method among conditional treatment continuation plus money back guarantee based on health outcome and expenditure cap, refund or utilization cap/fixed cost per patient based on budget impact or other proposed methods (Korea MOHW, 2013).

Once the patent is over and a generic enters the market, the price of the original is adjusted and that of generics are set in relation to the originator's (adjusted) price, with a fixed discount. Prior to 2012, when the price of patent-

expired original medicine was reduced to the 80% of the previous level, the prices of generics were decided depending on the order of entry. The price of the first generic was set at 85% of the price of the original (or 68% of the price of the original before the entrance of a generic), that of the 2nd to 5th generic is set at the level of 85% of the price of the first generic, and that of the other generics was set 90% of the lowest price of the existing generic (Kwon 2009). However, changes in generic pricing were made recently. From March 2012, 30% reduction was made in the price of originator, 85% of which is the generic price (59.5% of previous price before generic entrance) in the first year after patent expiration. From the second year after patent expiration, the price for all generic medicines was set 53.5% of originator price (10% reduction from the year 1) regardless of the order of entry (Kwon and Kim 2012).

Providers are reimbursed the amount that they actually paid to purchase drugs (Actual Acquisition Price), which is essentially a no mark-up policy. A provider may purchase a medicine cheaper than other providers through bidding process. If they purchase a medicine cheaper than the maximum reimbursable price, patients who use that medicine will pay the purchased price and providers will be reimbursed based on their purchased price. This no mark-up policy was adopted in November 1999 to eliminate the drug profit that health care providers enjoyed and was criticized as a main factor to the increase in pharmaceutical expenditure.

3. Pharmaceutical cost containment strategy

1) Listing and price control

As reform measures in December 2006, Korean government introduced new

rules in the pricing of pharmaceuticals. First, positive listing based on cost-effectiveness was introduced in 2006, replacing the conventional method of negative listing. Second, price negotiation on the price of 'original' medicines between the NHIS and pharmaceutical manufacturers was introduced, instead of external reference pricing with the average price of 7 countries. At the same time, price for the generic medicine including off-patent original medicines was cut by 20% in 2006 and additional price cut was made for generic medicines in March 2012 (Kwon, Kim et al. 2014).

In addition, market-based actual transaction pricing, which allows providers to keep a given portion of the difference between the cost of purchase and reimbursement list price, was introduced in 2010. It was to guarantee transparency in pharmaceutical pricing and cut pharmaceutical costs by giving incentives for providers to purchase medicines in a cost-effective way and reveal/report the real cost of purchase (Kwon and Kim 2012). However, implementation of the new pricing system had been delayed after 1 year of introduction due to oppositions by the pharmaceutical industry that faced aggressive bargaining by big hospitals after the policy change.

2) Prescribing behavior & generic substitution

Since 2001, a national prescribing monitoring and feedback program (Better Prescribing Project, BPP) was introduced to generate a variety of information on prescribing practices nationwide. Prescribing behaviors of providers are regularly monitored on various outcome variables, including the rate of antibiotics prescribed, rate of injections prescribed, number of items per prescription and high

cost pharmaceuticals (Kwon, Kim et al. 2014). After the BPP, aggregated claims data show a steady decrease in the inappropriate utilization of antibiotics and injections over time. However, with the exception of antibiotics and injections, it remains unclear if the audit activity influences the physicians' prescribing behavior (Lee 2010).

From October 2010, financial incentives as a percentage of the savings in the expense of medicines prescribed have been provided to prescribers. The savings are calculated as the difference between expected expense and actual expense.[20] The amount of the financial incentive depends on the value of OPCI (Outpatient Prescribing Costliness Index) last year, ranging from 10 to 50%. When the OPCI is 1.0, 35% of the saving in expenditure is given to prescribers (if OPCI<1.0, greater than 35%; if OPCI>1.0, smaller than 35%). This policy is expected to give providers incentives for reducing pharmaceutical expenditure and prescribing in a cost effective way (Kwon and Kim 2012).

3) Copayment for prescription drugs

Before 2007, patients paid a fixed copayment of 1,500 KRW for every prescription dispensed at a community pharmacy, unless the total medicines cost per single prescription (including a dispensing fee) exceeds 10,000 KRW (about 10 USD), whereas patients paid 30% of total pharmaceutical spending when it is over the upper limit. In 2006, nearly 60% of prescriptions were priced lower than the

[20] Expected expense = medicines expense per day last year * number of days for medication this year

upper limit (10,000 KRW), the average costs of which was about 7,500 KRW. Hence, patients with medicines cost less than 10,000 KRW per slip paid only around 20% of total expenses. In this regard, there had been a concern that a fixed copayment would disproportionately benefit patients with temporary, symptomatic illnesses, because a prescription for chronic medications was more likely to go over the upper limit (Lee 2010).

In April 2007, government announced the removal of a fixed copayment for patients aged between 6 and 64 and, instead, applied a 30% coinsurance scheme (For instance, for a prescription costing 7,500 KRW in total expenses, payment is 2,250 KRW, where previously the payment was only 1,500 KRW). The elderly population continue to pay a fixed copayment as before if the expenses are less than 10,000 KRW (Lee 2010).

