Comparative Study on Legal and Regulatory Status of Eight Pharmaceutical Exporting Countries in the Western Pacific

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Comparative Study on Legal and Regulatory Status of Eight Pharmaceutical Exporting Countries in the Western Pacific

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This certifies that the Master′s thesis of Jong Hyuk Lee is approved.

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Abstract

1. Introduction

The pharmaceutical industry affects a population and its performance in various ways, including its health, satisfaction towards the public health sector, and especially the cost-effectiveness of service. Pharmaceutical cost is one of the leading causes of increased health expenditure. The high percentage of pharmaceutical expenditure as a share of total household expenditure blocks progress for the countries that have dedicated their resources to the achievement of universal health coverage. Many believe that local production of pharmaceuticals will decrease cost for transport, provide local employment, increase expertise, and decrease dependence on foreign supply. However, investments in local production will only be efficient if the production is cheaper locally than if the medicines are imported. This leads to a struggle for a balance between health policy aimed at increasing access to low-cost and quality medicines and industrial objectives optimizing profit and economic development.

2. Methods

First, for the quantitative data, the study collected relevant statistics from government and international sources. From the gathered data, countries with pharmaceutical exports over one hundred million US dollars were selected. For the second part of the study, the select countries' health law and pharmaceutical regulatory status were collected to find similarities in their availability.

3. Results

Other than high-income countries, only the larger developing countries showed the capacity to produce their own pharmaceuticals. This suggests a possibility of a multiple order effect, in which the pharmaceutical industry's capacity is limited not just by itself, but by other factors as well. Countries often used a single (or a set of laws) for a specific topic, and all countries identified areas in which they used multiple laws. Legal provisions that establish the regulatory framework were present in all eight countries. In some countries, regulatory functions were assigned to more than one agency. On the other hand, some regulatory authorities are given multiple functions – making it difficult to focus solely on drug regulation.

4. Conclusions

Framework law should be used to elaborate on the rights and duties of the pharmaceutical industry and describe the obligations and authorities of the responsible authorities. Pharmaceutical law should be comprehensive and cover all activities regarding pharmaceuticals, from their manufacturing to use. Pharmaceutical regulatory authorities should coverall all aspects of pharmaceutical regulations, without conflicting with other tasks or organizations within its boundaries. Legal coverage for education and quality control of health workers should be strengthened to ensure the supply of quality and skilled professionals for pharmaceutical research.

Suggestions for future research topics include a case study on practices and

changes that occur due to regulatory and legal coverage, and their association with outcomes in the pharmaceutical industry, the legal and sociopolitical context for local production, and their achievements, and the survey of accurate and timely information on the law and the health systems.

Keywords: Health systems, Pharmaceutical Industry, Health Law, Pharmaceutical Regulations

I. Introduction

1. Background

The pharmaceutical industry affects a population and its performance in various ways, including its health, satisfaction towards the public health sector, and especially the cost-effectiveness of service. The industry's benefits include decrease of public health expenditure, decrease of burden on medical care systems, improvement in quality of life, improvement of economic production, increase of job opportunities, and increase of overall economic growth and international competitiveness (Commission, 2014; Nusser, Tischendorf, Schuhmacher, & Reiß, 2010).

Access to quality medicines is a global concern, especially given the high prices of new pharmaceuticals and rapidly changing markets for health products that place increasing pressure on all health systems' ability to provide full and affordable access to quality health care. Pharmaceutical cost is one of the leading causes of increased health expenditure. The high percentage of pharmaceutical expenditure as a share of total household expenditure blocks progress for the countries that have dedicated their resources to the achievement of universal health coverage (Bigdeli, Laing, Tomson, & Babar, 2015; Wirtz et al., 2017). In low- and middle-income countries, pharmaceutical expenditure can account for 25% to more than 60% of the total health expenditure (Lu, Hernandez, Abegunde, & Edejer, 2011).

Local production of pharmaceuticals is an attractive idea for these countries, as it provides increased access for the population, as well as potential new source of income. Many believe that local production of pharmaceuticals will decrease cost for transport, provide local employment, increase expertise, and decrease dependence on foreign supply (Abbott & Reichman, 2007). Leaders of developing countries also believe that local production will help their nations achieve economic development (AU, 2007).

However, investments in local production will only be efficient if the production is cheaper locally than if the medicines are imported. Local production with foreign investment owned by a local government has potential to rig the market by protecting the local producer – often a fruit of nepotism or political favors – against more efficient importers (Ayittey, 2016; Bauer & Bauer, 1984; Easterly & Easterly, 2006; Guest, 2010; Meredith, 2005). Further, if the domestic capacity is inadequate, local production will lead to an increase in the supply of substandard drugs that may affect the health status of a population, both immediately and over time.

This leads to a struggle for balance between health policy aimed at increasing access to low-cost and quality medicines and industrial objectives optimizing profit and economic development by promoting a local – perhaps new – an industry whose products can be sold at a high cost on the international market (Morgan, McMahon, & Greyson, 2008). Supporting local production without strengthening legislation and enforcement, therefore, can bring detrimental results

for public health (Cockburn, Newton, Agyarko, Akunyili, & White, 2005).

2. Purpose

The purpose of the study is to find ways to improve law coverage to promote the pharmaceutical industry and local manufacturing of pharmaceuticals by comparing the health law coverage and the pharmaceutical regulatory authority of countries that are already producing and exporting pharmaceuticals. Thus, the aims of this study are threefold: a) to investigate and describe the current status of health law and policy in select Western Pacific countries; b) to find similarity and differences in the pharmaceutical policy and legislation in select Western Pacific countries, and c) to identify improvements that can be applied to other countries of the region.

3. Methods

The study employed a twofold strategy, combining both quantitative and qualitative data of the countries' health status. First, for the quantitative data, the study collected relevant statistics from government and international sources. From the gathered data, countries with pharmaceutical exports over one hundred million US dollars were selected. For the second part of the study, the select countries' health law and pharmaceutical regulatory status were collected to find similarities in their availability.

25 sovereign member states in the Western Pacific region were included in the first part of the study. The template for data collection was developed by the OECD Korea Policy Center and the WHO Collaborating Center for Health System and Financing. The typical sources of information were ministries of trade or commerce, customs data, and union and trade associations of respective countries. Socioeconomic indicators such as the total population, GDP, and life expectancy were obtained from various literature and datasets published by international organizations. More specifically, literature and databanks produced by the following organizations were reviewed: The WHO and its regional offices; the WB; the OECD, and the ITC.

Policy data for the pharmaceutical industry was collected for countries whose pharmaceutical export exceeded 100 million US dollars. These countries include Australia, China, Japan, Republic of Korea, Malaysia, New Zealand, Singapore, and Viet Nam. Data were obtained from regulatory sections of various country

profile instruments, government webpages, and publications by international organizations. The template for the collection was developed by the WHO and OECD and is listed in the 2018 collaborating report 'How Pharmaceutical Systems are Organized in Asia and the Pacific' (OECD, 2018). Data was also collected from pharmaceutical system reports produced by the ministry of health or its equivalent in the selected countries, other relevant organizations in each country, research articles, and reports. English was used as the main language for searching, and any inquiries made.

Monitoring for public health law coverage for the western Pacific countries was conducted by the WHO Western Pacific Regional Office and the Asian Institute for Bioethics and Health Law of Yonsei University. Data was collected from 2013 to 2016. In each country, Ministry of Health designated local researchers with public health law expertise conducted data gathering processes on public health laws from various archives including government archives and web-based databases. All country-level data - including legal systems, a list of public health law and their classification by types of legislation, and the existence of laws were aggregated using the developed tool (Kim, Lee, Sohn, & Hahm, 2012).

For the study, data on health legislation were collected and analyzed from the results of the survey. The study used a part of the assessment results on in-country analysis on public health laws to describe the pharmaceutical law situation in the Western Pacific Region

4. Terminology and abbreviations

'Drug,' 'Medicine,' and 'Pharmaceuticals' have been used to describe pharmaceuticals due to differences in terminology used by governments, and differences in translation outcomes.

Abbreviations for country names follow the two-letter abbreviations of the ISO 3166-1 alpha-2 codes defined by the International Organization for Standardization as part of its ISO 3166-1 to represent countries, dependent territories, and other areas of interest(ISO). The abbreviations and the full-name for the 37 countries in the Western Pacific are listed below.

Table 1. Name and abbreviations of Western Pacific Countries

Country	Abbreviation
American Samoa (USA)	AS
Australia	AU
Brunei Darussalam	BN
Cambodia	KH
China	CN
Cook Islands	CK
Fiji	FJ
French Polynesia (France)	PF
Guam (USA)	GU
Hong Kong SAR (China)	HK
Japan	JP
Kiribati	KI
Lao People's Democratic Republic	LA
Macao SAR (China)	MO

Malaysia	MY
Marshall Islands	MH
Micronesia, Federated States of	FM
Mongolia	MN
Nauru	NR
New Caledonia (France)	NC
New Zealand	NZ
Niue	NU
Northern Mariana Islands, Commonwealth of the (USA)	MP
Palau	PW
Papua New Guinea	PG
Philippines	PH
Pitcairn Island (UK)	PN
Republic of Korea	KR
Samoa	WS
Singapore	SG
Solomon Islands	SB
Tokelau (New Zealand)	TK
Tonga	TO
Tuvalu	TV
Vanuatu	VU
Viet Nam	VN
Wallis and Futuna (France)	WF

Other abbreviations, including those for medicines, pharmaceuticals, organizations, and various related terminologies follow those used in the existing literature, or given by the originator.

Table 2. Miscellaneous abbreviations used in the study

Name	Abbreviation
Sustainable Development Goals	SDG
Universal Health Coverage	UHC
World Health Organization	WHO
Organization for Economic Cooperation and Development	OECD
World Bank	WB
World Trade Organization	WTO
International Federation of Pharmaceutical Manufacturers & Associations	IFPMA
The Pacific Community	SPC
Special Administrative Region	SAR
Gross Domestic Product	GDP[1]
Over-the-Counter	OTC
United States Dollar	USD
Out-of-pocket payment	OOP
Good Manufacturing Practice	GMP
Good Distribution Practice	GDP[2]

[1] Used to examine variables with economic context

[2] Used to examine selection and distribution process of pharmaceuticals

III. Pharmaceutical Industry in the Western Pacific Countries

1. Health Industry status in the western Pacific countries

A. Socioeconomic Status

a. Population

Among selected countries, China ranked as the most populated country with 1.39 billion (2018). Japan followed in second place with a population of 126.5 million (2018), and Philippines placed third with 106.7 million (2018), both less than 10% of China's population. Palau, Nauru, and Tuvalu recorded the smallest population among surveyed countries, with populations of 18 thousand (2018), 13 thousand (2018), and 12 thousand (2018) respectively. Below table shows the population size of the 25 countries selected in the study as of 2018.

b. Life expectancy

Life expectancy at birth was examined for 21 countries. Japan had the longest life expectancy at 83 years (2017), followed by Singapore (82.9 years, 2017), Korea (82.6 years, 2017), and Australia (82.5 years, 2017). Papua New Guinea exhibited the shortest life expectancy at 64.0 years (2017) and was followed by Fiji and Lao PDR (67.3 years, 2017), and Federated States of Micronesia (67.6 years, 2017). Marshall Islands, Nauru, Palau, and Tuvalu were excluded from the figure due to missing data.

c. GDP

Western Pacific is a region with the widest range of economic status. As such, the variation in GDP per capita was very large. Highest GDP per capita was Singapore's (USD 64,581.90, 2018) followed by Australia (USD 57,305.30, 2018), New Zealand (USD 41,966.00, 2018), and Japan (USD 39,286.70, 2018). The country with the lowest GDP per capita in the region was Cambodia (USD 1,512.10, 2018), followed by Kiribati (USD 1,625.30, 2018), Solomon Islands (USD 2,162.70, 2018), and Vietnam (USD 2,563.80, 2018). Of the 25 countries surveyed, nine countries whose GDP per capita are below USD 3,995 are considered low-middle income countries, and seven are considered high-income countries, with GDP per capita above USD 12,376.

B. Human resources for health

a. Physician density

The density of physicians in the 25 countries was calculated per 1,000 population. Due to the inconsistent availability of data in many countries, the baseline for this analysis was set in 2010. The latest data for each country were used in the analysis, with no country's data gathered beyond the year 2017. Australia had the highest density at 3.56 physicians per 1,000 population. Papua New Guinea had the lowest density at 0.05 physicians per 1,000 population. At thirteen, nearly half of the surveyed countries had less than 1 physician per 1,000 population. These countries are Cambodia (0.17), Vietnam (0.17), Federate States of Micronesia (0.18), Solomon Islands (0.2), Kiribati (0.2), Samoa (0.34), Marshall Islands

(0.46), Lao PDR (0.50), Tonga (0.52), Viet Nam (0.82), Fiji (0.84), and Tuvalu (0.92).

b. Pharmaceutical personnel density

The density of pharmaceutical personnel, including pharmacists and pharmaceutical assistants and/or technicians per 10,000 population were surveyed and analyzed.

Due to the inconsistent availability of data in many countries, the baseline for this analysis was set in 2008. The latest data for each country were used in the analysis, with no country's data gathered beyond the year 2016. The density of pharmacists and other pharmaceutical personnel did not show a similar pattern. In most countries, the number of pharmacists was greater than the number of pharmaceutical technicians or assistants, but in Samoa (2.19 to 0.87), Brunei Darussalam (4.01 to 1.7), Nauru (6.30 to 1.77), and Fiji (1.42 to 0), the number of pharmaceutical technicians and assistants were many times greater. Japan had the highest density of pharmacists (18.02 per 10,000 population) among surveyed countries. Mongolia placed second with 9.13 per 10,000 population, but the density was only half that of Japan. Australia ranked third for density (8.69). Kiribati had the lowest density of pharmacists at 0.26 per 10,000 population, followed by Cambodia at 0.34. Nauru had the highest density of pharmaceutical technicians or assistants at 6.30 per 10,000 population and had 1.77 pharmacists per 10,000 population. Fiji had no available data for pharmacist density.

The density of pharmacists and the density of physicians showed a similar, but not identical trend. Australia, Japan, Korea, and Mongolia had the highest density (although varying positions) of both physicians and pharmacists, and Cambodia and Papua New Guinea had (excluding Kiribati) the lowest density. The degree of role sharing between the two roles in the Western Pacific cannot be explored in detail due to insufficient information.

c. Nurse and midwife density

The degrees of freedom nurses have in prescribing and dispensing medicine differed vastly from one country to another, and sometimes even within a country. Nevertheless, their density per 1,000 population was surveyed and compared.

Due to the inconsistent availability of data in many countries, the baseline for this analysis was set in 2009. The latest data for each country were used in the analysis, with no country's data gathered beyond the year 2018. As with the densities for physicians and pharmacists, the density for nurses and midwives was highest in Australia (12.7), Japan (11.5), New Zealand (11), and Korea (7). Singapore ranked higher than Korea at forth with 7.2 nurses per 1,000 population. The country with the lowest nurse and midwife density was Philippines at 0.2 per 1,000 population, followed by Papua New Guinea (0.5), and Cambodia and Lao PDR (both 1 per 1,000 population). Statistic for Nauru was not available and was discarded from the analysis.

