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Abbreviation	Description
A7	Seven advanced reference countries（US,UK,Italy,German,Japan,Swiss and France）
AADHAR	The name of "Personal Identity Card"
ACE	Agency for Care Effectiveness
AMED	Japan Agency for Medical Research and Development
AO	Administrative Order
APEC	Asia-Pacific Economic Cooperation
API	active pharmaceutical ingredients
ASCI	Advertising Standards Council of India
BIA	Budget Impact Analysis
BIS	Bureau of Indian Standards
BKHCN	Ministry of Science and Technology (Bo Khoa hoc va Cong nghe).
BMI	Basic Medical Insurance
BPJS	Badan Penyelenggara Jaminan Sosial (National Health Insurance System)
BPL	Below Poverty Line
BPOM	the National Agency of Drug and Food Control in Indonesia
C&SD	Census and Statistics Department
CAGR	compounded annual growth rate
CAPA	Chinese Association for Pharmaceutical Agents
CCFDIE	China Center for Food and Drug International Exchange
CDE	Center for Drug Evaluation
CDSCO	Central Drugs Standards Control Organization
CEA	cost-effectiveness analysis
CECA	Comprehensive Economic Cooperation Agreement
CFAs	clearing and forwarding agents
CFDA	China Food and Drug Administration
CGHS	Central Government Health Scheme
CGHS	Central Government of India
CGMH-LK	Chun-Guang Memorial Hospital
CHAS	Community Health Assist Scheme
CL	Compulsory Licenses
CMA	cost minimization analysis
CMA	Cheaper Medicines Act
CMO	Contract Manufacturing Organization
CPC	Communist Party of China
CPF	Central Provident Fund
CPF Board	Central Provident Fund
CPG	Clinical Practice Guidelines
CPI	Consumer Price Index
CPIA	China Pharmaceutical Industry Association
CPR	Certificate of Product Registration
CRO	Contract Research Organization
CSM	Coalition for Safe Medicines
CSMBS	Civil Servants Medical Benefit Scheme in Thailand
CUA	Cost Utility Analysis
DAC	Drug Advisory Committee
DAV	Drug Administration of Vietnam
DAVA	Drugs Authentication and Verification Application
DCA	Drug and Cosmetics Act
DCGI	Drug Controller General of India
DCR	Drugs and Cosmetic Rules
DE	Data Exclusivity
DET	Drug Expenditure Target
DGFT	Directorate General of Foreign Trade
DHR	Department of Health Research
DIP	Department of Intellectual Property
DIPP	India Department of Industrial Policy & Promotion
DIT	Department of Internal Trade
DOH	Department of Health
DPRB	Drug Price Regulatory Board
DPRI	Drug Price Reference Index
DREC	Drug reimbursement evaluation committee
DRG	Diagnosis Related Groups
DRG-GB	Diagnosis-related Groups-based Global Budget
DRGs	Diagnosis Related Groups
DTC	Direct to Consumer
EDB	Singapore Economic Development Board
EDPMS	Electronic Drug Price Monitoring System
EPCG	Export Promotion Capital Goods
EPF	Employees Provident Fund
ESIS	Employment State Insurance Scheme
ESIS	State Insurance Corporation
EUSFTA	European Union-Singapore Free Trade Agreement
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FEC	Formulary Executive Council
FIE Importer	Foreign Investment Enterprise

Abbreviation	Description
GCP	Good Clinical Practice
GDP	Good distribution practices
GDUFA	Generic Drug User Fee Act
GFATM	Global Fund to fight AIDS,TB and Malaria
GLP	Good Laboratory Practice
GNI	Gross National Income
GoM	Group of Ministers
GPFI	GP Farmasi
GPIN	Global Product Identification Number
GPO	Group Procurement Office
GPO	Group Purchasing Office
GPP	Good Pharmacy Practice
GQCE	Generic Quality Consistency Evaluation
GSP	Good Supply Practice
GTIN	global trade identification number
HIRA	Health Insurance Review and Assessment Service
HITAP	Health Intervention Technology Assessment Program
HKAPI	Hong Kong Association of the Pharmaceutical Industry
HKSAR	Hong Kong special administrative region
HPS	Self-estimated price
HRDF	Human Resource Development Foundation
HSA	Health Sciences Association
HSA	Health Science Authority
HTA	Health technology assessment
IA	Insurance Authority
ICBs	International Competitive Bids
ICER	Incremental cost-effectiveness ratio
ICP	Internet content provision
IDMA	Indian Drug Manufacturers 'Association
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IJSRM	International Journal of scientific research and management
INDQC	National Institute of Drug Quality Control of Vietnam
IP	Intellectual Property
IPD	Intellectual Property Department
IPD	Individual Participant Data
IPMG	International Pharmaceutical Manufacturers Group
IPO	Intellectual Property Office
IPOPHL	Intellectual Property Office of the Philippines
IPR	Intellectual Property Rights
IRPMA	International Research-Based Pharmaceutical Manufacturers Association
IRR	Implementing Rules and Regulations
JAO	Joint Administrative Order
JAV	Japan Association of Vaccine Industries
JETRO	Japan External Trade Organization
JHA	Japan Health Insurance Association
JKMA	Japan Kampo Medicine Manufacturers Association
JKN	Jaminan Kesehatan Nasional (National Health Insurance)
JST	Japan Science and Technology Agency
KHIDI	Korea Health Industry Development Institution
KIPO	Korean Intellectual Property Office
KOSIS	Korean Statistical Information Service
KPBMA	Korea Pharmaceutical and Bio-Pharma Manufacturers Association
KRPIA	Korean Research -based Pharmaceutical Industry Association
KWAP	Kumpulan Wang Persaraan
LKPP	The Government Goods / Services Procurement Policy Institution in Indonesia
LPNK	a Non-Ministry Government Institution in Indonesia
LTC	Long Term Care
LTCI	Long Term Care Insurance program
MA	marketing authorisation
MAB	Medicine Advertisements Board
MAF	Medication Assistance Fund
MAH	Marketing Authorization Holder
MAPS	Association of Pharmaceutical Suppliers
MCDA	MultiCriteria Decision Analysis
MCI	Medical Council of India
MEA	Managed Entry Agreement
MFDS	Ministry of Food & Drug Safety
MHLW	Ministry of Health and Welfare
MIDA	Malaysian Industry Development Authority
MOA	Mechanism of action
MOH	Ministry of Health
MoHFW	Ministry of Health and Family Welfare
MOHRSS	Ministry of Human Resources and Social Security
MoLHR	A Ministerial regulations in Indonesia
MoPH	Ministry of Public Health in Thailand
MOPI	Malaysian Organisation of Pharmaceutical Industry

Abbreviation	Description
MOST	Ministry of Science and Technology
MRP	Maximum Retail Price
MTAB	medical technology assessment board
MWP	Maximum Wholesale Price
MyIPO	Intellectual Property Corporation of Malaysia
NADFC/NAFDC	National Agency of Drug and Food Control in Indonesia
NCE	New Chemical Entity
NCKUH	National Cheng Kung University Hospital in Taipei
NDA	Non-Disclosure Agreement
ND-CP	Government Decree (Nghi dinh Chinh phu)
NDSDC	National Drug System Development Committee
NEDL	National Essential Drug List
NEDO	New Energy and Industrial Technology Development Organization
NEML	National Essential Medicines List
NHC	National Health Commission of China
NHFPC	National Health and Family Planning Commission
NHI	National Health Insurance
NHIA	National Health Insurance Association
NHIS	National Health Insurance Service
NHS	National Health Security
NHSA	National Healthcare Security Administration
NHSO	National Health Security Office
NIC	National Informatics Center
NICE	National Institute for Health and Care Excellence
NICE	National IP Center for Enforcement
NIP	National Immunization Program
NLED	National List of Essential Drugs
NLEM	National List of Essential Medicines
NMPA	National Medical Products Administration
non-SSI	non-small scale industry
NPCA	National Pharmaceutical Commercial Association of R.O.C
NPPA	National Pharmaceutical Pricing Authority
NRDL	National Reimbursement Drug List
NRL	National Reimbursement List
NTUH	National Taiwan University Hospital
OCPA	Oncology Prior Authorization Program
OECD	Organization for Economic Cooperation and Development
OLIC	a subsidiary of Fuji Chemicals Industrial in Thailand
OoP	Out of Pocket
OPD	OutPatient Department
OPPI	Organization of Pharmaceutical Producers of India
OTC	Over the counter
PAA	Pharmaceutical Affairs Act
PAN	Personal Identity Card
PBI	Medical insurance for low-income people in Indonesia
PBRS	Pharmaceutical Benefit and Reimbursement Scheme
PCHI	Per Capita Household Income
PCN	Primary Care Network
PCPI	Philippine Chamber of Pharmaceutical Industry
PCT	Patent Cooperation Treaty
PE	Pharmacoeconomics evaluation
PEDU	Pharmacoeconomics and Drug Utilization Unit
PG	Pioneer Generation
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PhiHealth	Philippine Health Insurance Corporation
PhIRDA	China Pharmaceutical Innovation and Research Development Association
PMS	Post Marketing Surveillance
PPDS	Pharma Promotion and Development Scheme
PPMA	Philippine Pharmaceutical Manufacturers Association
PPP	Purchasing Power Parities
PRBOP	Professional Regulatory Board of Pharmacy
PRC	People's Republic of China
PReMA	Pharmaceutical Research & Manufacturers Association
Private Insurance	Organization issuing private insurance
PSS	Pharmaceutical Society of Singapore
PSUR	Periodic Safety Update Report
PTE	Patent Term Extension
PVA	Price Volume Agreement
PVS	Price & Volume survey
QALY	Quality Adjusted Life Year
RDP	Regulatory Data protection
RDPAC	R&D-based Pharmaceutical Association Committee
RDU	Rational Drug Use
Refined DRG	Refined Diagnosis-Related Group
Refined DRPS	Refined Diagnosis-Related Payment Scheme
RFID	Radio Frequency Identification

Abbreviation	Description
RHSs	reorganization of the former six regional health systems
RO	representative office
ROC	Republic Of China
RRP	recommended retail price
RSA	Risk Sharing Agreements
RSBY	Rashtriya Swasthiya Bima Yojana
SCL	Special Comprehensive License
SDL	Standard Drugs List
SECC	Socio Economic Caste Census
SFDA	State Food and Drug Administration
SHI	social health insurance
SIQ	Special Import Quotas
SMEs	Small and Medium-sized Enterprises
SMP	Safety Monitoring Period
SOCSO	Social Security Organization
SOP	standard operating procedures
SRA List	Stringent Regulatory Authority List
SSS	Social Security Scheme
State Insurance	Respective State Government
TBP	Tuas Biomedical Park
TCELS	Thailand Center of Excellence for Life Science
TCMs	Traditional Chinese Medicines
TFDA	Taiwan Food and Drug Administration
TGPA	Taiwan Generic Pharmaceutical Association
THAIMED	The Medical Device Technology Industry Association
TIPO	Taiwan Intellectual Property Office
TKDL	Traditional Knowledge Digital Library
TKDN	Local Content Requirement in Indonesia
TNMSC	Tamilnadu State Medical Services corporation
TPADA	Taipei Pharmaceutical Agents and Distributors Association
TPIL	Therapeutic Products Importer's Licence
TPMA	Thai Pharmaceutical Manufacturers Association
TPMA	Taiwan Pharmaceutical Manufacturer's Association
TPMDA	Taiwan Pharmaceutical Manufacture & Development Association
TPMMA	Taiwan Pharmaceutical Marketing & Management Association
TPRMA	Taiwan Research-based Biopharmaceutical Manufacturers Association
TPWL	wholesaler's licence for therapeutic products
TR	Technology Review
TRAIN	Tax Reform for Acceleration and Inclusion
TRIPS	TradeRelated Aspects of Intellectual rights
TSMIA	Thai Self Medication Industry Association
UCPMP	Uniform code for Pharmaceutical Marketing Practices
UCS	Universal Health Coverage Scheme
UHC	Universal Health Coverage
UK-NHS-NICE system	the UK-National Health Service (NHS)- The National Institute for Health and Care Excellence (NICE)
UMA(A)O	Undesirable Medical Advertisements (Amendment) Ordinance
USSFTA	US-Singapore Free Trade Agreement
VAT	Value Added Tax
VNPCA	Vietnam Pharmaceutical Companies Association
VSS	Vietnam Social Security
WAP	Weighted average price
WHO	World Health Organization

EXECUTIVE SUMMARY 2020

China	RDPAC/PhIRDA	1. 2019 NRDL update was finalized in Nov. 70 new drugs successfully listed through reimbursement negotiation. 2. Volume-based procurement was expanded to additional 25 provinces in Sep. 2019. 2nd batch volume-based procurement may initiate soon
Hong Kong	HKAPI	More on the private trade market instead of the public sector, under the dual track system of hong kong that the public and private market share the same market size.
India	OPPI	No major changes from 2018
Indonesia	IPMG	Access to healthcare has greatly increased from 92.3 million services per year to more than 233.8 million services per year in 2018. However, BPJS-K as the agency for JKN/UHC has been facing deficit since its inception. This resulted in the lack of adoption of innovative medicines in JKN. Other challenges in JKN are generic categorization, absence of transparent evaluation process and too much focus on cost-containment efforts. The government is to find new, innovative ways to finance JKN. Other issues prevailing are Halal Certification Law, Local Content Requirements (TKDN) and Patent Law 2016. BPOM, the local FDA, has strengthened its organization by revamping its structure and increasing quantity and quality of its human resources. It officially has simplified the regulatory requirements and shortened the marketing authorization process and implemented this through digitalization.
Japan	JPMA	Promotion code was subsequently revised based on the “guidelines on information provision in connection with promotional activities for ethical drugs” in september 2019. Full-scale implementation began in april 2019 for hta . The mechanism targets drugs and medical devices with large markets, but excludes items used for the treatment of rare disease with insufficient treatment methods and items used only for children. The results of the analysis will not be used to determine the feasibility of insurance reimbursement, but will be used to make price adjustments after listing on the nhi price list.
Korea	KPBMA/KRPIA	In order to strengthen the transparency of drug distribution, the 'drug supply report', which had previously been legally mandated only to pharmaceutical manufacturing companies, has been expanded to distributors since January 2019. As a result, distributors who violate their obligations to report drug supplies are subject to administrative penalty. The Korean government is enacting policies to expand national health insurance coverage. To manage the national health insurance finance, overall drug price adjustments are expected in the future by managing the rational & efficient use of drugs. In addition, the government plans to improve the new drug listing system by expanding the application of RSA to non-innovative new drug in 2020 and expanding the exemption scope of economic evaluation.
Malaysia	PhAMA	No significant change of marketing circumstance is confirmed since 2018. malaysia economy and the medical market keep growing. government is now considering drug price control using international reference pricing.
Philippines	PHAP	2019 marks the start of healthcare reform for the Philippines. Two landmark legislations were signed last February: the “Universal Healthcare Act” and the National Integrated Cancer Control Act. Implementing rules for these regulations were issued towards the end of the year, but certain reforms were already initiated by the Department of Health to start the transition. For example, increase in social health insurance already started, as well as the institutionalization of Health Technology Assessment. The government also announced its plans to implement an expanded price control mechanism, as well as plans to institute compulsory licensing mechanisms As the new laws are intended to progressively transform the healthcare system over 10 years, impact to the healthcare system is yet to be felt. We expect some changes to be felt starting 2020.
Singapore	SAPI	ALPS, the newly established purchasing agency of MOH will consolidate efforts to centralize procurement across the three healthcare clusters, thereby enhancing patient access to medicines in the public sector. The Agency for Care Effectiveness (ACE) is piloting manufacturer-led submission of health technology assessment (HTA) technical dossiers; if successful, this approach may be adopted; permitting manufacturers to participate in the HTA submission process. Adoption of technology will be strongly encouraged and leveraged to support transition to the integrated healthcare system.
Taiwan	IRPMA	No major changes from 2018
Thailand	PReMA	Thailand pharmaceutical market in 2019 is not different from the previous year. the focus of public healthcare are cost containment, rational drug use and support of local pharmaceutical industry. on private side, ministry of commerce began to take measures to regulate drug prices following reports that some private hospitals overcharge patients for drugs.
Vietnam	PG	Vietnam has achieved substantial improvements in key public health metrics such as average life expectancy and infant mortality. This reflects key economic reforms of the late 1980s where the healthcare system transitioned from a fully public model to one that allows greater private involvement, and expanded access to quality care. Today, the pharmaceutical market in Vietnam is growing at a rapid pace and has increased from USD2.7 billion in 2015 to around USD4.0 billion estimate MAT Q2 2019 at a Compound Annual Growth Rate (CAGR) of 10.6% based on the growth during 2015 to 2017. The hospital segment makes up more than two-thirds of the Vietnam pharma market, and will continue its dominance as social health insurance (SHI) coverage increases. Almost 82% of the population is now covered by the SHI system, and the target for coverage in 2020 has been raised to 90%. The retail channel, though not as large, has demonstrated faster volume growth (15%). This reflects growing demand for pharmaceuticals. The whole industry now employing some 44,000 employees. Of the overall industry, innovative pharmaceuticals play an important role and represent an estimated 22% of total market value, about 3% of total volume. From 2015-2018, the segment grew at an estimated CAGR of 10.6% from USD594.00 million to USD802.62 million, hiring 7,300 people. The healthcare sector in Vietnam is at a crossroads: as per capita income rises, infrastructure investments by the Government are increasing, and demand for quality healthcare products and services continue to rise. At the same time, Universal Healthcare Coverage and limited private sector financing are putting pressure on the State budget. New regulations regarding the registration (Circular 32/2018), tender (Circular 15/2019) of drugs, as well as business operations (Decree 54/2017) have been issued, which are expected to facilitate better and faster access to high quality pharmaceutical products. The Health Insurance Law is expected to be revised soon, which represents an opportunity for Vietnam to introduce solutions that address the current budget concerns, while promoting long-term sector development, with a more active role and contribution from the private sector. [Reference: Value of Innovation Report 2018, conducted by KPMG in collaboration with Pharma Group]

Category	Item	China	Hong Kong	India	Indonesia	Japan	Korea	Malaysia	Philippines	Singapore	Taiwan	Thailand	Vietnam
		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Economic status	Population	1,427.65 million people (2018),, Source: United Nations Statistics	7.37 million people (2018), Source: United Nations Statistics	1,352.64 million people (2018), Source: United Nations Statistics	267.67 million people (2018), Source: United Nations Statistics	127.20 million people (2018), Source: United Nations Statistics	51.17 million people (2018), Source: United Nations Statistics	31.53 million people (2018), Source: United Nations Statistics	106.65 million people (2018), Source: United Nations Statistics	5.76 million people (2018), Source: United Nations Statistics	23.73 million people (2018), Source: United Nations Statistics	69.43 million people (2018), Source: United Nations Statistics	95.55 million people (2018), Source: United Nations Statistics
	Elderly population ratio (≥ 65 yrs)	166,58 million people (2018),, Source: National Bureau Statistics of China	1.32 million (17.6%) [Mid-2019, Census and Statistics Department HKSAR]	Population ages 65 and above (% of total) in India was reported at 5.989 % in 2017, according to the World Bank collection of development indicators, compiled from officially recognized sources	5.7% (2018) Source Link : http://www.bps.go.id/publication	28.1% (2018) ["Demographic forecast," Bureau of Statistics of the Ministry of Internal Affairs and Communications]	14.4% (2018) Source: Major Indicators of Korea, Korean Statistical Information Service (KOSIS)	≤ 14 y/o, 23.3%; 15 - 64 y/o, 70.0%; ≥ 65 y/o, 6.7% (2019) [Department of Statistics, Malaysia] Life expectancy: male: 72.2 years; female: 77.3 years (2019) [Department of Statistics, Malaysia]	>64 years: 4.8% 15-64 years: 63.5% <15 years: 31.7% [WHO Regional Office for South-East Asia, 2018 http://apps.searo.who.int/PDS_DOCS/B5438.pdf]	581,700 (Singapore citizens and permanent residents, 2019, Dept. of Statistics, Singapore)	15.13% [Department of Statistics, Ministry of Health and Welfare; October 2019]	12.9% [2019 United Nation estimates]	7.275% (male 2,710,562 / female 4,239,888) (2018) [World Bank]
	No. of physicians (per 1,000 people)	2.59 (2018)- Source: National Health Commission Statistics yearbook 2019	1.9 Doctors 1.0 Registered Chinese medicine practitioners 0.3 Dentists 0.4 Pharmacists 7.1 Nurses	https://tradingeconomics.com/india/population-ages-65-and-above-percent-of-total-wb-data.html	0.66 doctors 0.14 dentist 207,927 (134,340 doctors; 31,852 dentists; 37,870 specialist; 3,865 specialist dentist) Source Link : http://www.kki.go.id/index.php [See Info Statistic] *Data is collected from the Indonesian Medical Council (KKI) website by February 1st , 2019.	2.52 (2016) ["Survey of Physicians, Dentists and Pharmacists," Ministry of Health, Labour and Welfare]	1.99 102,471 (2018) Source: Major Indicators of Korea, Korean Statistical Information Service (KOSIS)	1.8 (2017) [Health Facts 2018]	3.56 per 10,000 population [WHO-OECD, 2016, https://iris.wpro.who.int/bitstream/handle/10665.1/13982/9789290618485-eng.pdf]	2.4 (2018, Dept. of Statistics, Singapore)	2.93 (2018) [Department of Statistics, Ministry of Health and Welfare; October 2019]	0.45 [2019 export.gov]	0.86 (2018) [Statistical Yearbook of Vietnam 2018]

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Economic status	No. of hospitals	997434 (2018)- Source: National Health Commission Statistics yearbook 2019	Public Hospitals: 43 [2019, Hospital Authority] Private Hospitals: 12 [2019, Department of Health]	1,96,312 [Source: Healthcare, January 2017- Indian Brand Equity Foundation https://www.ibef.org/download/Healthcare-January-2017.pdf]	Total number of hospitals : 2,906 (private & public) -Public : 1053 (36.24%) -Private : 1,853 (63.76%) Source Link : http://sirs.yankes.kemkes.go.id/rsonline/report/ Total number of health care center : 9,993 as of Dec 2018 Source Link : http://www.pusdatin.kemkes.go.id/resources/download/pusdatin/profil-kesehatan-indonesia/Data-dan-Informasi_Profil-Kesehatan-Indonesia-2018.pdf [See table 2.1 in the report]	Total: 179,090 Public hospitals(National/public medical institutions) : 5,884 Private hospitals (Others) :173,206 (2018) *National/public medical institutions ["Survey on Medical Institutions (dynamics) and Hospital Report," Ministry of Health, Labour and Welfare]	Total: 93,184 (2018) (Tertiary hospital: 42 / General hospital: 311, Hospital: 1,465 / Healthcare Institute: 1,560 / Clinic: 31,718 / Dental hospital: 237/ Dental clinic: 17,668 / Midwifery clinic: 21 / Hospitalized health center: 15 / Health center: 241 / Health subcenter: 1,317 / Primary Health care post: 1,905 / Oriental hospical:307 / Oriental clinic: 14,295 /Pharmacy: 22,082) Source: National Health Insurance Statistical Yearbook 2017, HIRA	Hospitals controlled by Ministry of Health 144 (42,302 beds) Government hospitals: 10 (3,892 beds) Clinics: 3,234 Private hospitals: 200 (14,799 beds) Private clinics: 7,571 (2017) [Health Fact 2018]	Total: 1,224 hospitals Level 1 non-departmental hospitals, 64%; Level 2 hospitals, 26%; Level 3 specialty hospitals, 10% Government: 434; Private: 790 [WHO Regional Office for South-East Asia, 2018]	Ministry of Health Singapore – Health Facilities 2018 Total number of hospitals 28 Acute hospitals 19 (public 10, not-for-profit 1, private8) Psychiatric hospitals 1 (public) Community hospitals 8 (public 4, not-for-profit 4) Public polyclinics 20, Private general practitioner clinics 2222 Public dental clinics 245, private dental clinics 876 Pharmacies 258 Source: 2019, Department of Statistics, Singapore (https://www.singstat.gov.sg/find-data/search-by-theme/society/health/latest-data)	483 (2018) [Department of Statistics, Ministry of Health and Welfare; October 2019]	1,421 [2019 export.gov]	Total: 13,583 General hospital 1,085; Regional polyclinic 579; Medical service unit in commune, precincts offices and enterprises 11,830 (2017) [Statistical Yearbook of Vietnam 2018]
	Hospital beds (per 1000 people)	6.03 (2018)- Source: National Health Commission Statistics yearbook 2019	5.28 [Calculated based on Total number of Hospital beds and population] Total number of Hospital beds: 39,683 Public Hospitals: 28,329 Private Hospitals: 4,644 Nursing Homes: 5,830 Under Correctional Institutions: 880 [2017, Health Fact Hong Kong 2018 edition]	0.95 [2015] [Source: Healthcare, January 2017- Indian Brand Equity Foundation https://www.ibef.org/download/Healthcare-January-2017.pdf]	1.33 [Ministry of Health data and information center report in 2017] http://sirs.yankes.kemkes.go.id/rsonline/report/ [See table 2.11 in the report]	13.7 [World Bank 2009]	13.65 (2018) Source: Major Indicators of Korea, Korean Statistical Information Service (KOSIS)	1.98 (2018) [https://codeblue.galencentre.org/2019/11/27/malaysias-2020-hospital-bed-target-below-developed-nations/]	1.2 per 1000 [WHO-OECD, 2016]	2.6 (Total hospital beds 14554 according to MOH statistics 2018)	5.74 (2018) 7.09 (hospital beds + clinical beds) [Department of Statistics, Ministry of Health and Welfare; October 2019]	2.41 [2019 export.gov]	2.8 beds/1,000 population (est. 2018) [Statistical Yearbook of Vietnam 2018]
	GDP (Current USD, Billion)	13,606 （RMB 900309*108） - Source: National Health Commission Statistics Yearbook 2019	364.4 billion [2018, Census and Statistics Department HKSAR]	2,600.8 Billion [World Bank 2017]	1,042 Billion [2018] (current US$, World Bank Website]	4,860.4 Billion (2018) ["International Comparison of GDP," Cabinet Office]	1,588 Billion (2018) Source: Main Annual Indicators, Korean Statistical Information Service (KOSIS)	354.3 Billion (2018) [World Bank]	330.91 Billion [World Bank, 2018]	364.157 Billion (World Bank 2018)	617.7 Billion (2018) [National Statistics]	504.993 Billion 2018 [World Bank 2019]	245.214 Billion (2018) [World Bank]
	GDP Growth Rate (annual %)	6.6%, Source: National Bureau Statistics of China	+6.8% [Census and Statistics Department HKSAR]	6.62% [World Bank 2017]	5.27% (from 2000 - 2019 y/y) Source : Statistic Indonesia (BPS) Supported Link : https://www.tradingeconomics.com	FY2018 Real 0.7% (year-on-year) FY2018 Nominal 0.5% (year-on-year) ["GDP Statistics," Cabinet Office]	2.7 %(2018) Source: Main Annual Indicators, Korean Statistical Information Service (KOSIS)	4.7% (2018) [World Bank]	6.2% [World Bank, 2018]	3.31% [World Bank 2018]	2.4% [Q3 2019; National Statistics]	4.1% [World Bank 2019]	7.07% (2018) [World Bank]