4. Service delivery (distribution)

When domestic manufacturers and importers obtain market authorization from the Korean FDA, wholesalers distribute drugs to sellers, such as hospitals and pharmacies. In hospitals, inpatients can obtain medicines from drug dispensaries within hospitals (with 20% co-payment), while patients using outpatient services receive prescriptions to obtain drugs from pharmacists (outside of the hospital) after the implementation of the separation of prescribing and dispensing. Consumers can purchase OTC drugs without doctor's prescription at pharmacies, some of which consumers can purchase in supermarket. There were vigorous debate between pharmacists and the general public on the sales of some OTC drugs in the supermarket.

In 2008, DUR program, which will automatically monitor physicians' prescribing and pharmacists' dispensing patterns, was implemented to safeguard against adverse drug interactions and to improve the cost-effective consumption of pharmaceuticals. At the point of prescription and dispensing, information is sent to HIRA to check any potential adverse effects between the drugs being prescribed/dispensed and those that the patient is currently taking (prescribed/dispensed by other providers).

5. Key challenges

1) Policy intervention to control pharmaceutical expenditure

Despite various policy interventions, pharmaceutical expenditure keeps rising. Decomposition result for the change in pharmaceutical expenditure from 2008 to 2013 shows that the quantity of drugs and utilization of high priced medicines (substitution of expensive medicines for cheap ones) rather increased even though the overall level of pharmaceutical price dropped during the period (Kwon, Heo et al. 2013). Thus policy interventions to change the quantity of drugs or prescribing behavior, in addition to price control, are needed.

Table 30. Decomposition of the change in pharmaceutical expenditure from 2008 to 2013

	2008.10-2009.9	2009.10-2010.9	2010.1-2011.9 (Market based actual transaction price)	2012.4-2013.3 (price cut for generic medicines)
Total pharmaceutical expenditure	1.111.	1.183	1.226	1.067
Variations in drug quantity	0.560	1.097	1.124	1.160
Variations in drug price	0.970	0.955	0.931	0.755
Variations in product composition(mix effect)	1.083	1.129	1.171	1.217

Reference period: 2007.10-2008.9
Source: Kwon, Heo et al. (2013)

Several interventions can be considered. First, global budget needs to be implemented to control pharmaceutical expenditure. It can take the form of an overall limit on total health expenditure or can be sector specific such as targeting pharmaceutical expenditure. If it focuses on pharmaceutical expenditure, it can set total budget either for prescribing physician or for pharmaceutical company. Several issues should be discussed to implement this policy such as how to set the budget and how to allocate the budget across geographic areas, services, and programs, etc. Second, therapeutic reference pricing can be considered, that is, defining wider groups of "therapeutically equivalent" products, not clusters of bio-equivalent products. Although recent policy set the same price across bio-equivalent products and removed price difference across them, more utilization of more expensive ingredients can lead to the increase in pharmaceutical expenditure.

2) Transparency of pharmaceutical sector

To increase the transparency of pharmaceutical price and decrease the price of medicines through price competition, several policies have been implemented. When providers were reimbursed the actual purchasing price (up to the maximum allowable price) in the previous no mark-up policy, they lacked financial incentives to negotiate on prices or purchase low-cost medicines, and health insurances used to reimburse the maximum allowable price. There has been a concern that pharmaceutical manufacturers and distributors did not compete on price or quality, but provided (illegal) rebate to hospitals. As government wanted to introduce price competition on pharmaceuticals, a financial incentive was implemented to encourage hospitals' price negotiation. The incentive policy provided health care providers 70 percent of the difference between the maximum allowable price and the actual purchasing price as a

financial incentive (Kwon, 2010). However, this policy has been delayed one year after it was launched.

On the other hand, the government launched the anti-rebate law for medicines in order to eradicate wide-spread illegal rebates in pharmaceutical marketing. The regulation is to bring criminal charges against both doctors and pharmacists for receiving illegal kickbacks from pharmaceutical companies since previous regulation punished only drug companies but not doctors and pharmacists for the provision of illegal kickbacks. With the introduction of the "Dual Punishment System" reform, criminal punishment for illegal rebates is extended to those recipients of rebates.

Chapter 5. Developing collaboration in pharmaceutical policy in Asia-Pacific countries

1. Recent pharmaceutical situation and policy in Asia-Pacific countries

In low- and middle-income countries of Asia, per capita pharmaceutical expenditure is one third of that in OECD countries. However, pharmaceutical expenditure has rapidly increased with a growth rate of 6.3% over the past decade, which is two times higher than in OECD countries (3.5%). Furthermore, the share of pharmaceutical spending in total health expenditure in Asia is twice that of OECD countries (29.7% vs. 15.6%). Meanwhile, the share of OOP payment in pharmaceutical spending is more than 50% in most low- and middle-income countries of Asia.

There are several factors leading to high financial burden due to medicines in low- and middle-income countries of Asia. Although many countries have attempted to achieve universal coverage to improve access to care and to protect people from high financial burden, many people are still un-covered by public financing scheme, its benefit package is not sufficient and does not cover medicines, and it imposes high copayment. Even if some medicines are in the reimbursement list, they may not be available in public health care facilities, and people should purchase them in private facility with OOP payment.