C. Health Expenditure

a. Expenditure per capita

Figure 9 shows the total health expenditure per capita of 25 countries in the Western Pacific region in United States Dollars. Total health expenditure per capita was highest in Australia (USD 5,002.36) among the surveyed countries. Japan (USD 4,244.04) and New Zealand (USD 3,745.42) ranked second and third respectively. Total health expenditure per capita was the lowest in Papua new Guinea (USD 55.15), followed by Lao People's Democratic Republic (USD 55.21), and Cambodia (USD 77.67) with less than one hundred US dollars spent per capita.

b. Share of GDP (%)

All 25 target survey countries were analyzed. Most countries in the region did not exceed 15% in health expenditure as a share of GDP, except for the cases of Marshall Islands (23.29%), and Tuvalu (15.45%). Japan was the only high-income country in the region to exceed 10% share of GDP as health expenditure (10.93%). Papua New Guinea had the lowest percentage of GDP share as health expenditure (1.98%) followed by Brunei Darussalam (2.34%) and Lao People's Democratic Republic (2.36%).

c. Composition of the health expenditure

i. Public vs. Private

Total health expenditure as a share of GDP was calculated as a ratio of public and private expenditure. Private expenditure was calculated by subtracting

government expenditure percentage from total health expenditure. Both were then divided by their sum to give the ratio.

All 25 target survey countries were analyzed. The ratio of public (21.81% to 94.93%) and private (5.07% to 78.19%) composition varied within the Western Pacific region. Brunei Darussalam's health expenditure was mostly composed of public expenditure (94.93%), ranking it first in the region. This was followed by Tuvalu (84.52%), Japan (83.59%), and New Zealand (78.65%). On the other hand, the private contribution to the total health expenditure was highest in Cambodia (78.19%), followed then by Federated States of Micronesia (72.16%), and Philippines (68.46%). Neither GDP ($r = 0.08$) nor GDP per capita ($r = 0.36$) was directly related to the ratio of public and private shares of total health expenditure.

Increase in private expenditure, especially in low to middle-income countries means denied access to healthcare due to high out-of-pocket payment. Detailed analyses or data about the impacts of private spending on the populations' poverty status, such as catastrophic health spending, has not yet been reported in the Western Pacific region.

d. Out of pocket and other financing sources

Out of pocket expenditure was surveyed for all 25 target countries. Subtracting for OOP from Private expenditure, and external health expenditure from total expenditure, other sources of financing were also calculated.

Figure 8 shows four different types of sources composing total health spending. Public (including social insurance schemes), OOP, external, and others. Externa source is defined as both direct and indirect transfers and distribution of foreign funds into the national health system. The composition of health expenditure is influenced by the characteristics of each country. General public spending (tax revenue) was highest in Brunei Darussalam, Japan, and Tuvalu. Specific figures for public spending have been discussed above. The proportion of OOP in total health expenditure was the lowest in Tuvalu (0.67%), followed by Nauru (1.15%), Federated States of Micronesia (2.63%), and Solomon Islands (4.60%). Comparing these with external sources of funding (12.16%; 34.51%; 26.17% respectively) suggest that the population's capacity to personally pay for healthcare is heavily impaired and have to rely on other sources of funding.

The proportion of OOP was also low in Brunei Darussalam (5.07%), but no external or 'other' source of funding was indicated. The case was similar in other high-income nations of Australia, China, Japan, Korea, New Zealand, and Singapore, as they all indicated 0% share of total health expenditure came from foreign sources. The proportion of OOP was highest in Cambodia (58.56%), Philippines (53.94%), and Lao People's Democratic Republic (46.44%). The proportion of external financing was the highest in Federated States of Micronesia (69.24%), nearly twice the share of other pacific island countries such as Marshall Islands (35.38%), Vanuatu (34.61%), and Nauru (34.51%). Brunei Darussalam, Papua New Guinea, and Singapore reported 0% share of 'other' finances, indicating the absence of private or prepaid health services.

2. Pharmaceutical industry status in the western Pacific countries

A. Pharmaceutical Expenditure

Pharmaceutical expenditure can be divided into various sources and types, such as inpatient and outpatient, and over-the-counter, with types being patent, generic, and many others. However, it is difficult to accurately measure the exact size of each, especially in settings like inpatient services where the services are not reported separately in most countries. Outpatient pharmaceutical expenditure is often estimated. This study examines the composition of pharmaceutical expenditure and studies the relationship between these indicators and the economic status of the country using GDP per capita.

Due to data unavailability, pharmaceutical expenditure was collected at different timepoints. For Brunei Darussalam, Fiji, Marshall Islands, Mongolia, and Tonga, the data for 2014 was collected. Kiribati, Solomon Islands, and Tuvalu's data were collected using the 2011 data. Any data that was unavailable but could be calculated using other variables – for example, pharmaceutical expenditure as a proportion of total health expenditure can be calculated from total pharmaceutical expenditure and total health expenditure – were done so but were not specified in the results.

a. Expenditure per capita

Western Pacific region had a varying level of pharmaceutical expenditure data ranging from 4.30 USD to 841.70 USD per capita. Pharmaceutical expenditure per capita was highest in Japan (841.70 USD), followed by Marshall Islands (513.58 USD), Australia (482.50 USD), and Korea (341.00 USD). It was lowest in Solomon islands (4.30 USD), and Kiribati (9.00 USD) where it did not exceed 10 USD per capita.

b. Share of the health expenditure (%)

Pharmaceutical expenditure as a share of the total health expenditure was calculated. Results varied across countries in the region, from 41.10% in Vietnam to 4.3% in New Zealand. It must also be noted that the expenditure as a share of health expenditure has a different trend from the pharmaceutical expenditure per capita. The two had very little correlation (r=0.06). While pharmaceutical expenditure per capita distinctly showed that higher-income countries spend more per capita than developing countries – and especially small pacific island countries, the share of total health expenditure varied even within the same income group.

Pharmaceutical expenditure's share of total expenditure was highest in Vietnam (41.10%), followed by Marshall Islands (33.06%), and Lao People's Democratic Republic (30.80%). Six countries, on the other hand, showed under 10% share of total health expenditure. These are New Zealand (4.30%), Tuvalu (4.88%), Singapore (5.10%), Solomon Islands (5.97%), Tonga (6.30%), and Australia

(8.90%).

c. Composition of the expenditure

i. Public vs. private

The composition of pharmaceutical expenditure is diverse in the region. In general, the trend of public vs. private ratio for pharmaceutical expenditure is very similar to that of the total health expenditure (r=0.84), with some exceptions. The proportion of the public sector in pharmaceutical expenditure was the largest in Tuvalu and Solomon Islands, both with no private pharmaceutical costs. This was followed by Brunei Darussalam (89.60%).

The proportion for the public sector was the lowest in Philippines (15%), followed by Lao People's Democratic Republic (16.5%), and Vietnam (16.50%). Of the eighteen countries surveyed, thirteen had 40% or more public share of pharmaceutical expenditure.

ii. Prescription vs. OTC

Pharmaceutical expenditure was then separated into two types of dispensation: Prescription and OTC. Due to the unavailability of data across countries, including all of small pacific island countries and many low-middle income countries, the survey was conducted only in nine countries. Composition of pharmaceutical expenditure had variations, but all countries exhibited preference of prescription over OTC, that all countries had over 70% of total pharmaceutical expenditure in prescription drugs. Japan had the highest rate of prescription usage

(93.9%), and Philippine was lowest at 73.1% of total sales.

iii. Patent vs. generic

Drugs were categorized into patent (original) and generic drugs. Due to limited data, only nine countries were surveyed.

Composition by patent status varied across countries. Countries where the proportion of patented original medicines were greater than 50% were Japan (79.70%), Australia (68.90%), New Zealand (56.10%), and Singapore (56.60%). Vietnam (20.30%) had the smallest proportion of patented medicine in pharmaceutical expenditure.

The proportion of generics was greatest in China (63.50%), followed by Vietnam (54.50%). These were the only countries to have over 50% proportion in Generics. The proportion of the ‘other,’ assumed to be unbranded generics, was in all cases smaller than both patented and generic medicines. Philippines had the largest proportion (26.9%), while Japan had the lowest.

B. Pharmaceutical Trade

Table 3. Pharmaceutical import and export

Country	Pharmaceutical Exports (million USD)	Pharmaceutical Imports (million USD)	Trade Balance (million USD)
Australia	**2,968.14**	**8,173.23**	**-5,205.10**
Brunei Darussalam	1.12	76.79	-75.68
Cambodia	8.02	296.20	-288.18
China	**8,866.10**	**27,900.03**	**-19,033.93**
Federated States of Micronesia	0.07	0.36	-0.29
Fiji	9.59	34.62	-25.03
Japan	**5,546.98**	**25,510.33**	**-19,963.35**
Korea, Rep of	**3,479.17**	**6,496.88**	**-3,017.71**
Lao PDR	0.00	0.03	-0.03
Malaysia	**238.10**	**1,485.83**	**-1,247.73**
Mongolia	0.13	118.08	-117.94
Nauru	0.03	0.83	-0.80
New Zealand	**319.24**	**1,008.87**	**-689.63**
Papua New Guinea	0.21	52.67	-52.46
Philippines	39.77	1,638.39	-1,598.62
Samoa	0.04	5.38	-5.35
Singapore	**8,352.71**	**2,931.46**	**5,421.25**
Tokelau	0.46	0.21	0.25
Tonga	0.07	1.29	-1.23
Vanuatu	0.03	5.03	-5.00
Viet Nam	**159.46**	**3,027.15**	**-2,867.69**

Sources: (ITC, 2019)

21 of 25 countries had accurate data for both import and export of pharmaceuticals, in addition to general total expenditure. Singapore exported the largest number of pharmaceuticals at 8.35 billion USD. It was also the only

country in the region to achieve a positive trade balance of 5.42 billion USD by importing 2.93 billion USD of pharmaceuticals – less than a third of its exports. China, on the other hand, placed first in pharmaceutical imports with 27.9 billion USD. This created a -19 billion USD balance as the country exported 8.87 billion USD – third in the region. Countries with an import amount of over 100 million USD are selected in bold. The detailed trade profiles of the eight countries are listed below, with HS code for specific product descriptions.

Table 4. Pharmaceutical trade components

	HS Code	TOTAL	3001	3002	3003	3004	3005	3006
AU	Import	8173.2	34.1	2340.7	46.6	5338.2	158.5	255.2
	Export	2968.1	26.1	1065.7	78.1	1749.7	9.9	38.7
CN	Import	27900.0	60.3	8360.1	307.9	18139.5	228.5	803.6
	Export	8866.1	1290.7	683.9	687.3	3945.6	1434.6	824.0
JP	Import	25510.3	108.2	7750.3	305.5	16425.9	234.7	685.7
	Export	5547.0	35.0	870.7	254.0	3946.2	224.8	216.2
KR	Import	6496.9	76.3	2051.9	94.5	3878.2	123.7	272.1
	Export	3479.2	27.7	2388.2	65.1	790.7	85.7	121.7
MY	Import	1485.8	6.8	154.4	15.2	1245.3	41.0	23.1
	Export	238.1	0.1	6.4	18.0	185.1	6.6	21.8
NZ	Import	1008.9	12.0	254.8	23.5	635.3	37.3	45.9
	Export	319.2	11.4	154.6	22.7	124.0	3.5	3.1
SG	Import	2931.5	398.4	644.6	8.6	1553.1	74.9	251.9
	Export	8352.7	479.0	2301.7	327.7	4864.2	121.8	258.1
VN	Import	3027.1	16.6	335.8	60.0	2491.8	36.2	86.8
	Export	159.5	1.2	5.8	6.2	120.7	21.3	4.2

Sources: (ITC, 2019)

China showed the largest amount of export of dried glands and other organs (3001)

at 1.2 billion USD, followed by Singapore at 479 million USD. The other six countries reported much less export of category 3001, with the lowest being Malaysia at 0.1 million USD. South Korea exported the most human and animal blood products (3002) at 2.4 billion USD, closely followed by Singapore at 2.3 billion USD. The export of medicaments consisting of mixed or unmixed products (3004) showed the greatest difference between countries, with Singapore showing the largest export at 4.9 billion USD and Viet Nam the lowest at 120 million USD. China and Singapore were the only two countries to show export of over 100 million USD are all categories, with Australia, Japan, and Korea following. Malaysia, New Zealand, and Viet Nam showed an export of 100 million USD or more in only one or two categories. Details of the countries' regulatory status and health law coverage are discussed in the sections below.

III. Regulatory Status of the Eight Pharmaceutical Exporting Countries

Ensuring equitable access to medicines is the core of a well-functioning health system (WHO, 2007). All elements involved in this can be categorized as a pharmaceutical system in a subset of the larger health systems. Pharmaceutical systems, sectors, or industries have been used interchangeably in previous studies (Roberts & Reich, 2011; Smith & Hanson, 2012), and there are no explicit consensus or a defined framework on what constitutes a pharmaceutical system, despite many works on access to medicines, pharmaceutical systems, and their performance (Bigdeli et al., 2012; Brudon, Rainhorn, & Reich, 1999; Cameron, Ewen, Ross-Degnan, Ball, & Laing, 2009; PAHO, 1995; WHO, 2008; Windisch et al., 2011).

The Management Sciences for Health's pharmaceutical management framework identifies four management sections for pharmaceutical systems: selection, procurement, distribution, and use (Quick et al., 1997). These functions are controlled by policies, laws, and regulations in an effort to sustain the public commitment to the supply of medicines (Embrey, 2013). These are the coordinating center for the entire system that directly interacts with all components. Health law is essential to advance health, as it can be used to establish and manage health systems, allocate powers, set standards, and authorize or restrict action (Ibrahim, Burris, Hays, & Practice, 2012). It also provides

framework for organizing the system and coordinating the activities of various stakeholders to achieve the system's intended objectives. As a related component, regulatory systems focus on ensuring the safety and quality of products and services delivered.

For this section of the study, eight countries who showed pharmaceutical export of more than 100 million US dollars were further surveyed for their pharmaceutical regulations and availability of health laws. The criteria for selection are described in the Methods section of the study. The coverage and availability were then compared against each other to determine what differences or commonalities existed in the coverage that may have resulted in the differences in the amount and scale of the pharmaceutical export.

1. Health Law Status

Establishing and strengthening an effective system however requires a solid governance, which in turn requires a robust law. WHO defines health systems as 'all organizations, people, and actions whose primary intent is to promote, restore, or maintain health' (WHO, 2007) and identifies six 'building blocks' of health systems: services delivery; health workforce; information; medical products, vaccines, and technologies; financing; and leadership and governance. The report further goes to state that strengthening the health system as 'improving these six health system building blocks and managing their interaction in ways that achieve more equitable and sustained improvements across health services and health outcomes.' In the system however, the reactions and the interactions can induce policy-resistance of the system, brining unintended consequences from well-intentioned actions (Atun & planning, 2012; De Savigny & Adam, 2009; Sterman, 2006).

Law can promote and fulfill the right to health and regulate services and products to ensure quality, safety, and efficacy of the deliverables. Therefore, health law – and especially those relating to the establishment and the regulation of a pharmaceutical system – plays a crucial role in achievement of a quality and timely access to medicines, and their formation requires an understanding of the interactions and correlations with other forms of actions and regulations to influence public health.

Robust public health law system is an effective way to establishing a resilient

governance structure (Marks-Sultan et al., 2016). Law and regulatory authority can also facilitate the cooperation and regulation of both government and non-governmental bodies and their activities. Public health law researchers have provided their expertise to health practitioners and policymakers for many decades. Researchers have endeavored to determine the correlation between laws and the conditions, actions, and ideas that surround public health, and have attempted to influence the improvement of health conditions of the population (Ibrahim et al., 2012) Legal epidemiology – study of law as a factor in the change of health outcomes in a population - is one such discipline of public health law that focuses on law's effect on health (Burris, Ashe, Levin, Penn, & Larkin, 2016). Despite many examples of law and policy influencing public health outcomes, systematic evaluations need to be conducted to clearly indicate which law, policy, or regulatory measures change, harm, or facilitate public health conditions. The importance of legal epidemiology is increasing (IoM, 2012), but extremely rare – especially for developing countries and international analysis. Legal epidemiological research has been conducted in the region (Lee & Kim, 2019), but none have yet to focus specifically on pharmaceutical systems.