Category	Item	China	Hong Kong	India	Indonesia	Japan	Korea	Malaysia	Philippines	Singapore	Taiwan	Thailand	Vietnam
		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Economic status	Consumer prices (annual %)	2.1% (2018), Source: National Bureau Statistics of China	+3.1% yoy [Census and Statistics Department HKSAR]	3.33% [World Bank 2017]	Indonesia's annual consumer price inflation decreased to 3.0 percent in November of 2019 from 3.13 percent in the previous month. In the long-term, the Indonesia Consumer Price Index (CPI) is projected to trend around 149.49 Index Points in 2020, according to our econometric models. Cited from links : 1.https://tradingeconomics.com/indonesia/inflation-cpi https://tradingeconomics.com/indonesia/consumer-price-index-cpi	1.0% (2018) Inflation rate, average consumer prices *Inflation rate based on the Consumer Price Index (CPI) [IMF]	1.5% (2018) Source: Statistical Database, Korean Statistical Information Service (KOSIS)	0.9% (2018) [World Bank]	5.2% [World Bank, 2018, https://data.worldbank.org/indicator/FP.CPI.TOTL.ZG]	0.44% [World Bank 2018]	0.39% [Nov 2018; National Statistics]	1.6% [World Bank 2019]	3.5% (2018) [World Bank]
	Unemployment, total (% of total labor force) (national estimate)	3.8% (2018), Source: National Bureau Statistics of China	1.2% [Census and Statistics Department HKSAR]	Unemployment Rate in India increased to 3.52 percent in 2017 from 3.51 percent in 2016 https://tradingeconomics.com/india/unemployment-rate	Unemployment Rate in Indonesia slightly decreased to 5.20 percent in the third quarter of 2019 from 5.34 percent in the third quarter of 2018. Cited from link https://tradingeconomics.com/indonesia/unemployment-rate	2.4% (2018) [Harmonized Unemployment Rates (HURs), OECD]	3.8% (2018) Source: Statistical Database, Korean Statistical Information Service (KOSIS)	3.4% (2019) [World Bank]	5.4% [Philippine Statistics Authority, 2019, https://psa.gov.ph/content/employment-rate-july-2019-estimated-946-percent]	4.2% [World Bank 2018]	3.80% [Oct 2019; National Statistics]	0.9% [2019 tradingeconomics.com]	1.99% (2018) [World Bank]
Pharmaceutical distribution	Pharmaceutical market size	85,778 million USD (2018, Ex-Manufacturer, 1USD=6.9 CNY, IQVIA Constant rate) Source: IQVIA	1,759 million USD (2018, Ex-Manufacturer, 1USD=7.8 HKD, IQVIA Constant rate) Source: IQVIA	16,843 million USD (2018, Ex-Manufacturer, 1USD=71.9 IDR, IQVIA Constant rate) Source: IQVIA	2,866 million USD (2018, Ex-Manufacturer, 1USD=14,788.5 IDR, IQVIA Constant rate) Source: IQVIA	77.458 million USD (2018, Ex-Manufacturer, 1USD=112.8 JPY, IQVIA Constant rate) Source: IQVIA	15,173 million USD (2018, Ex-Manufacturer, 1USD=1,127.3 KRW, IQVIA Constant rate) Source: IQVIA	1,689 million USD (2018, Ex-Manufacturer, 1USD=4.2 MYR, IQVIA Constant rate) Source: IQVIA	3,840 million USD (2018, Ex-Manufacturer, 1USD=53.2 PHP, IQVIA Constant rate) Source: IQVIA	891 million USD (2018, Ex-Manufacturer, 1USD=1.4 SGD, IQVIA Constant rate) Source: IQVIA	5,951 million USD (2018, Ex-Manufacturer, 1USD=30.8 TWD, IQVIA Constant rate) Source: IQVIA	4,438 million USD (2018, Ex-Manufacturer, 1USD=32.8 THB, IQVIA Constant rate) Source: IQVIA	3,763 million USD (2018, Ex-Manufacturer, 1USD=23,320.9 VND, IQVIA Constant rate) Source: IQVIA
	Generic ratio in the market	78.3% (2018) Source: IQVIA	38.7% (2018) Source: IQVIA	90.3% (2018) Source: IQVIA	76.9% (2018) Source: IQVIA	28.9% (2018) Source: IQVIA	58.3% (2018) Source: IQVIA	60.0% (2018) Source: IQVIA	71.1% (2018) Source: IQVIA	42.8% (2018) Source: IQVIA	28.9% (2018) Source: IQVIA	57.2% (2018) Source: IQVIA	75.0% (2018) Source: IQVIA

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Pharmaceutical distribution	Overview of pharmaceutical distribution	The Chinese pharmaceutical distribution market has developed steadily but at a slower rate in recent years. The industry rose by 10.4% year on year to RMB1.8393 trillion in 2016 and is expected to hit RMB2.9784 trillion in 2021 at a growth rate of 10% over the next five years driven by favorable policies and downstream demand. Western medicine sales dominate the Chinese pharmaceutical distribution market, accounting for 74.4% in 2016; East China and Central South China hold relatively higher percentages, up to 61.1% together in 2016. The country has developed a competitive landscape where there are national pharmaceutical distributors represented by China National Pharmaceutical Group Corporation (Sinopharm), China Resources Pharmaceutical Commercial Group, Shanghai Pharmaceuticals and Jointown Pharmaceutical Group and regional ones represented by NanJing Pharmaceutical, Guangzhou Pharmaceuticals, Chongqing Pharmaceutical, Huadong Medicine, Sichuan Kelun, Zhejiang Int'l, Realcan Pharmaceutical, Guangxi Liuzhou Pharmaceutical Co., Ltd. and Luyan Pharma Co., Ltd. which compete with each other. By the end of Nov 2016, there were 12,975 pharmaceutical wholesalers nationwide which competed fiercely in a lowly concentrated market. Top3 champions seized only a combined 28.7% share of the market in 2016. As medical reform policies are implemented and consolidation in pharmaceutical wholesale industry accelerates, the Chinese pharmaceutical distribution market will show trends as follows: 1) pharmaceutical E-commerce will become an important model; 2) pharmaceutical supply chain management will be upgraded; 3) capital market will play a bigger role in integration of enterprises; 4) cross-border integration of pharmaceuticals and E-commerce will continue; 5) stiffer competition will improve market concentration; 6) Wholesale-retail integration will spur industry consolidation. Source: https://www.researchandmarkets.com/reports/4396078/china-pharmaceutical-distribution-industry	Major wholesalers such as Zuellig, DKSH, and DCH account for the main part (70%); Public market: public Hospitals and Department of Health: 51% Private: Hospitals, clinic and Pharmacies:49% No separation of dispensing and prescription	Before 1990, pharmaceutical companies used to establish their own depots and warehouses that are now replaced by clearing and forwarding agents (CFAs). CFAs Organisations are primarily responsible for maintaining storage (stock) of the company's products and forwarding SKUs to the stockiest on request. Most companies keep 1–3 CFAs in each Indian state. On an average, a company may work with a total of 25–35 CFAs. Unlike a CFA that can handle the stock of one company, a stockist (distributor) can simultaneously handle more than one company (usually, 5–15 depending on the city area), and may go up to even 30–50 different manufacturers. The stockiest, in turn, after 30–45 days (a typical credit or time limit) pays for the products directly in the name of the pharmaceutical company. The CFAs are paid by the company yearly, once or twice, on a basis of the percentage of total turnover of products.	Pharmaceutical Distribution technical guidelines are regulated under NADFC regulation No. HK.03.1.34.11.12.7542/2012 and Certification of Pharmaceutical distribution is regulated by NADFC regulation No.25/2017 that rules GDP certification; application, online registration via http://www.sertifikasicdob.pom.go.id NADFC exercises overall supervision and control through the Food and Drug Administration (FDA) of the state governments	Ethical drugs account for 96% of drug distribution to medical institutions and dispensing pharmacies, mostly distributed through drug wholesalers. There are 2 forms of OTC drugs for consumers, distribution by drug wholesalers and direct sales from manufacturers to drug stores, and the proportion is 50% each. GMP (Good Manufacturing Practice) is established mainly for the manufacture of ethical drugs, and drugs manufactured according to the GMP with regulated quality are shipped. In the distribution stage such as storage, unloading, and transportation of drugs, the utmost attention is paid to the maintenance of drug quality, such as designation of storage method and transportation in a refrigerator, in accordance with JGSP (Japanese Good Supply Practice on quality and safety management of drug supply). Drugs with assured quality, efficacy, and safety are delivered to more than 179,000 medical institutions and more than 59,000 insurance pharmacies through wholesalers nationwide. With ethical drugs, which account for the majority of distribution, there is a mechanism to investigate the actual market price and revise the drug price based on the results. The Ministry of Health, Labour and Welfare, which is the supervisory authority, executed the "Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/Pharmacies" in April 2018 for the purpose of appropriately conducting the drug price survey and improving the efficiency of distribution for a better distribution environment. https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000197503.pdf#search=%27%E5%8C%BB%E7%99%82%E7%94%A8%E5%8C%BB%E8%96%AC%E5%93%81%E3%81%AE%E6%B5%81%E9%80%9A%E6%94%B9%E5%96%84%E3%81%AB%E5%90%91%E3%81%91%E3%81%A6%E6%B5%81%E9%80%9A%E9%96%A2%E4%BF%82%E8%80%85%E3%81%8C%E9%81%B5%E5%AE%88%E3%81%99%E3%81%B9%E3%81%8D%E3%82%AC%E3%82%A4%E3%83%89%E3%83%A9%E3%82%A4%E3%83%B3%27	・Drugs distributed to medical institutions in 2018 were worth 27.2 trillion won which was up by 8.4% compared to 25.1 trillion won the year before. Among these, prescription drugs accounted for 88.2% or 22.1 trillion won. - By medical institution, general hospitals accounted for 5.5 billion5,473.5 million won (21.8%), hospitals for 1.6 billion1,641.8 million won (6.0%), clinics for 2.1 billion2,099.6 million won (7.7%), pharmacies for 17.3273 trillion won (63.6%), and others for 235.3 billion won (0.9%). - Drug sales price in total for each distribution stage were: 2.7 trillion won for medical institutions, 19.2 trillion won for wholesalers in manufacturers/importers, 15.2 trillion won between wholesalers, and 22.3 trillion won from wholesalers to medical institutions. ・As of the end of December, the number of finished drug product distributors was 3,211, and Among them, 2,739（85.3%）were wholesalers, 472(14.7%) were drug manufacturers / importers. ・The top 5% of those in terms of the volume distributed annually account for 68% of the pharmaceutical market. - By business type, manufacturers accounted for 80.5% followed by 73% of importers and 59.2% of wholesalers. ・There were 13 items of OTCs sold at convenience stores as of 2018 and their total sales amount were 37.18 billion won. Source: Health Insurance Review & Assessment Service / Korea Pharmaceutical Information Service	Hospitals and clinics can purchase drugs either directly from manufacturers or through highly controlling contracts with MoH Maker ⇒ distributor ⇒ medical institution Total Market Value estimated at RM7.5 billion as of 2018 [PhAMA Industry Fact Book 2018 Edition]	The manufacture, distribution, and sale of pharmaceutical products is regulated by the Food and Drug Administration (FDA). For an establishment to manufacture and distribute products, a License to Operate must be secured from the FDA. Subsequently, the product may be applied to be registered. Once completed, products may now be distributed and sold in FDA-licensed distributors, retailers and hospital pharmacies. The Department of Health (DOH), on the other hand, is responsible for ensuring access. For the DOH, access will include accessibility (access programs), availability (supply), and affordability (pricing). The DOH also exercises overall supervision of the FDA. Quick facts (Philippine Competition Commission, 2018): ·Relies heavily on importation (100% of APIs are imported) ·Major sources of drug products; India (28.4%), Europe (11.8%), East Asia (10%), Other South Asia (4.8%), ASEAN (4.1%) ·25.1% of market share is from one big local company ·2 major wholesaler distributors ·Retail channel dominates distribution (87.2% vs 12.8% from hospitals) ·Country of generics: 76% by volume and 57% by sales	Most multinational brands are distributed through one of the three regional wholesaler/distributors - Zuellig Pharma Singapore, DKSH, and DCH Auriga.	In Taiwan, makers have direct sales system to many large hospitals and use wholesalers in some case of sales including private clinics and pharmacies which accounts for about 30 percent of the market.	There are 2 major channels of distribution Hospital Channel: As a result of the state healthcare provisions which go to civil servants and to other recipients, the value of medicines distributed through hospitals runs to around 79% of the total market for medicines. Of this total, three-quarters (or 60% of the total market) is accounted for by state hospitals, with private hospitals accounting for the remaining quarter (or 20% of the total market). Drugstore Channel: Currently, drugstores are maintaining around a 21% share of the total pharmaceuticals market. Across the country, there are approximately 15,000 pharmacies, with 30% of these in Bangkok. About 80% of the total are stand-alone stores (mostly SMEs); the remaining 20% being outlets of pharmaceutical chain stores owned by large-scale operators in the form of either direct ownership or franchises. Modern traders (such as discount stores, supermarkets, convenience stores, and specialty stores focusing on healthcare products), in particular, are expanding their product lines by adding areas offering pharmaceutical and medical supplies, etc. With the strengths of having extensive branch networks, these operators could serve the demands covering a large consumer base.	The hospital segment makes up more than two-thirds of the Vietnam pharma market, and will continue its dominance as social health insurance (SHI) coverage increases. Almost 82% of the population is now covered by the SHI system, and the target for coverage in 2020 has been raised to 90%. The retail channel, though not as large, has demonstrated faster volume growth (15%). Distribution of pharmaceuticals is done through local companies. Foreign companies cannot engage in the distribution sector for pharmaceuticals in Vietnam. Vietnam's WTO Schedule of Commitments on Services has intentionally excluded pharmaceuticals from the sectors for which market access is open to distribution by foreign investors. To be licensed for marketing in Vietnam, a drug must have a marketing authorisation (MA) number issued by the Drug Administration of Vietnam (DAV) under the Ministry of Health (MOH). Under the Circular 32/2018/TT-BYT guiding the drug and medicinal materials registration coming into effect from 1 September 2019, following the Law on Pharmacy No. 105/2016/QH13, an MA number for a drug should be issued within 12 months of the receipt of a complete application dossier. Drugs granted MA numbers can be imported into Vietnam without an import license.

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Pharmaceutical distribution	GDP, GSP, GPP implementation status	No license grants but still need implementation	N/A	The Indian Government has issued a consolidated paper through Central Drugs Standards Control Organization (CDSCO) on good distribution practices (GDP) for pharmaceutical products to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process like procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices. At present transportation of drugs are carried out by third parties like contractors and sub-contractors in most cases. Contamination, cross contamination, mix-ups, adulteration and presence of spurious drugs are an issue in the unregulated distribution chain. Involvement of unauthorised entities in the distribution chain is also a concern. The guidelines are to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process. These include procurement, purchasing, storage distribution, transportation, documentation and record keeping practices in the chain from the manufacturing plant to the medical stores. The draft guidelines suggest there will be collaboration and an agreement in place with all the agencies involved in the storage, distribution and transportation. The distributor and the organisation he belongs to shall be held responsible for the activities that it performs related to the distribution of products. Export and import of pharmaceutical products will require appropriate licenses and drug distributors and subcontractors will require authorisation. Besides training the people in the distribution chain as per pre-defined standard operating procedures (SOP), managements will have to ensure safety standards for people and property, environment and product integrity. Protective garments have to be given to people handling hazardous materials. The guidelines will mandate a documented quality policy, detailing intentions and requirements of distributors regarding quality, authorised by the management. Various jobs in the distribution chain will be detailed and will require an organisational chain. Procedures for procurement and release shall be in place to ensure pharmaceutical products are sourced from approved suppliers and distributed by approved agencies. Procedures will be in place to ensure documentation so that the products are traceable in the supply chain and help in monitoring product recall. The guidelines also specify following Good Storage Practices and regulation of storage premises like warehouses. https://www.businesstoday.in/sectors/pharma/good-distribution-practices-for-pharmaceutical-products-coming-soon/story/282948.html	When purchasing from maker, accumulation of data on production batch, quantity, and expiry date is mandatory. When selling to hospitals, etc., it is mandatory to accumulate data on the name of the delivery site, date of delivery, address, telephone number, and information on who received the delivery of the purchaser, as well as information on the therapeutic agent, such as the name and form of the product, detailed product information, production batch, ED, quantity, invoice number, and delivery method (whether delivered by car or motorbike; whether delivered by agent or company's own courier). Psychotropic drugs or narcotic ingredients (drugs from which narcotic ingredients can be isolated by a simple process) can only be sold at hospitals or pharmacies with a permanently stationed supervisor pharmacist.	GDP available The supervisory authority is General Affairs Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare. GDP in Japan is prepared on the basis of PIC/S GDP, and it is operated as a voluntary standard for the time being and not as a ministerial ordinance. However, since the Guidelines include the provisions of current ministerial ordinances on transportation and storage (GMP Ordinance, GQP Ordinance, Pharmaceutical and Medical Device Act, Regulations for Buildings and Facilities for Pharmacies), the minimum compliance requirements are included. There are 2 licenses related to GDP, a marketing license (for drug manufacturers) and a wholesale license (for distribution warehouses of pharmaceutical manufacturers, wholesalers, etc.).	・An individual who intends to be a drug wholesaler, pursuant to Article 45 of the Pharmaceutical Affairs Act and Article 36 of the Enforcement Regulation of the Pharmaceutical Affairs Act, shall be approved by the head of local government. ・Article 31-2, Enforcement Decree of the Pharmaceutical Affairs Act : A pharmaceutical wholesaler shall be equipped with the business area and warehouse prescribed by the Ministerial Decree of Health and Welfare by the Minister of Health and Welfare ・Article 47, Pharmaceutical Affairs Act & Article 44, Enforcement Regulation of the Pharmaceutical Affairs Act : Drug providers(individual who received MA approval of drug, drug importers, drug wholesalers) shall comply with the Observances for Managing the Distribution and Maintaining Order in the Sales of Drugs. ・Drug providers shall comply with the matters prescribed in the Specification for Management of Distribution Quality of Drugs(Attachment 6, Enforcement Regulation on the Safety of Drugs, etc.)	GDP: The competent authority is the National Pharmaceutical Regulatory Agency (NPRA)	The Food and Drug Administration implements GDP and GSP as part of the licensing requirements for distributors and retailers. The WHO standard for GDP and GSP was adopted in 2013 through Administrative Order No. 2013-0027. In addition, a local cold chain management standard is being implemented by FDA through Bureau Circular No. 2007-003.	・ The Health Sciences Association (HSA)'s "GUIDANCE NOTES ON GOOD DISTRIBUTION PRACTICE, version 2015 August" are implemented as GDP guidelines. ・ The Pharmaceutical Society of Singapore (PSS)'s "Good Pharmacy Practice Guide, version 2009 March" is implemented as a GPP guideline. ・ There are no specifications for GSP, but it is handled in accordance with GDP	GDP guidelines exist. For cold chain products (requiring distribution at a low temperatures) application should be submitted by August 31, 2016; for (controlled) drugs requiring safety management) it should be done by September 30, 2016; in case 10 or more export and account settlement licenses are possessed, application should be submitted on or before June 30, 2017; for ordinary ethical pharmaceuticals, it should be done on or before December 31, 2017; for external medicine and non-prescription drugs, it should be done on or before June 30, 2018; for other manufacturers and distributors designated at the first stage, approval must be obtained by the end of December 2018. To improve the integrity of the quality of medicinal products, TFDA positively amend the regulation of the Pharmaceutical Affairs Act. The amendment of Article 53-1 of the aforementioned act had been approved by The Legislative Yuan, Republic of China and issued on 14th June 2017. The law defines the companies who wholesale, import or export the medicinal products shall comply GDP. TFDA will continue amending related regulations and reaching the consensus of timetable in stage with related association, and then, accomplishes the GDP execution in Taiwan.	There is no GDP, GSP as regulatory requirement. However, there is GPP (Good Pharmacy Practice) for pharmacy to be fully implemented with all pharmacies in 2022.	GDP: mandatory license for wholesaler/distributor of pharmaceuticals GSP: mandatory license for exporters, importers of pharmaceuticals, or providers of storage services GPP: mandatory license for retailers

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Pharmaceutical distribution	Central logistical management requirement (e.g.Serialization/barcode requirement)	Vaccine Law requires implementation of traceable system and valid from Dec 1,2019	Has been a plan to introduce barcode in the public hospital system	On 10th January 2011, Directorate General of Foreign Trade (DGFT) issued guidelines for the Implementation of a track and trace system incorporating barcode technology as per GS1 standards for all drugs and pharmaceutical products exported from India. Draft requirements for serialization and traceability of product in the domestic Indian market have also been proposed, but have not been finalized. The regulations mandated the application of GS1 compliant barcodes to products' primary, secondary and tertiary packaging. Under the government's traceability rules, pharmaceutical labels must include a global trade identification number (GTIN), batch number, expiration date and serial number. All export pharmaceutical consignments should be marked and coded at various packaging levels using GS1 barcode standards. DGFT issued this mandate as a step towards implementing a traceability system to address counterfeit and ineffective product recall challenges, which affects the entire healthcare supply chain, from manufacturers all the way to patients, wholesalers, distributors, exporters and healthcare providers. The traceability system was named DAVA, which means “medicine” in the Indian language (and is also the abbreviation for Drug Authentication and Verification Application). This system has made it possible to gain real-time visibility to pharmaceuticals produced and exported from India. DAVA relies on the use of Global Trade Item Numbers (GTINs) plus serial numbers by manufacturers to easily identify the various packaging hierarchy levels of pharmaceuticals such as primary, secondary and tertiary (when a trade item) levels. Information is captured through GS1-128 and GS1 Data Matrix barcodes. Specifically, exported drug products must carry a one or two-dimensional barcode encoding a universal global product identification code in the form of a 14-digit Global Trade Item Number (GTIN), along with the product’s batch number, expiration date, and unique serial number. For all products manufactured on or after April 1, 2016, non-small scale industry (non-SSI) manufacturers must serialize the secondary and tertiary package. SSI manufacturers must serialize all product packages at the secondary and tertiary level on or after April 1, 2017. Serialization of the primary package is optional for exported products. Manufacturers must aggregate9 lower-level packaging to higher-level packaging and upload this “parent child” information to the Drugs Authentication and Verification Application (DAVA) database—a central, country-wide database for storage of serialization data developed and managed by the National Informatics Center (NIC). https://www.loftware.com/blog/indian-government-extends-deadline-for-serialization-of-pharmaceutical-products/ Int. J. Pharm. Sci. Rev. Res., 47(2), November - December 2017; Article No. 16, Pages: 85-91 GS1 Healthcare Reference Book 2016-2017	(same as above)	It is organized as "Traceability (display of distribution barcode, etc.)." For ethical drugs, labeling of GS1 code is required to ensure medical safety. Recently, the Ministry of Health, Labour and Welfare released the “Partial Revision of ‘Guidance for Barcode Labeling of Ethical Drugs’” as on August 30, 2016 for the promotion of traceability and efficiency of drug distribution, obligating those products to be shipped after April 2021 (April 2023 under special circumstances) to label a new barcode including variable information in addition to the product code which has been obligatory from before. Moreover, labeling of JAN code (GTIN) is required for OTC drugs.	・Article 47-3, Pharmaceutical Affairs Act : The Minister of Health and Welfare designated a specialized agency, “Korea Pharmaceutical Information Service” for information control of distribution of drugs(collection, investigation, processing, utilization and provision of information on distribution of drugs, such as manufacture, importation, supply and details of use of drugs). ・In cases where a person who has obtained approval for drugs, an importer and a wholesaler of drugs has supplied medical centers, pharmacies and wholesalers of drugs with drugs, he/she shall submit details of such supply to the Korea Pharmaceutical Information Service. ・Pharmaceutical serialization system - “Serial number”, a unique number is assigned to individual drug in the minimum packaging unit, and the entire distribution process from production to consumption is tracked in real time. - Designated drugs and ETC drugs are reported at the time of shipment of the product, and OTC drugs and ETC drugs without serial number can be reported at the end of next month. Supply details shall be reported through the attached form of the Enforcement Regulation of the Pharmaceutical Affairs Act as follows. All finished drugs: Attached form 24-2, Enforcement Regulation of the Pharmaceutical Affairs Act. OTC: Attached form 24, Enforcement Regulation of the Pharmaceutical Affairs Act. ETC without Serial number: Attached form 24-2, Enforcement Regulation of the Pharmaceutical Affairs Act. (Guideline on the Use and Management of Barcodes and RFID Tags for Drugs(MHLW Notification) Article 5 – the serial number can be omitted to the drug applicable to attachment 1-2) ・In order to manage serial number conveniently, the barcode system is being operated and defined in Guideline on the Use and Management of Barcodes and RFID Tags for Drugs(MHLW Notification) Article 5, Paragraph 7. (Source: Health Insurance Review & Assessment Service, Korea Pharmaceutical Information Service)	In the process of implementing GS1 ‘Track & Trace’ system The price of the hologram safety label supply by Techno Secure Print Sdn Bhd Company starting 1 September 2019 is RM0.064 / label unit. The supply of hologram safety labels to the industry is 14 days from the date of order. [Pharmaceutical Services Programme]	There were plans to implement serialization following the initial discussions from Asia-Pacific Economic Cooperation (APEC). The plan was to first implement global product identification number (GPIN), to proceed to serialization. However, in consideration of the readiness of the local industry to comply, serialization was implemented on a voluntary basis. The policy for voluntary compliance is provided under FDA Circular No. 2016-011.	There were plans to implement serialization following the initial discussions from Asia-Pacific Economic Cooperation (APEC). The plan was to first implement global product identification number (GPIN), to proceed to serialization. However, in consideration of the readiness of the local industry to comply, serialization was implemented on a voluntary basis. The policy for voluntary compliance is provided under FDA Circular No. 2016-011.	QR code for all OTC drugs before end of 2019. All OTC drugs newly launched in or after 2017 need to be compliant with QR code requirement.	There are no regulatory requirements concerning serial numbers.	Marketing Authorization number or number of import license (if applicable), both granted by the Ministry of Health, must be reflected on the pharmaceutical product label prior to being placed on the market.

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Promotion	Promotion code	RDPAC Code of Practice 2019 updated on Dec 6th ,2018 • Promotion CODE and Ethics in the 10th China Healthcare Submit of Entrepreneurs, Scientists and Investors (Oct 10th) and 6th china Inbound-outbound Forum 2019 (Nov 3rd). On Nov 1st, RDPAC co-organized Corporate Compliance International Conference Pharmaceutical Forum and introduced Code evolvement and core value. PhIRDA Code of Practice 2018 updated • PhIRDA Code of Practice was approved on the Fifth Meeting of the 10th PhIRDA General Assembly. • The implementation of the Code is the signal of PhIRDA being the 1st organization in China that makes the code of practice for domestic pharmaceutical industry. The Code further facilitates China's domestic ethical and risk management system.	HKAPI Code of Practice Prevention of Bribery Ordinance enforced by Independent Commission of Against Corruption Trade Description Ordinance enforced by Custom and Excise Department	There are many Laws & Codes referred for Marketing & Ethical promotion of drugs in India 1.UCPMP (Uniform Code for Pharmaceutical Marketing Practices) – Most recent 2.The Code of Pharmaceutical Practices, 2012 by Organization of Pharmaceutical Producers of India (OPPI) 3.Drugs & Cosmetics Act, 1940 4.Drugs & Magic Remedies (Objectional advertisement) Act, 1954 5.Code of Self-regulation in Advertising by The Advertising Standards Council of India (ASCI) 6.WHO Code of Pharmaceutical Marketing Practices 7.IFPMA Code of Pharmaceutical Marketing Practices 8.The Competition Act, 2002 9.Essential Commodities (Control of Unethical Practices In Marketing Of Drugs) Order, 2017 – In Review Process However 2 most followed codes are: 1)Uniform Code of Pharmaceuticals Marketing Practices, 2014 ("UCPMP Code") 2)The Code of Pharmaceutical Practices, 2012 by Organization of Pharmaceutical Producers of India (OPPI) Uniform Code of Pharmaceuticals Marketing Practices, 2014 ("UCPMP Code") is a voluntary code issued by the Department Of Pharmaceuticals ("the Department") relating to marketing practices for Indian Pharmaceutical Companies and as well medical devices industry. Although the UCPMP Code was initially implemented for a period of 6 months & extended in 2016 till further orders. Recent developments suggests that Department is in the final stages of issuing an executive order making the UCPMP Code mandatory for the drug manufacturing industry. It is expected that the order will cover doctors, chemists, hospitals, and states. Further, it is also expected that there could be inclusion of the stringent penalty provisions in the UCPMP Code. Updated version UCPMP Code which is now called as Essential Commodities (Control of Unethical Practices in Marketing of Drugs) order 2017 is pending with law ministry of India in final stages which will take form of law & become compulsory http://www.mondaq.com/india/x/592756/food+drugs+law/Uniform+Code+Of+Pharmaceuticals+Marketing+Practices+2014Expected+To+Be+Made+Mandatory+Soon http://timesofindia.indiatimes.com/articleshow/59603596.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst https://pharmastate.blog/2018/07/05/laws-codes-for-marketing-of-drugs-india/	IPMG CODE OF PHARMACEUTICAL MARKETING PRACTICES January 2019 version IPMG's latest Code of Ethics is now aligned with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) standards and expected to be socialized in early January, 2019. Reference : http://www.ipmg-online.com/index.php?modul=issues&cat=ICoC	JPMA member companies must always ensure high ethical standards and transparency in their business activities, fulfill their accountability in interactions with researchers, healthcare professionals, patient groups, etc., and respond to the trust of society. JPMA Code of Practice is an industry voluntary code that further develops the "Ethical Drug Promotion Code" and provides standards of conduct for interactions between all officers and employees of member companies and researchers, healthcare professionals, patient groups, etc. Promotion Code is part of the JPMA Code of Practice was formulated in January 2013 and revised in May 2017. It was subsequently revised based on the revision of the IFPMA in November 2018 Code, and based on the "Guidelines on Information Provision in Connection with Promotional Activities for Ethical Drugs" in September 2019. JPMA Code of Practice also requires compliance with the "Fair Competition Code concerning Restriction on Provision of Premiums in Ethical Drug Marketing Industry" established by the Fair Trade Council of Ethical Drug Marketing Industry. JPMA Code of Practice http://www.jpma.or.jp/about/basis/code/ Guidelines on Information Provision in Connection with Promotional Activities for Ethical Drugs https://www.mhlw.go.jp/content/000359881.pdf#search=%27%E5%8C%BB%E7%99%82%E7%94%A8%E5%8C%BB%E8%96%AC%E5%93%81%E3%81%AE%E8%B2%A9%E5%A3%B2%E6%83%85%E5%A0%B1%E6%8F%90%E4%BE%9B%E6%B4%BB%E5%8B%95%E3%81%AB%E9%96%A2%E3%81%99%E3%82%8B%E3%82%AC%E3%82%A4%E3%83%89%E3%83%A9%E3%82%A4%E3%83%B3%27	・In Korea, distribution of pharmaceutical products is carried out in line with Korean Good Drug Distribution Practice and the distribution records of all finished drug products are required to be sent to the Korea Pharmaceutical Information Service within the Health Information Review and Assessment Service. In addition, offering drugs at discounted prices or exclusive sales activities for a certain medical institution are banned to promote sound pharmaceutical distribution practices. Drug manufacturers providing monetary compensation to physicians, pharmacists, etc., in an attempt to boost drug sales is against relevant laws. (Source: Pricing and Reimbursement of Pharmaceutical Products in Korea, Chang, Seon-mi, 2017.06)	PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products https://www.phama.org.my/view_file.cfm?fileid=129	The DOH, through the FDA implements Administrative Order No. 2015-0053 which serves as the guideline for the promotion and marketing of prescription pharmaceutical products and medical devices. The said policy builds on two APEC documents: the Mexico City and Kuala Lumpur Principles which deals with codes on business ethics. As these APEC documents are voluntary, the issuance of the Administrative Order 2015-0053 makes the code of ethics mandatory for the Philippines. From the industry sector, the Pharmaceutical and Healthcare Association of the Philippines established its Code of Practice following the IFPMA Code.	In addition to SAPI Code of Conduct 2019 (SAPI Code) by the Singapore Association of Pharmaceutical Industries (SAPI) promotion code, there are domestic laws relevant to anti-corruption, such as the Prevention of Corruption Act. www.sapi.org.sg [PREVENTION OF CORRUPTION ACT [https://sso.agc.gov.sg/Act/PCA1960]	A Code of Practice was established by IRPMA in July 2003, and it is available on the website. [http://www.irpma.org.tw/EN/marketing3]	There is a National Ethical Framework developed by the National Drug System Development Committee (NDSDC) and announced in 2015. A revised 2nd edition was issued in 2016. PReMA's Code of Practice has been revised with issuance of the 12th edition in 2019. The Thai Pharmaceutical Manufacturers Association (TPMA) has also adopted and implemented their code of practice with a revised 2nd edition issued in 2018. The 3rd revision is planned for 2020.	Pharma Group Code of Pharmaceutical Marketing Practices (Pharma Group Code of Ethics), in line with IFPMA Code Adopted on 1 January 2014; Amended for the first time by the Pharma Group General Assembly on 27 January 2016, effective 1 June 2016 Amended for the second time by the Pharma Group General Assembly on 6 December, 2018, effective 1 January, 2019. https://www.eurochamvn.org/sites/default/files/uploads/PG%20Code%20of%20Ethics%202019_approved%206%20Dec%202018.pdf