Pharmaceutical pricing and reimbursement mechanism play a significant role in access to and appropriate use of medicines. Whereas most OECD countries have applied a wide range of policies to regulate the pharmaceutical sector and to guarantee the appropriate use of medicines at national level, these policies are not well developed in Asian low- and middle-income countries due to political barrier as well as capacity problems. There is a concern on the reasonableness of medicines price, too. Manufacturers or distributor are often allowed to set the price freely in some countries and prices are regulated only in the public sector. Although

policy such as international reference pricing is implemented, there are still technical problems, including which countries are used as a comparison group and how to calculate reference prices. High mark-up is also an important factor leading to high payment, and percentage mark-up encourages providers to provide more expensive medicines.

Most Asian countries employed the essential medicine list or reimbursement medicine list. However, medical facilities sometimes have problems in supplying sufficient medicines in their facilities. Sometimes, as the list has too many medicines, it does not follow the basic concept of essential medicine list defined by WHO, “those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford" (WHO Expert Committee on the Selection and Use of Essential Medicines 2003).

Recently, many countries attempt to enhance the efficiency and effectiveness of health care systems to improve the access to and quality of health care. HTA such as PEA have been implemented in most advanced countries. In Asian countries, there is an increasing interest in how to encourage the use of cost-effective medicines and treatment. However, HTA tools are not employed actively due to the shortage of expertise and available data. In low- and middle-income countries of Asia, cost containment policy has mainly focused on the regulation of maximum allowable reimbursable price. But governments also need to control the quantity and mix (e.g., originator vs. generic medicines) of pharmaceuticals for cost containment. Payment system reform for health care providers will contribute to pharmaceutical cost containment, too.

2. Asia Pacific network on pharmaceutical policy and financing

Although regional collaboration and policy learning among Asia-Pacific countries can benefit the countries in the development of pharmaceutical policy and financing and achieving universal access to medicines, the collaboration has not be realized. In contrast, European countries established PPRI (Pharmaceutical Pricing and Reimbursement Information) to share information and key issues of pharmaceutical policy and to seek for collaboration. Insurers and authorities across twenty eight 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.

Based on this achievement, Health Economics Department at Gesundheit Österreich/Austrian Health Institute is designated as a WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in 2010. This network conducts the following activities (http://whocc.goeg.at/):

- Provides scientific advice and technical assistance to WHO and its Member States/regions on performing and interpreting price surveys and comparisons; on understanding, collecting and analyzing pharmaceutical pricing and reimbursement information and on the development of national reporting systems.

- Further develops and refines the methodological framework for indicators to measure, compare and benchmark pharmaceutical policies, in coordination with the WHO database development process.

· Assists in the organization of meetings of WHO Member States/Regions in the field of pharmaceutical pricing and reimbursement, allowing for an exchange of information and experience, disseminates information on pharmaceutical policies (via websites, studies and network meetings) and works on the development and promotion of a common understanding and language on pharmaceutical issues.

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 (WHA67.22) 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".21

Therefore, it is necessary to hold a meeting to discuss the current status of pharmaceutical policies and to collaborate for developing evidence-based policies in Asia-Pacific countries. The meeting will formally propose a launching of a network on pharmaceutical policy and financing, which has three broad areas for potential future collaboration through regular communication and meeting of a network of government officials, insurance agency representatives, and academic researchers, including:

[21] WHA67.22 Access to essential medicines

- Generating evidence about the impact of pharmaceutical policies/strategies to enhance access to medicines;

- building institutional and human capacity for effective medicines policy development and implementation practices under universal health coverage;

- and sharing information for decision-making, including information on pricing, cost and value of medicines based on HTA.

References

Albreht, T., E. Turk, M. Toth, J. Ceglar, S. Marn, R. P. Brinovec, M. Schäfer, O. Avdeeva and E. van Ginneken (2009). Slovenia: Health system review, Health Systems in Transition. 11 (3): 1-168.

Ali, G. K. M. (2009). "How to establish a successful revolving drug fund: the experience of Khartoum state in the Sudan." Bulletin of the World Health Organization 87:139-142. doi: 10.2471/BLT.07.048561

Anantachoti, P., C. Choompon, B. Chatpitun and R. Siwamutita (2004). "How much do we pay for medicines? A drugstore price survey across Thailand." Thai J. Pharm. Sci 28(3-4): 111-123.

Antonissen, Y. (2012). Belgium, PPRI poster 2012: Generics. Available at http://whocc.goeg.at/Literaturliste/Dokumente/CountryInformationPosters/10c_BE2_Poster_AntonissenYoeriska_2012.pdf

APCNMP - Asia Pacific Conference on National Medicines Policies (2013). Conference Report. Aust Prescr 36 Suppl 1:S1-56..

Babar, Z., M. Ibrahim, H. Singh, N. Bukahri and A. Creese (2007). "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia." PloS Medicine, 4:3.

Bahri, S., N. Othman, M. Ahmad Hassali, A. Shafie and M. Mohamed Ibrahim (2009). A national survey on the use of medicines by Malaysian consumers. Kuala Lumpur Pharmaceutical Services Division, Ministry of Health.

Bailey, M. (2002). "Review of drug-related legislation in the Republic of Fiji Islands." Pacific health dialog 9(1): 68-75.

Bailey, M. (2004). Affordability of medicines in Fiji. Fiji school of medicine.

Ball, D. and K. Tisocki (2009). Public Procurement Prices of Medicines in the Philippines. Health Action International Global.