A. Workforce

As one of the building blocks of the health system, health workforce plays a crucial role in the improvement of local production, research, and export of pharmaceuticals. As service providers and researchers, health workers provide skill and knowledge to the development of new drugs, technologies, or techniques that can be used for improving health outcomes.

Table 5. Health law for workforce (1)

	Health Workforce	Minimum number
AU	Health Practitioner Regulation National Law Act	Health Practitioner Regulation National Law Act
CN	Law of The People's Republic of China on Medical Practitioners	N/A
JP	Medical Care Act Medical Practitioner Act Pharmacists Act Massage, Acupressure, Acupuncture and Moxibustion Act	N/A
MY	Medical Act Medical Assistants (Registration) Act Midwives Act Nurses Act Registration of Pharmacists Act Dental Act	N/A
NZ	Health Practitioners Competence Assurance Act Medical Practitioner Act Health Service Personnel Act Pharmacy Act	Health Practitioners Competence Assurance Act Medical Practitioner Act Health Service Personnel Act Pharmacy Act
KR	Framework Act on Health and Medical Service	Medical Care Assistance Act Framework Act on Health and Medical Services
SG	Constitution of the Republic of Singapore	N/A
VN	Law on Health examination and treatment Pharmaceutical law Education law Tertiary Education law	Decree on decentralizing the management of state administrative and non-business payrolls Decision approving the Masterplan on development of Vietnam's healthcare system up to 2010 with a vision to 2020; Joint Circular guiding staffing norms for State health service provision units

Table 17 shows the availability of dedicated health laws for health workforce and minimum number of health workers in each country. China, Japan, Malaysia, and Singapore did not show a dedicated law defining the minimum number of health workforce. All countries had one or more laws that governed the overall activities

of its health workers. Singapore was unique in that it identified the constitution as the law that governed its health workforce. Australia, China, and Korea responded that they had a single law for health workforce, while Japan, Malaysia, New Zealand, and Viet Nam showed multiple laws for health workforce.

Table 6. Health law for workforce (2)

	Classification	Distribution	Quality Control
AU	Health Practitioner Regulation National Law Act	N/A	Health Practitioner Regulation National Law Act
CN	N/A	N/A	Law on Licensed Doctors of the People's Republic of China Law on Practicing Doctors of the People's Republic of China
JP	N/A	N/A	Medical Care Act
MY	N/A	N/A	Medical Act Medical Assistants (Registration) Act Midwives Act Nurses Act Registration of Pharmacists Act Dental Act
NZ	Health Practitioners Competence Assurance Act Medical Practitioner Act Health Service Personnel Act Pharmacy Act	Health Practitioners Competence Assurance Act Medical Practitioner Act Health Service Personnel Act Pharmacy Act	Health Practitioners Competence Assurance Act
KR	Medical Service Act Framework Act on Health and Medical Service Pharmaceutical Affairs Act Medical Technicians, etc. Act	Framework Act on Health and Medical Services Regional Public Health Act	Medical Service Act
SG	Allied Health Professions Act Optometrists and Opticians Act Dental Registration Act Medical Registration Act Nurses and Midwives Act Pharmacists Registration Act Traditional Chinese Medicine Practitioners Act	N/A	Allied Health Professions Act Optometrists and Opticians Act Dental Registration Act Medical Registration Act Nurses and Midwives Act Pharmacists Registration Act Traditional Chinese Medicine Practitioners Act
VN	Joint Circular guiding staffing norms for State health service provision units	Joint Circular guiding staffing norms for State health service provision units	Law on Health examination and treatment Pharmaceutical law Education law Tertiary Education law

Law coverage for health worker classification, distribution, and quality control were surveyed. No laws for classification of health workers were identified for China, Japan, and Malaysia. While Australia and Viet Nam had single laws for classification of health workers, New Zealand, Korea, and Singapore had multiple laws for classification of various types of health workers.

Only three countries responded as having a law controlling the distribution of their health workers (New Zealand, Korea, Viet Nam). Of these, while New Zealand and Korea responded as having multiple laws guiding the distribution of health workers, Viet Nam responded that a joint-circular (ninth in the country's legal hierarchy) managed the distribution.

All surveyed countries had more than one law for the quality control of health workers. Australia, Japan, New Zealand and Korea used a single law to ensure the quality of its health workers, while China, Malaysia, Singapore, and Viet Nam use multiple laws. Of specific note is the case of Singapore, who used same set of laws for the classification and quality control.

B. Financing

Medical research requires reliance on sustainable funding, as it is a time-consuming, resource extensive endeavor. Advances in technology have led to improvement in healthcare, but also in health expenditure as well (Sorenson, Drummond, & Kanavos, 2008). Pharmaceutical sector is especially vulnerable, as it is a market characterized by rapid change and high expenditure (Serra-Sastre & McGuire, 2009).

Table 7. Health law for financing

	Health Financing	Safety-net
AU	Finance Law Health Insurance Act	Health Insurance Net Health Legislation Amendment Act
CN	Basic Healthcare and Health Promotion Law	N/A
JP	Public Assistance Act Health Insurance Act National Health Insurance Act Aged Medical Care Secure Act Income Tax Act	Public Assistance Act
MY	Employees Provident Fund Act Employees' Social Security Act Workmen's Compensation Act Private Healthcare Facilities and Services Act Fees Act	Workmen's Compensation Act Employees Provident Fund Act Employees' Social Security Act Fees Act
NZ	Public Health and Disability Act	Public Health and Disability Act
KR	Framework Act on Health and Medical Services National Health Insurance Act National Health Promotion Act	National Health Insurance Act Medical Care Assistance Act
SG	Central Provident Fund Act Medical and Elderly Care Endowment Schemes Act	Central Provident Fund Act Medical and Elderly Care Endowment Schemes Act
VN	Law on State budget; Law on Health Insurance Law on Social Security Law on Enterprise Taxation	Law on Health Insurance Law on Social Security Law for National Reserve

Law coverage for health financing and safety-net mechanism were surveyed. Excluding China, all countries possessed one or more laws controlling health financing and safety-net mechanism. China did not have a law relating to safety-net mechanism. Malaysia was unique in that while other countries' laws were focused on national health insurance, government fund, or basic healthcare, their laws for health financing and safety-net were more focused on employee compensation, social security, and providing basic support for workers when injured.

C. Pharmaceuticals and Medical Devices

Use of ineffective, poor quality pharmaceuticals can lead to detrimental health consequences, sometimes leading to death. It also undermines public confidence in the state's health systems, workers, and pharmaceutical manufacturers.

Table 8. Health law for pharmaceuticals and medical devices (1)

	Pharmaceuticals	Medical Devices
AU	Therapeutic Goods Act National Health Act	Therapeutic Goods Act
CN	Pharmaceutical Administration Law	Regulations on Supervisory Management of Medical Devices
JP	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
MY	Poison Act	Medical Device Act Medical Device Authority Act
NZ	Medicines Act	Medicines Act
KR	Pharmaceutical Affairs Act	Medical Devices Act
SG	Health Products Act	Health Products Act
VN	Pharmaceutical Law	Decree on Medical Devices Management

Table 20 shows the legal coverage for pharmaceuticals and medical devices. All countries possessed one or more laws relating to pharmaceuticals and medical devices. Australia, Japan, New Zealand and Singapore used a single law to regulate both aspects, with National Health Act 1953 as an additional law for pharmaceuticals in case of Australia. China, Malaysia, Korea, and Viet Nam used different laws for the two aspects, and China and Viet Nam's laws for the two differed in their legal hierarchy, both with higher law for pharmaceuticals (Law) than medical devices (Regulations and decree, respectively).

Table 9. Health law for pharmaceuticals and medical devices (2)

	Access to Medicines	Quality Control	Vaccine
AU	N/A	Therapeutic Goods Act	Child Care Legislation Amendment Act
CN	N/A	Pharmaceutical Administration Law	Law on Vaccine Administration
JP	N/A	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices	Vaccination Act
MY	N/A	Private Healthcare Facilities and Services Act	N/A
NZ	N/A	Medicines Act	Health Immunization Regulation
KR	Pharmaceutical Affairs Act	Medical Service Act Framework Act on Health and Medical Service Medical Appliances Act:	Prevention of Contagious Diseases Act
SG	Control of Essential Supplies Act	Health Products Act	Infectious Diseases Act
VN	Pharmaceutical Law Law on Health Insurance	Law on Health Examination and Treatment Pharmaceutical Law Law on Health Insurance Law on Goods and Products Quality	Law on People's Health Protection Law for the Prevention and Control Of Communicable Disease

Table 21 shows law coverage for access to medicines, quality control, and access to vaccines. Only three countries had laws relating to access to medicines (Korea, Singapore, Viet Nam) while all countries responded as having more than one law for quality control of pharmaceuticals and medical devices. All countries, excluding Malaysia, possessed a law related to vaccines. Australia, China, Japan, New Zealand, and Singapore used the same law for the regulation of pharmaceuticals and their quality control. Countries that responded as having a law relating to vaccination showed that their laws were focused on prevention of

infectious diseases or improving vaccination. However, Australia was an exception to this as the legislation relating to vaccination was the Child Care Legislation Amendment Act, indicating that the country's vaccine measures was focused on children.

D. Information and Research

There is a longstanding belief that academic research creates new knowledge that fuels new opportunities in the market (Griliches, 1958). Research provides a foundation on which new opportunities for addressing health issues can stand upon. These new opportunities stem from advances in our increasing understanding of biology and emerging technologies.

Table 10. Health law for information and research

	Health Research	Health Information	Information Technology
AU	National Health and Medical Research Council Act	N/A	N/A
CN	Law of the People's Republic of China on Progress of Science and Technology	N/A	N/A
JP	Law on Clinical Research.	N/A	N/A
MY	Malaysian Health Promotion Board Act Occupational Safety and Health Act	Prevention and Control of Infectious Disease Act	Telemedicine Act
NZ	Health Research Council Act	Health Act	Public Health and Disability Act
KR	Framework Act on Health and Medical Services	Framework Act on Health and Medical Service Medical Service Act	Framework Act on Health and Medical Services
SG	Agency for Science, Technology and Research Act National Research Fund Act Medical (Therapy, Education and Research) Act National Registry of Diseases Act Infectious Diseases Act Medicines Act	Statistics Act National Registry of Diseases Act Infectious Diseases Act	N/A
VN	Law on Science and technology	Law on Statistics	Law on Information Technology

Law coverage for health research and information are shown in Table 22. All surveyed countries, except for Japan, have responded as having one or more laws relating to health research. China and Viet Nam's laws relating to health research was their respective laws on science and technology, while other countries had dedicated laws for health. Singapore responded as to having six laws that related to health research, each for research agency, funds, medical research, diseases, and medicines. Malaysia also responded to having two laws – one each for health promotion, and safety. Other countries had one law relating to health research. Japan was unique in that until 2018, they did not have a law on health research and responded that while the government supports and funds the research, it does not regulate it as research is considered independent. Japanese law came to force in 2018.

Australia, China, and Japan responded as not having any law relating to health information. Korea and Singapore responded as to having more than one law relating to health information. Both Singapore and Viet Nam stated that the Law on Statistics was one of the laws relating to health information.

Only Malaysia, New Zealand, Korea, and Viet Nam responded as to having a law relating to use of information technology. Of these four countries, Viet Nam was the only country to refer to a law on information technology, rather than a law relating to health.

E. Prescription and Manufacturing

Table 11. Health law for prescription and manufacturing

	Prescription	Manufacturing
AU	National Health Act	Therapeutic Goods Act
CN	Law of The People's Republic of China on Medical Practitioners	Pharmaceutical Administration Law
JP	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
MY	Poisons Act Sale of Drugs Act	Dangerous Drugs Act
NZ	Medicines Act	Medicines Act
KR	Medical Service Act	Pharmaceutical Affairs Act
SG	Health Products Act	Health Products Act
VN	Pharmaceutical Law	Health Products Act

Table 23 describes the law availability for prescription and manufacturing. All countries responded to having laws relating to prescription and manufacturing of drugs. Japan, Malaysia, and Singapore responded as having a single law relating to both prescription and manufacturing (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices; Medicines Act 1981; and Health Products Act respectively), while other countries used different laws for the two domains.

2. Pharmaceutical Regulation Status

To further compare the pharmaceutical systems of the eight countries, the pharmaceutical regulation status was surveyed. The results are as follows.

Table 12. Pharmaceutical regulation

	Insurance System	Authority	Legislation	National Policy
AU	National Health Service	Therapeutic Goods Administration	National Health Act	Non-legislative National Medicines Policy
CN	Social Health Insurance	National Medical Products Administration	Pharmaceutical Administration Law	National Essential Medicines Policy
JP	Social Health Insurance	Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare	Medical Care Act, Health Insurance Act	No Formal National Medicines Policy
MY	National Health Service	National Pharmaceutical Regulatory Agency	Poisons Act Sale of Drugs Act Control of Drugs and Cosmetics Regulations	National Medicines Policy
NZ	National Health Service	Medicines and Medical Devices Safety Authority	The Medicines Act The Medicines Regulations	Medicines New Zealand
KR	Social Health Insurance	Ministry of Food and Drug Safety	Pharmaceutical Affairs Act	National Medicine Policy Plan
SG	Mixed	Health Sciences Authority	Health Products Act	No Formal National Medicines Policy
VN	Social Health Insurance	Drug Administration of Vietnam	Pharmaceutical Law	National Strategy for Pharmaceutical Sector Development

Australia, Malaysia, and New Zealand use national health service system as its financing system, which uses general tax revenue to finance its health services. China, Japan, Korea, and Viet Nam used a social health insurance system, in which all population are registered for a compulsory membership, and workers,

enterprises, and government pay contribution into a social health insurance fund (Carrin & James, 2005). Singapore uses a mixed financing system that involves both a national life insurance and scheme and a central fund for Singaporeans and permanent residents (S. M. o. Health). All countries have existing regulatory authority for pharmaceuticals and key legislations. All countries, except for Japan and Singapore, have a national medicines policy.

A. Authorization and licensing

Table 13. Authorization and licensing

	Tasks	Regulations
AU	Assessment, monitoring, and enforcement of standards, licensing of local and foreign manufacturers	Therapeutic Goods Act, Therapeutic Goods Regulation, Non-Legislative National Medicines Policy
CN	Authorization of pharmaceuticals, drug standard setting, establish classification system, implementation of regulatory standards at the local level	Pharmaceutical Administration Law, Regulations for Implementation of The Drug Administration Law, Provisions for Drug Registration
JP	Manufacturing, marketing, accreditation	Pharmaceutical and medical Devices Act, Pharmaceutical Affairs Law,
MY	Authorization and categorization of drugs in the market	Poisons Act, Sale of Drugs Act, and Control of Drugs and Cosmetics Regulations
NZ	Regulation of therapeutic products	Medicines Act
KR	Approval and registration	Pharmaceutical Affairs Act
SG	Licensing and authorization	Health Products Act
VN	Licensing, registration, inspection, advertising management, price management of pharmaceuticals and manufacturers	Pharmaceutical Law

Table 11 shows the tasks conducted by the national regulatory authority (see Table 10) for each country with respect to authorization and licensing. All countries had one or more regulations that govern the authorization and licensing

process for pharmaceuticals. The authority's tasks range from licensing and authorization in many countries to manufacturing, marketing, and accreditation (Japan), and advertising management (Viet Nam).