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Promotion	Hospital visit regulations	NMPA (CFDA) released the pilot policy <the registration rules on medical representatives>comment-seeking version. Industry feedbacks no later than January 19th, 2018. The final policy has not been released yet. In principal the draft calls for a restricted management to the visit to medical institutions by representatives of pharmaceutical manufactures. Several provincial healthcare authorities issued regulations on strictly restricting and limiting such hospital visit. Source: National Medical Products Administration	Not in Hong Kong but yes in Macao.	MEDICAL REPRESENTATIVES ARE NORMALLY ALLOWED IN BOTH GOVERNMENT & PRIVATE HOSPITALS IN INDIA. HOWEVER FOLLOWING CHANGES ARE BEING SEEN IN RECENT TIMES: IN MAJORITY OF THE PRIVATE HOSPITALS THERE ARE FIXED DAYS FOR DOCTORS CALL & REPRESENTATIVES ARE ALLOWED IN PARTICULAR TIME WINDOW TO BE INSIDE HOSPITAL IN GOVERNMENT HOSPITALS MEDICAL REPRESENTATIVES CAN TYPICALLY MEET DOCTORS POST THEIR DAILY OUTPATIENTS SOME HOSPITALS ARE ALSO CHARGING MONTHLY OR DAILY FEES FOR ENTRY OF MEDICAL REPRESENTATIVES & REPRESENTATIVES ALSO HAVE TO PROVIDE THEIR GOVT ISSUED PERSONAL IDENTITY CARD (PAN OR AADHAR) FOR INFORMATION PURPOSES Though very miniscule at this stage but some corpora	Some hospitals in the metropolis have established their own regulations on visits by pharmaceutical companies. In sales by agencies, contact with doctors and nurses is prohibited. The only persons who can be visited in hospitals are Purchasing Dept. staff and supervisory pharmacists. However, there are no such restrictions on the medical devices. Some hospitals have rules for MR visit by internal rules, which includes prohibition of visiting, or specifying the meeting place.	Basic Principles of JPMA Code of Practice state that "Advances in medical and pharmaceutical science and improvements in public health depend on the information-sharing interactions by the entire medical community, which includes researchers, healthcare professionals, patients, wholesalers, and JPMA member companies. Integrity is essential to these interactions, and there must always be confidence that decisions are made on an ethical and patient-focused basis." Under the Principles, the JPMA member companies comply with the visit regulations specified by medical institutions. In addition, as the number of medical institutions adopting a complete appointment system as part of the visiting regulations is increasing, member companies are devising methods of information service, such as the use of the Internet, in response to environment changes.	・In Korea, distribution of pharmaceutical products is carried out in line with Korean Good Drug Distribution Practice and the distribution records of all finished drug products are required to be sent to the Korea Pharmaceutical Information Service within the Health Information Review and Assessment Service. In addition, offering drugs at discounted prices or exclusive sales activities for certain medical institutions are banned to promote sound pharmaceutical distribution practices. Drug manufacturers providing monetary compensation to physicians, pharmacists, etc., in an attempt to boost drug sales is against relevant laws. (Source: Pricing and Reimbursement of Pharmaceutical Products in Korea, Chang, Seon-mi, 2017.06)	There are no barriers impeding access to doctors at private medical institutions.	Hospital visits are allowed, provided the engagements with healthcare professionals are ethical and focuses on the provision of medical information.	・ There are no barriers impeding access to doctors at private medical institutions. Other self-regulation of interactions with medical institutions is as set forth in detail in Article 7 of the promotion code. ・ Specified in detail in SAPI Code of Conduct 2019	Some hospitals have established their own regulation on visits by the pharmaceutical companies but no clear policy in most hospitals. Only few hospitals have announced/verbally informed to industry about their policy on regulating MR visiting. (ex. CGMH-LK, NTUH, NCKUH).	There are no legal regulations. Some of the hospitals have own regulations e.g. a prohibition to carry a bag with a brand name when visiting a hospital or waiting areas to wait for doctors to come out of his office.	Drug introducers employed by a pharmaceutical business establishment (pharmaceutical companies) and issued a “Drug introducer” card by the head of the establishment in order for them to provide drug information to medical practitioners. Drug introducers must meet the following requirements: a) Holding an associate degree in medicine or pharmacy; b) Employed and developed, trained by a pharmaceutical business establishment in skills and professional competencies pertinent to drug introducing activities and pharmaceutical legal normative documents. Responsibilities of drug introducers 1. To wear the "drug introducer" card issued by the pharmaceutical business establishment and comply with the internal rules set out by medical service establishments when introducing drugs. Drug introducers may only introduce drugs at the consent of medical practitioners. 2. To introduce drugs already licensed for marketing in Vietnam strictly according to the list of drugs assigned to him/her by the pharmaceutical business establishment and only disseminate drug information printed on the drugs’ label, package insert that have been registered for marketing or drug information contents that have been confirmed for the purpose by Health Ministry’s competent authority. 3. To produce legal documents proving the drug information contents are regulatory-conforming when so requested by the heads of medical service establishments or medical practitioners. 4. To collect reports on adverse reactions of drugs, reports related to the quality of drugs while introducing drugs in order for the pharmaceutical business establishment to synthetize and report the information to Ministry of Heath’s competent authority according to Ministry of Health-promulgated National guidance on pharmacovigilance. 5. Not to commit the following acts: a) Providing drug information which deviates from what has been registered with, confirmed by competent regulatory authorities or publishing drug information materials the content of which has not been confirmed by the competent regulatory authority; b) Introducing drugs not assigned to him/her by the pharmaceutical business establishment; c) Using material incentives in any form to influence physicians, drug users in order to promote the prescribing, sales and use of drugs; d) Introducing, providing drug information not consistent with the documents prescribed in Clause 3 Article 76 of the Pharmaceutical Law; e) Comparing and introducing drugs of his/her business establishments as better than those of other establishments without supporting scientific literature approved by the competent authority; e) Introducing non-drug products; g) Engaging in activities related to the purchase, sale and consignment sale of drugs with medical practitioners; h) Approaching patients, gaining access of medical records, prescriptions, discussing or requesting for patient-related information; i) Disseminating information to target subjects other than those which have been approved by the Ministry of Health’s competent authority. Responsibilities of the heads of medical service establishments where there are drug introducers operating: 1. To permit only the persons holding "Drug introducer" card to carry out drug introduction activities and to disseminate drug information materials that have been licensed for marketing or confirmed by the Ministry of Health’s competent authority. 2. To set out and implement internal regulations specifying participant composition, venue and timing for the holding of drug information sessions for medical practitioners and other relevant regulations so as to enable drug introducers to carry out drug information activities on the premises in compliance with the provisions of this Circular. 3. To institute measures to prevent the establishment’s medical practitioners from prescribing and providing medication counseling for personal profits under the influence of material, financial or any other form of incentives offered by drug introducers. 4. To immediately suspend drug introducers’ activities on the establishment premises if the latter are found not performing according to the terms of responsibility of a drug introducer. (Circular 07/2018/TT-BYT dated 12 April 2018)

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Promotion	Advertising regulations	Drug advertisements must comply with the provisions of the “Measures for Review of Drug Advertisements” (Issued March 13, 2007; SFDA Order No. 27).This review requires compliance with the “Advertising Act”, “Drug Control Act” (Refer to Research Paper No. 383 “Collected Papers on Chinese Drug Laws and Regulations”), “Decree for the Enforcement of the Drug Control Act”, “Standards for Announcing Reviews of Drug Advertising”, and other national regulations on the control of advertising.	The Undesirable Medical Advertisements Ordinance (UMAO), Cap. 231, was first enacted in 1953. It aims to protect public health through prohibiting or restricting the publication of advertisements for medicine, surgical appliance or treatment that may induce the seeking of improper management of certain health conditions. In order to widen the scope of the UMAO, the Undesirable Medical Advertisements (Amendment) Ordinance 2005 (UMA(A)O) was enacted by the Legislative Council in 2005. Broadcast Codes of Practice by Communications Authority Trade Description Ordinance enforced by Custom and Excise Department	The Advertising Standards Council of India (ASCI) established in 1985 has adopted a Code for Self-Regulation in Advertising. It is a commitment to honest Advertising and to fair competition in the market-place. It stands for the protection of the legitimate interests of consumers and all concerned with Advertising - Advertisers, Media, Advertising Agencies and others who help in the creation or placement of advertisements. In India, the business of medicines is regulated by the Drug and Cosmetics Act, 1940 (DCA) and the Drugs and Cosmetics Rules, 1945 (DCR). Until 2015, the DCA and DCR did not regulate DTC advertising except for the content that appeared on the label of the product. The DCR now prohibits the manufacturers of medicines identified in Schedule H, H1 and X of the DCR from indulging in any form of advertisement. The language used to prohibit DTC advertising makes it amply clear that ‘public interest’ is not a cushion any longer to advertise medicines. http://www.expressbpd.com/pharma/management-pharma/direct-to-consumer-advertising-of-medicines-and-medical-devices-a-call-for-action-2/404419/	Advertising restrictions are implemented under the guidance of BPOM. [IPMG CODE OF PHARMACEUTICAL MARKETING PRACTICES January 2019 version	Considering inadequate advertisement of drugs, quasi-drugs, cosmetics, medical devices, or regenerative medical products may greatly affect public health and hygiene, the Ministry of Health, Labour and Welfare, together with the Pharmaceutical and Medical Device Act, issued the "Revision of the Code of Fair Practices in the Advertising of Drug and Related Product" in September 2018, which regulates advertisements of drugs, etc. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/koukokukisei/index.html In addition to JPMA Code of Practice, the Association has established "Guidelines for Preparation of Ethical Drug Product Information Brochure" as an industry voluntary code and provides points to consider in preparing promotional materials, etc. http://www.jpma.or.jp/about/basis/drug_info/	As a rule, it is prohibited to advertise prescription drugs to the general public, but as exceptions it is possible to advertise drugs for infection prophylaxis that are defined by the “Infectious Disease Control and Prevention Act”, as well as advertisement on media targeting medical and pharmaceutical experts. Anyone intending to promote drugs through advertising shall have their advertisements reviewed by the Minister of the Ministry of Food and Drug Safety in advance. Currently, Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) is carrying out advertising review activities commissioned by the MFDS.	According to Article 4B of the 1956 Pharmaceutical Affairs Act, all advertisements of registered pharmaceuticals must be approved by the Medicine Advertisements Board (MAB) of the Pharmaceutical Services Programme. According to MAB policy, advertisements must be reliable, accurate, without falsehoods, beneficial, balanced, up to date and dignified, and contain verifiable information. Health-related assertions or displays (explanations, assertions, and comparisons) must be verifiable facts. Applications for advertisements are submitted to MAB together with the examination fee of 300 Malaysian Ringgits. It takes 5 business days for MAB to process the examination procedures, and the advertising permit is valid for 3 years. [Report of survey on regulations and procedures related to the health foods business in Malaysia, March 2015/JETRO]	Following Administrative Order No. 65 s. 1989, only products that are classified as over-the-counter may be advertised. For prescription drugs, advertisement is limited to medical journals. Content of advertisements must be compliant with existing approved labeling materials.	· Self-regulation of advertising is similarly described in detail in Article 5 of the aforementioned SAPI Code. · Guidelines on advertising of ethical pharmaceuticals are set forth in detail in the Health Sciences Association (HSA)’s "GUIDE ON ADVERTISEMENTS AND SALES PROMOTION OF MEDICINAL PRODUCTS", "EXPLANATORY GUIDANCE TO THE HEALTH PRODUCTS (ADVERTISEMENT OF THERAPEUTIC PRODUCTS) REGULATIONS 2016".	Advertisements are defined and regulated in Article 24, and 65 to 70 of Pharmaceutical Affairs Act. https://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0030001 Also, Article 44 to 47 of Pharmaceutical Affairs Act Enforcement Rules. https://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0030002	Thailand has pharmaceutical advertising regulations. Prescription drugs can only be advertised to Healthcare Professionals only. Non-prescription drugs (OTC drugs) can be advertised to the public. Both must submit advertisements to the FDA for prior approval.	Marketing to consumers Only non-prescription drugs can be advertised to consumers. However, non-prescription drugs whose use should be restricted or subject to the supervision of a doctor, according to the recommendations of the competent state body, cannot be advertised. It is prohibited to advertise to consumers: · Drugs without a valid marketing authorisation (MA) number in Vietnam. · Prescription drugs. · Vaccines or medical biological products used for disease prevention. · Non-prescription drugs whose use should be restricted or should be supervised by a doctor, as recommended in writing by the competent state administrative body. Drug advertising is the only marketing activity permitted to consumers. The advertising of drugs can be in the following forms: · Advertisements in books, newspapers, magazines, leaflets, and posters. · Advertisements on billboards, placards, panels, banners, objects which are illuminated or appear in the air or underwater, means of transportation, and other mobile objects. · Advertisements on radio and television. · Advertisements in electronic newspapers, company websites, and websites of advertising service providers. · Advertisements on other means of advertising as permitted by law. Over-the-counter drugs can be advertised to consumers. It is strictly prohibited to use any material or financial benefits in any form to influence doctors or drug users in order to motivate the prescription and use of drugs. Accordingly, providing consumers with free samples or any special offers is prohibited. Drug trading establishments are only permitted to advertise drugs that such establishments themselves trade, and they can only advertise on their lawful websites. Drug trading establishments can authorise another entity to advertise drugs on their website, provided that the entity is an advertising service provider which possesses a license for internet content provision (ICP) issued by the Ministry of Information and Communications and a business registration certificate for advertising services as stipulated by law. Advertisements on the website must be conducted in a separate column and not be mixed with other content on the website. The following notice must be clearly stated in such column: "this page is for drug advertising only". This sentence must be in bold and have a larger font size than the font size of the advertisement content, and always appear on the top of the page. Drug advertisement in this form must be separate, and for the avoidance of doubt, the advertising of many drugs at the same time causing overlapping or intermingling is not permitted. A drug advertisement on a website in the form of a video clip must comply with regulations for the advertising of drugs on radio or television. Marketing to healthcare professionals: Drugs can generally be introduced to health officials by medical representatives. They can provide drug information documents or organise drug introduction seminars for health officials, or they can display and introduce drugs at specialised health conferences and seminars. The information to be provided to professionals must include the following primary items: · Drug name, which can be a proprietary or original name. · Active ingredients. · Strength/concentration. · Form of preparation. · Indications. · Contraindications. · Dosage. · Method of administration. · Use of the drug by special subjects. · Information relating to drug warnings and safety and other essential information. Advertising of a drug in newspapers, magazines, leaflets, on billboards, signs, panels, posters, banners, illuminative objects, aerial or underwater objects, means of transport, and other movable objects must include the following information: · Name of the drug, which is the name specified in the decision on the drug's registration number of circulation in Vietnam. · Active ingredients: ▪ for Western medicine: using international nomenclature; ▪ for a herbal medicament: using the Vietnamese name (except medicinal material whose names in Vietnamese are unavailable. In this case, using the original name of the country of origin together with the Latin name); · Indications. · Method of administration. · Dosage. · Contraindications and/or recommendations for special users such as pregnant women, breast-feeding women, children, elderly people, and sufferers of chronic diseases. · Precautions and what to avoid, and notes on the use of the drug. · Side effects and harmful reactions. · Name and address of drug manufacturer (name and address of distributor can be added). · The phrase "Carefully read instructions before use". · At the end of the first page of the drug advertising document: ▪ the number of the slip on receipt of the registration dossier for drug advertising of the DAV in the following form: XXXX/XX/QLD-TT, date/ month/ year; ▪ the date of printing the document. For multiple-page documents, pages must be numbered, with the first page indicating the total number of pages and the number of the page providing detailed information on the drug. The Law on Advertising prohibits the following: · Advertising using direct comparison of the prices, quality or efficiency of one company's drugs to those of another company's drugs of the same kind. · Advertising using the words "best", "the best", "only", "number one" or words with similar meaning, without the following legitimate documents: ▪ results of market surveys from legally established and operating market research organisations; ▪ certificates or equivalent papers from competitions or exhibitions of regional or national scale in which such products have been voted and recognised to be "best", "only" "the best", "number one" or phrases with similar significance. If the legitimate documents outlined above are to be used in advertising, the documents will remain valid for one year from the date the certificates were granted or from the date the results of market surveys were received. The advertisements must present fully, clearly, and exactly the names of these documents. (Distribution and marketing of drugs in Vietnam: overview by Tilleke & Gibbins, Law stated as at 01-Dec-2019, Vietnam)

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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system		1. A national level basic medical insurance system, including 1)Basic Medical Insurance for Employees 2)Basic Medical Insurance for Urban & Rural Residents (Combined previous Basic Medical Insurance for Urban Residents with the New Rural Cooperative Medical Scheme as one scheme): 2. Other social /private/commercial insurance as supplementaries, etc.	There is no mandatory public medical insurance system. 1. Government hospitals The number of beds in government hospitals accounts for over 90% of the total, and medical services are provided at a low co-pay. 2. Doctors in private practice, private hospitals Patient bears full cost (individual + employee insurance + private insurance). · Around 48.1% of Hong Kong's resident population were covered by private health insurance. (2017 Thematic Household Survey) Voluntary Health Insurance Scheme was implemented on April 1 which is a voluntary private insurance scheme subsidized/directed and support by the government with tax exemption as incentive	Types of Medical Insurance in India 1.Rashtiya Swasthiya Bima Yojana (RSBY) RSBY (Rashtriya Swasthiya Bima Yojana) has been launched by Ministry of Labour and Employment, Government of India to provide health insurance coverage for Below Poverty Line (BPL) families. RSBY provides protection to BPL households from financial liabilities arising out of health shocks that involve hospitalization. Beneficiaries under RSBY are entitled to hospitalization coverage up to Rs. 30,000/- for most of the diseases that require hospitalization. Government has even fixed the package rates for the hospitals for a large number of interventions. Pre-existing conditions are covered from day one and there is no age limit. Coverage extends to five members of the family which includes the head of household, spouse and up to three dependents. Beneficiaries need to pay only Rs. 30/- as registration fee while Central and State Government pays the premium to the insurer selected by the State Government on the basis of a competitive bidding. 2.Employment State Insurance Scheme (ESIS) Employees' State Insurance Scheme of India, is a multidimensional social security system tailored to provide socio-economic protection to worker population and their dependants covered under the scheme. Besides full medical care for self and dependants, that is admissible from day one of insurable employment, the insured persons are also entitled to a variety of cash benefits in times of physical distress due to sickness, temporary or permanent disablement etc. resulting in loss of earning capacity, the confinement in respect of insured women, dependants of insured persons who die in industrial accidents or because of employment injury or occupational hazard are entitled to a monthly pension called the dependants benefit. 3.Central Government Health Scheme (CGHS) The "Central Government Health Scheme" (CGHS) provides comprehensive health care facilities for the Central Govt. employees and pensioners and their dependents residing in CGHS covered cities. The Central Govt. Health Scheme provides comprehensive healthcare to the CGHS Beneficiaries in India. The medical facilities are provided through Wellness Centres (previously referred to as CGHS Dispensaries) /polyclinics under Allopathic, Ayurveda, Yoga,Unani, Sidha and Homeopathic systems of medicines. 4.State Government sponsored programs There are some proactive state governments which are running healthcare schemes for people in their own states such as the Yeshasvini Co-operative Farmers Health Care Scheme of Karnataka, Rajiv Aarogyasri Community Health Insurance Scheme of Andhra Pradesh, Comprehensive Health Insurance Scheme of Kerala 5. Public Service Units: Many public service units such as India Railways pays for healthcare expenditure of their own employees in their own hospitals for minor illnesses & complex treatment can be done in corporate hospitals affiliated to or notified by Railways or other PSUs 6. Private Insurance: Private insurance can procured by paying annual premiums from providers which provides you cashless hospitalization at affiliated private hospitals. But treatment cost or insurance coverage is often capped to particular amount & if hospitalization expenditure goes beyond the stipulated amount then parson needs to bear the expenses for the same. https://www.nhp.gov.in/national-health-insurance-schemes_pg Ayushman Bharat Scheme 2018; will cover over 100 Million poor and vulnerable families providing cashless coverage of up to USD 7500per family per year for secondary and tertiary care hospitalisation. This will be the world's largest government funded health care programme. Every person listed in the Socio Economic Caste Census (SECC) database will automatically be enrolled in the scheme. While the beneficiaries can avail benefits in both public and empanelled private facilities, the payment for treatment will be done on package rate (to be defined by the government in advance) basis. https://www.businesstoday.in/top-story/modi-ayushman-bharat-scheme-health-care-socio-economic-caste-census-pandit-deendayal-upadhyay-modicare-prajaa/story/281504.html	The 2004 National Social Security Law (Law No. 40/2004) envisages coverage of the entire population through JKN, a mandatory program evolving from existing insurance programs. Until the end of 2013, Indonesia was supported by three major social health insurance programs: Jamkesmas (Jaminan Kesehatan Masyarakat/the government-financed health coverage program for the poor and near-poor); Jamsostek Health (the social health insurance program for formal sector workers); and Askes (the social health insurance program for civil servants). The 2011 BPJS (Badan Penyelenggara Jaminan Sosial/Social Security Administration) Law (Law 24/2011) declared the transformation of PT Askes into Health BPJS. The Health BPJS began implementation of the JKN officially on January 1, 2014 with 121.6 million participants, 96.4 million of whom are participants (poor and near poor) whose premium is paid by the government (PBI), and the remainder are ex-participants of Askes and Jamsostek Health.	1. Health Insurance (JHIA （Japan Health Insurance Association）, Health Insurance Societies) 2. Seamen's Insurance 3. Mutual aid associations (national and local government officers, etc., and teaching faculty of private educational institutions) 4. National Health Insurance (NHI) 5. Medical care system for the elderly aged 75+	Under the "National Health Insurance System", all citizens belong to either system between Workplace health insurance for salaried worker or District health insurance for non-salaried worker. The Korean health insurance scheme officially started from 1977 for companies with 500 employees or more. After gradual expansion of healthcare coverage, Korea achieved universal healthcare coverage in 1989.	Rolled out mySalam (Social Health Insurance for B40) 1. Pension system for civil servants: Medical fees at public medical institutions are set by the Fee Act, and patients' co-pays are small. 2. Employees Provident Fund (EPF): Many private medical institutions are proceeding to introduce advanced technology. Waiting times are short, but fees are high at these facilities. [2017 Annual Report on Conditions Overseas Ministry of Health, Labour and Welfare]	1.Social Health insurance, through Philippine Health Insurance Corporation (PhilHealth) 2.Voluntary private insurance exists, providing supplemental coverage to non-poor households.	· Central Provident Fund (CPF) system (Personal account savings management system for social security expenditures. Includes pension, etc.) 1. Medisave (Employees and their families. Compulsory enrollment): personal medical account 2. Medishield Life (Compulsory insurance that supplements part of the high-cost inpatient treatment that is not completely covered by Medisave; initiated in November 2015. Originally it was voluntary insurance known as Medishield, but exceptions for severely ill persons and the elderly, which did not used to be eligible for benefits, were completely abolished, and the scope of coverage was broadened.) 3. Medifund (Voluntary insurance for people on fixed income who cannot pay medical expenses) 4. CareShield Life, basic long-term care insurance scheme for people become severely disabled, the scheme is to be implemented in 2020. In addition, for subsidized patients (low-income, the elderly >65yrs old with Pioneer Generation (PG) card, for total bill generated from the public healthcare system, there is up to 80% of government subsidy. 5. CHAS (Community Health Assist Scheme) is eligible for lower-to-middle income households, as well as Pioneers to receive subsidies for medical and dental care at GP and dental clinics. 6. Eldershield, basic long-term insurance scheme for people with severe disability, especially during old age. 7. Government Subsidies at public healthcare institutions, for Singapore citizen and permeant residents who receive treatment in public hospitals, they receive up to 80% subsidy of the total bill. 8. Polyclinic drug subsidies 9. Public specialist Outpatient Clinics (SOCs) service and drug subsidies 10. [MOH Healthcare schemes & subsidies: https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies]	National Health Insurance: compulsory social insurance program for all citizens with official residency or foreign national citizens with Alien Resident Certificate. The National Health Insurance program classifies the insured into six categories depending on their employment status. [Handbook of Taiwan's National Health Insurance 2018–2019]	Civil Servants Medical Benefit Scheme (CSMBS) Social Security Scheme (SSS) Universal Health Coverage Scheme (UCS) Private insurance	1. Social health insurance following the insurance law (compulsory insurance) - At designated medical institutions, 80 to 100% of medical expenses are covered by insurance 2. Private insurance / commercial health insurance

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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Responsible Organisations	National Healthcare Security Administration established in March 2018.	The Insurance Authority (IA), which is an independent statutory body, administers the Insurance Ordinance which has provisions governing the regulation of insurers and insurance intermediaries (agents and brokers) in Hong Kong	RSBY: Central Government of India (Ministry of Labour and Employment, Government of India) ESIS: State Insurance Corporation CGHS: Central Government of India State Insurance: Respective State Government Private Insurance: Organisation issuing private insurance	1.BPJS Health is a JKN implementing institution to serve National Health Security of Indonesian citizen which was used to be PT ASKES (health insurance public corporation PT Asuransi Kesehatan). - Based on Bill No.24/2011 about BPJS, ASKES changed to BPJS Kesehatan as of January 1, 2014 BPJS-K is doing the premium collection & polling, carrying out active purchasing for health services 2.DJSN The National Social Security Council is formulating the general policy, doing the supervision and control of programs and institutions, also developing budget proposal for contribution assistance and operational costs of BPJS-K Other relevant ministries, e.g Ministry of Finance, MoH, Ministry of Internal Affairs, Social Ministry, local governments etc	1. JHIA（Japan Health Insurance Association）, Health Insurance Societies 2. JHIA（Japan Health Insurance Association 3. Mutual Aid Associations 4. Municipalities, National Health Insurance Union 5. Association of Medical Care Services for Older Senior Citizens	MOHW (Ministry of Health and Welfare) determines health insurance policy and supervises general operation of NHI scheme. NHIS (National Health Insurance Service), as a single insurer, is in charge of operation and managing national health insurance (NHI). The grounds for its establishment are set forth in Article 12 of the National Health Insurance Act as follows: “(Insurer) The provider of health insurance shall be the National Health Insurance Corporation”. NHIS has responsibilities such as review of the insured, imposition and collection of premiums, insurance reimbursements, and negotiation of medical fee schedule with healthcare service provider etc. HIRA (Health insurance Review and Assessment Service) review appropriateness of medical fee claims, assesses the service quality of healthcare institutions, and evaluates medical necessity of healthcare service by provider	Ministry of Finance (MoF), Central Bank of Malaysia and Great Eastern 1. Pension system for civil servants: KWAP (Kumpulan Wang Persaraan) 2. EPF: KWSP fund under the jurisdiction of the Ministry of Finance [2017 Annual Report on Conditions Overseas Ministry of Health, Labour and Welfare]	Philippine Health Insurance Corporation (PhilHealth)	・1, 2, 4: CPF Board (Central Provident Fund) ・3. Medifund committee [Report of Survey on Medical and Social Welfare Services in Singapore, January 2014, JETRO, MoH]	Department of Social Insurance, Ministry of Health and Welfare National Health Insurance Administration, Ministry of Health and Welfare	CSMBS: Comptroller General’s Department, Ministry of Finance SSS: Social Security Office, Ministry of Labor UCS: National Health Security Office (Independent agency affiliated with the Ministry of Public Health) Private insurance: Insurance companies	1. Vietnam Social Security 2. Private corporation
		Insurance coverage	95% population covered by basic medical insurance: Basic Medical Insurance for Employees (316.73 million) Basic Medical Insurance for Urban & Rural Residents (897.41 million)	According to the Census and Statistics Department ("C&SD"), as many as 3.26 million people or 47% of local population were protected by health insurance in 2016, comprising 1.48 million people with IHI* policies only, 0.86 million with group-based policies only and 0.92 million with both types of policies. *IHI products can be further divided into four broad types, namely (a) hospital insurance reimbursing hospitalization cost; (b) out-patient insurance reimbursing treatment cost in doctor consultation at clinics; (c) hospital cash insurance offering income protection to policy holders which may not be related to inpatient cost; and (d) critical illness insurance offering a lump-sum amount of cash to policy holders upon confirmation of critical illness which may be unrelated to treatment cost.	27% of Indian population is covered under insurance; the break-up of 27% population is as follows Public Insurance (State or central government) 80% Others 20% https://indianexpress.com/article/india/only-27-per-cent-indians-have-health-insurance-report-4978687/	Target Universal Healthcare Coverage 2019: 257.6 million participants Achievement per 1.2.2019 (BPJS-K): 217.5 million participants or 81.8% of total UHC, out of which 96.6 million are PBIs or 90,1% of the target, whereas wage earner segment reached only 60.2% participants out of 54.3 million target.	100%. All Japanese citizens, permanent residents, and any non-Japanese residing in Japan with a visa lasting three months or longer are required to be enrolled in either National Health Insurance or Employees' Health Insurance. [Shibuya City Office National Health Insurance (NHI)[https://www.city.shibuya.tokyo.jp/eng/living/health.html]	Korean health insurance scheme officially started from 1977 for companies with 500 employees or more. After gradual expansion of healthcare coverage, Korea achieved universal healthcare coverage in 1989.	Government launched mySalam B40 Scheme for B40 group on 24th Jan 2019. It covers 45 types of critical illnesses and polio. It is voluntary for the purchase of private healthcare insurance (54-56% as of 2016*) [*Investigation report for healthcare system and policy in ASEAN, 2018 JETRO]	87% of 2019 projected 2019 population [PhilHealth, 2019, https://www.philhealth.gov.ph/about_us/statsncharts/snc2019_1st.pdf]	For most of the subsidies mentioned above, the coverage depends on a combination of several criteria including individual’s family income, whether public or private healthcare facilities, in-patient or out-patient and others. Medishield Life & Integrated Shield Plan covers all Singapore Citizen & PRs ~ 2.75 million people (2018) Eldershield – covers 1.38 million seniors (2018)	Covered almost the entire population (99.6%) as of 2017. [National Health Insurance Administration]	100%. Under the system, all citizens are covered by public insurance (CSMBS, SSS and UCS)	According to the Report No. 413/BC-CP dated 20 September 2019 of the Vietnam Government to the Vietnam National Assembly, it is estimated that around 85 million people have joined social health insurance, or 89,8 percent of the population.