Barber, S. L., B. Huang, B. Santoso, R. Laing, V. Paris and C. Wu (2013). "The reform of the essential medicines system in China: a comprehensive approach to universal coverage." Journal of global health 3(1).

Barnieh, L., F. Clement, A. Harris, M. Blom, C. Donaldson, S. Klarenbach, D. Husereau, D. Lorenzetti and B. Manns (2014). "A systematic review of cost-sharing strategies used within publicly-funded drug plans in member countries of the organisation for economic co-operation and development." PLoS One 9(3): e90434.

BIZCLIR (2009). Philippines Health CLIR Pilot Diagnostic: Health Business Climate Legal and Institutional Reform. USAID Business Climate, Legal and Institutional Reform (CLIR) Project.

Blumenthal, D. and W. Hsiao (2005). "Privatization and its discontents—the evolving Chinese health care system." New England Journal of Medicine 353(11): 1165-1170.

Bureau of Policy and Strategy & Thailand Ministry of Public Health (2012). Thailand health profile report 2008-2010. Available at http://www.moph.go.th/ops/thp/thp/en/index.php?id=288&group_=05&page=view_doc

CDPHI - Cambodia Department of Planning and Health Information & WHO (2008). Strategic framework for health financing 2008-2015. Available at http://www.who.int/health_financing/documents/cam_frmwrk.pdf.

Cameron, A., M. Ewen, D. Ross-Degnan, D. Ball and R. Laing (2009). "Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis." Lancet 373(9659): 240-249.

Cantillon, P. and R. Jones (1999). "Does continuing medical education in general practice make a difference?" BMJ: British Medical Journal 318(7193): 1276.

Carlson, J. J., S. D. Sullivan, L. P. Garrison, P. J. Neumann and D. L. Veenstra (2010). "Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers." Health Policy 96(3): 179-190.

Carone, G., C. Schwierz and A. Xavier (2012). Cost-containment policies in public pharmaceutical spending in the EU. Brussels, Belgium, European Commission. 461.

Chen, Y. and S. O. Schweitzer (2008). "Issues in Drug Pricing, Reimbursement, and Access in China with References to Other Asia-Pacific Region." Value in Health 11(s1): S124-S129.

China National Health Economics Institute (2012). National health accounts report 2012. Beijing, Ministry of Health, People's Republic of China.

Choi, N.-K. and B.-J. Park (2010). "Strategy for establishing an effective Korean drug utilization review system." J Korean Med Assoc 53(12): 1130-1138.

Consumer Council of Fiji (2010). Prices and practices: Pharmaceutical survey 2010, Suva, Fiji : Consumer Council.

David, L. C. and M. A. B. Geronimo (2008). Sector Performance Review: Performance Assessment of FOURmula ONE for Health, 2007. Manila, Philippines: Department of Health.

Diack, A., A. Seiter, L. Hawkins and I. S. Dweik (2010). Assessment of Governance and Corruption in the Pharmaceutical Sector: Lessons Learned from Low and Middle Income Countries. Health, Nutrition and Population (HNP) Discussion Paper, The International Bank for Reconstruction and Development, The World Bank.

Dickson, M., J. Hurst and S. Jacobzone (2003). Survey of pharmacoeconomic assessment activity in eleven countries. OECD health working papers. Paris, OECD.

Docteur, E. and V. Paris (2009). Ensuring Efficiency in Pharmaceutical Expenditures, OECD Publishing.

Eggleston, K. (2009). Introduction. Prescribing Cultures and Pharmaceutical Policy in the Asia-Pacific. K. Eggleston, Shorenstein APARC, distributed by Brookings Institution press.

Eichler, H. G., S. X. Kong, W. C. Gerth, P. Mavros and B. Jönsson (2004). "Use of Cost-Effectiveness Analysis in Health-Care Resource Allocation Decision-Making: How Are Cost-Effectiveness Thresholds Expected to Emerge?" Value in Health 7(5): 518-528.

Ekman, B., N. T. Liem, H. A. Duc and H. Axelson (2008). "Health insurance reform in Vietnam: a review of recent developments and future challenges." Health Policy and Planning 23(4): 252-263.

Espin, J., J. Rovira and A. de Labry (2010). Policy paper in external reference pricing, WHO/HAI.

Furet, J., G. Marinoni and G. Ando (2013). "Economic Evaluation in France: Methodology and Impact on the Country's Pricing and Reimbursement (P&R) System." IHS Healthcare and Pharma.

GaBI online (2011). "How successful is the reference pricing system in Belgium" Posted 19 August 2011, Retrieved 15 May 2014, from http://gabionline.net/layout/set/print/Generics/Research/How-successful-is-the-reference-pricing-system-in-Belgium

GaBI online (2013). "Policies and Legislation" Posted 2 April 2013, Retrieved 15 May 2014, from http://www.gabionline.net/layout/set/print/Country-Focus/Portugal/Policies-and-Legislation

Grol, R. and J. Grimshaw (2003). "From best evidence to best practice: effective implementation of change in patients' care." The lancet 362(9391): 1225-1230.

Gross A. (2013) "2013 Thailand Pharmaceutical Market Update" Posted 21 June 2013, Retrieved 15 June 2014, from http://www.pacificbridgemedical.com/publications/2013-thailand-pharmaceutical-market-update/

Hanvoravongchai, P. (2013). Health Financing Reform in Thailand: Toward Universal Coverage under Fiscal Constraints. UNICO Study Series 20. The World Bank,Washington DC.