B. Selection

Table 14. Selection

	Who	Purpose	Criteria
AU	Pharmaceutical Benefits Advisory Committee	Drug recommendation for inclusion in the benefits scheme	Safety, efficacy and cost-effectiveness
CN	Essential Medicines List	Listing of drugs and setting of requirements for revenues	Disease patterns in the country
JP	Drug Price Standard	Medicines to be included in the National Health Insurance	Quality, safety, efficacy, and cost
MY	Pharmaceutical Services Division, Ministry of Health	Listing of medicines in the ministry of health formulary	Safety, efficacy, best and current treatment options, population needs, current treatment guidelines and cost-effectiveness
NZ	Pharmaceutical Management Agency	Securing best health outcomes within fixed budget	Need, benefits, cost, suitability
KR	Health Insurance Review and Assessment Service, And Pharmaceutical Benefit Review Committee	Decide which medicines are included in the positive list. Reviewed by the National Health Insurance Policy Deliberation Committee	Effectiveness and budget impact
SG	Drug Advisory Committee, Ministry of Health	Recommendation for the standard drug list	Disease patterns in the country
VN	Department of Health Insurance, Ministry of Health	Development of the major drug list as basis for selecting drugs and as reference for insurance reimbursement	Disease patterns in the country

Table 12 describes the regulatory authority, its purpose, and the criteria for selection of pharmaceuticals in each country. All countries showed presence of

regulatory authority for selection of pharmaceuticals. Japan, Malaysia, Singapore, and Viet Nam identified as having a department within its Ministry of Health or its equivalent in charge of medicines selection, but Australia, China, Korea, and New Zealand stated as having a separate – though governmental – authority as having the regulatory power to select pharmaceuticals. China, Singapore, and Viet Nam identified that their criteria for pharmaceutical selection followed the disease patterns in the country, while Australia, Japan, Korea, Malaysia, and New Zealand stated that cost, effectiveness, and safety were the key criteria for selection.

C. Procurement and reimbursement

Table 15. Procurement and reimbursement

	Regulatory body
AU	Pharmaceutical Benefits Advisory Committee
CN	Ministry of Human Resources and Social Security and National Health Commission
JP	Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare
MY	Pharmaceutical Services Division, Ministry of Health
NZ	Pharmaceutical Management Agency
KR	Health Insurance and Review and Assessment Service
SG	Drug Advisory Committee, Ministry of Health
VN	Department of Health Insurance, Ministry of Health

All countries were identified as having a regulatory body for procurement and reimbursement of pharmaceuticals. As with authority for selection, Japan, Malaysia, Singapore and Viet Nam identified as having a department within its Ministry of Health as in charge of the procurement and reimbursement, while Australia, China, Korea, and New Zealand identified as having a separate agency for procurement and reimbursement. Australia, Malaysia, New Zealand, Korea, Singapore, and Vietnam also had the same regulatory body in charge of selection, procurement, and reimbursement of pharmaceuticals, while China and Japan had separate entities in charge of selection, and procurement and reimbursement.

D. Control

Table 16. Price control

	Price control mechanism
AU	Pharmaceutical benefits scheme
CN	National development and reform commission controls the price Essential medicines included in the reimbursement lists
JP	Regulated if it is reimbursed by the National Health Insurance Service.
MY	No price control for medicines
NZ	No price control for medicines
KR	Regulated if it is reimbursed by the National Health Insurance Service.
SG	No price control for medicines
VN	For select medicines, declaration of wholesale price is required.

Table 14 shows various price control mechanisms employed by the countries. Malaysia, New Zealand, and Singapore stated that they had no price control mechanism for medicines. Australia, Japan, and Korea showed that medicines included in their respective insurance schemes were controlled. China stated that essential medicines were included in its price control list, while other medicines were selected by the National development and reform commission for price control.

E. Pricing

Table 17. Pricing

	Price-setting agency	Public sector pricing
AU	Department of Health	Negotiation of final price
CN	National Development and Reform Commission	Drugs listed under the national reimbursement list are fully reimbursed.
JP	Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare	Price of each drug is announced by MHLW after consultation with the Central Social Insurance Medical Council.
MY	Ministry of Domestic Trade, Cooperatives and Consumerism	Managed through the procedures and instruction of ministry of finance.
NZ	Pharmaceutical Management Agency	Co-payment and additional costs when necessary
KR	Ministry of Health and Welfare	Reimbursement determined by negotiations between the National Health Insurance Service and the manufacturer and reviewed by the NHIPDC. Pharmaceutical Benefit Review Committee sets price for essential drugs if negotiation fails. .
SG	None	National subsidized medical services and treatments at government hospitals. Drug Advisory Committee decides drugs for subsidy based on various factors
VN	Ministry of Health, Ministry of Finance	Vietnam Social Security guides for payment and managing cost of drugs. Drugs on the reimbursement list funded through the health insurance fund.

Regulatory authority for price setting and their methods for pricing were surveyed in Table 15. Singapore indicated that while it had no price setting agency, all people were entitled to subsidized medical services at government hospitals. Other countries indicated their Ministry of Health as the price-setting agency with the exception of China and Malaysia, who stated that National Development and

Reform Commission and the Ministry of Domestic Trade, Cooperatives and Consumerism were their respective price-setting agencies. For private sector or – in cases of Australia, Japan, and Korea – medicines not on the reimbursement lists, the payment was out of pocket. Countries did indicate presence of private health insurance.

F. Distribution

Table 18. Distribution methods

	Public	Private
AU	Wholesale and retail distributions are done privately. Methods of supply from the pharmacy include imprest, individual inpatient supply, prescriptions, requisitions and borrowing.	
CN	The ministry of commerce decides on the administration of pharmaceutical distribution based on related regulations.	From Manufacturer to Wholesale Distributor to Dispensing Unit
JP	All public and private hospitals, clinics and pharmacies are legally obliged to subscribe as providers	
MY	Through public and private hospitals and clinics	
NZ	Private wholesalers distribute to both public and private hospitals	
KR	All public and private hospitals, clinics and pharmacies are legally obliged to subscribe as providers	
SG	Mixed public-private system. Hospital care in the public sector is organized into two vertically integrated delivery networks, national healthcare group and Singapore health services. The community health assist scheme subsidizes visits to any of the participating clinics for acute conditions, specified chronic illnesses, specified dental procedures, and recommended health screening.	
VN	Mixed public-private system	

Table 16 shows distribution methods for pharmaceuticals in the eight countries. All countries except for China were identified as having a mixed public-private distribution method. Japan and Korea indicated that all of their medical institutions – be they public or private – were mandatorily registered as service providers under the insurance scheme and thus subject to a single distribution system. Australia and New Zealand both responded that private wholesalers were used to distribute to both public and private hospitals, while Malaysia and Viet Nam used a mix of public and private sale points. Singapore uses two delivery

networks for the public sector, while subsidizing visits to other participating private clinics. China is the only country to respond as having a separate delivery system for public and private sectors. For its public sector, the country uses a three tier system that distributes to primary, secondary, and tertiary hospitals. For its private sector, the manufacturers sell to wholesaler who then sell to dispensers.

IV. Comparison of the Eight Pharmaceutical Exporting Countries

1. Legal Framework and Coverage

The public health laws with respect to pharmaceutical system has been reviewed with number of laws covering the topics differed from country to country, and gaps in laws noted. Complex law system can lead to socioeconomic development, and typical assumption is that higher income countries will have better health law systems than mid- or low-income countries (Anderson, Becher, Winkler, & health, 2016). However, analysis revealed that income or poverty did not differentiate the extent to which health law can improve.

Table below shows the summary and the comparison of the eight countries' health law framework and coverage.

Table 19. Summary and comparison of health law framework and coverage

	Australia	China	Japan	Korea	Malaysia	New Zealand	Singapore	Viet Nam
System	Common	Socialist	Civil	Civil	Common + Sharia	Common	Common	Socialist
Coverage	Workforce: 4/5 Financing: 2/2 Pharmaceuticals and Devices: 4/5 Information and Research: 1/3 Prescription and Manufacturing: 2/2	Workforce: 2/5 Financing: 1/2 Pharmaceuticals and Devices: 4/5 Information and Research: 1/3 Prescription and Manufacturing: 2/2	Workforce: 2/5 Financing: 2/2 Pharmaceuticals and Devices:4/5 Information and Research: 1/3 Prescription and Manufacturing: 2/2	Workforce: 5/5 Financing: 2/2 Pharmaceuticals and Devices: 5/5 Information and Research: 3/3 Prescription and Manufacturing: 2/2	Workforce: 2/5 Financing: 2/2 Pharmaceuticals and Devices: 3/5 Information and Research: 3/3 Prescription and Manufacturing: 2/2	Workforce: 5/5 Financing: 2/2 Pharmaceuticals and Devices: 4/5 Information and Research: 3/3 Prescription and Manufacturing: 2/2	Workforce: 3/5 Financing: 2/2 Pharmaceuticals and Devices: 5/5 Information and Research: 2/3 Prescription and Manufacturing: 2/2	Workforce: 5/5 Financing: 2/2 Pharmaceuticals and Devices: 5/5 Information and Research: 3/3 Prescription and Manufacturing: 2/2
Commonly Used	Health Practitioner Regulation National Law Act National Health Act Therapueitc Goods Act	Pharmaceutical Administration Law Law of The People's Republic of China on Medical Practitioner	Medical Care Act Public Assistance Act	Framework Act on Health and Medical Services Medical Service Act Medical Care Assistance Act National Health	Medical Act Medical Assistants (Registration) Act Midwives Act Nurses Act Registration of Pharmacists Ac	Health Practitioners Competence Assurance Act Medical Practitioner Act Health Service Personnel Act Pharmacy Act	Allied Health Professions Act Optometrists and Opticians Act Dental Registration Act Medical Registration Act	Law on Health examination and treatment Pharmaceutical law Education law Tertiary Education law Joint Circular

Table 19. Summary and comparison of health law framework and coverage (Cont)

	Australia	China	Japan	Korea	Malaysia	New Zealand	Singapore	Viet Nam
Commonly Used			Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices	National Health Insurance Act	Dental Act Employees Provident Fund Act Employees' Social Security Act Workmen's Compensation Act Fees Act	Public Health and Disability Act Medicines Act	Nurses and Midwives Act Pharmacists Registration Act Traditional Chinese Medicine Practitioners Act Central Provident Fund Act Medical and Elderly Care Endowment Schemes Act Health Products Act Infectious Diseases Act	Joint circular guiding staffing norms for State health service provision units Law on Health Insurance Law on Social Security

Table 19. Summary and comparison of health law framework and coverage (Cont)

	Australia	China	Japan	Korea	Malaysia	New Zealand	Singapore	Viet Nam
Other	N/A	Uses laws of different hierarchy	Its Law on Clinical Research came into force in 2018	Only country to state a framework law	N/A	N/A	Only country to state the constitution	Uses laws of different hierarchy

All countries showed coverage of at least one law in each category of health systems (Workforce, Financing, Pharmaceuticals and Devices, Information and Technology) and prescription and manufacturing, with gaps and differences in coverage. Some of these can be contributed to the differences in legal systems. Australia, Malaysia, New Zealand, and Singapore have common law(A. O. J. J. o. S. P. L. PACIFIC, 2009)– which typically puts less emphasis on public health in its main writing but rather integrates it into other documents such as national health plans (*National Strategic Plan 2016 - 2020 Executive Version*, 2015)

All countries had laws for health workers, with Singapore as the only country to indicate that the constitution – highest level of law – was the guiding document for health worker's activities. While coverage of other aspects of health workforce varied, all countries possessed laws for the control of health workers. Countries also responded to having laws for health financing, with China the only country to not have a law for safety-net mechanism. All countries also possessed one or more laws regulating pharmaceuticals and medical devices, but only Korea, Singapore, and Viet Nam had laws relating to the access to medicines. Five of the eight countries responded as to having a same law govern the regulation and the quality control of pharmaceuticals. All countries had laws relating to health research, with that of Japan being the newest, having come into force in 2018. Before then, Japanese government did not regulate health research. Finally, all countries had coverage for prescription and manufacturing of drugs.

Study of the coverage revealed certain commonalities and differences in how

health systems of each countries were covered. Major findings are as follow:

1. Korea was the only country to apply a framework law that governed all aspects of the health system. While other laws did exist to cover the details of each aspect of the system, the framework law was also present to narrate general principles and obligations so that other implementing legislations and authorities can determine measures to be taken (Knuth & Vidar, 2011).
2. Countries often used a single (or a set of laws) for a specific topic. For example, Australia responded as having its Therapeutic Goods Act responsible for all pharmaceutical-related aspects of health system. Similar can be said for Japan's Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, New Zealand's Medicines Act, and Singapore's Health Products Act.
3. All countries identified areas in which they used multiple laws. One example is Singapore's law coverage of health workforce classification, in which the country responded as having seven separate laws defining each of its workers. On the contrary, Australia responded as having a single law defining all health workforce.
4. Two countries with socialist law system – China and Viet Nam – were also the only countries to respond with laws of different hierarchy. China responded that its law for medical devices was the Regulations on Supervisory Management of Medical Devices while its law for pharmaceuticals was Pharmaceutical Administration Law. Legislation Law of the People's Republic of China defines that laws are issued by the

National People's Congress, while regulations are issued by the State Council, and thus have a lower standing in the legal hierarchy (China, 2005). Viet Nam used laws, decrees, decisions, and joint circulars – in decreasing orders of hierarchy – to indicate coverage for health workforce and pharmaceuticals.

Law for health can be improved upon in many ways(Lee et al., 2015). Health law structure is often a hind sighted development disregarding any evidence or expertise, created to settle ongoing or outstanding issues. Thus the law and supporting regulatory authority are often poorly designed, ineffective, or not well-enforced(WHO, 2006). Some are also low priority or not relevant to the country – legislation regulating the use of state-of-the-art medical devices, for example, has less use in least developed countries and will be put on a lower drafting priority. Other factors, such as sociopolitical environment, no necessity, or no relevant existing legislation may hinder the development.

Legal provisions for pharmaceutical regulatory authority should be comprehensive as to include all aspects of regulation – from marketing, import, manufacturing, quality control, and prescription (Ashigbie, 2010). The laws for the components of the health systems should also able to be used to cover multiple aspects of the system, as demonstrated by the eight countries.

A recommended approach is the use of framework law. While constitutional provisions may be too broad - as in the case of Singapore, and lower-hierarchy

regulations and circulars can be narrow and discuss a certain topic, a framework law can elaborate further on the rights and duties of the industry and describe general principles and obligations. Advantages of adopting a framework law are many: The content of the pharmaceutical industry and the obligation of authorities and organizations can be broadly described, better responsibility distribution can be arranged, and can give a precise definition and scope of the industry. The framework law can also be used to found grounds for remedy, clarification, or a creation of a subsidiary legislation (Bojic Bultrini, Vidar, Knuth, & Rae, 2009). A framework act should consider philosophical framework; definition of its coverage; establishment of essential functions; definition of roles and responsibilities; improvement of existing services; and setting adequate penalties among other elements (Chichevalieva, 2011).

However, another somewhat contradicting recommendation is that not all aspects of the health system has to be covered by law. Law is merely a tool for the improvement of the system – and the pharmaceutical industry by extention. Many of the problems are solved by a reform or a drafting of a new law, but rather through improved infrastructure, training, and innovative strategies (Gostin & Hodge, 2000). No country in the survey – except for Viet Nam – has shown full coverage. Japan, for example, did not have a law dedicated to clinical research until the early 2018. Half the countries surveyed did not have a law on access to medicines or minimum number and distribution of health workforce. As stated above, other government documents such as national health policies or guidelines can be used in substitution of a legislation.

2. Pharmaceutical Regulatory Authority

The results of the survey regulatory coverage yielded in-depth information on the status of surveyed countries. Though differing in system, all countries in the survey had a mix of regulatory bodies and mechanisms to control pharmaceutical expenditure and guarantee quality, efficacy, and efficiency in care – with varying configurations and strictness.