<table>
<tr><th>Category</th><th>Item</th><th>Types</th><th>China</th><th>Hong Kong</th><th>India</th><th>Indonesia</th><th>Japan</th><th>Korea</th><th>Malaysia</th><th>Philippines</th><th>Singapore</th><th>Taiwan</th><th>Thailand</th><th>Vietnam</th></tr>
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<tr>
<td>Insurance & drug pricing system/Public healthcare system</td>
<td>Current status of medical insurance system</td>
<td>Target population</td>
<td>1. Basic medical insurance for employees:
Centers on workers in urban corporations
2. Basic Medical Insurance for urban & rural residents:
residents in urban and agricultural areas, including non-employees, i.e. children and elders</td>
<td>All as it is in the private market.</td>
<td>
<table>
<tr><th>Type of insurance</th><th>Target Population Covered</th></tr>
<tr><td>Rashtriya Swasthya Bima Yojna (RSBY)</td><td>Below Poverty Line (BPL) families included in the district BPL list prepared by State government</td></tr>
<tr><td>Employees State Insurance Scheme (ESIS)</td><td>All the employees from Any establishment having more than 10 employees who earn up to Rs 21000 per month + Their dependants.</td></tr>
<tr><td>Central Government Health Scheme</td><td>Central government employees+ Certain autonomous, semiautonomous and semi – government Organisations. + Members of parliament, governors, Accredited journalists.</td></tr>
<tr><td>Private Health Insurance</td><td>Pan India Mostly urban population with minimal reach in rural area</td></tr>
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<td>As of January 1st 2019, the National Health Security (NHS) participants have reached 215.8 million members or 83.77% out of total population Indonesia, comprising:
96.6 million PBI (poor and near-poor people)
33.1 million registered by the regional govt
17.2 million civil servants, armed forces etc
32.7 million wage earners out of 54.3 million and
36.1 million informal sector out of 60.8 million
Source :
Presentation of Minister of Health re CoB on January 10, 2019</td>
<td>1.General employees and family members (67.55 million)
2. Seamens and family members (120,000)
3. National and local government officers, etc., and teaching faculty of private educational institutions and family members (8.70 million)
4. Farmers, self-employed and other retirees of employees' insurance (32.94 million)
5.Persons aged 75+, etc. (16.78 million)
[As of the end of March 2017]</td>
<td>Health Security System is included "National Health Insurance scheme", "Medical Aid Program" and "Long-term Care Insurance program".
・National Health Insurance (NHI) scheme: The NHI scheme of Korea covers the whole population residing within in territory of Korea. The major source of financing is contributions from the insured and government subsides.
・Medical Aid Program: Medical Aid program by the government is policy assistance scheme to secure the minimum living standard of low-income householders and to assist with the self-help by providing medical service
・Long-term Care Insurance program (LTCI): The LTCI program was first introduced in July in 2008 to alleviate financial burden on nursing and to encourage health promotion and living stabilization. The program aims at the elderly with difficulties in activities of daily living due to geriatric disease or old age by supporting physical activities and household.</td>
<td>B40 (socio-economic classification)
1. Enrollees in pension system for civil servants: 1.6 million people (principal, retiree, spouse, children up to age of 18)
2. EPF: employees of private corporations, the self-employed, housewives, etc. Even civil servants can select EPF</td>
<td>Target of the government is to cover 100% population, especially with the passage of Republic Act No. 11223 or the Universal Healthcare Act.</td>
<td>1. Medisave (Employees and their families. Compulsory enrollment): personal medical account
2. Medishield Life (Compulsory insurance that supplements part of the high-cost inpatient treatment that is not completely covered by Medisave; initiated in November 2015. Originally it was voluntary insurance known as Medishield, but exceptions for severely ill persons and the elderly, which did not used to be eligible for benefits, were completely abolished, and the scope of coverage was broadened).

3. Medifund (Voluntary insurance for people on fixed income who cannot pay medical expenses)
4. CareShield Life, basic long-term care insurance scheme for people become severely disabled, the scheme is to be implemented in 2020.
5. CHAS (Community Health Assist Scheme) is eligible for lower-to-middle income households, as well as Pioneers to receive subsidies for medical and dental care at GP and dental clinics
6. Eldershield, CPF enrollees aged 40 or older (unless they decline, they are automatically enrolled)
7. Government Subsidies at public healthcare institutions, for Singapore citizen and permeant residents who receive treatment in public hospitals, they receive up to 80% subsidy of the total bill The monthly PCHI criteria for each subsidy tier will be raised, with increases ranging from $100 to $300
[MOH Healthcare schemes & subsidies: https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies]</td>
<td>All citizens with official residency or foreign national citizens with Alien Resident Certificate.</td>
<td>CSMBS: approx. 5.0 million people
For government employees and those who retire from government employment at the mandatory retirement age, including their parents, spouse, and up to 3 children under the age of 20.
SSS: approx. 14.6 million people
For employees of private corporations (aged 15 to 60, employee only). In recent years, new administrative officials of the government have been covered as well.
UCS: approx. 48.8 million people
For citizens not covered by the 2 aforementioned insurance schemes</td>
<td>Compulsory to join social health insurance:
1.Civil servants, employees in state enterprises, employees in non-state enterprises with more than 10 employees, pensioners, people on subsistence allowance for the elderly
2.National Assembly representatives, People's Council members, preschool teachers, social welfare target groups, dependents of police and armed forces staff
3.Workers in non-state enterprises of more than 1 employee, cooperative, other Organisations, war veterans, the poor
4.Children under age 6
5.Students
6.Farmers
7.Dependents of laborers and cooperative members</td>
</tr>
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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Financing of Healthcare	In Basic Medical Insurance for Employees, insurance premium is jointly shared by employers and their employees. Basically, the corporate share is 6-10% of the employees' wages (vary by provinces), and the individual share is about 2%. In Basic Medical Insurance for Urban & Rural Residents, the share of subsidy from local and central government are around 67.5% in 2019, Source: National Healthcare Security Administration	Analyzed by financing scheme, 50% of the current health expenditure was paid via the government schemes, 35% was by household out-of-pocket payment in 2015/16. Payment via privately purchased insurance schemes and employer-based insurance schemes taken together accounted for 15% in 2015/16. Over the past decade or so, the share attributed to privately purchased insurance schemes had shown a distinct uptrend. [Oct 2018, Domestic Health Accounts, Food & Health Bureau] https://www.fhb.gov.hk/statistics/en/dha/dha_summary_report.htm#D	**Type of insurance** / **Target Population Covered** Rashtriya Swasthya Bima Yojna (RSBY) — 75% by Central Government, 25% by state government Employees State Insurance Scheme (ESIS) — Contribution (from employers and employees) and interest income. States bear one-eighth of medical care costs. Central Government Health Scheme — Employee contribution (varies from Rs. 15 to Rs 150 per month based on salaries) + Central government funds. Private Health Insurance — Self-Paid	[1] PBI: Government funded (national treasury). Covers poor and near poor people of 96.6 million members at Rp 25.500/pm/capita [2] Non-PBI: Civil servants etc pay 5% of the salary, 3% of which is borne by the employer Wage earners pay 5% of the salary, out of which 4% is borne by the employer Informal sector pays according to hospital classes per month per capita as of January 1, 2020 (PresDecree 75/2019) Class 3 Rp 25.500 Rp 42.000 Class 2 Rp 51.000 Rp 110.000 Class 1 Rp 80.000 Rp 160.000 The MoH has issued a ministerial decree no 51/2018 on cost-sharing and co-payment which would alleviate the financial burden of the government, but is however not yet implemented due to legal and technical considerations	Regarding 1-4, in addition to the financial resources from insurance premiums, there are government funding and subsidies as follows. 1. Japan Health Insurance Association (16% of benefits, etc.), Health Insurance Societies (fixed amount) 2. Seamen's Insurance (fixed amount) 4.Municipal National Health Insurance (41% of benefits, etc.), National Health Insurance Union (39.6-47.2% of benefits, etc.) Regarding 5., 10% from insurance premiums, 40% from support money, and 50% from public funds (State: 4; Prefecture: 1; Municipality: 1	Financial resource of the NHI scheme consist of Insurance Premium contributions collected by the insured and government subsidy. ・Insurance PremiumContribution account for 85.9% and government subsidy is 11.3% ・Government subsidy is comprised of general tax(73.4%) and surcharge on tobacco(26.6%). (Source: NHIS Statistical Yearbook, 2018)	Out of RM57.4 billion Total Health Expenditure in 2017, Public Sector spent 51.18% of this figure and the remaining by Private Sector. No public health insurance system, no nursing insurance is available. 1. Pension system for civil servants Individual's share of burden: no insurance premiums Government contribution: federal government, 5% of employee salary; state government, etc., 17.5% of employee salary 2. EPF Individual's share: Both labor and management make contributions to an individual savings account in the name of the enrollee ((in the form of a defined contribution), and each individual's deposits and dividends from investment (6.15% in 2021) are together applied to benefits paid at the time of retirement, etc. The amount of the contribution is periodically reviewed. Categories for amounts of contributions by age were revised with the July 2013 enforcement of a law raising the minimum retirement age from 55 to 60 years old.	1.Social Health Insurance With the passage of the UHC Act, PhilHealth is mandated to collect higher contributions and provide larger benefits: **Year** / **Monthly Basic Salary** / **Premium Rate** / **Monthly Premium** 2019 — P10,000.00 — 2.75% — P275.00 P10,000.01 to P49,999.99 — P275.00 to P1,375.00 P50,000.00 — P1,375.00 2020 — P10,000.00 — 3.00% — P300.00 P10,000.01 to P59,999.99 — P300.00 to P1,800.00 P60,000.00 — P1,800.00 2021 — P10,000.00 — 3.50% — P350.00 P10,000.01 to P69,999.99 — P350.00 to P2,450.00 P70,000.00 — P2,450.00 2022 — P10,000.00 — 4.00% — P400.00 P10,000.01 to P79,999.99 — P400.00 to P3,200.00 P80,000.00 — P3,200.00 2023 — P10,000.00 — 4.50% — P450.00 P10,000.01 to P89,999.99 — P450.00 to P4,050.00 P90,000.00 — P4,050.00 2024 to 2025 — P10,000.00 — 5.00% — P500.00 P10,000.01 to P99,999.99 — P500.00 to P5,000.00 P100,000.00 — P5,000.00 ・For the indirect contributors (i.e. poor), the government subsidizes their contribution. 2.Private health insurance Private health insurance offers various premiums coupled with various packages.	・ Under the CPF system as a whole, a savings fund accumulates with enrollees paying in 7.5–17% of their salary and companies paying in 5–20%, depending on the age of the enrollee. -Under the medical account component of the system, enrollees pay in 8–10.5% of their salary, and this fund supplements 1. Medisave and 2. MediisShield Life. The government does not contribute to the fund. ・ Medifund: Entire amount borne by national treasury ・ Elder Shield: Insurance premiums are paid from Medisave up until the age of 65. [CPF Contribution website https://www.cpf.gov.sg/Employers/EmployerGuides/employer-guides/paying-cpf-contributions/cpf-contribution-and-allocation-rates#Item587] [Healthhub Eldershield] https://www.healthhub.sg/a-z/costs-and-financing/8/eldershield	The system mainly derives its revenue from the premiums paid collectively by the insured, employers, and the government. Other revenues come from outside sources, such as fines on overdue premiums, public welfare lottery contributions, and a health and welfare surcharge on tobacco products.	CSMBS: general tax (General account held by Ministry of Finance) SSS: tripartite: payroll contribution from employee (5% of salary) + company (5% of salary) + government: (Ministry of Labor - may not be paid, depending on economic conditions (2.75% of salary), at the maximum of 15,000 THB. UCS: general tax Private Insurance: out of pocket / welfare Self-pay: overlap with CSMBS, SSS and UCS.	Employee: 4.5% of salary (employer 3%, employee 1.5%) The poor: 4.5% of minimum salary ($30, paid by government) Near poor: 4.5 % of minimum salary (Gov. supports at least 70% of the premium) Students: 4.5 % of minimum salary (Gov. supports at least 30% of the premium) Others: 4.5% of minimum salary (paid by participants)

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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Payment and coverage of healthcare expenses	In general a standard deductible, co-pay and ceiling are set and vary by regions.	Public Sector In-patient -General wards HK$75 for admission fee HK$120 per day occupying acute general bed HK$100 per day occupying non-acute bed -Out-patient General clinics HK$50 per visit, includes medicine, x-ray examinations and laboratory tests Special clinics HK$135 for the 1st attendance HK$80 per subsequent attendance HK$15 per drug item up to 16 weeks Accident and Emergency HK$180 per attendance Private Sector Insurance · Around 48.1% of Hong Kong's resident population were covered by private health insurance. (2017 Thematic Household Survey) · A government-regulated voluntary Health Protection Scheme with the aim to standardize and regulate private health insurance and healthcare services Out-of-pocket · General wards – HK$500 to HK$1,630 per day Consultation – HK$150 to HK$850 per visit	**Type of insurance** / **Coverage of healthcare expenses** Rashtriya Swasthya Bima Yojna (RSBY): All hospitalization charges (except certain specified exclusions) restricted as per package limits. Employees State Insurance Scheme (ESIS): Comprehensive coverage Includes preventive, primary, secondary and tertiary care, plus Cash Benefits for loss of wages due to Sickness, Maternity, Permanent disablement of self and dependents & rehabilitation Central Government Health Scheme: Medical care at all levels and home visits/care as well as free medicines and diagnostic services Private Health Insurance	Insurance premiums are lower for PBI than for Non-PBI, but there is no difference in the medical services received. Insurance premiums differ by class for PBI (Class 3) and Non-PBI (Classes 1, 2, 3). There is no difference in the medical services received, but there is a difference in the budget (benefit value) per head. · From primary medical care to advanced medical care, there is no charge for medical tests, examinations, outpatient treatment, inpatient treatment, or drugs. · Referral by a primary care physician is necessary in order to receive advanced medical care. · Only the level of the hospital room differs from one insured to another, and the insured medical activities are in principal the same. However, this is limited to public hospitals, BPJS-affiliated private hospitals, and health centers run by local governments. (1,710 public or private hospitals, 9,217 health centers) Total number of hospitals : 2,829 (private & public) -Public : 932 (32.3%) -Private : 1,897 (67.7%) Source Link : http://sirs.yankes.kemkes.go.id/rsonline/report/ Total number *of : ·health care center : 9,825 ·7,641 clinics; ·1,874 dentists; ·26,658 pharmacies, ·54,050 physicians in hospitals in 34 provinces *as of Dec 2017 Source Link : http://www.pusdatin.kemkes.go.id/resources/download/pusdatin/profil-kesehatan-indonesia/Data-dan-Informasi_Profil-Kesehatan-Indonesia-2017.pdf http://farmalkes.kemkes.go.id/2013/10/grafik-rekapitulasi-apotek/	·In-kind benefits. There are copayments as follows: End of compulsory education < 70 (30%) Prior to compulsory education (20%) 70 < 75 years (20%; 30% for active income earners) 75+ (10%, 30% for active income earners) High-cost Medical Expense Benefit Scheme: In order to ensure that the patient's copayment is not excessive, patients are reimbursed by the insurer for a portion exceeding the limit of the patient copayment per month after the patient's portion of medical expenses is paid at the counter of medical institutions. Copayment of meal and living expenses during hospitalization · Cash benefits: Injury and illness benefits (employee insurance), lump-sum birth allowance, etc.	● Insurance Benefits and Co-payments • Insurance Benefits ・Insurance benefits are provided for childbirth, health promotion, rehabilitation as well as prevention and treatment of sickness and injury in daily life. ※Two types of insurance benefits: benefit in kind, benefit in cash Insurance Benefits: benefits in kind (97.5%): -Medical Benefits (97.4%); -Physical check-ups costs (2.6%) Cash Benefits (2.5%): -Medical care costs (6.6%); -Benefits for the appliances of the disabled (7.8%); -Reimbursement in the co-payment ceiling system (73.3%); -Prenatal care costs (12.4%) •Co-payments ・A patient who receives healthcare treatment should pay co-payments that are part of total healthcare expense. In order to curtail overuse of healthcare service and to lesson concentration of healthcare service into large hospital, co-payments are differentiated according to the level of healthcare institutions and outpatient/inpatient service. Tertiary hospital: Inpatient 20%; Outpatient 60% General hospital: Inpatient 20%; Outpatient 45-50%* Hospital: Inpatient 20%; Outpatient 35-40%* Clinic: Inpatient 20%; Outpatient 30% Pharmacy: Inpatient -; Outpatient 30% * Differential application by region •Health insurance benefit coverage to lower the out-of-pocket (OOP) share of patients of serious case (Rare*, Serious diseases**) Rare* 10%; Serious** 5% * Rare disease: hemophilia, chronic renal failure, etc. ** Serious diseases: Cancer, Cardio vascular diseases, Cerebrovascular diseases, Tuberculosis and severe burn injury	For healthcare services provided by public sector, it is largely subsidized by government. [Public medical institutions] Outpatient treatment (general practitioner): 1 ringgit Outpatient treatment (specialist): Initial examination: free (referral from public institution), up to 30 ringgits (referral from private institution) Follow-up examination: 5 ringgits (excluding medical test fees) Inpatient treatment (room fee): 3-80 ringgits/day depending on the class of the room. [Private medical institutions] Outpatient treatment (general practitioner): 10–65 ringgits Outpatient treatment (specialist): Initial examination: 60-180 ringgits (excluding other technical fees, medical test fees, etc.) Follow-up examination: 35-90 ringgits (excluding other technical fees, medical test fees etc.) Inpatient treatment (room fee): No specific rule. Additional charge for medical test etc.	PhilHealth provides reimbursements to both government and accredited private facilities. Coverage include: ·Inpatient care, including room and board, professional fees, diagnostic, laboratory, and other medical examination services, prescription drugs ·Outpatient care, including professional fees, diagnostic, laboratory, and other medical examination services, personal preventive services, prescription drugs. Outpatient care initially covered the informal sector, but has now been expanded to the formal sector.	1, 2: Allocated to hospitalization, chronic illnesses, ambulatory surgery, high-cost laboratory tests and treatment, and some outpatient treatment 3. Hospitalization, outpatient treatment, nursing care expenses 6. Elder Shield (A fixed amount is paid to elderly persons with severe physical disabilities) 1. No co-pays under 1. Medisave and 3. Medifund. Patients bear the cost of general outpatient treatment and outpatient prescriptions for the common cold, etc., by themselves In 2. Medishield Life, upper limits are imposed depending on the number of days of hospitalization or the surgical procedures, and there are co-pays that depend on the deductible. 4. Careshield Life, monthly cash benefit starts at S$600 per month in 2020 and increase until age 67 6. If the patient received disability certification, payments of S$400 / month are made for a maximum of 72 months. In addition, there is a medical expense reduction system for persons aged 65 or older, as well as a financial support scheme for those not eligible for long-term care insurance. [MOH Healthcare schemes & subsidies: https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies] [MOH Careshield Life https://www.moh.gov.sg/careshieldlife/about-careshield-life]	In general, outpatients must pay a basic outpatient co-payment and a medication co-payment. Outpatient rehabilitation co-payment, if the rehabilitation therapy or traditional Chinese medicine therapy was given and inpatient co-payment if hospitalized. The basic co-payment is a fixed amount established for each hospital category The drug co-payment is a fixed amount established for each drug price category, and the burden rate is about 20% but upper limit is 200NTD/time. Inpatient co-payment is 5-30%(determined with ward and duration of stay) of the cost of hospitalization and as for the hospital room fees will be required if the room only one or two beds of the difference from actual cost and NHI bed(three or more beds, intensive care beds, and isolation beds). The patient's share of the cost of the hospital room is established as a fixed rate at the time of admission, based on the duration of the hospital stay	CSMBS: OPD - Fee for service, IPD - DRG Benefits in kind, No cash benefits. No restrictions on which medical institution can be consulted. No charge for medical fees at public hospitals. Partial coverage of medical fees at private hospitals SSS: 3,399 THB/person (2019) Benefits in kind Patient selects a designated hospital; free up to a certain limit Since 2015, benefits for obstetric delivery, children, the unemployed, chronic illness, and retirees have been increasing. UCS: 3,600 THB/person (2019) Benefits in kind Patients select a hospital from among the NHSO designated hospitals within the region under jurisdiction (most are public hospitals) for medical care. Objects of benefits are expanding beyond acute-phase treatment to include treatment for AIDS, dialysis, and many cancers, etc.	Coverage: 100% of the medical expenses can be claimed for those who are professional officers and non-commissioned officers and officers and non-commissioned officers specialized in technical areas, and who are serving in the people's security force; children aged less than 6 years old. 100% of the medical expenses can be claimed for cases where the total expense is lower than the level prescribed by the Government and conducted at commune hospitals; 95% of the medical expenses can be claimed for those who are entitled to pension, monthly allowance for reduction in working capacity; receiving monthly social welfare allowance as prescribed by the law; poor household members; ethnic minority people living in areas with difficult or extreme difficult socio-economic conditions. 80% of the medical expenses can be claimed for other individuals. In the event if an individual belongs to more than one category as mentioned above, he/she is eligible for the highest benefit for the insured category. Benefits: Examination and treatment, rehabilitation, antenatal care and birth giving; Level of Insurance Benefit: 100% - 95% - 80% health care expenditure. Services not be covered: Medical costs covered by other sources; Routine health check-up, family planning services, infertility treatment; Aesthetic services; Occupational diseases; work related accidents; suicide, self-harm activities, substance abuse, consequences of law violation, etc.

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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Methods of healthcare subsidy payment	Individual medical insurance card provided and benefit from basic medical insurance fund. The only drugs that are covered are those included in the medical insurance reimbursement list established by the national or local government	Public money is invested in hospitals directly. Private medical insurance: depends on content of contract. Elderly Health Care Voucher Scheme: people 65 get annual voucher amount of $2,000 In 2018, each eligible elder is also provided with an additional voucher amount of $1,000 on a one-off basis on 8 June. With effect from the same day, the accumulation limit of the vouchers has been increased to $5,000 (2 years) as a regular measure.	Healthcare expenditure (Per capita) in USD: USD 63 Healthcare expenditure as % of GDP: 3.9% OF GDP PUBLIC Health Expenditure: 1.15 %	They are paid through reimbursement of medical institutions by BPJS, and enrollees do not make any payments. Primary care: Capitation for medical service fees; payment on basis of a price table for laboratory fees and drug costs. Secondary care: Payment on the basis of the Ina-CBG system (Indonesia Case Based Groups)	Fee-for-service payment Introduction of DPC/PDPS for comprehensive evaluation and fixed payment of hospital acute inpatient care	Reimbursement Mechanism ・The healthcare expense are calculated based on fee-for service for all services and referral levels. ・Fee-for-service = Resource – Based relative Value X unit Price per score. ・The Resource-Based Relative Value is calculated by considering the amount of work and resources such as manpower, facilities, equipment, and risks of insurance benefits. ・The unit price per score is annually determined by the mutual agreement between NHIS president and representatives of the healthcare provider groups. ・Diagnosis Related Groups(DRG). ・In order to redeem problems of fee-for-service, the DRG system started from 2002. And New DRG that supplemented prior to DRG was introduced from 2009. Per Diem ・Applied to healthcare expenses of inpatients in geriatric LTC（Long Term Care）care hospital and psychiatric hospital (Source: NHIS. National Insurance System in Korea)	N/A	Social health insurance is paid to the hospital. Claims are collected by the hospital and submitted to PhilHealth, which then reviews the claims. Depending on the case-rate, some will require co-payment.	See 'Payment and coverage of healthcare expenses'	If the patient presents the National Health Insurance IC card distributed by the authorities at the time of examination, he/she is responsible for only part of the examination fee and drug fee.	CSMBS: Fee for service, IPD - DRG. No charge for medical fees at public hospitals. Partial coverage of medical fees at private hospitals SSS and UCS: Capitation	May be applied to hospitals that have agreements with the Medical Insurance Fund (only the one public hospital named on the insurance card), specialized hospitals stipulated by the Ministry of Health, and government-run hospitals in case of emergency. At other hospitals, the Medical Insurance Fund will bear the cost commensurate with the fees charged by specialized hospitals stipulated by the Ministry of Health. (The difference is borne by the patient as a co-pay)
		Healthcare expenditure per capita (USD)	640.03USD, (1CNY=0.15USD)（1CNY=0.15USD） 4237（RMB,2018） Source: National Bureau Statistics of China	2,906 USD (2017/18, converted from HKD to USD on Nov 2019 rate) Total health expenditure amounted to HK$167,581 million in 2017/18, with annual per capita spending at HK$22,672. [Oct 2018, Domestic Health Accounts, Food & Health Bureau] https://www.fhb.gov.hk/statistics/en/dha/dha_summary_report.htm#D	63 USD	112 USD [World Bank 2016]	3,007 USD (340,000 yen (920,000 yen for 75+) [FY2017] 1 USD=110.39 yen)	3,192 USD PPP [OECD Health Data, 2018] (OECD Average 3,994 USD)	361.52 USD (2016) [World Bank]	328.9 USD [WHO-OECD, 2016]	2462.39USD [World bank 2016]	1,572USD [2018; National Health Insurance Administration]	221 USD [World Bank 2016]	USD170 (2017) [2018 Business Monitor International report]
		Healthcare expenditure (% of GDP)	6.4% (2018) Source: National Bureau Statistics of China	From 1989/90 to 2015/16, total health expenditure rose at an average annual rate of 5.9% in real terms, faster than the corresponding increase of 3.8% in Gross Domestic Product (GDP) during the same period. As a result, total health expenditure as a percentage of GDP went up from 3.6% in 1989/90 to 6.2% in 2017/18. [Oct 2019, Domestic Health Accounts, Food & Health Bureau]	3.9%	3.1 % [World Bank 2016]	7.87% [FY2017]	8.1 % [OECD Health Data, 2018] (OECD Average 8.8%)	4.24 % (2017) [MoH]	4.7% [WHO-OECD, 2016]	4.47 % [World Bank 2016]	6.58% [2018; National Health Insurance Administration]	3.71% [World Bank 2016]	6% [KPMG Value of Innovation Report]

