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略語	名称
AADHAR	The name of "Personal Identity Card"
ACE	Agency for Care Effectiveness
AMED	Japan Agency for Medical Research and Development
APEC	Asia-Pacific Economic Cooperation
ASCI	Advertising Standards Council of India
ASKE	Health coverage system in Indonesia
BIA	Budget Impact Analysis
BIS	Bureau of Indian Standards
BPJS	Badan Penyelenggara Jaminan Sosial (National Health Insurance System)
BPL	Below Poverty Line
BPOM	the National Agency of Drug and Food Control in Indonesia
CAGR	compounded annual growth rate
CAPA	Chinese Association for Pharmaceutical Agents
CDE	Center for Drug Evaluation
CDSCO	Central Drugs Standards Control Organization
CEA	cost-effectiveness analysis
CECA	Comprehensive Economic Cooperation Agreement
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
CMO	Contract Manufacturing Organization
CPC	Communist Party of China
CPF	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
DPCO	Drugs Price Control Order
DPRB	Drug Price Regulatory Board
DRG	Diagnosis Related Groups
DRGs	Diagnosis Related Groups
EPCG	Export Promotion Capital Goods
EPF	Employees Provident Fund
ESIS	Employment State Insurance Scheme
ESIS	State Insurance Corporation
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FIE Importer	Foreign Investment Enterprise
FORNAS	National Formulary (Indonesia)
FTA	US Free Trade Agreement
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
GoM	Group of Ministers
GPFI	GP Farmasi
GPIN	Global Product Identification Number
GPO	Group Procurement Office
GPO	Group Purchasing Office
GPP	Good Pharmacy Practice
GSP	Good Supply Practice

略語	名称
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
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
JAMSOSTEK	Jaminan Sosial Tenaga Kerja (Indonesia)
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
MDTCA	Ministry of Domestic Trade and Consumer Affairs
MEA	Managed Entry Agreement
MFDS	Ministry of Food & Drug Safety
MHLW	Ministry of Health and Welfare
MIDA	Malaysian Industry Development Authority
MOA	Ministry of Agricultural and Agro-based Industry
MOH	Ministry of Health
MoHFW	Ministry of Health and Family Welfare
MoLHR	A Ministerial regulations in Indonesia
MoPH	Ministry of Public Health in Thailand
MOPI	Malaysian Organisation of Pharmaceutical Industry
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
NAIS	National Adult Immunisation Schedule
NCIS	National Childhood Immunisation Schedule
NCKUH	National Cheng Kung University Hospital in Taipei
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

略語	名称
NEML	National Essential Medicines List
NHC	National Health Commission of China
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 IP Center for Enforcement
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
OECD	Organization for Economic Cooperation and Development
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
PPKM	behavior restrictions
PPMA	Philippine Pharmaceutical Manufacturers Association
PPP	Purchasing Power Parities
PRC	People's Republic of China
PReMA	Pharmaceutical Research & Manufacturers Association
Private Insurance	Organization issuing private insurance
PSBB	large-scale social restrictions
PSP	Pharmaceutical Services Program
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
Refined DRG	Refined Diagnosis-Related Group
RFID	Radio Frequency Identification
RHSs	reorganization of the former six regional health systems
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
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

略語	名称
State Insurance	Respective State Government
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
TRIPS	TradeRelated Aspects of Intellectual rights
TSMIA	Thai Self Medication Industry Association
UCEP	Iniversal Coverage for Emergency Patients
UCPMP	Uniform code for Pharmaceutical Marketing Practices
UCS	Universal Health Coverage Scheme
UHC	Universal Health Coverage
UMA(A)O	Undesirable Medical Advertisements (Amendment) Ordinance
VAT	Value Added Tax
VNPCA	Vietnam Pharmaceutical Companies Association
VSS	Vietnam Social Security
WHO	World Health Organization