These variations also influence public finance of pharmaceuticals and therefore their costs. Observed differences in regulation and pharmaceutical expenditure should be interpreted not as a lone body, but as a conjunction with different health industry variables including volume and composition of medicine consumption, dispensation and prescription practices at all levels, and their impact. Table below shows the summary and the comparison of the eight countries' pharmaceutical regulatory authority.

Table 20. Summary and comparison of pharmaceutical regulatory authority

	Insurance System	Legislation and Policy
Australia	National Health Service	Both
China	Social Health Insurance	Both
Japan	Social Health Insurance	No Policy
Korea	Social Health Insurance	Both
Malaysia	National Health Service	Both
New Zealand	National Health Service	Both
Singapore	Mixed	No Policy
Viet Nam	Social Health Insurance	Both

Table 20. Summary and comparison of pharmaceutical regulatory authority (Cont.)

	Number of Organizations in Charge	Organizations Duties
Australia	Therapeutic Goods Administration, Department of Health:	Assesses and monitors ensure therapeutic goods are of an acceptable standard
	Pharmaceutical Benefits Advisory Committee	Recommends new medicines for listing on the pharmaceutical benefits scheme
China	National Medical Products Administration	Supervises safety of pharmaceuticals, devices, and cosmetics
	Ministry of Human Resources and Social Security	Manages labor policies and social security
	National Health Commission	Manages health and sanitation of the country
	National Development and Reform Commission	Formulates policies for economic and social development
Japan	Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare	Implements measures for securing the efficacy and safety of drugs, cosmetics and medical devices

Table 20. Summary and comparison of pharmaceutical regulatory authority (Cont.)

	Number of Organizations in Charge	Organizations Duties
Korea	Ministry of Food and Drug Safety	Responsible for safety and efficiency of foods, pharmaceuticals, medical devices and cosmetics
	Health Insurance Review and Assessment Service	Reviews and assesses healthcare costs and healthcare service quality
	Ministry of Health and Welfare	Coordinates and oversees health and welfare related affairs and policies
Malaysia	National Pharmaceutical Regulatory Agency, Ministry of Health	Implements quality control on pharmaceutical products
	Pharmaceutical Services Division, Ministry of Health	Responsible for ensuring that public gets access to safe, efficacious and quality pharmaceutical products
	Ministry of Domestic Trade, Cooperatives and Consumerism	Responsible for domestic trade, co-operatives, consumerism, franchise, companies, intellectual property, competition, controlled goods, price control, pyramid scheme, consumer rights, trader
New Zealand	Medicines and Medical Devices Safety Authority	Responsible for the regulation of therapeutic products
	Pharmaceutical Management Agency	Responsible for deciding which medicines and medical devices are funded

Table 20. Summary and comparison of pharmaceutical regulatory authority (Cont.)

	Number of Organizations in Charge	Organizations Duties
Singapore	Health Sciences Authority	Regulates health products, secures national blood supply, and represents the national expertise in forensic medicine, forensic science and analytical chemistry testing capabilities.
	Drug Advisory Committee, Ministry of Health	Responsible for providing evidence-based recommendations to MOH for public funding of pharmaceuticals
Vietnam	Drug Administration of Vietnam	Responsible for authorization and assessment of good manufacturing practice, and licensing for pharmaceuticals
	Department of Health Insurance, Ministry of Health	Responsible for selection of pharmaceuticals to be included in the insurance
	Ministry of Finance	Responsible for the finances of Viet Nam, including the national budget, tax, and the finances of state corporations.

All countries had regulatory authority, legislation, and policies for control of pharmaceuticals, with the exception of Singapore who lacked a national policy. Countries had a mix of regulatory authority for selection and procurement of pharmaceuticals. Most countries gave power to a dedicated department in its Ministry of Health, but some countries – such as Korea – established a new government organization for specific purpose. All countries except China had a mixed form of public-private distribution system. Japan and Korea's medical institutions were mandatorily registered as service providers and were subject to a single distribution system. All countries responded to allowing private health insurance – be that in replacement of or in addition to the national insurance.

In the study, all of the eight countries indicated presence of some form of a pricing mechanism that were highly personalized. Despite the use of price control mechanisms, pricing policies do have their limitations. External pricing may induce strategic introduction or disturb lowering of prices with lower ability to pay. Other selection and pricing methods can also lead to issues of access if companies simply decide to remove their products from the market due to unsatisfactory results. Novel approaches to pricing for developing countries should be discussed as alternatives to traditional mechanisms, with difficulties clearly addressed at all levels.

Study of the regulatory coverage resulted in certain commonalities and differences. Three major findings are as follow:

1. Legal provisions that establish the regulatory framework were present in

all eight countries.

2. In some countries, regulatory functions were assigned to more than one agency. For example, in Australia, the Therapeutic Good administration and the Pharmaceutical Benefits Advisory Committee are each responsible for a number of regulatory functions. Similarity, in China Ministry of Human Resources and Social Security, and the National Health Commission were given regulatory authorities. When the regulatory responsibility is dispersed, coordination between agencies become crucial for an effective regulation.
3. On the other hand, some regulatory authorities are given multiple functions – making it difficult to focus solely on drug regulation. If the authority responsible is also assigned other, non-regulatory functions, resource distribution, organization mandates, or other conflicts of interest may occur.

Pharmaceutical legislation is the basis of pharmaceutical regulation – defining the standards and specifications to be applied. Guidelines and standards are tools that give authorities with means of implementing this legislation. When such tools are lacking or conflict with one another, application of the legislation may be difficult and lead to break in confidence in government's ability and transparency of enforcement (Ratanawijitrasin, Soumerai, Weerasuriya, & Medicine, 2001).

A clear mission of the regulatory authority is therefore important in motivating its staff, and thus successful regulation and promotion of the industry. A dubious or

conflicting duty prevents clear pursuing of regulatory process. Thus, pharmaceutical laws should be comprehensive, and cover all activities regarding pharmaceuticals, from their manufacturing and use. These should also lead to quality standards and guidelines that can be used as tools in the regulatory process. These standards should be applied without exception to all pharmaceuticals, regardless of their country of origin or their intended location of use – be it domestic or export.

Relevant authorities should also cover all aspects of pharmaceutical regulations in a balanced manner. These actions should not be conflicted with other tasks that the regulatory authority may be charged with. Inefficiency in regulatory process will delay decision-making process and lead to decreased access to pharmaceuticals or delay and setback in research and manufacturing. Authorities should develop various strategies to prioritize and streamline the process and increase efficiency of the resources present.

Authorities should also communicate regularly with their partners and clients. As can be seen from Table 20, no country – except for Japan – gives power over the pharmaceutical industry to a single organization. They should also acknowledge the right of the stakeholders – companies, researchers, and health workers – to be provided with accurate information on regulatory procedures and information on drugs in the country.

3. Health Industry Statistics and Local Production

Local production is strongly associated with a country's health indicators such as GDP, human resources, and healthcare expenditure (Kaplan & Laing, 2005). The Western Pacific region is very diverse in its profile of healthcare system, financing, expenditure, and socio-ecologic conditions. Australia was the highest spender of health expenditure per capita (5,002.36 USD) while Papua New Guinea and Lao People's Democratic Republic showed spending less than 60 USD. Public share of health expenditure also varied between countries, with countries such as Brunei Darussalam's government paying almost entirety of its health expenditure (95%), to Philippines and Cambodia, where the government was responsible for less than 40% of the total health expenditure. The two countries also showed highest private health expenditure at 73.98% and 66.27% respectively.

Pharmaceutical expenditure also varied greatly among the countries in the region. Pharmaceutical expenditure per capita was highest in Japan, followed by Marshall Islands, while lowest in Solomon Islands, Kiribati, Tonga, Tuvalu, and Lao People's Democratic Republic. None of the mentioned countries' expenditure exceeded 20 USD per capita. (USD 4.30 9.00; 13.40; 14.22 respectively). Tuvalu and Solomon Islands reported the highest public share of pharmaceutical expenditure (100%), closely followed by Brunei Darussalam (89.60%). Private share of pharmaceutical expenditure was highest in the Philippines (85%), Lao People's Democratic Republic (83.5%), and Viet Nam (83.5%).

Compared with the public and private shares of the total health expenditure, private share of pharmaceutical expenditure was higher, implying that much of the out-of-pocket expenditure was invested into purchase of pharmaceuticals, especially in countries such as Philippines, Lao People's Democratic Republic, and Viet Nam, where both OOP and private share of pharmaceutical expenditure are high. Barring few exceptions, countries with significantly higher public sector share of total pharmaceutical expenditure were either high income or upper-middle income countries. Those with significantly higher private sector values were low- middle-income countries.

Table below shows the summary of pharmaceutical exports of the eight countries, including their highest and lowest export categories.

Table 21. Summary of pharmaceutical export

	Income group	**Population (in 1,000)**	**Export Amount (in million USD)**	**Main Export**	**Least Export**
Australia	High	24,992	2968.14	3004	3005
China	Upper-Middle	1,392,730	8866.1	3004	3002
Japan	High	126,529	5546.98	3004	3001
Korea	High	51,365	3479.17	3002	3001
Malaysia	Upper-Middle	31,529	238.1	3004	3001
New Zealand	High	4,886	319.24	3002	3006
Singapore	High	5,639	8352.71	3004	3005
Viet Nam	Low-Middle	95,540	159.46	3004	3001

Korea and New Zealand were the only countries to have category 3002 (blood

products) be their main exports. Others responded that category 3004 (Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic use) was their main exports. As for the category of least export, five of the eight countries indicated 3001 (Dried glands and other organs for organo-therapeutic uses), while Australia and Singapore responded 3005 (Wadding, gauze, bandages and the like), China 3002, and New Zealand 3006 (Pharmaceutical goods such as sterile suture materials, and contraceptive preparations).

Of the 25 initially surveyed countries, only eight countries – five high-income, two upper-middle income, and one low-middle income – showed capacity for local production. Other than high income countries, only the larger developing countries showed capacity to produce its own pharmaceuticals. This suggests a possibility of a multiple order effect, in which the pharmaceutical industry's capacity is limited not just by itself, but by other factors such as manufacturing of containers, or shipping (Amara, Aljunid, & Sciences, 2012).

The study expected to find some association between local production and export and the total population. However, that was not the case. Pharmaceutical production is not a labor-intensive production but a technology and innovation-driven endeavor. Positive association between production, export, and population is more likely due to a simple concentration – sheer number of people increases the possibility for creating new technologies for pharmaceutical industry, and the market to consume its products. Therefore, it can be assumed that it is the quality

of human resources in a country and not its total population that affects the production of pharmaceuticals. The capacity of the country's educational system and workforce regulation therefore is crucial. China, Malaysia, and Viet Nam are not wealthy countries as measured by the GDP per capita, but their large populations and high-quality education system allows for a formidable industry in the region (Amara et al., 2012). Strengthening the legal coverage for the education and quality control of health workers therefore suggests a future improvement in the industry's capacity.

V. Discussions and Conclusion

1. Strengths and limitations to the research

The study has strength in that it is the first study to extensively examine the pharmaceutical regulations and health law coverage of the region with association to health statistics. Specific issues, policies, or laws have been reported on and dealt with(Choi, Park, & Kim, 2018) but research showing the scale and their correlation are scarce(Magnusson, 2017). The study's scope both in coverage of the regulatory authority and law, make it a unique legal epidemiology study of the region and its pharmaceutical statistics – especially regarding its local production and exports, and thus provides a wide scope of the region.

Another advantage of the study is that the data of the health law and regulatory authority used for the analyses were collected by local experts familiar with their local systems. Unlike a foreigner-oriented data collection, a local expert can minimize the bias or misunderstanding of the domestic situation and thus provide a more accurate and country-specific data. Study also shows the empirical data of how legislations and regulatory power can affect the pharmaceutical industry. Research connecting these components in a quantifiable way are not common, but the study shows that a legal epidemiology study of a global – or at least regional – level is feasible. This, however, also leads to the limitations of this study.

The study has several limitations. As with any study involving review of existing documents, there is a concern that important data or publications may have been

unintentionally ignored. The search relied heavily on online databases and the study may have missed important information that are unavailable online.

Another limitation is the balance between complexity and pragmatism of the study. Analyzing the complexity of the pharmaceutical industry and its broader relations in society requires a multidisciplinary perspective and resources. The study recognizes that a simple comparative analysis of eight countries' health law coverage does not fully capture important interactions within and between systems.

Western Pacific region is home to many different types of legal systems, from common law to sharia, and to socialist law and combinations thereof. Legal structure, hierarchy, and importance of topics differ within each system, and surveying the existence of regulatory authority and legal coverage without knowledge of the implementation or regulation provides itself with a distinct limit of understanding (Burris et al., 2010). Without analysis of the practices and changes that occur within the country due to the legal and regulatory coverage, the attempt at understanding the pharmaceutical systems will be akin to trying to solve a complex math equation without knowing the formula.

Health law coverage as a variable was measured from 2011 to 2019, while health and pharmaceutical statistics often came from no before than 2015. Pharmaceutical regulatory data was measured from 2013 to 2019. Measurement times for all three components of the study are different, and even using similar

indicators make interpretation less than ideal. Health law can and does affect health outcomes, but the causal relationship between the three variables cannot be determined – only providing for associations between the study variables. Potential for unknown confounders are present, and these may lead – or have led – to bias of results. Cross-country nature of the analyses in the study required consistent sets of data for specific time period, but missing values for some countries made controlling impossible.

Another limitation was the unavailability of quality data. Though most prominent in the pacific island states, as stated above, the lack of timely and accurate data was not limited to those states. Attempting to understand country-specific system with limited – and perhaps outdated – information was difficult. Significant amount of missing data in status, systems, or legal information caused unintended differences and selection bias. Measurement errors in any of the three parts of the study is possible. To minimize these unnecessary variations, a standardized and up-to-date information is required. Should quality data become available, future research should endeavor the effects of other core variables, such as private health expenditure per capita, or differences in effect of external healthcare funding between the poor and the rich population.

Last limitation came from the language barrier. While many countries in the region do use English as one of its official languages or at least have official translations, some countries did not use English as a native language or provide official translation. Pharmaceutical systems data analysis mostly relied on English

translation of the official government pages or publications – that seldom offered full data given in the native language – or analyses of World Health Organization or other international organizations.

2. Suggestions for future research

There are many possibilities for future research with connection to the current study. The research can focus either on the implementation of regulatory and legislative measures on various countries and their effects on the pharmaceutical systems or focus on a smaller region to gather further data. In either case, the foremost research to be conducted must be that of policy surveillance to observe and collect real-time data of how governments use legislations, regulations and policies to promote health, and how non-governmental organizations, from small clinics to multinational pharmaceutical corporations, respond to them (Burris, Hitchcock, et al., 2016; Presley, Reinstein, Webb-Barr, Burris, & Ethics, 2015)

Scarcity of quality data – in conjunction with competing priorities – have traditionally been barriers to improvement in pharmaceutical systems. With quality data provided through policy surveillance, future studies may not be limited to analyses of past data and their association, but also to development of a range of region-relevant solutions. Acknowledging the limited resources and scarcity of capacity, future studies of the region should focus on devising a solution based on open-regional concept that does not enforce the burden of a state's pharmaceutical and health system on its own shoulder, but rather devolve and partner with internal or foreign institutions and partner governments through collaborative engagements.

Accurate information is also needed on distribution, and types of different pharmaceutical producers in respective countries. Local production can include a range of products from raw materials to intermediates for assembly to finished

dosages. Similarly, production in developing countries by multinational pharmaceutical companies need to be accurately surveyed as these productions are local, without local ownership. Accurate, standardized accounting from manufacturers, customs, or other trade groups are thus required.