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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Public Health expenditure, (% of GDP)	4.56% (2018) Source: National Bureau Statistics of China	The public share in total health expenditure went up from 40% in 1989/90 to 51% in 2015/16. Public health expenditure as a percentage of GDP increased from 1.5% to 3.1% during the same period. [Oct 2018, Domestic Health Accounts, Food & Health Bureau]	1.15%	1.4% [2016 – knoema.com]	38.4% (State: 25.3%; Regional: 13.1%) [FY2017]	4.8% [OECD Health Data, 2018] (OECD Average 6.6%) * Reference Government and compulsory health insurance schemes, % of current expenditure on 59.8% (OECD Average 73.8%)	2.17 % (2017) [MoH]	1.61% [WHO-OECD, 2016]	2.437 % [World Bank 2016]	3.9%	2.88% [World Bank 2016]	3.8% [White Book EuroCham 2018]
		Others	Uniform directives for urban health insurance and rural health insurance were established by the 2016 State Council opinion. There is a plan to draw up bills for enforcement regulations at each Ministry within the year.	The private share in total health expenditure went down from 60% in 1989/90 to 49% in 2015/16. Yet, private health expenditure as a percentage of GDP grew moderately from 2.2% to 3.0% during the period. [Oct 2018, Domestic Health Accounts, Food & Health Bureau]	N/A	BPJS-registered public health centers and private clinics are the gatekeepers in charge of primary care (covered by insurance). Without a referral from these institutions, it is not possible to use insurance at public or private hospitals providing advanced care.	N/A	・ Payment of outpatient treatment fee is basically 30% of co-payment. Especially. The patients aged 65 or over is a fixed co-pay of 1,500 KRW up to a total amount under 15,000 Won, and the benefit is 70 percent (co-pay 30 percent) for over 25,000 Won. (Refer to section of "Methods of healthcare subsidy payment")	・ The Ministry of Health is planning to control the ceiling price for medicines at wholesale and retail levels. ・ Private medical insurance plans are regulated by the Malaysian Central Bank and Ministry of Health, and there are tax deductions for purchase of such plans by individuals.	PhilHealth is currently contemplating shifting to diagnosis-related groups-based global budget (DRG-GB) from its all case rates scheme. With the passage of the UHC Act, PhilHealth is reviewing all benefit packages in the coming two years, aligned with the HTA process.	N/A	N/A	Percentage in new drug makers' sales CSMBS: 85-90% SSS: Less than 10% UCS: Less than 10%	N/A
	Overview of pharmaceutical reimbursement	Overview of pharmaceutical reimbursement	The National Reimbursement Drug List was updated by NHSA in 2019. 148 drugs were newly listed in NRDL regular list. 97 products were successfully listed through 2019 national negotiation, including 70 new products and 27 contract renewal Source: National Healthcare Security Administration	N/A	N/A	No specific reimbursement system for drug cost; it is included under BPJS-K under the Ina-CBG system since the introduction of UHC in 2014. In primary care: payment based on a price table. It seems to have carried over the content of the old system. • Civil servants participating in the ASKES system of medical benefits, as well as their families and voluntary subscribers can receive drugs free of charge. ・ Persons participating in the JAMSOSTEK system of worker's social insurance can receive drug cost reimbursement within limits.	・In-kind benefits. There are copayments as follows: End of compulsory education < 70 (30%) Prior to compulsory education (20%) 70 < 75 years (20%; 30% for active income earners) 75+ (10%, 30% for active income earners) High-cost Medical Expense Benefit Scheme *Special or Specified Medical Care System: Basic portion (basic hospitalization fee, etc.) of medical care not covered by health insurance for advanced medical care and clinical trials is covered by health insurance	July 1977: Drug price standards were established along with the introduction of the Work Place Health Insurance System. Introduction of reimbursement system based on actual transaction price in November 1999 Change to listing of all drug items (Negative List System) in July 2000 Change to selective listing (Positive List System) in December 2006.	Drug expenses: 8% of the government's total annual expenditures At public hospitals, all drug costs are paid by the government. At teaching hospitals, the individual pays a small co-pay. This system does not apply to private hospitals.	Under existing regulations, only drugs listed in the Philippine National Formulary shall be considered for reimbursement. The following are quick facts on the formulary inclusion process: ·Submission for inclusion happens every January only of each year ·Submission is limited to the formulary executive council members, DOH health facilities, and medical societies ·Inclusion process lasts for a year or more ·Since the current benefit packages are very limited and no specific allocation for medicines, most of the time the benefit packages pay for the hospital and professional fees, putting medicines as out-of-pocket.	・ A Standard Drug List system has been established. ・ Moreover, a Medication Assistance Fund (MAF) system, which bears the cost of high-priced drugs, was established in 2010 and provides supplementation up to a maximum of 90% for purchases of drugs listed in the standard drug list. ・ MAF-Plus scheme: A MAF-Plus scheme for determining whether or not a fund for non-standard medications is necessary at each medical institution, has also been introduced. [Report of Survey on Medical and Social Welfare Services in Singapore, January 2014, JETRO, MoH]	Reimbursement will be applied with reimbursement price approved drug by National Health Insurance Administration. Reimbursement submission will be accepted for NDA approved drugs and will have HTA assessment by CDE (Center for Drug Evaluation) and reviewed by Expert Committee and need to accept by PBRS (Pharmaceutical Benefit and Reimbursement Scheme) Expense Control Although the National Health Insurance is universal service, there are various expending control scheme had implemented. (ex. DET: Drug Expenditure Target, MEA: Managed Entry Agreement) DET: Drug Expenditure Target: Set target of the annual drug expense and adjust by the price for the exceeded par. Currently actual adjustment is occurred every year after the implementation. PVA: Price Volume Agreement: 5-year contract is needed if the product meets one of the following conditions. 1. Forecast or actual exceed 200M/year for new drug during any year of first 5 years. 2. Forecast or actual exceed 100M/year for new drug during any year of first 5 years. Claw back 30-40% of exceeded part of agreed forecast between company and NHIA. MEA: Managed Entry Agreement is including two scheme PVA (Price Volume Agreement: apart from above PVA) and RSA (Risk Sharing Agreement). PVA is financial base claw back scheme and RSA is outcome base claw back scheme.	Reimbursement depends upon the type of insurance enrolled in: CSMBS: NLED and non-NLED (with conditions) medicines, restrictions on some of high cost anticancer/hematologic drugs SSS: benefit in kind. According to NLED. UCS: benefit in kind. According to NLED.	Reimbursement is provided for items listed in the list of drugs eligible for medical insurance payments and for pharmaceuticals that hospitals bid for. Vietnam Social Security guides Provincial (and District) Social Securities for payment and managing cost of drugs as they directly pay health-care providers. Drugs on the Reimbursement Drug List (developed by Ministry of Health, latest list stipulated by Circular 30/2018/TT-BYT dated 30 Oct 2018) are funded through the Health Insurance Fund through government health establishments (hospitals) under contract with a health insurance institution.

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Insurance & drug pricing system/Public healthcare system	Overview of pharmaceutical reimbursement	Presence/absence of Essential Drug List/Positive List/Negative List; EDL/Positive list/Negative list	NEDL was updated by NHC in September 2018. The number of essential drugs increased from 520 to 685, which include 417 chemical drugs and 268 TCMs. A prioritized usage of NEDL is recommended by government. Source: National Health Commission of China	N/A	In India National List of Essential Medicines (NLEM) formed in 2011 decides the essential medicines. The list is prepared by the Union Ministry of Health and Family Welfare. The NLEM is a dynamic list and is reviewed every 3 years to include or exclude drugs as relevant to the newest medical innovations and aligned to the current market competition India has National List of Essential Medicines published & updated in FY.2015, which includes 376 drugs under price control http://apps.who.int/medicinedocs/en/m/abstract/Js23088en/	Drug procurement system of BPJS-K: 1. Regulator (MoH) and LKPP (Govt. Central Procurement Agency) are the two main actors, where: 2. MoH sets the Drug Requirement Plan (bottom-up process), selects the selection team to develop the ForNas (National Formulary), sets up the Tariff Team for HPS (Harga Perkiraan Sendiri - self-assessed prices) as the basis for LKPP to negotiate with the potential suppliers, and creates the Negotiation Team with the LKPP to agree on prices: one winner with the lowest price for one molecule in one province 3. Based on point 2, LKPP issues the E-catalogue and signs an umbrella agreement with the resp. winners of the tender process 4. Users (local health agencies, hospitals, clinics, patients) order based on e-catalogue contracts and paid by BPJS-K based on claim reimbursement 5. The MoH issued the NDEL (National Drug Essential List) with a ministerial decree no. HK.01.07/MENKES/395/2017 listing drugs which have to be available in public health institutions (hospitals and puskesmas)	The NHI Drug Price Standard specifies the drug items that can be used for insurance-covered medical care.	Since December 2006, the Korean government has employed the "positive list system". The positive list system means that grant benefits selectively to products offering excellent treatment and high economic value. The Korean government introduced the positive list system in December 2006, which mandates insurance cover only for drugs with proven efficacy and cost-effectiveness. Prior to this, insurance had covered most drugs regardless of their prices, so long as they were approved by the Ministry of food drug safety, and consequently, drugs were widely prescribed by doctors. However, under the new system, the government determines the list of drugs to be covered by insurance, based on their cost-effectiveness. Under positive system, pharmaceutical companies make voluntary decisions to apply for coverage of drugs that have been approved, and only cost-effective drugs are selected for coverage. After HIRA evaluates the drug for coverage decision, NHIS takes care of price negotiation	Essential Drug List is available (NEML = National Essential Medicines List) Currently 4th edition of NEML dated 6 September 2016 is available. The 4th edition contains 321 chemical entities within 30 therapeutic groups. The therapeutic groups are further divided into sub-therapeutic groups followed by the medicines' chemical entities (generic names). For each chemical entity, the corresponding dosage form and the level of care are stated on the same row. When prescribing the medicines, the prescribers should ensure that the indications are registered with the Drug Control Authority of Malaysia. For prescribers within Ministry of Health (MOH) facilities, the registered indications must also be listed in the MOH Medicines Formulary. 5th edition of NEML is being finalized. At public hospitals, only those items included in the "Ministry of Health (MOH) Drug Formulary: Blue Book" can be used. This formulary includes both NEMLs and Innovative medicine, and the process of getting an innovative medicine listed in the Blue Book takes 2 to 3 years. Evaluation criteria at the time of listing include efficacy, safety, and price comparisons with existing drugs that are already listed in the Blue Book.	The Philippine National Formulary serves as the essential drug list of the Philippines. As of December 2018, there are 676 drugs included in the formulary list, out of the 19,381 registered drug products in the FDA.	· A Standard Drug List (SDL) has been prepared by Public Healthcare institutions, Drug Advisory Committee (DAC), and Ministry of Health (MOH) · The Standard Drugs List (SDL) was established in 1979 It is modeled on the WHO Essential Drug List It applies to patients who receive assistance for public medical care Drug access is not linked to listing in the SDL list Providers of medical services are not limited to drugs listed in the SDL · There are two types of list: SDL1 and SDL2. · SDL1 is for basic drugs. Patients pay S$1.40/item/week · SDL2 is for high-priced drugs. Patients pay 50%. [http://www.who.int/medical_devices/02_keng_ho_pwee.pdf]	"Necessary drugs" are established by Articles 4, 34, and 35 of "National Health Insurance Drug Benefit Items and Payment Criteria." "Essential Drugs list" established according to Article 27-2 of Pharmaceutical Affairs Act established by TFDA. (June 2018)	National List of Essential Drugs (NLED) The NLED constitutes a positive list reimbursable by the three public health insurance systems to encourage rational use of medicines. Exemption for the CSMBS permits reimbursement of unlisted drugs with signatory approval by three attending physicians. For new launches, the application for listing can only be made after a 2-year safety monitoring period (SMP), and the PMS information must be included in the application package. In this way, it can be accessed by all patients. After inclusion, products will be subjected to price regulation with up to 70% discount. The latest NLED was announced on April 17, 2019	Vietnam does have such a list which is separate from the Reimbursement Drug List (developed by Ministry of Health, latest list stipulated by Circular 30/2018/TT-BYT dated 30 Oct 2018) Essential Medicine list of Vietnam was first introduced in 1985, reviewed every 2 years and the revision of the list itself can take 2 years.

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Insurance & drug pricing system/Public healthcare system	Overview of pharmaceutical reimbursement	Out of pocket expenses and/or ratio of medicines	NHC announced that in 2018 average individual out-of-pocket medical expenses reduced to below 30%. Source: National health Development Research Center	N/A	Out of pocket medical expenses make up about 62% of all healthcare costs in India. 50-60% of OOP expenses are on account of purchase of medicines. https://www.thehindu.com/business/out-of-pocket-spend-makes-up-62-of-health-care-costs/article21860682.ece https://www.firstpost.com/india/indias-healthcare-woes-out-of-pocket-medical-expenses-pushed-55-million-into-poverty-in-2017-says-phfi-study-4773741.html	According to the statement of the Minister of Health on January 10, 2019, the OOP share is declining from 54.8% in 2010 to 48.7% in 2016 of the total health financing since the introduction of the JKN program	End of compulsory education < 70 (30%) Prior to compulsory education (20%) 70 < 75 years (20%; 30% for active income earners) 75+ (10%, 30% for active income earners) The maximum amount of copayment is set according to the High-cost Medical Expense Benefit Scheme.	Out of pocket expenses The Share of out-of-pocket medical expenses is 32.9%. (2018) (OECD Average 20.5%) (Compulsory schemes 59.8%, Voluntary health care payment schemes 7.4%) Raito of medicines The share of medicines in total medical expenses is 19.3%. In detail, the proportion of prescribed medicines is 16.0%, and OTC 3.3%. (2018) * OOP for prescription prescribed medicines is 33.7%. Medicine spending per person is $ 617.2 (Current PPPs) (Prescribed medicines $ 511.1, OTC $106.1) [OECD Health Data, 2018]	At public medical institutions, medical fees are set on the basis of the Fee Act, and if you are a Malaysian citizen, you can be examined for a fee ranging from one to several ringgits. Fees for medical tests, surgery, hospitalization, and drug costs are also set low. These are free of charge for low-income people and civil servants, etc. At private hospitals, the patient's co-pays are high（approx 38% is out of pocket）.	Healthcare out-of-pocket is at 53.9% [Philippine Statistics Authority, 2019, https://psa.gov.ph/pnha-press-release] 85% of total pharmaceutical expenditure is out of pocket (WHO-OECD, 2016)	・ There is supplementation from the Medisave account, etc., but the account itself is almost entirely self-funding, with some contributions by the employer. [IQVIA]	The drug co-payment is a fixed amount established for each drug price category, and the burden rate is about 20% and upper limit is 200NTD/Time.	Depends on what insurance the patient is enrolled in. Under UCS no Out of pocket, but there are a wide range of limitations on the medical institutions that can be consulted and the drugs that can be received. The same is true of SSS. If a non-NLEM drug is used, the patient bears the full cost him/herself.	Co-pays are 0–20%, depending of the category of insured.
		Availability of pricing system for reimbursed medicines	No. The national guideline for reimbursement payment standard has not been released.	N/A	N/A	Refer to the drug procurement system above	The health insurance-covered medical institutions or pharmacies shall make an insurance claim based on the price specified in the drug price standard.	In the case of drugs approved by MFDS, it is possible to apply for reimbursement assessment. However, under the positive listing system, whether the reimbursement depends on the results of the appropriateness evaluation including cost effectiveness.	N/A	PhilHealth will only reimburse cases with medicines that are included in the formulary. However, there is no explicit allocation for medicine costs	Yes [IQVIA]	Yes	There is no reimbursed price of medicines under SSS and UCS as total medical benefit is paid on capitation basis. For the CSMBS, reimbursement for OPD script is based on mark-up margin on top of the procurement price. For IPD, coverage is based on diagnosis-related grouping (DRG).	Yes
		Pricing organization	Most of drugs are free pricing in China. National Healthcare Security Administration is only responsible for the pricing of some special drugs, such as toxic and narcotic drugs.	N/A	1.NPPA is an Organisation of the Government of India which was established, inter alia, to fix/ revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995. 2.The Organisation is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. 3. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels. http://www.nppaindia.nic.in/	The Government Goods / Services Procurement Policy Agency (abbreviated as LKPP) is a Non-Ministry Government Institution (LPNK) which is under and report to the President of the Republic of Indonesia See also the drug procurement system above	The Minister of Health, Labour and Welfare determines in response to the report from the Central Social Insurance Medical Council ("Chuikyo") . The Chuikyo may seek opinions from the drug pricing Organisation established in the Council if necessary for drug pricing.	There are three Organizations of Health Insurance System. The Ministry of Health and Welfare (MoHW) legislates related laws and supervises and manages NHI Organizations. National Health Insurance Service (NHIS) and Health Insurance Review and Assessment Service (HIRA) are entrusted by the government to operate the system.	Medicines Pricing Branch, Pharmacy Practice and Development Division, Pharmaceutical Services Programme, Ministry of Health (The unit handling Blue Book listing is the Formulary Management Branch. Both branches report to the Pharmacy Practice and Development Division)	N/A	Price of medicines in Private sector is subject to market competition. At public hospitals, prices are indirectly controlled by a tender system operated by the Group Procurement Office (GPO). Since 2015, Cost-effectiveness assessments recommendations for some specific innovations have led to price capping at public sector.	NHI reimbursement covers both Western and traditional Chinese medicines. The amounts are determined by the NHIA's Expert Committee and PBRS (Pharmaceutical Benefit and Reimbursement Scheme) Joint Committees, which oversees listing, pricing recommendations and coverage restrictions.	The Sub-Committee for the Development of the Median price under the National Drug System Development Committee/NDSDC establishes a maximum procurement price for both NLED and non-NLED.	Ministry of Health shall review dossiers declaring, redeclaring prices of foreign drugs imported to Vietnam, dossiers declaring prices of domestically produced drugs, dossiers requesting supplementation, modification of information of drugs of which the prices have been declared, redeclared. The Minister of Health shall set up an Intersectoral committee on drug price comprising of representatives from Ministry of Health, Ministry of Finance, Vietnam Social Security and relevant agencies, units to provide advice to the Minister on the review of declared, redeclared drug prices in the following cases: a) The drug declared has a concentration, strength different from the drugs' that have been publicized on Ministry of Health's web portal; b) Drugs that come in a dosage form different from the drugs' that have been publicized on Ministry of Health's web portal; c) New drugs; d) Drugs that are on the List of drugs subject to price negotiation, brand name drugs, drugs manufactured on EU-GMP or PIC/S-GMP conforming manufacturing lines of an ICH member country of Australia or drugs manufactured on Vietnam MOH-certified WHO-GMP conforming manufacturing lines and that are licensed for marketing in an ICH member country or Australia by the national competent authority, that have their redeclared price increased by the following rate: - More than 10% for the drugs that have the price of the smallest package unit ranging from above 5.000 (five thousand) đồng to 100.000 (one hundred thousand) đồng. - More than 7% for the drugs that have the price of the smallest package unit ranging from above 100.000 (one hundred thousand) đồng to 1.000.000 (one million) đồng. - More than 5% for the drugs that have the price of the smallest package unit ranging from above 1.000.000 (one million) đồng.

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Insurance & drug pricing system/Public healthcare system	Overview of pharmaceutical reimbursement	Pricing process	N/A	N/A	Essential Medicines: Branded generics: cost base pricing method which is used more for regulating prices in India uses cost components like cost of API, cost of excipients, cost of duties applicable, cost of labour and overheads, and cost packaging material and then on this price the margins/profits are added. The retail prices of formulations are worked out as per the formula given in para 7 of DPCO, 1995 viz. “R.P. = [M.C.+C.C.+P.M.+P.C.] × [1+MAPE/100] + E.D.” Where, RP: Retail price stands for - RP, MC: Material cost, CC: Conversion cost, PM: Packaging material cost, PC: Packaging charges, MAPE: Maximum allowable post-manufacturing expenses, and ED: Excise duty stands for ED Transfer pricing mechanism method: used mainly by MNC’	See above drug procurement system	•Regarding new drugs, after the regulatory approval, upon receiving the application for listing in the NHI price list by business operators, an Organisation calculating drug prices shall formulate a draft of the calculation and report it to the Chuikyo. Upon receiving the report from the Chuikyo, the Minister of Health, Labour and Welfare shall, in principle, register the drug in the NHI price list within 60 days after the regulatory approval. •For existing listed drugs, their actual sales price to medical institutions and pharmacies shall be investigated and their list prices shall be repriced periodically based on the results.	After market approval, a pharmaceutical company submits an application for a new drug or new molecular entity to HIRA, HIRA performs an economic evaluation and assesses the appropriateness of benefit inclusion of the drug. Upon HIRA's assessment results, the NHIS negotiates with the pharmaceutical company on pricing. Finally, the Ministry of Health and Welfare publishes the final price to the public after review by the NHI policy deliberative committee within the Ministry.	Medicines Pricing Branch develop medicine price database based on information obtained from every level in the medicine distribution chain, as reference in the negotiation process and monitoring of medicine prices.	N/A	The list of drugs approved under the SDL or MAF is reviewed annually by the MoH to take account of changes in clinical practice, the evolving needs of patients and advances in medical science. In May 2017, some reforms were introduced to the drug evaluation and decision-making process for subsidy listing, with Singapore’s national HTA agency, Agency for Care Effectiveness (ACE), taking on a pivotal role in the SDL or MAF listing procedure. Through its evaluations and recommendations, ACE aims to guide public healthcare institutions, doctors and patients on making evidence-based decision on choosing clinically effective and cost-effective healthcare treatments, in addition to driving government’s subsidy decisions on health technologies – including the MoH’s decision on SDL/MAF listing. ACE has officially replaced the supporting role of the PEDU to the MoH DAC in assessing and deciding whether a drug should be subsidized by the MoH. The MoH continues to expand subsidies for vaccinations as part of the government’s public health agenda. In April 2019, the human papilloma virus (HPV) vaccine was extended to subsidy listing for girls in secondary school. The MoH also announced in July 2019 that, from 2020, adult patients will receive subsidies for vaccines recommended under the National Adult Immunization Schedule. The list of recommendations will be published by the end of 2019, with affected vaccines expected to be made available at polyclinics and CHAS clinics. This decision reflects the persistently low uptake rate for certain vaccines as well as the government’s aim to reduce the incidence of preventable diseases. [IQVIA]	Following a drug’s marketing approval by the TFDA, a drug maker has to submit a subsequent application to the NHIA for further evaluation, review and pricing by the appropriate committees. Reimbursement submission will be accepted for NDA approved drugs and will have HTA assessment by CDE (Center for Drug Evaluation) and reviewed by Expert Committee and need to accept by PBRS (Pharmaceutical Benefit and Reimbursement Scheme). The PBRS meeting is conducted once a month with drugs and medical devices alternating as the subject focus. The purpose of the meeting is to reach a resolution on drug listing and pricing for the NHI, which is based on a Health Technology Assessment (HTA) analysis report and other data provided by applicant manufacturers.	Medicines are categorized as “price-controlled products” under the Ministry of Commerce (Price and Service Act) although the agency permits operation of market mechanism (no enforcement of fixed pricing system). Free pricing for the new drugs launched is permitted. Threat is from median price setting for public procurement which has potential impact on the industry from the gap between “median price for public hospitals” and “market price for private hospitals”. On May 30, the Ministry of Commerce began to take measures to regulate drug prices following reports that some private hospitals overcharge patients for drugs. Suppliers have been instructed to submit the purchase and sale prices of over 3,800 items used under the Universal Coverage for Emergency Patients (UCEP) program to the Department of Internal Trade (DIT). They are also required to inform the DIT of potential price increase 15 days prior.	Importers, manufacturers shall declare intended wholesale price, intended retail price of a drug (where there is a need to declare the retail price) prior to placing the first lot of the drug it imported on Vietnam market. After market approval, if drug is eligible for reimbursement by national health insurance, it will follow the relevant tender/procurement process.

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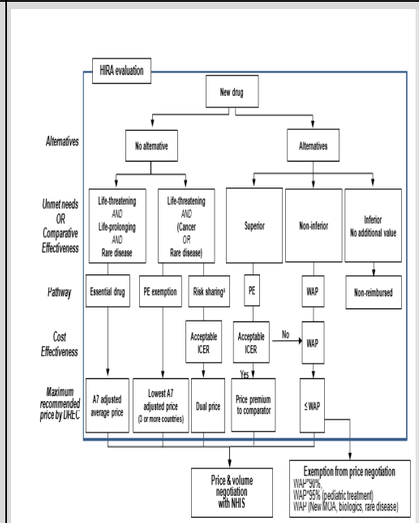
Insurance & drug pricing system/Public healthcare system	Overview of pharmaceutical reimbursement	Pricing rules/methods	No government pricing requirement for most of the drugs in market, except for certain kind of drugs, i.e. toxic and narcotic drugs.	Pricing rules are not applicable. Tendering system.	N/A	Same as above Note: the setting of HPS is non-transparent resulting in prices in some cases so low that no providers are willing to offer. The government realized this and will amend the situation in the coming tender process in 2020.	The price of new drugs shall, in principle, be calculated by the comparable pricing method. (Among drugs already listed in the NHI drug price list, a most similar to a new drug in terms of indications, pharmacological action, composition/chemical structural formula, dosage form, formulation category, and formulation/dose regimen, is selected as a comparator drug and calculated by comparing the daily drug price. Furthermore, based on clinical data, premiums are added based on its level of innovation, usefulness, marketability, etc. If there are already 3 or more similar drugs, it is deemed as a new drug with limited novelty, and the drug price is calculated at a low level based on the rules. Drugs already marketed overseas are further adjusted according to the foreign average price adjustment rule.) *For already-listed drugs, the actual sales price to medical institutions and pharmacies is investigated, and a new price is calculated by adding consumption tax and a certain percentage of the current drug price to the weighted average of transaction price by brand.	 Figure 1. Evaluation scheme of new drug New medicines can select the listing pathway according to characteristics such as the clinical usefulness, comparator, severity, type of diseases etc. (Figure 1. Evaluation scheme of new drug) In the first year of generic drug entrance after patent expiration, original drug price will set at 70% of original price, and subsequently lowered to 53.55%. Price of generic drug is set at 59.5% of the original drug price in the first year, and subsequently lowered to 53.55%. The President of HIRA reports the assessment result to the Ministry of Health and Welfare. Then, the Minister determines whether the medicines are covered or uncovered along with the upper limit amount, and makes the results public, after review by the NHI policy deliberative committee.	Medicines Pricing Branch will do for pricing rule management ·Monitor and control activities related to medicine pricing. ·Develop policies, guidelines and Standard Operating Procedure (SOP) related to monitoring and control of medicine pricing and drug tariff development. ·Dissemination of information related to medicine prices to consumers and staff in Ministry of Health. -Provide recommended retail price (RRP) reported by wholesaler to be used as a reference price in purchasing by the consumer Provide list of medicine prices for labelling of medicines supplied to outpatients in MOH facilities.	N/A	Group Procurement Office negotiates a bulk procurement price through a centralized tender system for public sector procurement. However, some medicines can be purchased by regional clusters and individual hospitals. At private sector, hospitals can negotiate price directly with manufacturers based on market competition.	"National Health Insurance drug payment program and payment standard" The NHIA regulates drug pricing and reimbursement in Taiwan. When setting reimbursement prices, it references the prices of a basket of ten benchmark countries (A10), including Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, the UK and the US. The reference prices for these A10 benchmark countries are based on information published by their respective national health authorities, and typically include any combination of the manufacturers' cost, wholesale price, pharmacy mark-up, VAT, and the prescription price. Category 1 drugs are priced at the median of the ten reference countries, while the drug prices for Category 2 are determined by any one of five major methods. Under both drug categories, additional reimbursements may be granted for drugs if certain R&D-related conditions are met. *Category 1 (breakthrough innovative product, with a substantial improvement of therapeutic value over comparators), Category 2A (new drug demonstrating moderate improvement over best comparator), or 2B (new drug similar to best comparator).	Free pricing during launch with threats of median price setting as mentioned. NDSDC approved five criteria for median price setting including: cost-plus, profit ceiling, comparative pricing, price negotiation and pharmaco-economic evaluation. Currently, comparative pricing and price negotiations are adopted but with unclear, inconsistent and less meaningful negotiation process focusing on "cost-containment".	The review of drug prices as declared, redeclared by pharmaceutical business establishments shall be performed following the principles of: a) Not higher than the selling price of the drug in Asean countries; b) The accuracy of factors forming the product's selling price that are declared by the importer, the manufacturer or the establishment placing contract manufacturing orders of the drug; c) The appropriateness of the price in relation to the movement of price forming factors of the product such as raw materials, fuel, exchange rate, labor cost and other relevant costs in the case of price upward adjustment.