Hassali, M. A., A. A. Alrasheedy, A. McLachlan, T. A. Nguyen, S. K. Al-Tamimi, M. I. M. Ibrahim and H. Aljadhey (2014). "The experiences of implementing generic medicine policy in eight countries: A review and recommendations for a successful promotion of generic medicine use." Saudi Pharmaceutical Journal(0).

Hawkins, L. (2008). Background Report on Pharmaceutical Sector Governance and Financial Assessment. Consultant report, World Bank, Jakarta.

Hawkins, L. (2011). Competition Policy. Review series on pharmaceutical pricing policies and interventions: working paper 4. WHO/HAI Project on Medicine Prices and Availability. WHO/HAI.

Higuchi, M. (2008). Costs, availability and affordability of diabetes care in the Philippines, FASID Research Fellow Program FY2008.

Hirunrassamee, S. and S. Ratanawijitrasin (2009). "Does your health care depend on how your

insurer pays providers? Variation in utilization and outcomes in Thailand." Int J Health Care Finance Econ 9(2): 153-168.

Holloway, K. A. (2011). Indonesia: Pharmaceuticals in Health Care Delivery. Mission Report 10 - 23 July 2011. World Health Organization, Regional Office for South East Asia, New Delhi.

Holloway, K. A. (2012). Thailand: Drug Policy and Use of Pharmaceuticals in Health Care Delivery, World Health Organization, Regional Office for South East Asia, New Delhi.

Hsiao, W. C. (2007). "The political economy of Chinese health reform." Health Economics Policy And Law 2(3): 241.

HSRSP - Health Sector Reform Support Programme (2010). Health Care Financing in Nepal. HSRSP Report No. 2.21-5-10. Ministry of Health and Population Government of Nepal (http://www.hsrsp.org)

IMS Health (2012). The impact global pharmacost containment measures in Asia-Pacific, IMS Health.

IMS Health (2013). Asia Pacific insight, IMS Health.

Inajumi, J. (2008). Drug evaluation and pricing, Ministry of health, labor and welfare, Japan.

Jacobzone, S. (2000). Pharmaceutical policies in OECD countries: reconciling social and industrial goals, OECD Publishing.

Jirawattanapisal, T., P. Kingkaew, T.J. Lee, and M. C. Yang (2009). "Evidence-Based Decision-Making in Asia-Pacific with Rapidly Changing Health-Care Systems: Thailand, South Korea, and Taiwan." Value in Health 12(s3): S4-S11.

Kaló, Z., E. Docteur and P. Moïse (2008). Pharmaceutical pricing and reimbursement policies in Slovakia, OECD Publishing.

Kanavos, P. G., J. Y. Lim and C. S. Pascual (2002). On Improving the Poor's Access to Affordable Drugs. Philippine Health Policy Note. The World Bank, Human Development Unit, East Asia and the Pacific Region.

Kanchanachitra, C. (2010). Thai Health 2011: HIA: A Mechanism for Healthy Public Policy. Nakhon Pathom, Institute for Population and Social Research, Mahidol University.

Kaojarern, S. and O. Pattanaprateep (2012). "The effect of introducing inpatient mandatory generic drug substitution at Ramathobodi Hospital." Journal of the Medical Association of Thailand= Chotmaihet thangphaet 95(4): 519-525.

Knaul, F. M., E. González-Pier, O. Gómez-Dantés, D. García-Junco, H. Arreola-Ornelas, M. Barraza-Lloréns, R. Sandoval, F. Caballero, M. Hernández-Avila, M. Juan, D. Kershenobich, G. Nigenda, E. Ruelas, J. Sepúlveda, R. Tapia, G. Soberón, S. Chertorivski, J. Frenk (2012) "The quest for universal health coverage: achieving social protection for all in Mexico" Lancet; pblished Online August 16. http://dx.doi.org/10.1016/S0140-6736(12)61068-X

Koppel A, K. K., T. Habicht, P. Saar, J. Habicht and E. van Ginneken (2008). Estonia: Health system review, Health Systems in Transition. 10 (1): 1-230.

Kwon, S. (2008). Pharmaceutical Policy and Economics. Workshop in Health Economics and Financing. malaysia, August 19-20. .

Kwon, S. (2009). Pharmaceutical Policy in Korea. Prescribing culture and pharmaceutical policy in the Asia-Pcific. K. Eggleston. Washington, Brookings Institution Press: 31-44.

Kwon, S. (2010). "Incentive-based Pharmaceutical Reimbursement" Health Policy Monitor, April 2010. Available at http://www.hpm.org/survey/kr/a15/1

Kwon, S. (2011) "Health Care Financing in Asia: Key Issues and Challenges," Asia-Pacific Journal of Public Health 23(5): 651-661.

Kwon, S., C. Kim and T. Lee (2014). Korean Health System: Achievements and Challenges. Seoul National University & Korea Medical Institute, forthcoming, Asia Pacific Observatory.

Kwon, S., J. Heo, S. Kim and J. Park (2013). The Study on the effective post management for pharmaceutcial price. Seoul National University & HIRA.