Another possible venue for future research lies in the qualitative research into the practices and changes that occur due to regulatory and legal coverage, and their association with outcomes in the pharmaceutical industry. Study of this nature will be conducted first by content analysis of the relevant laws and their subsidiaries in the context of the state's legal system and proceed as to include surveys and expert interviews to describe real situations – thereby allowing a more comprehensive understanding of the influence of law and regulatory coverage on public health, and identify possible confounding variables that may have affected the initial analyses.

Lastly, case studies are needed to look at the legal and sociopolitical context for local production, and their achievements. Factors that are critical for determining viability of local production of pharmaceuticals need to be analyzed, with studies in low- and middle- income countries. These studies should be aimed at answering questions such as whether the local production saves foreign exchange or stimulates export (Africa, 2001), or if the local production can actually lead to improved access to pharmaceuticals. Testing these will be challenging and involve experts in law, economics, both pharmaceutical and industrial policies, and healthcare professionals.

3. Conclusion

The purpose of the study was to study ways to improve law and regulatory authority for the purpose of promoting the pharmaceutical industry. The study aimed to achieve that purpose by studying the health law coverage and the pharmaceutical regulatory authority in the eight countries of the Western Pacific region that exported more than 100 million USD in pharmaceuticals, and to compare their similarities and differences.

Eight countries were selected due to their pharmaceutical export capacity. Template used in the comparative study were created by the WHO, the OECD, and the Asia Institute for Bioethics and Health Law.

The result of the export statistics analysis is as follows. Other than high income countries, only the larger developing countries showed capacity to produce its own pharmaceuticals. This suggests a possibility of a multiple order effect, in which the pharmaceutical industry's capacity is limited not just by itself, but by other factors as well. It can be assumed that it is the quality of human resources in a country and not its total population that affects the production of pharmaceuticals.

The result of the health law coverage survey is as follows. Countries often used a single (or a set of laws) for a specific topic. For example, Australia responded as having its Therapeutic Goods Act responsible for all pharmaceutical-related aspects of health system. Korea was the only country to apply a framework law

that governed all aspects of the health system. All countries identified areas in which they used multiple laws. Two countries with socialist law system – China and Viet Nam – were also the only countries to respond with laws of different hierarchy.

The result of the pharmaceutical regulatory authority survey is as follows. Legal provisions that establish the regulatory framework were present in all eight countries. In some countries, regulatory functions were assigned to more than one agency. On the other hand, some regulatory authorities are given multiple functions – making it difficult to focus solely on drug regulation.

Based upon these results, the suggestions for improving the legal and regulatory status are as follow. Framework law should be used to elaborate on the rights and duties of the pharmaceutical industry and describe obligations and authorities of the responsible authorities. Pharmaceutical law should be comprehensive and cover all activities regarding pharmaceuticals, from their manufacturing to use. These should lead to regulatory standards and guidelines. Pharmaceutical regulatory authorities should coverall all aspects of pharmaceutical regulations, without conflicting with other tasks or organizations within its boundaries. Legal coverage for education and quality control of health workers should be strengthened to ensure supply of quality and skilled professionals for pharmaceutical research.

Lastly, the study faced its greatest difficulty in lack of timely, adequate, and

accurate data in many of its analysis variables. A robust policy surveillance research must be considered to gather accurate and timely data for use in future studies. Collaboration with local experts will allow accurate translation of the legal and regulatory context of the country and their effects unto the pharmaceutical settings.

The study reviewed the broad health law and pharmaceutical regulatory status and their similarities within select Western Pacific countries. Suggestions for future research topics to build upon its foundations include case study on practices and changes that occur due to regulatory and legal coverage, and their association with outcomes in the pharmaceutical industry, the legal and sociopolitical context for local production, and their achievements, and the survey of accurate and timely information on law and the health systems.

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Appendix

Appendix 1. Variables for health industry status

Health and Pharmaceutical System Indicators		
General Healthcare Status	Population	Number of populations
		Composition by age
		Life expectancy
	GDP	GDP per capita
Human resources	Physician density	-
	Pharmaceutical personnel density	-
	Nurses and midwife density	-
	Specialized surgical workforce density	-
Healthcare delivery	Government schemes	-
	Adult mortality	-
	Maternal mortality	-
	Child mortality	-
Health Expenditure	Expenditure per capita	-
	Expenditure share of GDP	-
	Composition	Puplic/private proportion
		Private financing sources
Pharmaceutical Expenditure	Expenditure per capita	-
	Expenditure share of health expenditure	-
	Composition	Public/private proportion
		Prescription/OTC proportion
		Patent/generic proportion
	Pharmaceutical Import	-
	Pharmaceutical Export	-
R&D Investment Amount	Government R&D investment	-

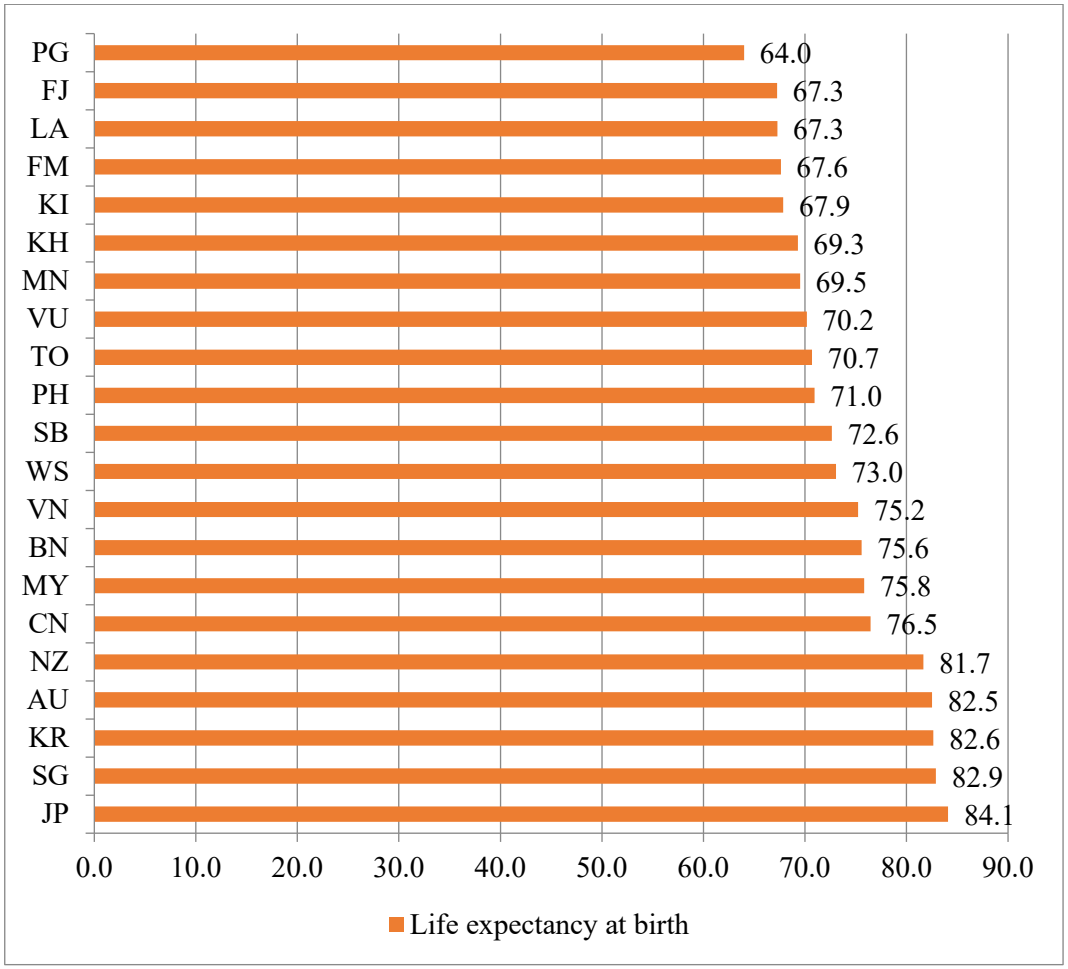
Appendix 2. Variables for pharmaceutical regulatory authority

Collected regulatory coverage data	
Pharmaceutical Regulations	Authority
	Legislation
	National Policy
Market Authorization/Licensing	Tasks
	Criteria
	Regulations
Selection	Authority
	Purpose
	Criteria
Procurement	Authority
	Number of Registered Medicines
	Number of Products on Essential Medicines List
	Number of Products on Procurement List
	Number of Products on Reimbursement List
	Process
Price Control	Process
Pricing	Authority
	Public Pricing
	Private Pricing
	Pricing Regulation in Public Sector
	Pricing Regulation in the Private Sector

Appendix 3. Population size in surveyed countries

Country	Population (1,000)
China	1,392,730
Japan	126,529
Philippines	106,652
Viet Nam	95,540
Korea, Rep of	51,635
Malaysia	31,529
Australia	24,992
Cambodia	16,250
Papua New Guinea	8,606
Lao PDR	7,062
Singapore	5,639
New Zealand	4,886
Mongolia	3,170
Fiji	883
Solomon Islands	653
Brunei Darussalam	429
Vanuatu	293
Samoa	196
Kiribati	116
Micronesia, Federated States of	113
Tonga	103
Marshall Islands	58
Palau	18
Nauru	13
Tuvalu	12

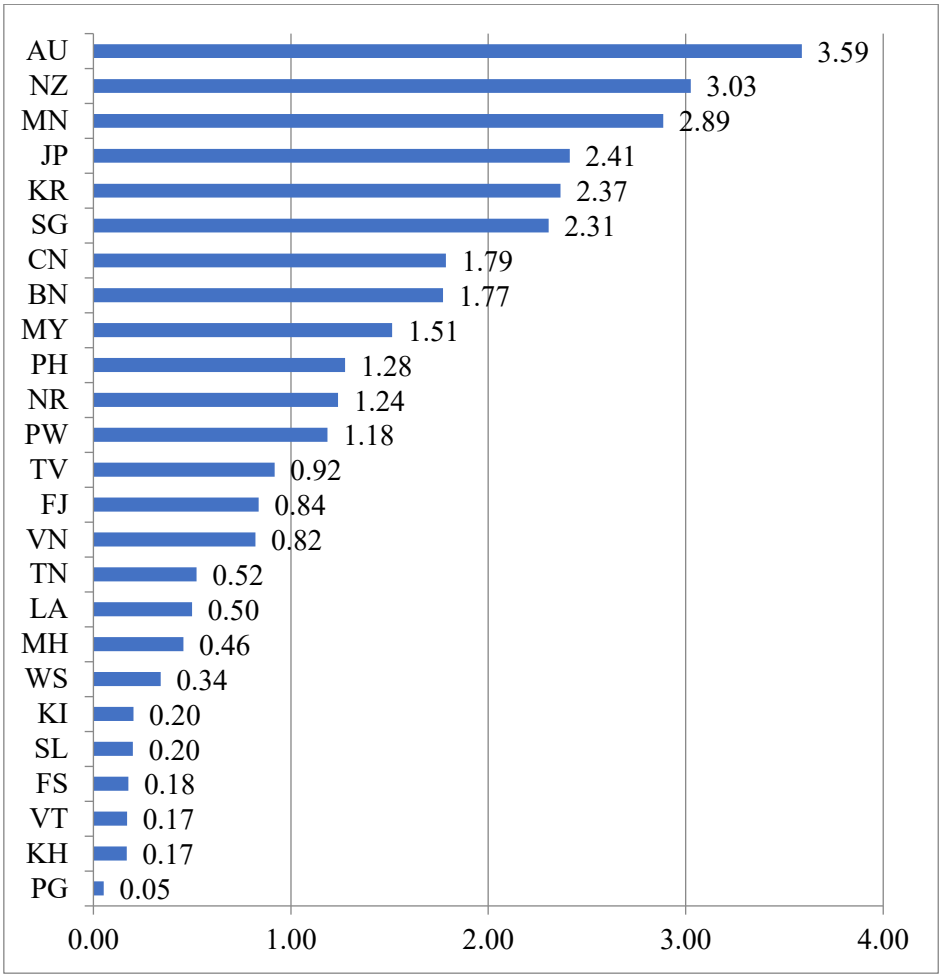
Appendix 4. Life expectancy at birth



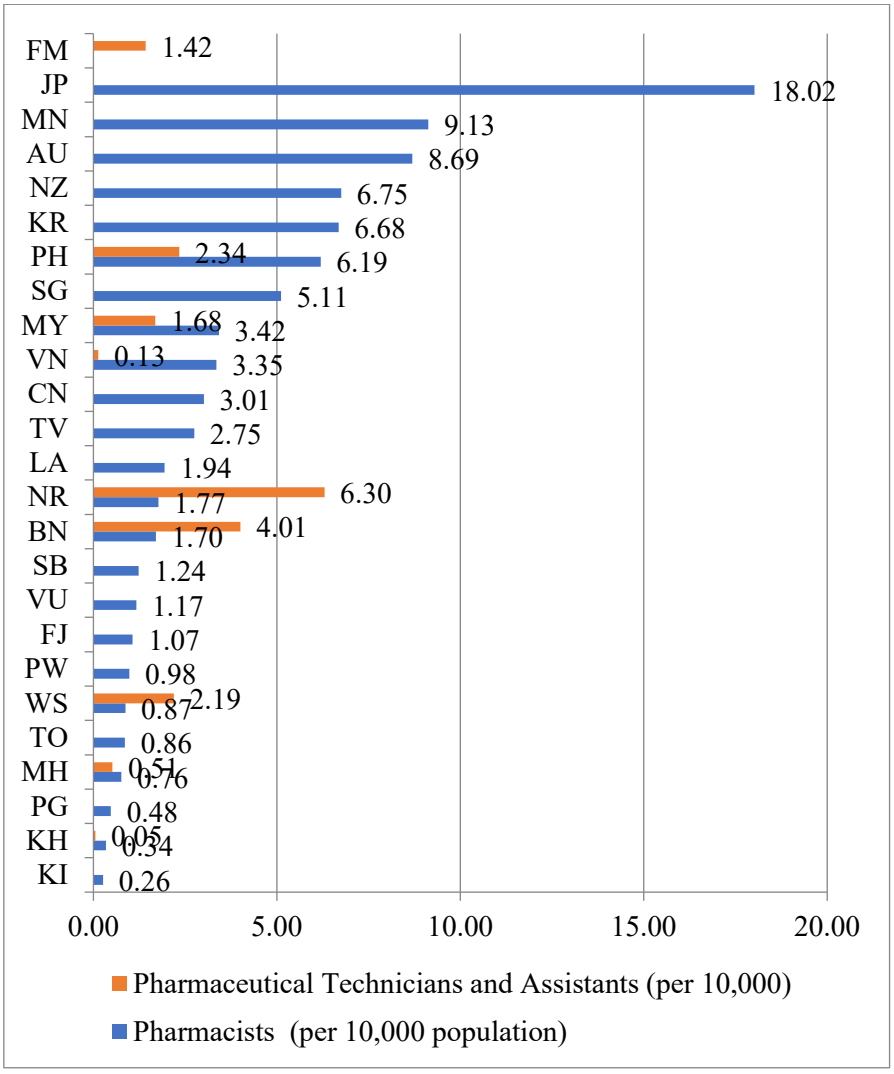
Appendix 5. GDP per capita

Country	GDP Per Capita USD
Singapore	64,581.90
Australia	57,305.30
New Zealand	41,966.00
Japan	39,286.70
Brunei Darussalam	31,627.70
Korea, Rep of	31,362.80
Palau	17,317.90
Malaysia (2018)	11,239.00
China	9,770.80
Nauru	9,030.10
Fiji	6,202.20
Samoa	4,392.50
Tonga	4,364.00
Mongolia	4,103.70
Tuvalu	3,707.00
Marshall Islands	3,621.20
Philippines	3,102.70
Micronesia	3,058.40
Vanuatu	3,033.40
Papua New Guinea	2,722.60
Lao PDR	2,567.50
Viet Nam	2,563.80
Solomon Islands	2,162.70
Kiribati	1,625.30
Cambodia	1,512.10