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Insurance & drug pricing system/Public healthcare system	Pharmaceutical reimbursement	HTA introduction	National Health Commission issued the “Notice on the Implementation of Drug Use Monitoring and Comprehensive Clinical Assessment” on April 9, 2019. National Center for Health Development Studies led the program of National Medicine Comprehensive Evaluation that incorporate HTA methodology with MCDA approach	HTA is optional in the enlistment system of public sector.	The Indian government has made a commitment to achieve Universal Health Coverage (UHC). These ongoing developments require a systematic process for generating policy-relevant evidence that can inform policy decisions regarding health resource allocation, i.e. clinical effectiveness studies, cost-effectiveness studies, budget impact studies, as well as ethical, social and political feasibility studies. This systematic and comprehensive process falls under the broad umbrella of health technology assessment (HTA) The Government of India’s Department of Health Research (DHR), part of the Ministry of Health and Family Welfare (MoHFW), is currently in the process of establishing a medical technology assessment board (MTAB), which will be the central agency for undertaking HTA in India. https://link.springer.com/content/pdf/10.1007%2Fs41669-017-0037-0.pdf	HTA in Indonesia is still in the early phase of development and needs more accountability and transparency in rolling out HTA process, from topic identification up to monitoring the recommendations Conducting HTA process in transparent and systematic manners needs to include economic evaluation for benefit packages which are “worth spent” and “affordable” using Cost Utility Analysis (CUA) model. Source : Presentation of Prof. Sudigdo Sastroasmoro, Pediatric Cardiology, a member of Indonesia Doctor Council & Pediatrician Council & Dr. Mardiati Nadjib, lecturer in University of Indonesia, Public Health Faculty	Full-scale implementation began in April 2019. The mechanism targets drugs and medical devices with large markets, but excludes items used for the treatment of rare disease with insufficient treatment methods (designated intractable diseases, etc.) and items used only for children. The results of the analysis will not be used to determine the feasibility of insurance reimbursement, but will be used to make price adjustments after listing on the NHI price list. Going forward, in addition to enhancing the cost-effectiveness analysis system, cases will be accumulated and the state and use of the system will be considered.	HTA guidelines completed in 2006. Started with introduction of positive list system in 2007 In South Korea, time to insurance reimbursement awarded for new drugs has prolonged with the introduction of HTA. Moreover, a shortage of human resources that can perform economic evaluations exists as a problem point. The results of evaluation, such as whether or not reimbursement is possible, the clinical efficacy, cost effectiveness, and the impact on insurance finances etc.	Introduced starting in August 1995. The main functions of the HTA section include conducting the Health Technology Assessment (HTA) and expedited Technology Review (TR), as well as preparing Clinical Practice Guidelines (CPG). * However, at the present time (August 2014), HTA assessment is not mandatory, either under the regulations or for inclusion in the MOH formulary, and there are no clear guidelines on the implementation of HTA assessments or the timeline for them.	The passage of the UHC Act allows the institutionalization of health technology assessment. Under the law: ·Creation of an HTA Council, supported by a secretariat and evidence generation unit ·Council will have 6 sub-committees: drugs, vaccines, clinical equipment and devices, medical and surgical procedures, preventive and promotive interventions, and traditional medicines Currently, the council is preparing its guidelines (process, methods)	In August 2015, Agency for Care Effectiveness (ACE) was established within MoH, with the aim to support national clinical policy decision-making through evidence-based assessment and produce national guidance on appropriate care. ACE evaluates the clinical efficacy and safety of the drug concerned in comparison to its main comparators, which are defined as either the treatment that is most likely to be replaced by the new drug or, in case of add-on treatments, the current treatment without the add-on product. The agency published its Drug Evaluation Methods and Process Guide in February 2018, which is intended to provide the industry with an overview of its methodology and increase the transparency of its processes and decision-making frameworks. For drugs deemed to offer equivalent, non-inferior clinical benefits relative to comparators, a cost minimization analysis (CMA) is conducted. If the drug is deemed to offer clinically superior efficacy over comparators, a cost-effectiveness analysis (CEA) is conducted. [ACE official website: http://www.ace-hta.gov.sg/our-process-and-methods.html]	The current reimbursement review process includes a comprehensive evaluation by Taiwan’s Center of Drug Evaluation (CDE) of the therapeutic and pharma-economic aspects of a new drug using a HTA. This evaluates the efficacy and/or effectiveness as well as the comparative safety of a new drug. Other aspects assessed include budget impact as well as related ethical, social and political issues. The HTA process involves several government agencies to collect evidence and finalise the assessment report. The categorisation of the drug is also determined during this stage, being included in either Category 1 (breakthrough innovative product, with a substantial improvement of therapeutic value over comparators), Category 2A (new drug demonstrating moderate improvement over best comparator), or 2B (new drug similar to best comparator). A HTA assessment report is completed and submitted to the NHIA within 42 days, and it provides the basis for the listing and pricing recommendations during the drug benefit expert meeting.	A health technology assessment agency under the MoPH, the Health Intervention Technology Assessment Program (HITAP), is primarily responsible for conducting economic evaluation of some drugs, especially high cost products. Its major mission is to efficiently and transparently assess and appraise health interventions and technologies. It does its assessment in several steps. For instance, every year HITAP asks various stakeholders – health-care providers, academics, hospital purchasers, payers, and patient advocacy groups – across the country for potential drugs that should be evaluated. The NLEM committee can also ask HITAP to assess certain products to help with its decisions. HITAP has its own experts to conduct pharmacoeconomic evaluations. It has developed not only national guidelines for economic evaluation but has also incorporated the World Health Organization guideline that average GNI per capita be considered as a cost-effective threshold. Recently, this threshold based on GNI per capita is set at Bt 160,000 per Quality Adjusted Life Year (QALY). HITAP assessments have sometimes been used to successfully negotiate drug prices with manufacturers before the drugs are listed on the NLEM.	HTA will be used as a primary tool to better shape the reimbursement list in the future

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<tr><th rowspan="2">Category</th><th rowspan="2">Item</th><th rowspan="2">Types</th><th>China</th><th>Hong Kong</th><th>India</th><th>Indonesia</th><th>Japan</th><th>Korea</th><th>Malaysia</th><th>Philippines</th><th>Singapore</th><th>Taiwan</th><th>Thailand</th><th>Vietnam</th></tr>
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<tr><td>Insurance & drug pricing system/Public healthcare system</td><td>Pharmaceutical reimbursement</td><td>Others</td><td></td><td></td><td>Different healthcare providers/ Hospitals have their own methods for procurement of Medicines
State governments: Have established independent Medical Corporations to oversee procurement of Medicines, these corporations decide type of drugs to be included in state formulary of medicines & estimate requirement based on consumption of these medications eg: Tamilnadu State Medical Services corporation (TNMSC)
Central Government Health Scheme: Drugs included in CGHS formulary are purchased twice or thrice a year through a rate contract with drug manufacturer for bulk purchase of these medications twice or thrice in a year. Formularies are updated every year to include new medications if any to be added.
Hospital affiliated to Public Service Units (Railways) or trust Hospital: Go for tender process & negotiate the price of medicines with Organisations
Private Hospital: Private hospitals have their own purchase departments & purchase medicines from authorized distributors of pharmaceutical companies based on demand of medications in individual hospitals Some corporate hospitals with more > 5 branches have started making centralized purchase of drugs
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3585974/</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
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Insurance & drug pricing system/Public healthcare system	Other	Procurement of medicines (Tendering/bidding)	Provincial centralized procurement internet bidding systems were set up in the past years. National Healthcare Security Administration now as the new authority for medical procurement will further regulate the process. A 4+7 cities volume-based procurement pilot was initiated in December 2018 and expanded to additional 25 provinces in Sep. 2019. 2nd batch volume-based procurement may initiate soon. Source：National Healthcare Security Administration	Process for adopting new drugs has been established at public hospitals, etc., based on Hospital Authority Drug Formulary scheme. Review criteria consist of superiority in treatment, evidence, adverse reactions, whether or not mentioned in international guidelines, and cost-effectiveness analysis It is tendering system. For patent drugs, using close tender and generics, using open tender.	Drug procurement is implemented under the Presidential Regulation No.157/2014 establishing government procurement regulatory body (LKPP) which manages government goods/service more efficient, effective and transparent. In the drug procurement process, E-catalog system has been one of the cores of the drug management system at government-owned healthcare facility which relates drug selection,procurement, distribution, and use processes. See also the above drug procurement process	Procurement of medicines (Tendering/bidding) In Japan, it is regulated that manufacturers cannot be involved in transactions of ethical drugs between wholesalers and medical institutions. Shifts in generic market share (only information without copyright that is available for disclosure is listed) / Generic market share and trends. Public information. New indicators: Quantity share: 72.1% (FY 2017) Old indicators: Quantity share: 47.4%, Monetary share: 17.5% (FY 2017) [Japan Health Insurance Association, Status of Drug Usage (September 2018)] New indicator: [Quantity of generic drugs] / ([Quantity of the original drugs that have a generic drug] + [Quantity of generic drugs]) Calculation method indicated in “Roadmap for Further Promotion of the Use of Generic Drugs” (Ministry of Health, Labour and Welfare, April 2013) Old indicator: [Quantity of generic drugs] / [Quantity of all ethical drugs] Calculation method used in "Action Program for Promoting the Safe Use of Generic Drugs” (Ministry of Health, Labour and Welfare, October 2007)	In the Korean drug distribution market, medicines are traded between wholesalers or pharmaceutical companies, medical institutions and pharmacies on a per-item basis, and transaction conditions are also generally set by item. In addition, in the case of OTC or national hospital bidding, it can be found the total price transaction, which is a contract for negotiating the total price of various products.		Inclusion in MOH Medicines Formulary (Blue Book) and bidding the MOH.	Similar to reimbursement policy, only medicines included in the formulary may be procured by government hospitals. DOH hospitals are able to benefit from centralized procurement, getting volume discounts. However, capacity building on forecasting and supply chain management is still necessary to maximize gains from pooled procurement. Medicines outside the formulary may still be procured by the government for its medicine programs, provided an explicit exemption is granted by the formulary executive council.	・ Singapore Health Services (SingHealth) Group Procurement Office handles drug procurement for public hospitals in Singapore. Two-thirds of hospital purchase in value and 90% of total volume in public sector are purchased through GPO. ・ Products that demonstrate good quality standard and supported by data are preferred at the tendering evaluation. [https://www.singhealth.com.sg/about-singhealth/procurement]	Differs from each hospital. Bidding by individual hospitals (1-year contract is common)	Prior to procurement, drug listing in both public and private hospital formularies are mandatory. There are 2 public procurement methods depending on the nature of the product: - Single-source medicines (sole supplier): specific method - Multi-source medicines: e-bidding with price performance consideration in accordance to the Public Procurement Act. Challenges are from the low median price set for both single-source and multi-source medicines. In addition, there are public procurement privileges for GPO produced medicines and generics listed in the Thai Innovation List limiting free and fair market competition.	There are two ways of conducting public drug procurement in Vietnam: (i) tenders by individual state-owned hospitals and (ii) centralized tenders. Tender packages: ·Innovative / Originator drugs that are subject to price negotiation as published by Ministry of Health ·Generics 1: EU-GMP or equivalent principles and standards in a country of the SRA list ·Generics 2: EU-GMP; or PIC/s GMP in ICH members ·Generics 3: assessed by Vietnam authority as conforming with GMP principles and standards & proven bioequivalence ·Generics 4: WHO-GMP ·Generics 5: remaining Validity of tendering time: ·Drugs subject to tendering by individual hospital: max 12 months ·Drugs subject to centralized tender: max 36 months

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Intellectual property rights/IP	Overview of Intellectual property right system	Patent law (Governing ministries)	December 2018, the Draft Amendment to the Patent Law was submitted to the 7th Session of the Thirteenth National People's Congress Standing Committee for deliberation. During January 4th to February 3rd, the draft was released on the official website of the National People's Congress of the PRC to solicit opinions from the public. The draft received 491 comments and opinions from 208 citizens, and also received 25 letters from companies, organizations and individuals. The main comments are: 1, increase patent protection for local appearance design; 2, better design the service invention system, not only reflects the role of service invention, but also avoid the adverse effect on the companies applying for patents and carrying out regular production and operation activities; 3, further improve and refine the Patent Term Extension System; 4, the responsibility of the parties concerned in the internet patent infringement cases, better combining the Electronic Commerce Law and Tort Liability Law; 5, complete the patent administrative protection system; 6, perfect the compensation system for patent infringement. The National Intellectual Property Administration seriously studied and considered the opinions brought by the public.	Patent Regulations (2010.2-) [2 types of patents] 1) Standard patents Patents granted by the Chinese Patent Office, European Patent Office (patents designating England in application), and British Patent Office) Term of patent: 20 years from application filing 2) Short-term patents Direct application to Hong Kong Patent Office (No novelty examination. Corresponds to Japanese utility model) Term of patent: 4 years from application filing Only a single 4-year extension is possible. [Intellectual Property Department/IPD]	The scenario largely remains unchanged in India. The Patents Act provides additional patentability criterion, further restricted by way of judicial precedent, requiring bio-pharmaceutical patents to prove "enhanced therapeutic efficacy" before it can be patented. Given that this is applicable to only one technology area, it conflicts with the non-discrimination principles provided by TRIPS Article 27 and WTO rules. This, coupled with Indiscriminate and mechanical use of Section 3(d) in patent applications by the IPOs, along with inconsistent interpretations of the terms 'efficacy', "enhanced therapeutic efficacy" and 'property' across the IPOs, have made patenting bio-pharmaceutical products extremely difficult in India.	The Patent Law has been revised with the Law No.03/2016 Term of patent: 20 years from application filing The term of a minor patent (simple patent) is 10 years Some contentious issues arising from this revision: Compulsory license by third party Local manufacturing of patented products (however, it might be possible to postpone this requirement) Second medical use patents are grounds for non-patentability Disclosure requirements regarding the source and origin of genetic resources	Patent Act (Law No. 121, 1959) Final revision: Law No. 70, 2018 (Promulgated on July 6, 2018) Effective date: July 6, 2018 Term of patent rights and initial date: 20 years from the filing date of the patent application, up to 5 years extension (Article 67 of the Patent Act) Patent Office	· Patent Act https://elaw.klri.re.kr/kor_service/lawView.do?hseq=47910&lang=ENG · Enforcement decree of the Patent Act https://elaw.klri.re.kr/kor_service/lawView.do?hseq=48755&lang=ENG · Term of Patent: 20 years from application filing · Term of Utility Model: 10 years from application filing · There is a system for extension of the patent term · Key Changes under Amended Patent Act (amended on January 8, 2019 and effective on July 9, 2019) (the "Amendment") - Treble damages for intentional or willful infringement/misappropriation Under the Amendment, Korean courts are now authorized to award punitive damages of up to three times the amount of actual damages for intentional or willful acts of infringement/misappropriation. The Korean courts will consider following factors in calculating the punitive damages: (i) whether the infringer has a dominant position; (ii) whether the infringer knew the act of infringement would cause harm to a patent owner, or intended such harm; (iii) the significance of any such damages; (iv) the economic benefits to the infringer from the infringement; (v) frequency and duration of the infringing activity; (vi) the criminal penalty for the infringing activity; (vii) the infringer's financial status; and (viii) what efforts the infringer has made to reduce the harm to the patent or trade secret owner. - "Reasonably expected" royalties as basis for damages calculation The previous Patent Act calculated royalty damages based on the royalty that would be "ordinarily expected" from an arm's-length license. However, the Amendment changes the standard from "ordinarily expected" to "reasonably expected," which allows courts to calculate a royalty that may be reasonable under the totality of the circumstances, regardless of whether similar royalties have actually been granted. - Accused patent infringer denying infringement must describe the actual product/process used The Amendment requires the accused infringer to provide details regarding the product or process actually used. If an accused infringer unjustifiably refuses to provide such details, the court may presume that the alleged infringer infringes the patent(s).	The Intellectual Property Corporation of Malaysia (MyIPO) is the office responsible for handling patents. IPO employs the first-to-file principle, wherein the date of application is the date on which it was received by the IPO. If satisfactory, the term of patent right is 20 years from the date of application. Currently, there is no system for extension of the patent term. The MyIPO is party to several international treaties, such as Patent Cooperation Treaty (PCT), Paris Treaty, Budapest Treaty, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).	The Intellectual Property Office (IPO) is the office responsible for handling patents. IPO employs the first-to-file principle, wherein the date of application is the date on which it was received by the IPO. If satisfactory, the term of patent right is 20 years from the date of application. Currently, there is no system for extension of the patent term. The Philippines is party to several international treaties, such as Patent Cooperation Treaty (PCT), Paris Treaty, Budapest Treaty, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).	· Amended patent law (2014.2) [2 review routes] 1) Positive Grant System: (Positive) documents for the results of review by patent offices of Japan, UK, the US, Canada, Australia, New Zealand, and South Korea are submitted to the Intellectual Property Rights Office and undergo supplementary examination in their own country. 2) Substantive Examination · "Self-evaluation" system in patent review was changed to "Positive Grant System", Patent Agent system was partially liberalized, and in pharmaceutical laws and ordinances related were amended. ·Amendment to Patents Act and Rules (2017.10) Key features of the amendments include: 1) Broadening of Grace Period. Applicants have the opportunity to obtain patent protection for their invention notwithstanding that it has been disclosed prior to the filing of the patent application. 2) Changes to Supplementary Examination. The supplementary examination route will not be available for patent applications filed on or after 1 January 2020. 3) Amendments to the Guidelines on Isolated Products from Nature. 4) Updates to the Guidelines on Assessment of Patent Post-Grant Amendments. https://www.ipos.gov.sg/docs/default-source/resources-library/patents/circulars/（2017）-circular-no-7---amendment-to-patents-act-and-rules-to-enter-into-force-on-30-october-2017.pdf [Systems for granting of technical, industrial, and intellectual property rights by JETRO Singapore] https://www.jetro.go.jp/ext_images/world/asia/sg/ip/pdf/semianr20140117_1.pdf · Term of patent: 20 years from application filing · Extension of patent term: Maximum of 5 years However, because extensions were permitted when the new drug review period exceeded 2 years, extensions are hardly ever permitted. [Singapore Patent Law Articles 36 and 36A] [Manual Industrial property XI, AIPPI Japan] [Ministry of Law, Intellectual Property Office of Singapore/IPOS] Japan Patent Office HP, "List of Laws and Regulations", http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/mokuji_e.htm, · After the Patent Law was amended, a system for positive examination of novelty and inventive step by examiners was introduced. Before the revision, patents had been registered if the applicant "requested registration", even if the examiner had given notice of opinions on novelty and inventive step. However, after the amendment, patents were not registered unless all notices of reasons for rejection issued by the examiner were resolved. [Patents (Amendment) Act 2012, 29A, Intellectual Property Management, Vol.66, No.8, 2016]	Taiwan has 3 kinds of intellectual property rights: patents, utility models, and designs. Status of new applications in first half of 2016 With the passage of the Pharmaceutical Affairs Act Amendment Bill on August 4, 2016, protection periods of 5 years and 3 years, respectively, were granted for exclusive rights over data for new drugs with new ingredients and new application of old drugs. When clinical studies are conducted in Taiwan, exclusive protection over data for new applications can be extended to 5 years. Patent Linkage for NCE drugs, patent information shall be disclosed in the system established by TFDA within 45 days after obtaining a drug license. At the same time that they apply to the Ministry of Health and Welfare for a drug license, makers of generic drugs need to make a declaration to the Ministry of Health and Welfare for the generic drug, on whether or not there are related patents, whether the patent rights have already lapsed, and that the patent owner's patent has not been violated, etc., and the Ministry of Health and Welfare will not accept the application until these qualifications have been met. When a party applies for approval review of a nonproprietary drug (generic drug) and asserts that the patent rights to the originator drug (new drug) are not violated or that the patent to the originator drug is invalid, the patent owner of the originator drug can file an infringement suit during the approval review proceedings for the generic drug. It is clearly stipulated that if the patent owner for the originator drug does not file an infringement suit, the applicant for approval review of the generic drug can file an action for declaratory judgment of whether or not it is violated. (Amended text, Article 60-1)	The 1979 Patent Act was amended by the 1999 Patent Act No. 3 (effective September 27, 1999) Duration and base date of patent rights: 20 years from date of application (Patent Act, Article 35) Ministry of Commerce /Department of Intellectual Property (DIP) [Patent Office "Overview of information on industrial property right offices or agencies and industrial property right systems in each country or region", updated on 2016.8.31] The last amendment enacted to the Patent Act was in 1999, however there are current amendments to the Patent Act pending at the State Council which may be ratified in 2019.	Patents are regulated by: Law on Intellectual Property 50/2005/QH11 Law 36/2009/QH-22 Amending, Supplementing a number of articles of Law on Intellectual Property Decree 103/2006/ND-CP detailing and guiding the implementation of a number of articles of Law on Intellectual Property regarding Industrial Property Circular 1/2007/TT-BKHCN guiding the implementation of Decree 103/2006/ND-CP Governing bodies: Ministry of Science Technology, National Office of Intellectual Property Ministry of Health Registered drugs containing active ingredients still within the period of IP protection can be protected by patent.

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Intellectual property rights/IP	Overview of Intellectual property right system	Trademark law	The amendment on the Trademark Law of the People's Republic of China was adopted on the 10th Session of the Standing Committee of the Thirteenth National People's Congress on 23 April 2019, the date of entry into force of the amendment is November 1st, 2019. Trademark Law: http://gkml.samr.gov.cn/nsjg/tssps/201903/t20190311_291862.html English Reference: http://english.mofcom.gov.cn/article/counselorsreport/asiareport/201904/20190402849943.shtml	Trademark law/eclecticism Term: 10 years from application (renewal possible)	· The Trademarks Act [Trademarks Act, effective September 15, 2003; Patent Office website] [Trademark Rules, effective September 15, 2003; Patent Office website] · On November 19, 2015, the India Department of Industrial Policy & Promotion (DIPP) publicly announced amendment of the trademark rules on its website, and public comment began. The amendment incorporated improved execution of expedited examination, including early processing of objections, increase of the fee, definition of well-known trademarks, application procedures for sound trademarks, and changes in the various forms, etc. [JETRO New Delhi, 201512]	Trademark Law: first-to-file principle Term: 10 years from application (renewal possible) An affidavit of use must be submitted for renewal procedures.	Trademark Act (Law No. 127, 1959) Final revision: Law No. 88, 2018 (Promulgated on Dec. 7, 2018) Effective date: Dec. 7, 2018 Term of trademark rights: 10 years from the date of registration. It can be further updated every 10 years (Article 19 of the Trademark Act). Patent Office	· Trademark Act https://elaw.klri.re.kr/kor_service/lawView.do?hseq=42777&lang=ENG · Enforcement decree of the Trademark Act https://elaw.klri.re.kr/kor_service/lawView.do?hseq=39314&lang=ENG · In Korea, a trademark right generally arises upon registration. Further, the Korean Trademark Act uses a “first-to-file” system instead of a “first-to-use” system. Actual use of a mark is neither a necessary condition for obtaining a trademark registration, nor does it provide any priority or advantage for registration in most cases. · Trademark owners are exclusively entitled to use a registered mark in connection with its designated goods/services. The term of protection for a trademark is 10 years from the registration date, and may be renewed indefinitely as long as the prescribed fees are paid. · A trademark that has not been used for three consecutive years is vulnerable to cancellation for non-use. Any party may bring a non-use cancellation action, and the burden of proof lies with the registrant of the mark. · A legitimate owner of a famous mark in a foreign country can bring an action against an alleged infringer i.e., owner of an imitation trademark in Korea. Notwithstanding whether the famous mark was only famous outside of Korea, the litigate owner of the famous mark can base its arguments on the fame of its mark outside of Korea at the time when the alleged infringer filed for registration of its imitation mark and the alleged infringer's bad faith intent.	Trademarks Bill 2019 (Bill) which was passed on 2 July 2019 will facilitate Malaysia's accession to the Madrid Protocol Under Ministry of Domestic Trade and Consumer Affairs. Trademark Law/principle of (compromised) prior use Duration: 10 years from application (renewable)	Similar to patents, IPO employs first to file principle for trademarks. Term granted is ten years, but there is no limit on the renewal (may be renewed continuously. Trademarks may require checking with the FDA to ensure compliance with existing brand names and labeling rules.	Term: 10 years from application filing (renewal possible every 10 years). Can be renewed for 10 years without limit. [https://www.ipos.gov.sg/understanding-innovation-ip/trade-mark]	Taiwanese trademark law (new Trademark Act): amended November 30, 2016	Enforced June 30, 2000 (1991 Trademark Law amended by 2000 Law No. 2) General principle of rights conferral: first-to-file principle Duration and base date of trademark rights: 10 years from date of application (Registered trademark is considered to be that registered on the date of application). In addition, it can be renewed every 10 years (Trademark Act, Article 53; Trademark Law, Article 42) [Patent Office “Overview of information on industrial property right offices or agencies and industrial property right systems in each country or region”, updated on 2016.8.31] The most recent version of the Trademark Act is from amendments that were enacted in 2016. The 2016 amendments include provisions to file multi-class applications, to file sound marks, and shorten the time period in responding to office actions and oppositions. The 2016 amendments also codified Thailand’s obligations under the Madrid Protocol.	Trademarks are regulated by: Law on Intellectual Property 50/2005/QH11 Law 36/2009/QH-22 Amending, Supplementing a number of articles of Law on Intellectual Property Decree 103/2006/ND-CP detailing and guiding the implementation of a number of articles of Law on Intellectual Property regarding Industrial Property Circular 1/2007/TT-BKHCN guiding the implementation of Decree 103/2006/ND-CP Term: 10 years after the registration Legal protection: Starts from date of registration

Category	Item	Types	China RDPAC/PhIRDA	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KPBMA/KRPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA	Vietnam PG
Intellectual property rights/IP	Overview of Intellectual property right system	Patent linkage	On November 24th, the General Offices of the Communist Party of China (CPC) Central Committee and the State Council have jointly issued “The Guideline on Strengthening Intellectual Property Rights Protection” (The Guideline), explicit to constantly improving the intellectual property rights (IPR) protection system, and use legal, administrative, economic, technological and social governance means to strengthen the IPR protection, promote the overall improvement of the protection ability and level. The Guideline has 2 main highlights: Highlight 1: The Guideline emphasized that, we must perfect the protection system in new form and new areas of industry. Exploring the establishment of drug patent linkage system and the drug patent term compensation system. The system is a great action to deepen the reform of the drug intellectual property system, indicates China’s strong determination to improve the intellectual protection on innovative drugs and to promote the innovative development of the pharmaceutical industry. In 2017, the General Offices of the Communist Party of China (CPC) Central Committee and the State Council have jointly issued Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Pharmaceutical and Medical Devices, it showed clearly that: Exploring the establishment of drug patent linkage system. In order to protect the legitimate rights and interests of the patent holder, reduce the risk of generic drug patent infringement and encourage the development of generic drugs, the drug review and approval and drug patent linkage system should be established. When an applicant applies for drug registration, the applicant should indicate the involved patent and its ownership status and notify the relevant pharmaceutical patent holder within the prescribed time limit. If there is any dispute over the patent right, the party concerned may file a lawsuit with the court, during which the technical review of the drug will not be suspended. For the drugs passing the technical review, the food and drug administration should make a decision if they are approved for marketing according to the court judgment, ruling or mediation; if the court judgment, ruling or mediation is not obtained over a certain period, the food and drug administration can give the approval. Carrying out the pilot project of drug patent term compensation system. Some new drugs should be selected for trial, and appropriate patent period compensation should be granted for the delay of marketing due to clinical trials and review approval. Present Situation of China Under the provision of article 18 of China’s existing Drug Registration Administration Regulation, for drugs with other patent owners in China, drugs marketing license holder shall submit a declaration that it does not constitute infringement to others’ patent. Where a patent dispute occurs, it shall be settled in accordance with the patent-related laws and regulations. In practice, when a dispute arises between brand name drug patentee and generic drug company, the generic drug approval procedure will be suspended until the patent period is expired. It may result in unfairness for generic drug companies. The Guideline on Strengthening Intellectual Property Rights Protection (2019) http://www.gov.cn/zhengce/2019-11/24/content_5455070.htm Related News: http://www.adamerck.net/news_xq/id-376.html Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Pharmaceutical and Medical Devices (2017) :http://en.china-hnftz.gov.cn/zwgk_details-697.html	Generics proven to infringing patent rights could be delisted the drug registration by the application of patent owner.	There is a lack of transparency and co-ordination between the Indian Patent Office and Indian Drug Regulatory Authorities, which leads to issuance of manufacturing licenses to companies during the term of a patent. There is a pressing need to establish a notification system, whereby patent holders are made aware of applications made for manufacturing licenses, so that appropriate action may be initiated.	None Only the holder of patent rights can submit an application for a drug including active ingredients that are patent protected, and the applicant must submit a patent certificate at the time of application.	PMDA shall not approve generic drugs if the active ingredient cannot be manufactured due to the existing patent for the active ingredient of the original drug. Note: In essence, only product and use patents are applicable (PFSB/ELD Notification No. 0605014 dated June 5, 2009)	As part of the Korea-US Free Trade Agreement, a patent-regulatory approval linkage system was introduced in Korea. Since March 2015, the patent-approval linkage system has been fully implemented, and has four major features: (i) original drug companies are allowed to list patents related to their products on the "Green List" (a public compendium of listed patents); (ii) generic companies are required to notify the patentee of their generic approval applications within 20 days if they do not intend to respect the listed patent(s); (iii) listed patentees may, within 45 days of receiving a generic notice, request a stay of generic sales if it first files a patent infringement or scope confirmation action against the generic or responds to a scope confirmation action filed by the generic (the sales stay term is 9 months from the generic notice receipt date); and (iv) generic companies that are successful in their patent challenges will qualify for marketing exclusivity for a certain period, meaning sales of the same generic product by other non-qualifying companies is prohibited during that period (the generic exclusivity period is 9 months from the latter of when the exclusive generic is approved or any other unchallenged listed patent expires).	N/A	The Philippines should reinstate patent linkage as a mechanism to allow patent holders to resolve patent disputes prior to the marketing of follow-on pharmaceutical products. An agreement must be made between the Intellectual Property Office of the Philippines (IPOPHL) and the FDA recognizing that a certificate of product registration for a generic medicine will not be issued by FDA unless the applicant can present a certification from IPOPHL confirming the patent covering a particular product has expired. Such coordinating mechanism existed in 2005 but has since been removed. Note, however, that local pharmaceutical companies are opposing patent linkage because it is being viewed as “anti-access”.	・ A patent linkage system was introduced by the US Free Trade Agreement (FTA) that took effect in January 2004. a. If a third party applies for marketing approval during the term of patent right declared in advance as a pharmaceutical or application patent for a new drug, the source will be made known to the patent owner. b. During the patent term, measures to prevent marketing approval for third parties are taken in marketing approval procedures for drugs, except when the consent or implicit permission of the owner of the patent for a new drug has been obtained. [Patent 2013, Vol. 66, No.10, 78-88] [JETRO website material, “JETRO Global Trade Investment Report” 2016 edition]	Patent Linkage was legislated in Pharmaceutical Affairs Act on Dec 2017. Patent Linkage implementation regulation which including both Chemical as well as Biologics has been announced on Jul 1, 2019 and took effect on Aug 20, 2019. If lawsuit filed, TFDA approval for generic application is stayed for 12 months. 12-month period of marketing exclusivity for the first generic applicant for market approval by successfully invalidating the relevant drug patent.	There is currently no patent linkage between the Thai FDA and the Department of Intellectual Property	DAV supports patentees by allowing them to supply granted patent information as an internal reference source for the MA granting process. However, in practice, some MAs are still granted for patent-infringing drugs. At present, there is no strong or efficient route to have a marketing authorization blocked or withdrawn in the event of patent infringement. Even when the Drug Administration of Vietnam is notified about a drug’s potential infringement, an MA for the drug in question may still be approved. An MA may only be ordered withdrawn after a lengthy administrative or civil suit for patent infringement. In this regard, there needs to be stronger coordination among the IP enforcement and health agencies.