Kwon, S. and S. Kim (2012). Pharmaceutical policy in Korea: role of health insurance in pricing, reimbursement and monitoring. Asia Pacific Conference on National Medicines Policies, Sydeny Australia.

Lavado, R. (2011). Improving Access to Affordable Medicines: An Examination of Prevailing Prices and Distribution of Village Drugstores in the Philippines. Draft Report. Philippine Institute of Development Studies.

Lee, I. (2010). Evaluating pharmaceutical policy in South Korea. Doctor, University of York.

Leopold, C. and C. Habl (2008). Pharmaceutical Pricing and Reimbursement Information: Austria. PPRI. S. Vogler and S. Morak.

Leopold, C., S. Vogler, A. K. Mantel-Teeuwisse, K. de Joncheere, H. G. M. Leufkens and R. Laing (2012). "Differences in external price referencing in Europe—A descriptive overview." Health Policy 104(1): 50-60.

Lieberman, S. S. and A. Wagstaff (2009). Health financing and delivery in Vietnam: looking forward. Health, Nutrition, and Population Series. Washington DC, World Bank.

Lilja, J., S. Salek, A. Alvarez and D. Hamilton (2008). Pharmaceutical Systems: Global Perspectives, John Wiley & Sons.

Limwattananon, C., S. Limwattananon, S. Pannarunothai and V. Tangcharoensathien (2009). Analysis of practice variation due to payment methods across health insurance schemes. Khon Kaen, Thailand: Khon Kaen University.

Liu, G. G., T. Fukuda, C. E. Lee, V. Chen, Q. Zheng, and I. Kamae (2009). "Evidence-Based Decision-Making on Medical Technologies in China, Japan, and Singapore." Value in Health 12(s3): S12-S17.

Matsushima, M. and H. Yamada (2013). Public Health Insurance in Vietnam towards Universal Coverage: Identifying the challenges, issues, and problems in its design and organizational practices. OSIPP Discussion Paper. DP-2013-E-003.

Meick, B. (2012). "INN Prescribing in Greece–The New Generic Frontier?" Posted 29 November

2012, Retrieved 10 May 2014, from http://healthcare.blogs.ihs.com/2012/11/29/inn-prescribing-in-greece-the-new-generic-frontier/

Meng, Q., G. Cheng, L. Silver, X. Sun, C. Rehnberg and G. Tomson (2005). "The impact of China's retail drug price control policy on hospital expenditures: a case study in two Shandong hospitals." Health Policy and Planning 20(3): 185-196.

Missoni, E. and G. Solimano (2010). Towards Universal Health Coverage: the Chilean experience. World Health Report Background Paper, World Health Organization.

Moïse, P. and É. Docteur (2007a). Pharmaceutical pricing and reimbursement policies in Mexico. Paris, OECD.

Moïse, P. and É. Docteur (2007b). Pharmaceutical pricing and reimbursement policies in Sweden. Paris, OECD.

Moon, S. (2012). The Impact of Health Insurance on Health Care Utilization and Catastrophic Health Expenditure in Vietnam. Master, Seoul National University.

Navarro, R. (2008). Managed Care Pharmacy Practice, Jones & Bartlett Publishers.

NCPAM - National Center for Pharmaceutical Access and Management (2014). Republic of the Philippines Department of Health, National Center for Pharmaceutical Access and Management (access date: Jul 15, 2014) URL: http://www.ncpam.doh.gov.ph/index.php/major-program?id=44 - 1-1-what-is-pndf.

NFC – National Formulary Committee (2008). "Philippine National Drug Formulary, Essential Medicines List, Volume I, 7th Edition. National Drug Policy-Pharmaceutical Management Unit 50 (NDP-PMU 50) Department of Health, Philippines."

Ngorsuraches, S. and V. Kulsomboon. (2010). "A View on National Health Insurance and Related Pharmaceutical Issues in Thailand." ISPOR connections: uniting research and practice 16(5):11-12.

Ngorsuraches, S., T. Wanishayakorn, P. Tanvejsilp and S. Udomaksorn (2013). "Relative importance of attributes of drug benefit plans: Thai civil servants' perspective." Res Social Adm Pharm 9(6): 731-740.

Ngorsuraches, S., W. Meng, B.-Y. Kim and V. Kulsomboon (2012). "Drug reimbursement decision-making in Thailand, China, and South Korea." Value in Health 15(1): S120-S125.

Nguyen, H. (2009). Principal-Agent Problems in Health Care: Evidence from Prescribing Patterns of Private Providers in Vietnam. Asia Health Policy Program Working Paper.

Nguyen, T. A. (2011). Medicine Prices and Pricing Policies in Vietnam. PhD, University of New South Wales.

Nguyen, T. A., R. Knight, E. E. Roughead, G. Brooks and A. Mant (2014). "Policy options for pharmaceutical pricing and purchasing: issues for low- and middle-income countries." Health Policy and Planning.