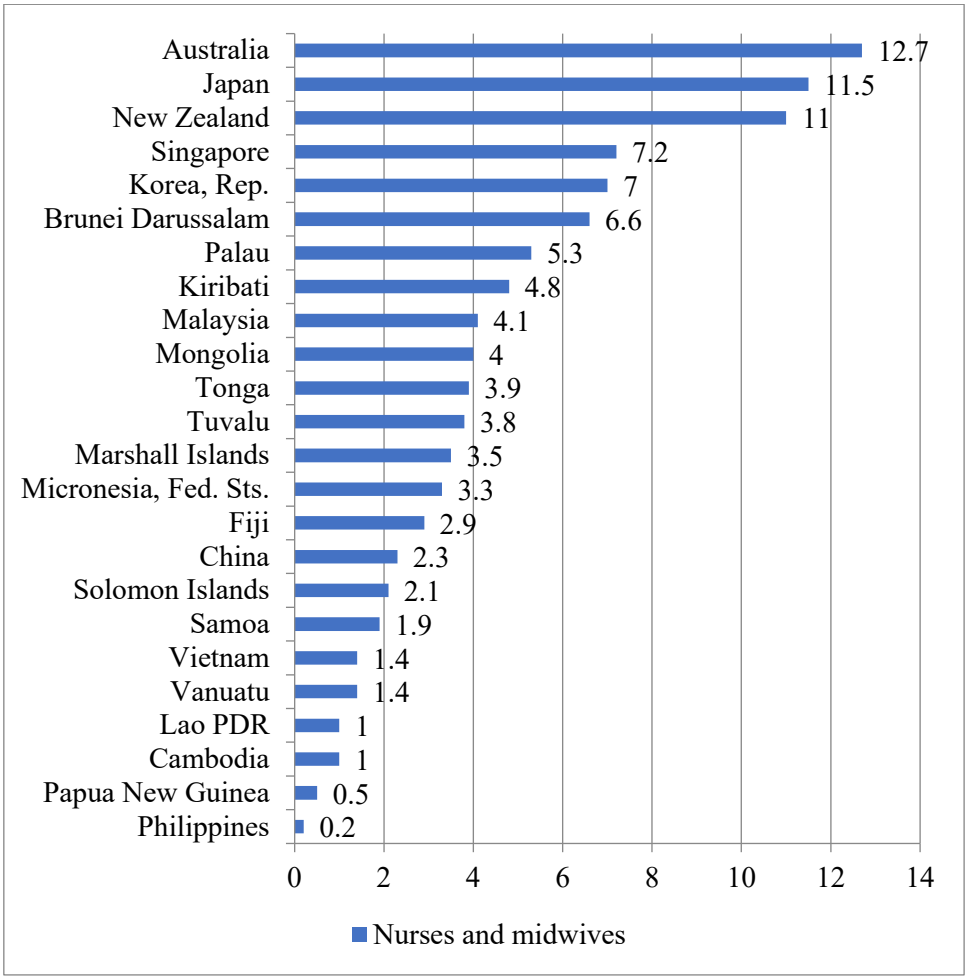
Appendix 6. Physician density



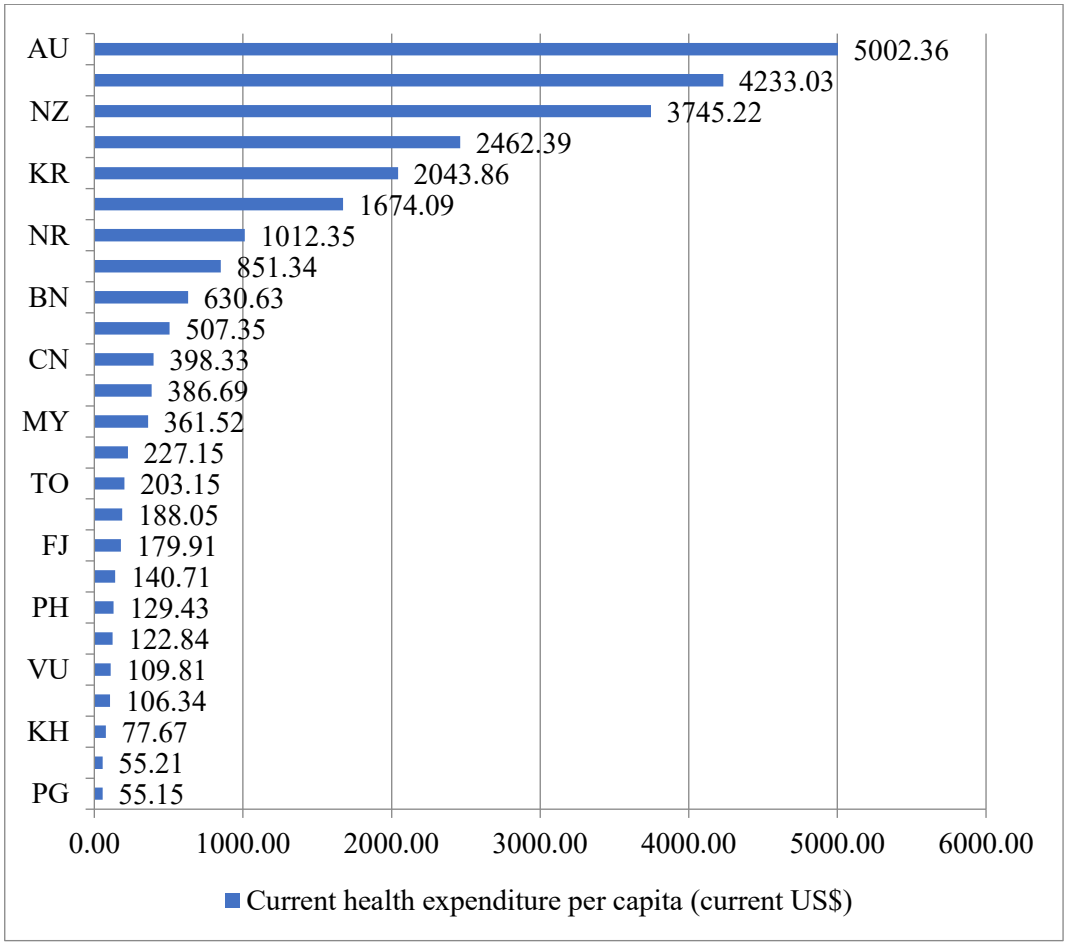
Appendix 7. Pharmaceutical personnel



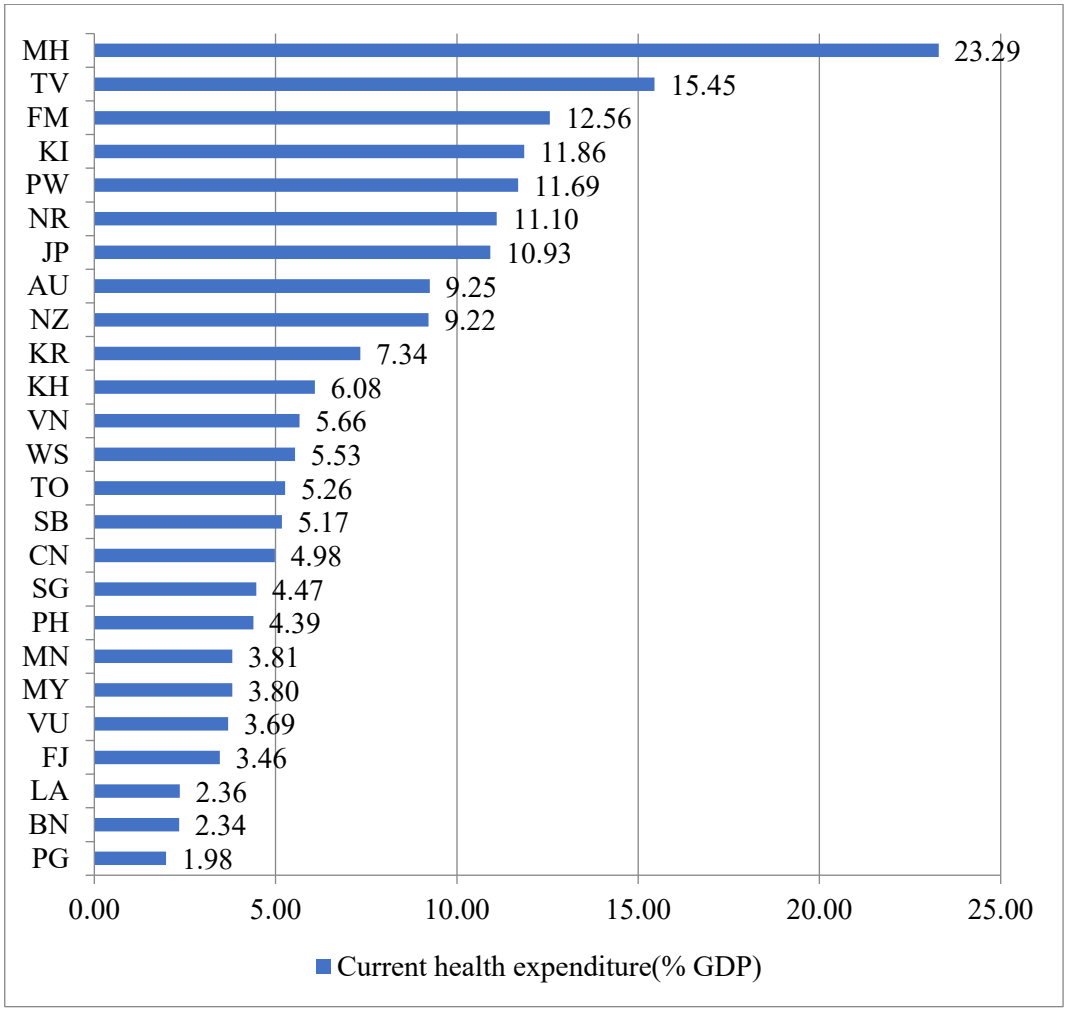
Appendix 8. Nurses and midwives density



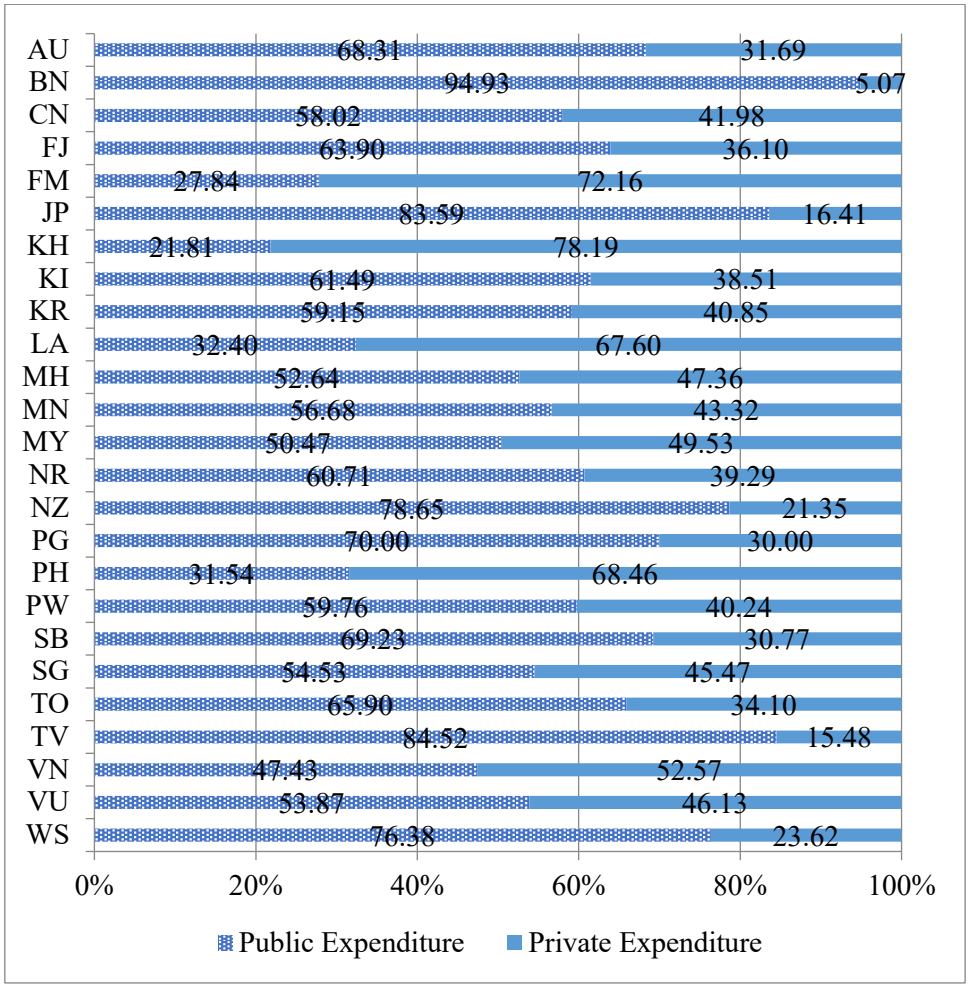
Appendix 9. Total health expenditure per capita (USD)



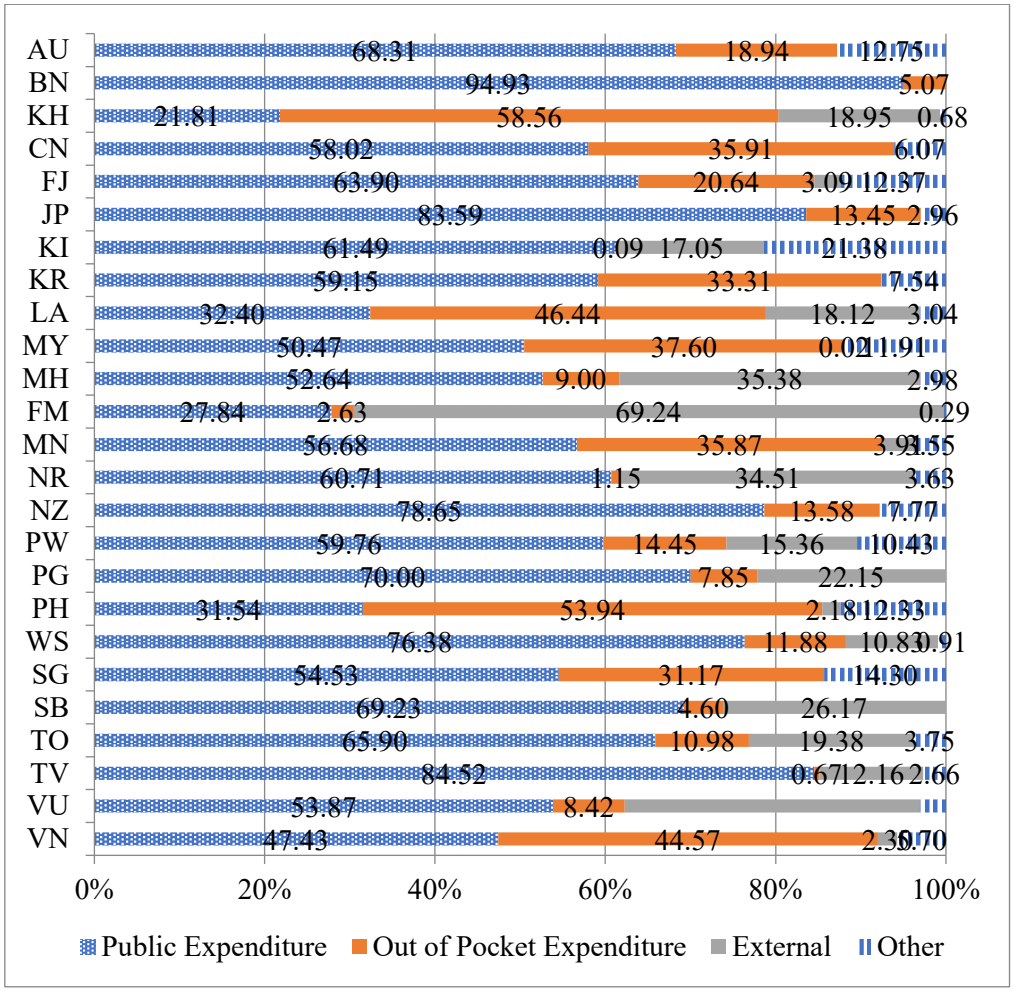
Appendix 10. Total health expenditure (% GDP)