Category	Item	Types	China	Hong Kong	India	Indonesia	Japan	Korea	Malaysia	Philippines	Singapore	Taiwan	Thailand	Vietnam
			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Intellectual property rights/IP	Overview of Intellectual property right system	Regulatory data protection	In April 2018 State Council indicated will consider maximum 6 years data exclusivity (DE) for newly approved innovative drugs to enforce IP protection. Source: Provisional Implementation Rules for Drug Data Protection (draft for comment) issued by National Medical Products Administration Innovative drugs approved for marketing in China shall be given a 6-year data protection period, and innovative therapeutic biological products shall be given a 12-year data protection period. For the drugs or biopharmaceuticals for therapeutic use that use the clinical trial data carried out in China, or the international multi-center clinical trial conducted in China to apply for marketing in China or in other countries/regions, 6-year or 12-year data protection period will be given after approval. If the application with international multi-center clinical trial data in China is applied later than in other countries, the data protection period will be given for 1 to 5 years depending on the situation, but the data protection period will not be given for the situation where the application is applied more than 6 years later. For the application that use the data from oversea but no clinical trial data collected from Chinese patients, protection period will be 1/4 of the time given by the above calculation method. After supplementing the clinical trial data of Chinese patients, protection period will be 1/2 of the time given by the above calculation method. For rare diseases therapeutic drugs or pediatric drugs, a 6-year data protection period is given from the date the indication is approved in China for the first time. The various protection periods granted for the same drug are calculated separately from the date of approval according to the corresponding drug registration application. During the protection period, without the consent of the data protection right holder, the National Medical Products Administration may not approve other applicants for the same type of drug marketing application, except that the applicant relies on the clinical trial data obtained by itself or the applicant who has obtained the marketing approval. https://www.cn-healthcare.com/article/20180427/content-502792.html	8 years (from 2012 onward)	India does not recognize RDP, which consequently allows for approvals for subsequent drug applications to be made relying on regulatory dossiers submitted by the original applicant in other well-regulated jurisdictions. Thus, even though the original applicant's products are patent protected, subsequent applicants are able to obtain marketing authorizations using the original applicant's regulatory data. This becomes even more of a public health issue when such data is used for approval of biologics, which differ from small molecules	N/A	As applications for generic drugs cannot be filed during the reexamination period (a post market surveillance period to confirm the efficacy and safety after marketing), the reexamination period substantially functions as a data protection period. New active ingredient: 8 years Additional indication: 4 years Rare Disease: 10 years Rare diseases and pediatric indications may extend the original reexamination period up to 10 years. (Article 14-4 of the PMD Act; PFSB Notification No. 0401001 dated April 1, 2007)	Korea does not provide for "data exclusivity" per se, but de facto data exclusivity is provided through the "re-examination" (or "post marketing surveillance") system. Under this system, during the re-examination period, any generic applicant must demonstrate the efficacy and safety of its drug by submitting data that is (a) independently generated (unless the original approval holder has given permission to use its data); and (b) equivalent to or exceeds the scope of the original approval holder's data. Because Korean generics typically find it difficult to meet these requirements, the drug re-examination system effectively operates to provide original approval holders with de facto data protection in Korea. According to Article 22 of the Regulations on Drug Safety, the re-examination period lasts 4 or 6 years after the first approval date, depending on the specific product type. The 6-year re-exam period applies to: new chemical entities; prescription drugs that differ from already-approved drugs in the active ingredient type or composition, prescription drugs having the same active ingredient as already-approved drugs, but in a different administrative form. The 4-year re-exam period applies to: prescription drugs having the same active ingredients and administration forms as already approved drugs, but providing a clearly different effect or efficacy, and other products as determined by the Ministry of Food & Drug Safety (MFDS) Commissioner. However, pharmaceuticals excluded from the re-exam process are insecticides that are not directly applied to humans, orphan drugs, products lacking novelty, products whose safety and efficacy have been fully established, and products which cannot satisfy re-exam requirements due to the sample size being too small for investigation. In the meantime, under Article 19 of the Orphan Disease Management Act (effective as of December 30, 2016), orphan drugs may receive a 10-year re-examination period if the indicated disease does not have any alternative treatment method or therapeutics. Further, if a pediatric use is additionally approved through clinical trials in Korea, a separate 4-year re-examination period for the pediatric use (from its approval date) can be granted (but this means that if the pediatric use is approved within 2 years of the new drug approval date, there is no additional re-examination period for the pediatric use beyond the original 6-year re-examination period).	For new drugs, for 5 years from time of application, calculated based on country of origin; Three years for new indication.	Similar to patent linkages, there is no data exclusivity in the Philippines.	· From the date on which marketing approval for a new drug, etc., is granted, it is not permitted to sell the same product or a similar product to another party for at least 5 years, based on the following: 1) Safety, efficacy information submitted to obtain marketing approval, 2) facts that are proved in marketing approval. [Patent 2013, Vol. 66, No.10, 78-88] [JETRO website material, "JETRO Global Trade Investment Report" 2016 edition]	NDA: A 5-year data protection period was additionally established by the Pharmaceutical Affairs Act, which took effect in February 2005. However, this is limited to cases where NDA application is filed with TFDA within 3 years of the international birth date (pharmaceutical approval) of the drug. New Indications: 3 years of data protection; if conducting clinical trials in Taiwan, 5 years of data protection. These are limited to cases where application is filed with TFDA within 2 years of the international birth date (pharmaceutical approval) of the drug.	There is no regulatory data protection that allows owner of clinical data to prevent reliance on said data by a third party.	Under the current regulations, in order to qualify for data protection in Vietnam, it is required that the request for data protection must be submitted within 12 months from the date a Marketing Authorization (MA) was first granted in any country in the world. This is not always feasible as this would require companies to immediately apply for MA in Vietnam as soon as a product is approved for circulation in any country in the world. Today, large number of innovative pharmaceutical companies have not managed to obtain the approval letter for RDP in Vietnam. The reasons quoted include the lengthy process, unclear guidelines about the right, data protection time being too short compared to registration time and the inability to meet the requirements. Vietnam should provide Automatic Regulatory Data Protection consistent with international standards, in particular putting in place a procedure that automatically grants RDP upon Marketing Authorization approval, without additional requirements.

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			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Intellectual property rights/IP	Overview of Intellectual property right system	Patent eligibility for secondary use, salt, polymorph, formulation, etc.	N/A	N/A	N/A	See above on issues of the revised Patent Law	Patents for secondary use, salt, polymorph, formulation, etc. are patentable subject matter. However, therapeutic methods for the treatment shall not apply to patented inventions.	Korea recognizes patent protection for secondary uses, salts, polymorphs, and formulations. However, patentability standards for salt and polymorph inventions are somewhat stricter in Korea than in other major jurisdictions.	Eligible	Under Republic Act No. 9502, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered the same substance, unless they differ significantly in properties with regard to efficacy.	N/A	Yes, according to TIPO (Taiwan Intellectual Property Office) regulation.	There is a restrictive eligibility for secondary use (i.e. “new use” patents) for pharmaceuticals and several decisions and determinations have been issued by patent authorities that have disallowed such patents.	N/A
		Patent term extension	At the end of 2018, the fourth amendment of the Patent Law of China (draft for comment) was published. The fourth amendment was submitted to National People’s Congress Standing Committee for deliberation, in January 4th, the amendment was published to solicit opinions from the public. In this draft, for pharmaceutical industry, the highlight would be Article 42 regarding the patent term, it did not only keep the proposal of extend the design patent term from 10 years to 15 years, but also added exception regulations of patent term extensions especially for innovative drugs: To compensate the time lost in the innovative drug review and approval procedures, for the innovative drug patent that initiated NDA in both domestic and overseas simultaneously, the State Council will extend the patent term for no more than 5 years. The total valid patent term of the innovative drug will be at most 14 years after being launched into the market. The Fourth Amendment of the Patent Law of China (draft for comment): http://www.npc.gov.cn/zgrdw/npc/lfzt/rlyw/2018-12/20/content_2067405.htm Related News: http://www.sohu.com/a/292343733_120056925	N/A	N/A	N/A	It can be extended up to 5 years. Multiple patents may be extended multiple times in accordance with additional indication, dosage form, etc. (Article 67 of the Patent Act)	· Any pharmaceutical patent (including compound patents, formulation patents, medicinal use patents, and manufacturing process patents) is eligible for a Patent Term Extension (PTE) as long as the patented invention was prevented from being worked immediately after the patent grant due to pharmaceutical regulatory approval requirements. Under the revised KIPO regulations effective as of March 2019, the PTE is only available for manufacturing process patents/claims, when they cover commercial manufacturing process of the approved product. However, a patent claiming only an intermediate, a catalyst used in preparing the final product, or an apparatus for preparing the final product is not eligible for a PTE. · The PTE period cannot exceed 5 years. The PTE period is calculated by adding the "time period for any testing required for product approval (e.g., clinical trials in Korea)" PLUS "the administrative review period for regulatory documents" MINUS "any delay(s) attributable to the patentee."	N/A	N/A	5 years https://www.ipos.gov.sg/docs/default-source/resources-library/patents/infopacks/patents-formalities-manual_1-nov-2018.pdf	5 years	There is no form of patent term extension or patent term restoration.	N/A

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			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Intellectual property rights/IP	Overview of Intellectual property right system	Compulsory license	In April 2018, in the State Council issued Opinion on Reforming & Improving Generic Drugs Supply & Usage Policies, it is further clarified on the process of the implementation of compulsory license, including who may initiate a compulsory license, as well as necessary pre-conditions, i.e. severe public health threats. Source: National Health Commission Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Pharmaceutical and Medical Devices (CN) (2017): http://www.gov.cn/zhengce/2017-10/08/content_5230105.htm (See article 14) Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Pharmaceutical and Medical Devices (EN) (2017): http://en.china-hnftz.gov.cn/zwgk_details-697.html	64. Compulsory licenses for standard patents (1) At any time after the expiration of three years from the date of grant of a standard patent any person may apply to the court on one or more of the grounds specified in subsection (2)- ((2) The grounds referred to in subsection (1) are- (a) where the patented invention is capable of being commercially worked in Hong Kong, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable; (b) where the patented invention is a product, that a demand for the product in Hong Kong is not being met on reasonable terms; (c) where the patented invention is capable of being commercially worked in Hong Kong by manufacture, that it is being prevented or hindered from being so worked- (i) in the case of a product, by the importation of the product; or (ii) in the case of a process, by the importation of a product obtained directly by means of the process or to which the process has been applied; (d) that by reason of the refusal by the proprietor of the patent to grant a license or licenses on reasonable terms- (i) the working or efficient working in Hong Kong of any other patented invention which involves an important technical advance of considerable economic significance in relation to the patent is prevented or hindered; or (ii) the establishment or development of commercial or industrial activities in Hong Kong is unfairly prejudiced; or (e) that by reason of conditions imposed by the proprietor of the patent on the grant of licenses under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent or the establishment or development of commercial or industrial activities in Hong Kong, is unfairly prejudiced. (3) The court may, if it is satisfied that any of those grounds are established, and subject to subsections (4) and (5), order the grant of a license on such terms as it thinks fit- (a) to the applicant, where the application is made under subsection (1)(a); or (b) to the person specified in the application, where the application is made under subsection (1)(b). (4) Where the application is made on the ground that the patented invention is not being commercially worked in Hong Kong or is not being so worked to the fullest extent that is reasonably practicable, and it appears to the court that the time which has elapsed since the grant of the patent was advertised in the Gazette has for any reason been insufficient to enable the invention to be so worked, the court may adjourn the hearing for such period as will in the opinion of the court give sufficient time for the invention to be so worked. (5) No order shall be made under this section unless the court is satisfied that the applicant has made reasonable efforts to obtain authorization from the proprietor on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. (6) No order shall be made under this section in respect of a patent ("patent A") on the ground mentioned in subsection (2)(d)(i) unless the court is satisfied that the proprietor of the patent for the other invention ("patent B") is able and willing to grant to the proprietor of patent A and his licensees a license under patent B on reasonable terms.	Given the multiple triggers for issuance of a CL, along with judicial decisions further broadening its scope, CL in its current form poses a threat to patent holders in India. There is a need for clarity with respect to what is considered 'working' of a patent in this respect, and whether import of a patented product would be considered working of the patent in India. Generic companies who intentionally threat the innovator companies should not be encouraged. Compulsory licenses are sovereign state authorizations which enable a third party to make, use, or sell a patented product without the consent of the patent holder. Provisions pertaining to compulsory licensing are provided for under both the Indian Patent Act, 1970, as well as the international legal agreement between all the member nations of WTO – the TRIPS. In India, Chapter XVI of the Indian Patent Act, 1970 deals with compulsory licensing while the conditions which need to be fulfilled for the grant of a compulsory license are laid down under Sections 84 and 92 of the Act. In accordance with Section 84(1) of the Indian Patent Act, 1970, after three years from the grant of a patent, any interested person may make an application for a compulsory license on the grounds that the patented invention: Does not satisfy the reasonable requirements of the public; Is not available to the public at a reasonably affordable price; and Is not worked in the territory of India. In addition to the aforementioned grounds, according to Section 92 of the Act, compulsory licenses can also be issued suo motu by the Controller of Patents pursuant to a notification issued by the Central Government if there is either a "national emergency" or "extreme urgency" or in cases of "public non-commercial use". The said section enables the Government of India to notify to the public of such extreme circumstances, whereupon, any person interested can apply for a compulsory license and the Controller in such case may grant to the applicant a license over the patent on such terms and conditions as he thinks fit. http://www.mondaq.com/india/x/617670/Patent/Compulsory+licensing	Ministry of Law and Human Rights Regulation No. 39/2018 on December 28, 2018, described the procedure for granting compulsory licensing (CL) for third party, not only for 'government-use' as in the past. Eligibility for such CL: 1. patent holder does not perform its obligation to manufacture product(s) or use process in Indonesia within 36 months after the patent is granted, 2. patent has been exploited by patent holder or licensee in a form and in a way that harms the public interest, or 3. patent as a result of development of previous granted patent cannot be exploited without using other party's patent that is still under the protection.	In the case of non-working, dependent patent or the public interest, a non-exclusive license may be requested (Articles 83, 92, and 93 of the Patent Act). However, no case has been granted yet.	Article 107(1) of the Korean Patent Act sets forth the following five circumstances under which the Commissioner of KIPO may authorize a non-exclusive license to work a patented invention without the consent of the patentee: (i) where the patented invention has not been worked for three or more consecutive years in Korea, except in the case of natural disasters, unavoidable circumstances or other justifiable reasons prescribed by Presidential Decree; (ii) where the patented invention has not been worked on a substantially commercial scale in Korea for three or more consecutive years without justifiable reasons, or where the domestic demand for the patented invention has not been satisfied to an appropriate extent and under reasonable conditions; (iii) where the working of the patented invention is especially necessary for the public interest; (iv) where the working of the patented invention is necessary to remedy a practice determined to be anti-competitive by judicial or administrative proceedings; or (v) where the working of the patented invention is necessary for the export of medicine to a country that intends to import the medicine in order to treat diseases that threaten the health of the majority of its citizens. Prior consultation with the patentee or exclusive licensee is required prior to filing a compulsory license petition. However, it is not required when the patented invention is to be non-commercially worked for the public interest or in cases falling under (iv) above (anti-competitive practices). Further, situations falling under (i) and (ii) above cannot be the basis for a compulsory license unless a period of 4 years has lapsed from the filing date. We note that no compulsory license for pharmaceutical patents has ever been granted in Korea.	Yes (Patent Law, Article 48, etc.) On September 29, 2004, Ministry of Domestic Trade, Co-Operatives and Consumerism (Former Ministry of Domestic Distribution) invoked compulsory license for the government to import anti-HIV drug products from Cipla of India for 2 years. In 2017, Malaysian government revoke patent of sofosbuvir to import it from Pharco of Egypt.	Under Republic Act No. 9502, IPO may grant compulsory licensing for patented drug products under the following cases: ·National emergency or other circumstances of extreme urgency; ·Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or ·Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anticompetitive; or ·In case of public non-commercial use of the patent by the patentee, without satisfactory reason; ·If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: Provided, that the importation of the patented article shall constitute working or using the patent; and ·Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health.	· At any time after the expiration of three years from the date of the sealing of any patent in the United Kingdom belonging to a class of inventions specified in the Schedule to this Act and where such patent has been registered in Singapore and remains in force, any person interested may apply to the Registrar upon any one or more of the grounds set out in subsection (2) of this section for a license under the patent. · Where a licence has been granted under section 3 or 5 of this Act and the patentee and the licensee are unable to agree within a reasonable time on the amount of royalty or compensation to be reserved to the patentee under the licence, the Registrar shall determine the royalty or compensation payable, but in no case shall the Registrar fix a royalty or compensation payable to the patentee under the licence exceeding ten per cent of the net ex-factory sale price in bulk of the patented article, to be determined in such manner as may be prescribed. [Patent (Compulsory Licensing) Bill https://sso.agc.gov.sg/Bills-Supp/15-1968/Published/19680513?DocDate=19680513]	Exists. Compulsory licenses are provided for by the Patent Act (amended January 18, 2017), and although it has been invoked for drugs and DVDs, there are no manufactured embodiments. In order to cope with national emergencies and other grave emergencies, the Patent Office must approve compulsory utilization of the necessary patent rights and swiftly notify the patent owners in accordance with an urgent decree or notification by the Central Administrative Office. When it becomes necessary to approve compulsory utilization in one of the following cases, the Patent Office can approve compulsory utilization upon application. 1. For non-profit purposes to promote public benefit 2. When execution of an invention or utility model will unavoidably violate a previous invention or utility model and represents an important technological improvement with economic significance compared to the previous invention or utility model 3. When the patent owner has conditions that limit competition or result in unfair competition and has been penalized by a court decision or Fair Trade Committee	Compulsory Licensing and Government Use of patents are allowed under the Patent Act. The pending amendments to the Patent Act will reform the method by which compulsory licenses are granted according to the WTO Doha Agreement. There have been no compulsory licenses issued on pharmaceuticals since 2008.	Ministry of Health planned to draft Circular on Compulsory License, latest draft dated 2015. However, the draft regulations are missing several key components, such as allowing the rights holder to take part in the proceedings, and not requiring failed license negotiations as a prerequisite to a compulsory license being granted. Compulsory licensing has not been granted in Thailand since 2007, and has never been granted in Japan; thus, Vietnam should reconsider whether it is truly needed, and in any case needs to ensure that any regulations comply with international commitments.

Category	Item	Types	China	Hong Kong	India	Indonesia	Japan	Korea	Malaysia	Philippines	Singapore	Taiwan	Thailand	Vietnam
			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Intellectual property rights/IP	Overview of Intellectual property right system	Anti-counterfeit efforts	N/A	Introduction of two-dimensional barcodes, etc. An anti-counterfeit task force was inaugurated in 2007 and made by the joint effort of Custom & Excise Department, Department of Health, The Hong Kong Association of the Pharmaceutical Industry (HKAPI) and its members, and Consumer Council in 3 key direction: Public awareness information exposing counterfeit drugs is made public in the bulletin "Choice"•magazine published by Consumer Council with printed version of 100,000 circulations, also electronic version which could be accessed by China Enforcement Joint raid of industry, Custom and Excise Department and Department of Health Deterrence Revoke license and court sentence	Pharma industry in India has been slow to adopt track and trace measures like bar coding on packages but now companies are getting more responsive. "Initially companies have been slow to act against counterfeiting to avoid bad publicity and extra costs. But now the trend is changing. Companies are realizing that investing in anti-counterfeiting solutions can prevent revenue loss and thus make up for the extra costs. Some companies have put in place an SMS authentication scheme for customers. Those buying its products can message the batch number to the firm for product verification purpose. https://www.business-standard.com/article/companies/pharma-companies-step-up-campaign-against-spurious-drugs-115112501016_1.html	·BPOM/NADFC established a 4th Deputy Enforcement to counter illegal products equipped with execution authority ·NADFC has issued 230 revocation of selling & distributing counterfeit items in first quarter 2018 to combat counterfeit practices ·NADFC bill containing the law enforcement authority to be immediately passed as a regulation Raising consumers' awareness that there are counterfeit drugs on the market, and that they should purchase drugs at reputable stores. IPMG consistently combats any suspicious practice of selling counterfeit drugs and raise consumers' awareness through its website http://www.stopobatpalsu.com/	The Japanese Ministry of Health, Labor and Welfare has established the "Suspicious Drugs Reporting Network[http://www.yakubutsu.com/]," a website for edifying the general public on counterfeit medicines (provided in Japanese only). The Ministry has also announced that the government and enterprises will collectively address countermeasures for counterfeit medicines. [http://www.jpma.or.jp/english/globalhealth/statement/fake.html]	In Korea, it is prohibited to sell, store or display counterfeit drugs (Article 61, Pharmaceutical Affairs Act (PAA)). Violation of this prohibition can lead to the imposition of: Administrative sanctions: suspension of business and cancellation of approval (Article 76, PAA). Criminal sanctions: imprisonment for up to 5 years or a fine not exceeding KRW 50 million (Article 93, PAA). Additionally, under Article 3 of the Act on Special Measures for the Control of Public Health Crimes, a person who manufactures or sells counterfeit drugs can be punished as follows: If the [counterfeit] drug is seriously harmful to the human body: imprisonment from 5 years to life. If the value of the [counterfeit] drug, based on its retail price, is equal to or exceeds KRW 10 million per annum: imprisonment from 3 years to life. If the counterfeit drug results in death or injury to persons: death penalty or imprisonment from 5 years to life. The Ministry of Food and Drug Safety (MFDS) and the Prosecutors' Office have regulatory powers to prohibit counterfeit drugs. Additionally, the Korean Customs Office and Korean Intellectual Property Office can regulate the import and export of products infringing intellectual property rights, including counterfeit drugs. In the meantime, as of January 1, 2019, a Pharmaceutical Serialization System has been implemented. The system enables the tracking of the passage of drugs from production, import, distribution and consumption by identifying a unique serial number on each drug package, and thus should help prevent counterfeit/illegal drugs from entering the supply chain.	Malaysia part of Interpol Pangea operation Joint measures by Ministry of Health, groups of regional medical institutions, and Pharmaceutical Association of Malaysia (PhAMA) · Preparing for implementation of track & trace system	In 2014, various stakeholders convened to establish the Coalition for Safe Medicines (CSM) as a response to the call "to collaborate and cooperate with the FDA in advocating and implementing activities to raise the level of consciousness of the public about the dangerous effects to health of using counterfeit medicines". The FDA celebrates the 'National Consciousness Week against Counterfeiting" on an annual basis where the various stakeholders are invited to participate in the week-long activities. CSM serves as a platform for initiatives and programs to counteract the proliferation of substandard and falsified medical products. IPO is part of CSM and focuses on intellectual property matters	· Penal provisions have been established to punish the importer when a counterfeit drug is discovered at the time of custom clearance. · If a counterfeit drug is found by HSA, it is announced in an HSA news release to call attention to it and make it known widely. [HSA website https://www.hsa.gov.sg/illegal-health-products-found-in-singapore]	The competent regulatory authorities (Ministry of Health and Welfare) and the Intellectual Property Protection Police Corps, as well as the related agencies including Customs, Taiwan Police, Coast Guard, and Ministry of Justice Investigation Bureau are making efforts to control counterfeit drugs. In addition, the Ministry of Health and Welfare, together with the regional health bureaus under it, has established an "Allied Control Group (Chinese name: 聯合緝查小組) to tighten control of illicit drugs at medical institutions, pharmacies, and night markets, etc., with the cooperation of the police and consumer representatives. Moreover, the Ministry of Health and Welfare has established an expert group on control of illicit drugs (known as 打擊不法藥物專案會報 in Chinese) in collaboration with the Ministry of Justice, Taiwan Police, Coast Guard, Ministry of Finance Customs Bureau, and Law Enforcement Agency.	The Department of Intellectual Property is the secretariat for the National IP Center for Enforcement (NICE) which is an inter-agency group for addressing enforcement of anti-counterfeits. There has not been any involvement with the pharmaceutical industry in this group or its subcommittee, but there is potential that it can be an effective structure to address the issue of counterfeit medicine.	· Crime of Infringement is enforced for manufacture and sale of counterfeit goods [Penal Code Article 157] · Viet Nam Association for Trademark Protection opened a new office in Ho Chi Minh City as a counterfeiting countermeasure (2013.5). · Survey activity by Market Controller Office. · National Institute of Drug Quality Control of Vietnam (INDQC); tightening of surveillance by testing agency under government. · Border measures through cooperation with Customs (tightening of control) – Checking of quality through sampling of corporations with past violations
		Others			Requirement to file annual statements on working of patents under FORM 27 The Patent Act, 1970 requires all patent holders to file an annual statement summarizing the extent to which the patented invention has been commercially worked in India. The scope of Form 27 has not been updated or amended in nearly 45 years, and therefore does not reflect the realities of today's globalized nature of innovation and patenting activity. In fact, India is an outlier in requiring patentees to disclose the extent and manner in which they "work" their patent. While steps are being taken to further tighten compliance and oversight, it is hoped that the burdensome annual working statement requirements are simplified to require patentees to simply state whether or not a patent was worked in India Pre-grant opposition: Section 25(1) of the Indian patent (Amendment) Act 2005 provides a provision for filing a pre-grant opposition against a patent application. Under this provision any person, any third party or the Government may challenge the application of grant of patent and inform to the controller of Patents of the opposition, in writing against the grant of a patent after the application for a patent has been published and/but before the grant of the patent. Such law does not exist globally and is unique to India. Also since there is no defined timeframe, generic companies have misused this law in order to delay in the grant of patent. This coupled with No Patent term extension clause available in India is detrimental for innovators to launch their products in the country,					While the FDA defines that intellectual property rights are not covered by the product registration application and approval, the marketing authorization holder is responsible to protect their rights through the local court.			Based on the new Drug Act of 2019, the number of patent or petty patent application which went through the publication process according to the patent law have to be disclosed in the application for marketing registration of a drug formula.	