OECD (2005). Harmonising donor practices for effective aid delivery, Volume 3: Strengthening procurement capacities in developing countries. Paris, Organisation for Economic Co-

operation and Development.
OECD (2008). Pharmaceutical Pricing Policies in a Global Market, OECD.
OECD (2010). Value for Money in Health Spending, OECD Publishing.
OECD (2013). OECD Health statistics
OECD/WHO (2011). OECD Reviews of Health Systems: Switzerland 2011, OECD Publishing.
OECD/WHO (2012). Pharmaceutical expenditure, in Health at a Glance: Asia/Pacific 2012, OECD Publishing. http://dx.doi.org/10.1787/9789264183902-32-en.
Oortwijn, W., J. Mathijssen and D. Banta (2010). "The role of health technology assessment on pharmaceutical reimbursement in selected middle-income countries." Health Policy 95(2): 174-184.
Paris, V. and A. Belloni (2013). Value in Pharmaceutical Pricing, OECD Publishing.
Paris, V. and E. Docteur (2006). Pharmaceutical Pricing and Reimbursement in Canada. OECD Health Working Paper. Paris. 24.
Paris, V., M. Devaux and L. Wei (2010). Health Systems Institutional Characteristics, OECD Publishing.
PhilHealth Homepage (2014). http://www.philhealth.gov.ph/about_us/history.htm.
Picazo, O. F. (2012). Review of the Cheaper Medicines Program of the Philippines. Discussion Paper Series No. 2012-13, Philippine Institute for Development Studies.
PPRI (2007a). HUNGARY Pharma Profile Pharmaceutical Pricing and Reimbursement Information. PPRI.
PPRI (2007b). IRELAND Pharma Profile Pharmaceutical Pricing and Reimbursement Information. PPRI.
PPRI (2008). DENMARK Pharma Profile Pharmaceutical Pricing and Reimbursement Information. PPRI.
Rada, A. G. (2011) “Mandatory generic prescribing is expected to save Spain €2bn a year” BMJ 2011; 343 doi: http://dx.doi.org/10.1136/bmj.d4803 (Published 27 July 2011)
Rachmania, I. N. and M. H. Basri (2013). "Pharmaceutical Inventory Management Issues in Hospital Supply Chains." Management 3(1): 1-5.
Republic Act No. 950 (2008). "Universally Accessible and Cheaper Quality Medicines Act of 2008. An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or The Generics Act of 1988, and Republic Act No. 5921 or The Pharmacy Law, and for Other Purposes. Gloria Macapagal-Arroyo, President of the Philippines (June 6, 2008)"
Riedel, R., U. Repschlager, R. Griebenow, S. Breitkopf, S. Schmidt and A. Guhl (2013). "International standards for health economic evaluation with a focus on the German approach." J Clin Pharm Ther 38(4): 277-285.
Rietveld, A. H. and F. M. Haaijer-Ruskamp (2002). "Policy options for cost containment of pharmaceuticals." The International Journal of Risk and Safety in Medicine 15(1): 29-54.

Roberts, G., W. Irava, T. Tuiketei, R. Nadakuitavuki, S. Otealagi, S. Singh, M. Pellny, M. Fong, J. MoHammed, O. Chang and J. Tulloch, et al. (2011). The Fiji Islands Health System Review, Health Systems in Transition 1(1):1–140.

Roberts, M. J. and M. R. Reich (2011). Pharmaceutical reform: a guide to improving performance and equity, World Bank Publications.

Rokx, C., S. George, P. Harimurti, A. Tandon and A. Somanathan (2009). Health Financing in Indonesia: A Reform Road Map, World Bank Publications.

Roughead, E., K. Lhazeen, E. Socialine, S. Bahri, B. Park and K. Holloway (2013). "Monitoring medicines use to support national medicines policy development and implementation in the Asia Pacific region." WHO South-East Asia J Public Health 2: 113-117.

SAGPA - Swedish Agency for Growth Policy Analysis (2013). China's Healthcare System Overview and Quality Improvements. Direct response, 2013:03.

Saengpassa, C. and P. Sarnsamak (2012). "Govt aims to cut cost of civil-servant scheme." Posted 11 December 2012, Retrieved 15 June 2014, from http://www.nationmultimedia.com/national/Govt-aims-to-cut-cost-of-civil-servant-scheme-30195882.html

Saengpassa C. and P. Sarnsamak (2013). "Thai govt to rein in healthcare budget." Posted 3 January 2013, Retrieved 15 June 2014, from http://www.asianewsnet.net/Thai-govt-to-rein-in-healthcare-budget--40873.html

Sauvage, P. (2008). "Pharmaceutical pricing in France: a critique." Eurohealth 14(2).

Sharpe, R. E., Jr., D. C. Levin, L. Parker and V. M. Rao (2013). "The effect of the controversial US Preventive Services Task Force recommendations on the use of screening mammography." J Am Coll Radiol 10(1): 21-24.

Sivalal, S. (2009). "Health technology assessment in the Asia Pacific region." International journal of technology assessment in health care 25(S1): 196-201.

Sooksriwong, C., W. Yoongthong, S. Suwattanapreeda and F. Chanjaruporn (2009). "Medicine prices in Thailand: A result of no medicine pricing policy." Southern Med Review, 2: 10-14.

Sorenson, C., M. Drummond and P. Kanavos (2008). Ensuring value for money in health care: the role of health technology assessment in the European Union, WHO Regional Office Europe.

Sun, Q., M. A. Santoro, Q. Meng, C. Liu and K. Eggleston (2008). "Pharmaceutical policy in China." Health Affairs 27(4): 1042-1050.

Tangcharoensathien, V., S. Wibulpholprasert and S. Nitayaramphong (2004). "Knowledge-based changes to health systems: the Thai experience in policy development." Bulletin of the World Health Organization 82(10): 750-756.