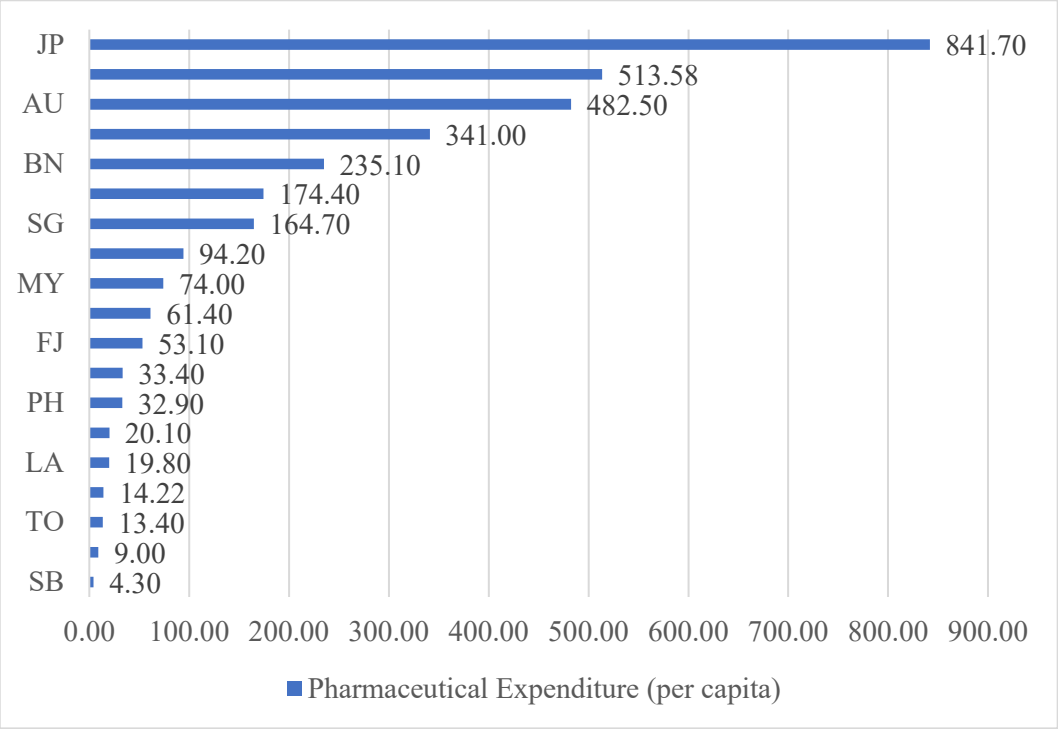
Appendix 11. Composition of health expenditure (1) – Public and private



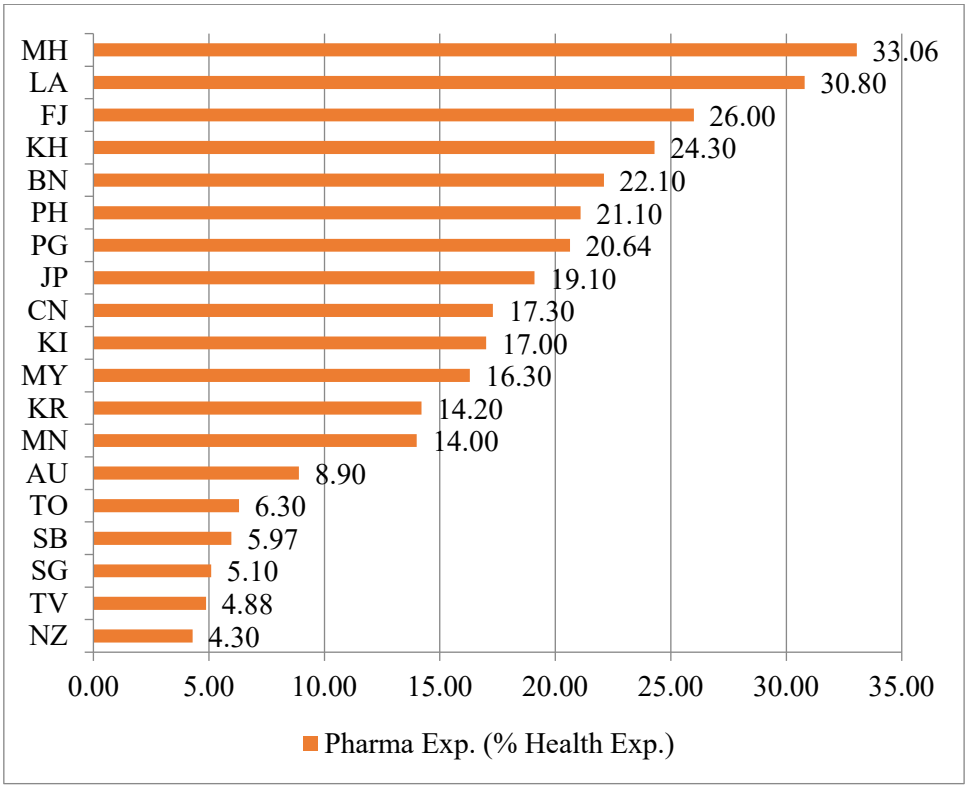
Appendix 12. Composition of health expenditure (2) – OOP and others



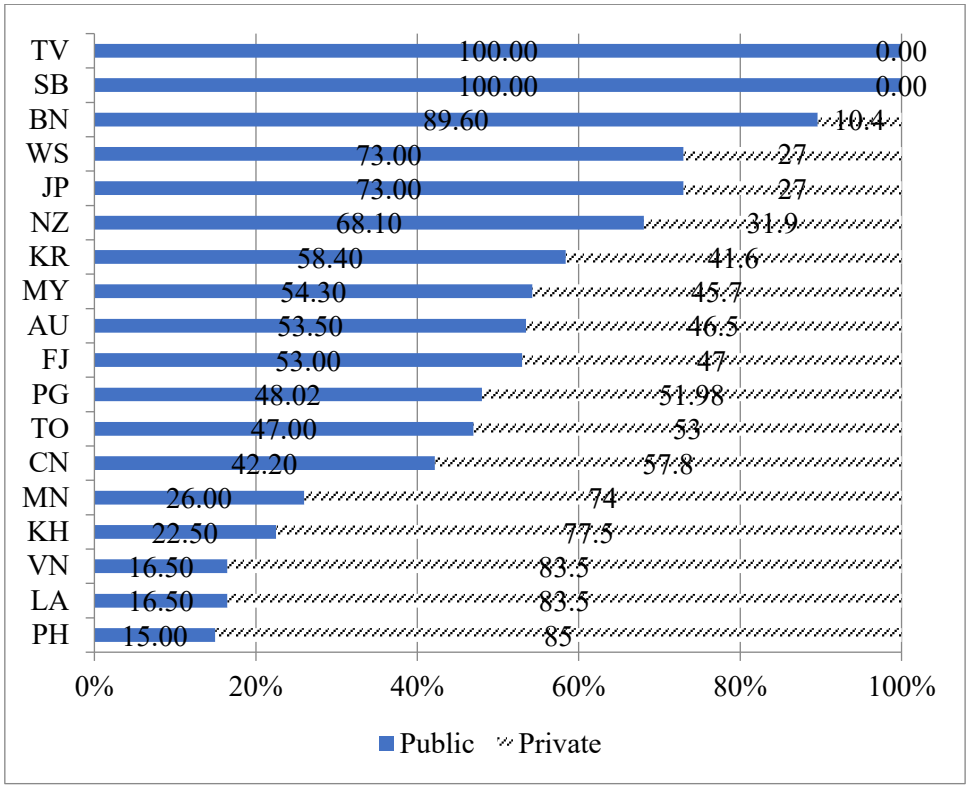
Appendix 13. Pharmaceutical expenditure per capita



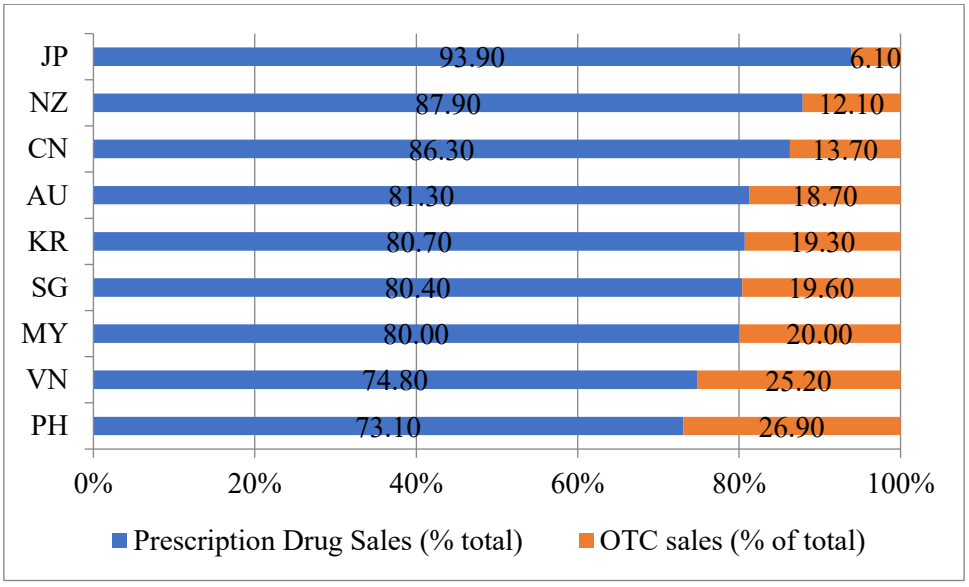
Appendix 14. Pharmaceutical's share of health expenditure



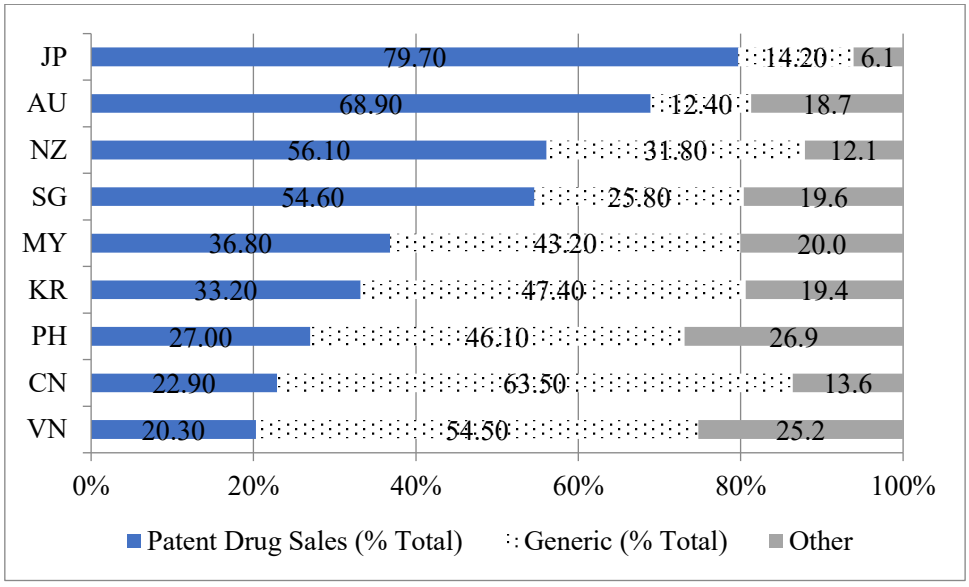
Appendix 15. Composition of pharmaceutical expenditure (1) - Public and private



Appendix 16. Composition of pharmaceutical expenditure (2) - Prescription and OTC



Appendix 17. Composition of pharmaceutical expenditure (3) – Patent, generic, and other



국문요약

서태평양 8개 제약 수출국가의 법 및 규제현황 비교연구

1. 서론

제약산업은 인구집단의 건강과 보건서비스의 만족도, 경제성 등 다양한 분야에 영향을 끼친다. 제약산업은 특히 보건비용의 증가에 가장 크게 기여하는 요인으로, 이로 인해 증가하는 가정의 보건 지출은 국가의 보편적 의료보장을 위한 노력과 자원의 투자를 무용하게 한다. 많은 이들은 의약품의 국내 생산이 유통비를 감소시키고, 지역 일자리와 인력의 전문성을 증가시키며, 외국 의존도를 낮출 것이라 믿는다. 하지만 국내 생산을 위한 투자는 그 의약품이 외국의 수입품보다 경제적일 때 효율적이다. 이는 보다 양질의 약품을 저렴한 가격에 제공하려는 보건정책과 수익 증대와 경제 개발을 하는 산업 정착의 갈등으로 이어진다.

2. 연구방법

본 연구의 첫 부분에서 각 정부 및 국제기구를 통하여 보건 지표를 수집하였다. 이후 그 지표를 통하여 제약 수출이 1억 미국 달러가 넘어가는 여덟 개의 국가를 선택하여, 국가들의 보건 법과 제약 산업 규제 현황을 분석하고 그 유사점과 차이점을 살펴보았다.

3. 결과

고소득국을 제외하면, 규모가 큰 개발도상국만이 자체적으로 제약생산이 가능함을 보여주었다. 이는 제약산업의 역량이 단순히 그 자체만으로 제한받는 것이 아닌, 외의 다단계적 효과가 있을 것이란 것을 짐작하게 한다. 국가들은 또한 하나 또는 한 그룹의 법을 사용하여 하나의 주제를 다루었고, 하나의 큰 법으로 여러 주제를 다루기도 했다. 또한 제약 산업의 규제를 다루는 법은 모든 국가가 보유하고 있었다. 몇몇 국가들은 제약 산업의 규제를 다수의 기관에 나눠 위임하였으며, 이 중 몇은 제약산업의 규제 뿐 아닌 다수의 역할을 수행하였다.

4. 결론

기본법을 통하여 제약산업의 권리와 목적을 뚜렷하게 명시하고, 규제기관의 목적과 권한을 지정해야 한다. 제약 관련 법은 충분히 포괄적으로 하여 제약의 생산에서 유통까지 모든 과정을 포함할 수 있어야 하며, 제약산업의 규제기관은 다른 임무 혹은 기구와 충돌하는 일 없이 그 임무를 수행할 수 있도록 설립되어야 한다. 또한 보건 인력의 교육과 질을 향상시켜 제약 연구를 수행할 연구진을 배출할 수 있도록 관련 법을 강화하여야 한다.
추후 연구 주제로는 규제와 법이 의료체계에 미치는 변화와 그것이 제약산업과 연결되는 과정의 사례 연구, 의약품의 국내 생산을 위한 법, 정치, 사회적 요소 및 조건, 그리고 의료체계와 연관 법에 대한 정확하고 시의적절한 정보 수집 방법 등을 들 수 있다.

핵심 되는 말: 의료체계, 제약산업, 의료법, 제약산업 규제