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Healthcare and Pharmaceutical industry policy	Investment restriction	On March 15, 2019, Foreign Investment Law of the People's Republic of China was adopted by 2nd session of the 13th National People's Congress. This Law shall come into force on January 1, 2020. http://www.mofcom.gov.cn/article/difang/201903/20190302845209.shtml http://language.chinadaily.com.cn/a/201903/22/WS5c94798ca3104842260b205f.html On June 28, 2017, with the approval of the CPC Central Committee and the State Council, the National Development and Reform Commission of the People's Republic of China and the Ministry of Commerce of the People's Republic of China released Catalogue of Industries for Guiding Foreign Investment (2017 Revision). This Law shall come into force on July 28, 2017. Simultaneously, Catalogue of Industries for Guiding Foreign Investment (2015 Revision) released by the National Development and Reform Commission and the Ministry of Commerce on March 10, 2015, shall be abolished. http://www.gov.cn/xinwen/2017-06/28/content_5206424.htm Industries where foreign investment is restricted 32. Medical institutions (including joint ventures and cooperation) Industries where foreign investment is prohibited 7. Application for the processing technology for prepared slides of traditional Chinese medicines, including steaming, stir-frying, broiling, and production for confidential prescription of Chinese patent drug	· There are no provisions limiting investment in the pharmaceutical industry. · running pharmaceutical import/export, manufacturing, pharma	The FDI Cap in the Indian pharmaceutical & Medical device sector has been extended up to 100%, through both the Greenfield and Brownfield strategies. The purpose of the same is to encourage foreign investors to invest in the vast and booming pharmaceutical sector of India in coming years. Union Cabinet has given its nod for the amendment of the existing Foreign Direct Investment (FDI) policy in the pharmaceutical sector to allow FDI up to 100% under the automatic route for manufacturing of medical devices subject to certain conditions	Current conditions for entry by foreign corporations; · Pharmaceutical companies are limited to own 85 % of capital or less, and in order to engage in marketing, they need marketing authorization and individual product marketing licenses. Raw materials production is however 100% open for foreign ownership · For medical devices, there are no capital restrictions, but MAH registration and individual product marketing licenses are required The Negative Investment List is now under revision, possibly to be issued soon and would open up the pharmaceutical companies to 100% foreign ownership	N/A	Basically, there are no regulations limiting investment. Controversially there are many policies to promote foreign investment	There is no restriction in particular for pharmaceuticals. · Foreign capitalization of pharmacies (traditional herbs, Chinese herbal medicine) is now allowed. · Land ownership is depending upon law of each state. .	There are no provisions limiting investment in the pharmaceutical industry.	· There are no provisions limiting investment in the pharmaceutical industry. · Investment in pharmacies is possible with a license granted by the Health Science Authority [HSA website] https://www.hsa.gov.sg/therapeutic-products/retail-pharmacy-licence/overview	Permission based on the “Statute for Investment by Foreign Nationals” is necessary in order for foreigners to invest in Taiwan. While investment by overseas Chinese and foreigners is in principle unrestricted, those investments falling within the “Negative List for Investment by Overseas Chinese and Foreign Nationals” are prohibited or limited as an exception. Moreover, investment by Chinese corporations requires permission based on “Investment permission for continental Chinese decree”, and only the types of businesses listed in “Investment by continental Chinese, by industry” are allowed. Industries related to pharmaceuticals are not included in the “Negative List”. [JETRO: Restrictions on Foreign Investment]	In almost all industries, the provisions of the Foreign Business Act make it impossible to start an enterprise with solely foreign capital or a majority of foreign capital, unless a foreign business license is obtained through the Ministry of Commerce. Another exception, under the Investment Promotion Act, it is possible for foreign-capital companies to establish a wholly owned company if approval is obtained from the Thailand Board of Investment.	There is no restriction of stock ratio, 100% foreign capital affiliated is available.
	Import, international distribution regulation	On October 30, 2018, National Medical Products Administration and National Health Commission, released the Procedure for the Review and Approval of Foreign New Drugs in Urgent Clinical Need and requirements for submission, and selected the first batch of foreign new drugs in urgent clinical need (a total of 48 drugs). http://www.nmpa.gov.cn/WS04/CL2050/331475.html On March 28, 2019, the Center for Drug Evaluation, NMPA released the “second batch of foreign new drugs in urgent clinical need”, including new drugs for rare disease treatment that had been approved to market in the United States, the European Union or Japan but not in China; new drugs used for the prevention and treatment of severe life-threatening disease or disease seriously affecting the quality of life; and new drugs under no effective treatment or with obvious clinical superiority. From May 1, 2018, import tariffs on all common drugs including cancer drugs, cancer alkaloid-based drugs, and imported traditional Chinese patent medicine would be exempted, so that all anticancer drugs actually imported by China will enjoy zero tariff. https://www.cn-healthcare.com/articlewm/20191101/content-1074493.html According to Customs Tariff Commission of the State Council, the Regulations of the People’s Republic of China on Import and Export Duties will come into effect in January 1, 2020. Import tariff of part of the commodities will be adjusted. http://m.mof.gov.cn/czxw/201912/t20191220_3447086.htm?from=singlemessage&isappinstalled=0	An import/export license is required for pharmaceuticals (including Chinese medicines and Chinese herbal medicines), regardless of the trading partner. * In order to import pharmaceuticals, it is necessary to apply for and obtain a pharmaceutical import license each time, ** and obtaining a Wholesaler Poisons License and product registration certificate (or similar document) before applying for the import license is mandatory. Even if a company is authorized as a Hong Kong corporation and exports items classified as locally produced in Hong Kong, a series of restrictions on pharmaceutical imports are applied.	**Drugs:** CDSCO (Central Drug Standard Control Organisation) provides Registration Certificate and issuing License for import of drugs into India. Both manufacturing site and product need to be registered. An application shall be made to the Licensing Authority in Form 40, either by the manufacturer himself, having a valid wholesale License, for sale or distribution of drugs or by his authorized agent in India either having a valid License to manufacture for sale of a drug or having a valid wholesale License for sale or distribution of drugs http://www.cdsco.nic.in/writereaddata/Guidance%20documents.pdf **Medical Devices:** The Central Licensing Authority is the authoritative body that oversees the importation of all classes of medical devices; the manufacture of Class C and D medical devices; the clinical evaluation and approval of investigational medical devices; and the clinical evaluation and approval of new IVDs. The responsibility of overseeing the manufacture of Class A and B medical devices and the sale, stocking, exhibiting, and distribution of all classes of medical devices is delegated to state licensing authorities.	It is mandatory that the marketed pharmaceutical products be produced in Indonesia within 5 years after registration. Marketing authorization for a product is however granted only to pharmaceutical manufacturing companies in Indonesia. Some exceptions from this localization requirement can be granted, e.g. small number of products requiring technology not available in Indonesia, government need, and products under patent.	N/A	None in particular	There is no description of direct restrictions on import of drugs by foreign-affiliated companies.	In order to import drug products, the following must be satisfied: ·The establishment involved in the importation must secure a License to Operate from the Food and Drug Administration ·The product to be imported must be registered with the Food and Drug Administration from 2012	· An importer’s licence for therapeutic products (TPIL) and a wholesaler’s licence for therapeutic products (TPWL) are required to import and wholesale therapeutic products respectively. · For the import and wholesale of an unregistered therapeutic product for patient’s use, apart from the TPIL and TPWL, a consignment approval from HSA’sTherapeutic Products Branch will also be required prior to the import. · Companies which are only importing therapeutic products solely for supply to ships/aircraft leaving Singapore, export or non-clinical use require an importer's licence for therapeutic product (TPIL). An importer's licence for restricted activity only may be applied for. [HSA website] https://www.hsa.gov.sg/therapeutic-products/dealers-licence/overview	Approval is required for importing pharmaceuticals.	For medicines and pharmaceutical products, it is necessary to obtain an import license in accordance with the Import and Export of Commodity Act (B.E. 2522 (1979)). The new Drug Act (No. 6) B.E. 2562 published in the Government Gazette on April 16, 2019. The key changes are: · New Drug Registration has to provide “Documents that show the number of patent or petty patent application which went through the publication process according to patent law” (Section 9). · The certificate of drug formula registration shall be valid for seven years from the date it was issued and need renewal. (Section 11). · New section added on procedure, regulations and conditions of drug research (Section 8) and the penalty fee (Section 12). · All fees in Drug Act 1967 has been replaced (Section 14). The Japanese-Thai Economic Partnership Agreement affords preferential treatment with exemption from tariffs (Type No. 30: medical supplies and pharmaceuticals)	Historically, most multinational pharmaceutical companies have done business in Vietnam via representative office (RO) model in Vietnam. With Pharmaceutical Law 105/2016 and Decree No. 54/2017/ND-CP, foreign pharmaceutical companies can establish pharma business establishment for importation (FIE Importer). Wholesale/Distribution is reserved for domestic companies. It has been clear that Vietnam does not intend for foreign companies to engage in the distribution sector for pharmaceuticals. Vietnam’s WTO Schedule of Commitments on Services has intentionally excluded pharmaceuticals from the sectors for which market access is open to distribution by foreign investors.

Category	Item	China RDPAC/PhIRDA	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KPBMA/KRPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA	Vietnam PG
Healthcare and Pharmaceutical industry policy	Industry development policy	Promotion of innovations and biopharmaceuticals; promotion of “Healthy China 2030”	The Innovation and Technology Bureau supports R&D on pharmaceuticals Food and Health Bureau supports clinical trials. The Policy Address of the government announced October 2018, that will develop Biomedical as a spearhead of the economy. https://www.policyaddress.gov.hk/2018/eng/policy.html	Department of Pharmaceuticals DOP is primarily responsible developing the Indian Pharmaceuticals sector Existing schemes 1.Pharma Promotion and Development Scheme (PPDS) : Grant assistance for Industry Studies, Workshops, Seminars, etc. 2. Intellectual Property Rights Facilitation Centers: Capacity building Grant assistance (capital and revenue) for setting up of IPR centers by Pharmaexcil, Industry bodies, etc. to assist industry in IPR matter http://planningcommission.gov.in/aboutus/committee/wrkgrp12/wg_pharma2902.pdf	Some tax incentives (tax holiday and tax allowance) might be granted for ‘pioneer industries’ such as API manufacturing, R&D activities locally etc. Please refer to the decree of MoFinance no. 35/2018	Comprehensive Strategy for Strengthening Pharmaceutical Industry (Formulated in 2015, revised in 2017) I. Promotion of Innovation (1) Improvement of R&D environment for creation of seeds in Japan Support for human resources development and potential growth areas (genomic medicine, drug discovery/nucleic acid medicines using iPS cells, biopharmaceuticals/biosimilars), such as utilization of real world data and improvement of clinical trial environment. (2) Strengthening cooperation between industry, academia, and government (practical application of excellent seeds originating from universities). (3) Cost reduction and efficiency improvement through pharmaceutical regulatory reform, etc. (4) Establishment of environment and infrastructure for fair evaluation. (5) Creation of global venture for promotion of drug discovery. II. Realization of High-quality and Efficient Medical Care (1) Securing stable supply of Basic Drugs, etc. Measures on drug prices for stable supply of "Basic Drugs" and promotion of the use of inexpensive drugs. (2) Acceleration of the use of generic drugs Examining drug price/medical service fee system and the vision for marketing of generic drugs, quality assurance measures, information service and dissemination/education, and measures taken by medical institutions, insurers, and prefectures. (3) Stabilization/modernization of distribution and promotion of appropriate price formation Further promotion of unit price-based negotiation, vision for distribution with a view to further promotion of the use of generic drugs, and vision for distribution coping with market changes and social demands. III. Global Expansion of Japan-origin Drugs (1) International support (2) Promotion of international regulatory harmonization strategy	There is Special Act on Fostering and Supporting the Pharmaceutical Industry introduced from 2012. This law aims to establish the basis for the development of the pharmaceutical industry through the systematic upbringing and support of the pharmaceutical industry, the enhancement of innovation and international cooperation, and creating an environment for attracting foreign investment. The detailed sub items are followings; 1. Mid- and long-term goals for fostering the pharmaceutical industry 2. Procurement and utilization plan of investment resources necessary for fostering pharmaceutical industry 3. Development and effective utilization of human resources necessary for fostering the pharmaceutical industry 4. International cooperation in the pharmaceutical industry and plans to support overseas market entry 5. Plan to support R & D and technology trading including new drugs 6. Innovative pharmaceutical companies supporting plan 7. Support plan for attracting domestic investment related to new drug research and development by foreign pharmaceutical companies 8. Other matters necessary for the upbringing of the pharmaceutical in	·Local company incorporated ·Manufacturing License application ·No restriction on foreign equity ownership ·Liberal expatriates employment policy ·Free movement of funds for foreign investments in Malaysia ·Protection of intellectual property rights ·Company tax rate 25% ·Individual tax rate from 0% - 26% ·Minimum conditions of employment under the Employment Act 1955 ·Responsible trade unions and harmonious industrial relations ·Compulsory contributions: -Employee Provident Fund (EPF) -Social Security Organisation (SOCSO) -Human Resource Development Fund (HRDF) -Investment guarantee agreements ·Double taxation agreements ·Controlled environmental management policy (http://www.mida.gov.my/home/manufacturing-sector/posts/)	This year, the Board of Investments (an office under the Department of Trade and Industry) has asked all pharmaceutical associations to craft an industry roadmap. PHAP along with other pharmaceutical associations have jointly discussed shared goals and target milestones covering up to 2040. This is in the process of finalization	· Support from the Economic Development Board (EDB) and economic and political stability are positive factors favoring Singapore as a manufacturing base. · The government will step up its efforts to attract investment in the pharmaceutical industry by promoting public-private partnerships, ensuring that the country has the infrastructure for economies of scale, and offering incentives to invest in digital health and medical technology. · While the MoH is keen to foster innovation in areas such as gene therapy, biologics and biosimilars, it remains wary of driving up demand for expensive new drugs too sharply. Pharmaceutical companies will continue to be frustrated by lengthy delays in formulary listing, as well as the cumbersome process for eligible patients to access MAF subsidies, which hinders the uptake of new therapies in the public sector. · The government continues to foster collaboration between the pharmaceutical, healthcare and biotechnology sectors to boost innovation and maintain Singapore’s status as an attractive destination for innovative product launches and R&D. This includes a shift towards more automated pharmaceutical operations, the creation of a clinical trial agreement template and the expansion of subsidy lists. These initiatives are supported by the stable operating environment, a world-class health infrastructure and a wealth of existing manufacturing facilities. [IQVIA]	Act for The Development Of Biotech And New Pharmaceuticals Industry is established to promote the development of local biotech and new pharmaceuticals industry (Jan 2017; Ministry of Economic Affairs)	There are several national initiatives to develop Thai industries in the medical, biopharmaceutical and health service sectors. Thailand 4.0 is an initiative that aims to elevate several technology sectors to “value creation” through regulatory reform, tax incentives and attracting FDI with the goal of technology transfer. One of the targeted sectors in Thailand 4.0 is the biopharmaceutical industry. In 2018 Thailand’s National Economic and Social Development Board issued its 20-year strategic plan. The plan includes strengthening human capacity and developing Thailand’s competitiveness as a medical hub. The Board of investment, in alignment with the national initiatives is also targeting FDI from medical device and biopharmaceutical industry with tax and other pull incentives. The National Legal Reform Committee, in alignment with the national initiatives, is reviewing all laws and licenses for relevance and seeking to cut unnecessary laws and licenses for ease of doing business. The Ministry of Public Health is reforming the Clinical Research environment in an effort to make Thailand more competitive in attracting clinical trials. Thai FDA is one of target government agencies to improve their licensing service so that the index of Thailand Ease of Doing Business can be more competitive to other economies. Services that they are reforming include one stop service, shortening health products reviewing process especially pharmaceutical products, etc.	Prime Minister Nguyen Tan Dung on June 9, 2014 signed Decision No. 879/QD-TTg to approve the Industrial Development Strategy through 2025, vision toward 2035: “Regarding pharmaceutical chemicals, to focus on researching pharmaceutical drugs from natural materials for the production of adjuvants and vitamins serving domestic medical treatment demand and for export in the subsequent period.” Vietnam aims to raise the share of locally-made medicines to 80% of the domestic market by 2020. Incentives are provided for technology transfer, toll-manufacturing drugs such as fast track registration for: Drugs produced under toll manufacturing or technology transfer arrangements that are drugs for cancer treatment, vaccines, biologics, new generation of antivirals, new generation of antibiotics. Brand name drugs produced under toll manufacturing or technology transfer arrangements in Vietnam.

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Healthcare and Pharmaceutical industry policy	Government counterpart	Requests from private companies that are directed to the CFDA go through China Center for Food and Drug International Exchange (CCFDIE), which is an independent business corporation under the direct control of CFDA.Requests from private companies that are directed to the National Health and Family Planning Commission go through Center for International Exchange and Cooperation, an independent business corporation that is under the direct control of National Health and Family Planning Commission.	Commerce and Economic development Bureau	Drug Controller General of India	· Ministry Of Health Republic Indonesia [http://www.depkes.go.id/] as policy maker · The National Agency of Drug and Food Control (NA-DFC) or BPOM as controlling body[http://www.pom.go.id/new/] Until 2000, NA-DFC was under the Ministry of Health, but it became a semi independent Organisation reporting to the President under the purview of the MOH in 2001. The parliament is however deliberating a BPOM Bill under the initiative of BPOM, which will make this agency in its existence sanctioned by a law, not only by a Presidential Decree, more powerful	Ministry of Health, Labour and Welfare(MHLW) Pharmaceuticals and Medical Devices Agency (PMDA)	· Ministry of Health and Welfare · Ministry of Food and Drug Safety	Ministry of Health (http://www.moh.gov.my/english.php) Malaysian Industry Development Authority (MIDA) (http://www.moh.gov.my/english.php)	Department of Health provides national health policies and standards. [https://www.doh.gov.ph/] Food and Drug Administration Philippines was created under the Department of Health to license, monitor and regulate food, drugs cosmetics and other health product. [https://ww2.fda.gov.ph/]	N/A	1. Organization of the head office of ROC Ministry of Health and Welfare 1) Department of Planning 2) Department of Social Insurance 3) Department of Social Assistance and Social Work 4) Department of Protective Service 5) Department of Nursing and Health Care 6) Department of Medical Affairs 7) Department of Mental and Oral Health 8) Department of Chinese Medicine and Pharmacy 9) Office of International Cooperation 10) Secretariat 11) Hospital and Social Welfare Organizations Administration 2. Auxiliary organs of Ministry of Health and Welfare 1) Food and Drug Administration 2) Center for Disease Control 3) National Health Insurance Administration 3. Taiwan Food and Drug Administration Cooperation Units 1) Center for Drug Evaluation 2) Taiwan Drug Relief Foundation	·Ministry of Public Health (MoPH); Thai FDA ·Ministry of Higher Education, Science, Research and Innovation; National Science Technology and Innovation Policy Office, Thailand Center of Excellence for Life Science (TCELS) ·Medical Science Faculty, Pharmaceutical Science Faculty ·Medical Council, Pharmacy Council ·National Economic and Social Development Board, The Prime Minister's Office, Ministry of Commerce	Ministry of Health (MOH)
	Supporting Associations and/or Organisations	N/A	N/A	Central Drug Standard Control Organisation Central Licensing Authority	Indonesia Investment Coordinating Board [http://www.bkpm-jpn.com/] IDI (Indonesian Medical Association), PERSI (Hospital Association)	Japan Agency for Medical Research and Development (AMED) Japan Science and Technology Agency (JST) National Institute of Biomedical Innovation, Health and Nutrition New Energy and Industrial Technology Development Organisation (NEDO) Organisation for Small & Medium Enterprises and Regional Innovation. Innovation Network Corporation of Japan Regional Economy Vitalization Corporation of Japan	· Korea Health Industry Development Institution (KHIDI)	It is not decided the ministry/regulatory agency to oversee biopharma technology. Bio-economy is currently under the purview of Ministry of Agricultural and Agro-based Industry (MOA)	In various stakeholder committees/councils established by the government on different areas of concerns, industry participation is through recognized associations and/or Organizations.	Singapore Economic Development Board (EDB) https://www.edb.gov.sg/en/news-and-events/insights/manufacturing/future-proofed-pharma.html	N/A	Board of Trade, Federation of Thai Industries Thailand Center of Excellence Life Office of The Thailand Research Fund	N/A
	Contract research Organisation	According to the statistics, from 2012-2016, the total sales volume of the CRO industry rises from 18.8 billion RMB to 46.5 billion RMB, the compound annual growth rate achieved 25.41%. It is estimated that the CRO industry will continue to maintain high growth in the next 5 years on the existing basis. The sales volume will reach 116.5 billion dollars, the compound annual growth rate will be 25.41%. As of December 2018, there are 1520 pharmaceutical outsourcing service companies (CRO/CMO) in China that are currently in existence. The development of pharmaceutical outsourcing service companies reached a peak during the year 2005-2015, benefits most from the introduction of GCP, GLP industry policies, and the influence of the rapid enlargement of pharmaceutical market. The newly established enterprises per year are kept at an average above 70. As the industry regulatory policy gets tighter, the industry enters a phase of adjustment, the pace of enterprises entering the market is slowing. Reference: https://www.cn-healthcare.com/articlewm/20190816/content-1067500.html http://www.chyxx.com/industry/201910/791114.html http://app.myzaker.com/news/article.php?pk=5af103eb77ac643de17d84be	N/A	N/A	Quintiles, Prodia, Pacific Bridge Medical, PAREXEL etc	N/A	N/A	IQVIA Covance Parexel Pharmal Product Development Questra Clinical Research Sdn Bhd Research Pharmaceutical Service	Several Contract Research Organizations are present in the country, such as IQVIA, PPD, ICON, PAREXEL, etc. These CROs have been attracted to the growth of the Philippines as clinical research hub.	IQVIA, CMIC, EPS, PAREXEL International, Novotech, intellin and more	N/A	Non-exhaustive list of active CRO's in Thailand IQVIA Parexel Acriles Covance PPD Asia Global Research	N/A

Category	Item	China	Hong Kong	India	Indonesia	Japan	Korea	Malaysia	Philippines	Singapore	Taiwan	Thailand	Vietnam
		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Healthcare and Pharmaceutical industry policy	Contract manufacturing Organization	China's CMO industry was established relatively late, comparing to the CMO giants, and the scale of China's CMO companies is quite small. However, the competitive advantages of China such as infrastructure, cost structure, patent protection is gradually making China one of the major manufacture outsourcing destinations of multinational companies. According to the statistics of Business insight, in 2017 China's CMO holds more than 8% of global market share, it is estimated that the figure will reach 9.7% in 2020. For now, China's CMO companies are mainly occupied by chemical drug CMOs, companies such as Porton Pharma, Zhejiang Jiuzhou Pharmaceutical, Asymchem Laboratories and STA Pharmaceutical now have rather large scale of production and competitive advantages. CMO industries in our country is still in its early stage, companies such as WuXi Biologics is actively making strategies of biopharmaceutical CMO. In the near future, benefit from the Marketing Authorization Holder (MAH) system, the large number of biotech talents and the flourishing biotech R&D enterprises, China's CMO market has great development potential. Reference: https://www.cn-healthcare.com/articlewm/20190816/content-1067500.html	N/A	N/A	Combiphar, Dexa Medica, Bernofarm, Sanbe Farma, Kalbe Farma, and other local pharmaceutical companies	N/A	N/A	As of 2017, a total of 251 facilities were licensed by the Drug Control Authority (DCA), Ministry of Health Malaysia. They are categorised into 158 (63%) facilities that produce traditional medicine, 83 (33%) facilities that produce pharmaceuticals and 10 (4%) facilities that produce veterinary products. (http://www.mida.gov.my/home/pharmaceuticals/posts/)	Existing legislations allow contract manufacturing in the Philippines. These provide alternatives for companies to just contract manufacture products locally instead of establishing their own manufacturing plants.	Beacons, A-Bio Pharma, and more	N/A	OLIC (Made a subsidiary of Fuji Chemicals Industrial on August 3, 2012) Inter Thai Pharmaceuticals (http://www.interthaipharma.com)	Local: DGH, Traphaco, Domesco, IMEXPHARM, OPC, Cuu Long, Pharmedic etc.
Pharmaceutical industry groups	Name of main Organization (Please insert weblink if available)	Approved by Ministry of Civil Affairs of the P.R.C China Pharmaceutical Innovation and Research Development Association (PhIRDA) http://www.phirda.com/ Chinese Pharmaceutical Association http://www.cpa.org.cn/ China Pharmaceutical Industry Association (CPIA) http://www.cpia.org.cn/ Subcommittee R&D-based Pharmaceutical Association Committee (RDPAC) http://www.rdpac.org/Index.aspx	The Hong Kong Association of the Pharmaceutical Industry (HKAPI)	Indian Drug Manufacturers' Association (IDMA) was formed in 1961: Membership of over 1000 wholly-Indian large, medium and small companies. Confederation of Indian Pharmaceutical Industry OPPI: Established in 1965, the Organisation of Pharmaceutical Producers of India (OPPI) represents the research-based pharmaceutical companies in India.	[1] International Pharmaceutical Manufacturers Group (IPMG): a group in which major foreign-affiliated companies participate http://www.ipmg-online.com/?&lang=eng [2] GP Farmasi (GPFI): an Organisation of local generic companies www.gpfarmasi.or.id	Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) Japan Pharmaceutical Manufacturers Association (JPMA) Japan Generic Medicines Association Japan Self-Medication Industry Japan Association of Proprietary Medicine Manufacturers Japan Ophthalmic Pharmaceutical Manufacturer's Association Japan Kampo Medicine Manufacturers Association (JKMA) Home Medicine Association of Japan Topical Formulation Council Japan Association of Vaccine Industries (JAVI) Intravenous Solutions Society Japan Blood Products Association Nationwide Household Delivery Drug Association Japan Association of Clinical Reagents Industries Pharmaceutical Contract Manufacturers Association Forum for Innovative Regenerative Medicine	1) Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) 2) Korean Research-based Pharmaceutical Industry Association (KRPIA) 3) Korea Biomedicine Association(KoBIA)	Pharmaceutical Association of Malaysia (PhAMA): Innovative R&D-based pharmaceutical companies. Malaysian Organisation of Pharmaceutical Industries (MOPI): local manufacturers of generic drugs. Malaysian Association of Pharmaceutical Suppliers (MAPS): imported generic drug companies (http://www.phama.org.my/)	Pharmaceutical and Healthcare Association of the Philippines (PHAP) http://www.phap.org.ph Philippine Chamber of Pharmaceutical Industry (PCPI) Philippine Pharmaceutical Manufacturers Association (PPMA)	Singapore Association of Pharmaceutical Industries www.sapi.org.sg	1.Taiwan Pharmaceutical Manufacturer's Association (TPMA) http://www.tpma.org.tw/ 2.Taipei Pharmaceutical Agents and Distributors Association (TPADA) http://www.tpada.org.tw 3.International Research-based Pharmaceutical Manufacturers Association (IRPMA) http://www.irpma.org.tw/ 4.Taiwan Pharmaceutical Marketing & Management Association (TPMMA) http://www.tpmma.org.tw 5.Taiwan Pharmaceutical Manufacture & Development Association (TPMDA) http://www.cpmda.org.tw/ 6.Chinese Association for Pharmaceutical Agents (CAPA) http://www.capa.org.tw 7.Taiwan Generic Pharmaceutical Association (TGPA) http://www.tgpa.org.tw 8.National Pharmaceutical Commercial Association of R.O.C (NPCA) http://www.npca.org.tw 9.Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA) http://www.trpma.org.tw/	·Pharmaceutical Research & Manufacturers Association (PReMA) www.prema.or.th [Thailand's research based pharmaceutical association] ·Thai Pharmaceutical Manufacturers Association (TPMA) [Thai domestic industry association] ·The Medical Device Technology Industry Association (THAIMED) ·Thai Self Medication Industry Association (TSMIA)	Pharma Group – represents innovative pharmaceutical industry (operating under EuroCham) International Quality Medicines – Generic & Biosimilar Sector Committee – represents international generics industry (operating under EuroCham) Vietnam Pharmaceutical Companies Association (VNPCA) – represents local pharmaceutical industry

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HKAPI	**The Hong Kong Association of the Pharmaceutical Industry** Sabrina Chan Karen Yuen
IPMG	**International Pharmaceutical Manufacturers Group** Parulian Simanjuntak Agustina Tjandra Destita Khairilisani Herlina Aziz
IRPMA	**International Research-Based Pharmaceutical Manufacturers Association** Heather Lin Linda Wu Stally Lee Yvonne Wang
JPMA	**Japan Pharmaceutical Manufacturers Association** Asia Committee of International Affairs, Code Compliance Committee, Intellectual Property Committee, Pharmaceutical Industrial Policy Committee, Quality & Technology Committee, Regulatory Affairs Committee
KPBMA	**Korea Pharmaceutical and Bio-pharma Manufacturers Association** Jeongmin Seo
KRPIA	**Korean Research-based Pharmaceutical Industry Association** Mijin Jung
OPPI	**Organisation of Pharmaceutical Producers of India** Sanjit Singh Lamba Ajay kumar Sharma Nitika Garg
PhAMA	**Pharmaceutical Association of Malaysia** Alice Chee Shi Hao Lim
PHAP	**Pharmaceutical and Healthcare Association of the Philippines** Teodoro Padilla Richard Simon Binos Emeline Bautista
PhIRDA	**China Pharmaceutical Innovation and Research Development Association** Xiaoti Lu Yuanlin Yang
PReMA	**Pharmaceutical Research & Manufacturers Association** Pitchapon Noonbhakdi
RDPAC	**China Association of Enterprise with Foreign Investment R&D-based Pharmaceutical Association Committee** Sara Wang Zhu Bo Wu Tong
SAPI	**Singapore Association of Pharmaceutical Industries** Christina Teo Regulatory Affairs Committee & Public Policy Committee
PG	**Pharma Group (Vietnam)**
RA-EWG	**Regulations and Approvals Expert Working Group**

With many thanks from PMRE Task Force:

PMRE Publication Team

Tomoyuki Otsuka (TF Lead)
Regulatory Affairs: Osamu Inagaki (Sub-Lead), Kazuhiro Kaneko, Jun Hirao, Naoko Matsui
Market Environment: Megumi Yoneyama (Sub-Lead), Hirokazu Matsukami, Hayato Deki
Secretariat: Kazuharu Matsuoka, Erina Yamada

PMRE Review Team

China：Nishiyama・Horie・Sato・Kuwahara（ME）, Kobayashi・Liu (RA)
Korea：Kim（ME), Okeya・Iwamoto（RA) /Taiwan：Kagawa（ME), Kiriyama（RA)
Thailand：Horio（ME), Yoneyama（RA) /Indonesia：Hayashi(ME), Sakai（RA)
Malaysia：Tashiro（ME） Kawai（RA) /Vietnam: Hosokawa（ME), Higashiyama（RA）
Philippines：Chiba (ME), Hanazawa (RA) /India：Kuwahara (ME), Goto (RA)
Singapore：Hori（ME), Katsukawa（RA) /Hong Kong：Matsukami（ME), Horio（RA)