Teerawattananon, Y., S. Tantivess, J. Yothasamut, P. Kingkaew and K. Chaisiri (2009). "Historical development of health technology assessment in Thailand." International Journal of

Technology Assessment in Health Care 25(SupplementS1): 241-252.

Teh-Wei, H. (2004). "The economic burden of depression and reimbursement policy in the Asia Pacific region." Australasian Psychiatry 12: S11-S15.

Thai working group on Observatory of Health and Policy (2010). Thailand Health Financing Review 2010.

Thailand's Health Insurance System Research Office (2012). Thailand's Universal Coverage Scheme: Achievements and Challenges. An independent assessment of the first 10 years (2001-2010). Nonthaburi.

Thatte, U., S. Hussain, M. de Rosas-Valera and M. A. Malik (2009). "Evidence-based decision on medical technologies in Asia Pacific: experiences from India, Malaysia, Philippines, and Pakistan." Value Health 12 Suppl 3: S18-25.

Thaweethamcharoen, T., P. Noparatayaporn, C. Nopmaneejumruslers and T. Bunrod (2013). "Cost Containment of a Reimbursement Restriction of Non-Essential Drugs Prescribing at Siriraj Hospital." Siriraj Med J 65: 77-80.

Tien, T. V., H. T. Phuong, I. Mathauer and N. T. K. Phuong (2011). A Health Financing Review of Vietnam-with a focus on social health insurance. World Health Organization

Vietnam MOH & Health Partnership Group (2013). Towards Universal Health Care. Joint Annual Health Review.

Vogler, S., N. Zimmermann, C. Leopold and K. de Joncheere (2011). "Pharmaceutical policies in European countries in response to the global financial crisis." South Med Rev 4(2): 69-79.

Wertheimer, A. I. (1988). "Quality control and drug utilization review." Pharm Weekbl Sci 10(4): 154-157.

Whitaker, D. , V. Walford and B. David (2013). Health care financing in the Asia pacific region. HLSP Institute. .

WHO (2001). How to develop and implement a national drug policy. 2nd ed. World Health Organization.

WHO (2009a). Health financing strategy for the Asia Pacific region (2010-2015), World Health Organization.

WHO (2009b). Review of pharmaceutical financing and expenditures in selected Pacific Island countries, World Health Organization.

WHO (2011a). The Fiji islands health system review. (Health Systems in Transition, Vol. 1 No. 1) Asia Pacific Observatory on Health Systems and Policies. .

WHO (2011b). The Philippines Health System Review. Health Systems in Transition. (Vol. 1 No.2) Asia Pacific Observatory on Health Systems and Policies. .

WHO (2011c). The World Medicines Situation 2011 3rd Edition.

WHO (2012). Malaysia health system review. (Health Systems in Transition, Vol. 2 No. 1) Asia Pacific Observatory on Health Systems and Policies. .

WHO (2014a). The Lao People's Democratic Republic health system review (Health Systems in Transition, Vol. 4 No. 1) Asia Pacific Observatory on Health Systems and Policies. .

WHO (2014b). South-East Asia Region: Indonesia statistics summary (2005 - 2012), from http://apps.who.int/gho/data/node.country.country-IDN?lang=en.

WHO (2014c). Western Pacific Region: Philippines statistics summary (2002 - 2012), from http://apps.who.int/gho/data/?theme=country&vid=15900.

WHO/Fiji MOH (2013). Fiji Pharmaceutical Country Profile. World Health Organization and Fiji MOH

WHO/Philippines MOH (2012). Philippines Pharmaceutical Country Profile. World Health Organization and Philippines MOH

WHO/Nepal MOH(2011). Nepal Pharmaceutical Country Profile. World Health Organization and Nepal MOH

WHO/Vietnam MOH (2012). Health Service Delivery Profile: Viet Nam. World Health Organization and Vietnam MOH

WHO Country Office for Vietnam (2010). Medicines Prices: Policy Options for Vietnam. WHO Briefing with the National Assembly-Committee on Social Affairs. Hanoi, Viet Nam.

WHO Expert Committee on the Selection and Use of Essential Medicines (2003). The selection and use of essential medicines. WHO technical report series. Geneva, WHO. 914.

WHO/HAI (2009). Thailand: Medicine prices, availability, affordability & price components,

WHO/HAI (2011). Working paper 2: The role of health insurance in the cost-effective use of medicines. Review series on pharmaceutical pricing policies and interventions, WHO/HAI project on medicine prices and availability.

WHOCC (2014). WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in Europe. URL: http://whocc.goeg.at/ (accessed 2014-04-14)

World Bank (2007). Social Protection. Vietnam Development Report 2008, Joint Donor Report to the Vietnam Consultative Group Meeting.

Yoongthong, W., S. Hu, J. A. Whitty, S. Wibulpolprasert, K. Sukantho, W. Thienthawee, H. Han and P. A. Scuffham (2012). "National drug policies to local formulary decisions in Thailand, China, and Australia: drug listing changes and opportunities." Value Health 15(1 Suppl): S126-131.

Yu, X., C. Li, Y. Shi and M. Yu (2010). "Pharmaceutical supply chain in China: current issues and implications for health system reform." Health Policy 97(1): 8-15.