EXECUTIVE SUMMARY

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	2021 COVID pandemic impact on the entire society and healthcare system is not an exception. However, compare with the situation in 2020, people in Hong Kong adopted the new normal and the market growth at 4.2% based on the report of IQVIA
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. The coronavirus (COVID-19) pandemic has posed unprecedented challenges in understanding pharmaceutical market trends and building reliable forecasts. As of early September 2021, Indonesia had reported over 4.15 million confirmed cases of COVID-19, with around 137,800 fatalities. A combination of large-scale social restrictions (PSBB) and localized restrictions (PPKM) have been introduced where outbreaks occur, with stricter local restrictions deployed intermittently where local cases have surged. A resurgence of infections from late June 2021, driven by the highly virulent Delta variant, marked the start of a third wave, with cases increasing rapidly in July. Infections declined through August and early September; however, the number of active cases remained relatively high and COVID-related hospitalizations remained elevated. Indonesia's vaccination campaign, launched in mid-January 2021, has been hindered by logistical challenges, supply issues and vaccine hesitancy. As of early September, around 70.8 million people (~27% of the population) had been given at least one shot, while 40.6 million people (~15% of the population) were fully vaccinated. The campaign is expected to accelerate from H2 2021; however, widespread coverage will not be achieved until 2023.
Japan	JPMA	The "Law for Partial Revision of the Law Concerning Quality, Effectiveness, and Safety of Pharmaceuticals and Medical Devices" promulgated on December 4, 2019 enacted the bar code display. It will be put into effect in December 2022. The cost-effectiveness analysis system started in April 2019. Drugs and medical devices with large market sizes or extremely high unit prices are evaluated, and the evaluation results are not used to judge whether or not insurance can be reimbursed, but are once listed in insurance and then used for price adjustment. Hereafter, the evaluation system will be enhanced, cases will be collected, and the ideal system and utilization method will be examined.
Korea	KPBMA/KRPIA	The Korean government is enacting policies to expand national health insurance coverage but continuously making effort to save NHI finance by price adjustment. To manage the national health insurance finance, pharmaceutical spending structure should be revised centered on innovative new drugs. The government plans to expand RSA scope to non-severe diseases drugs and also review the possibility of strengthening price management after listing.
Malaysia	PhAMA	The year 2021 has yet to bring significant and far-reaching impact to Malaysia's pharmaceutical industry. This is largely attributable to the continuation of many of the Malaysian government's policies and laws concerning the industry such as generous tax incentives and the maintenance of a constellation of effective intellectual property laws. Financially, 2021 has been projected to be a more profitable year for the industry despite slowing economic growth - largely due to the severity of the COVID-19 public health crisis. The government is currently considering the merits of the proposed policy of medicine price controls. The cba 2.0 has effectively highlighted the potential adverse consequences of the mpc policy. The Malaysian parliament in December has also passed the patent amendments bill 2021.
Philippines	PHAP	While the pandemic continues to bring the industry in a positive light, challenging pharmaceutical policies have been proposed and implemented in 2021. In particular, another round of price cuts reaching up to 96% was imposed on 71 products. The "covidization" of healthcare facilities negatively impacted the pharmaceutical industry, coupled with the mandatory price cuts implemented. While signs of recovering are showing, returning to pre-pandemic growth levels remains to be seen as the pandemic continues.
Singapore	SAPI	The Agency for Care Effectiveness (ACE) rolled out its new manufacturer-led health technology assessment (HTA) process in 2021 where companies are able to submit for their products to be evaluated for funding consideration and will be responsible for providing an evidence submission to ACE in order to support deliberations by the main Drug Advisory Committee (DAC). The new process serves to enable medicines to be evaluated close to the anticipated date of regulatory approval by the Health Sciences Authority (HSA), & expedite funding considerations to improve patient access to clinically necessary treatments. The Government also announced further revisions to enhance MediShield Life coverage for cancer treatment in September 2021, including the establishing of a positive list of clinically proven and cost-effective outpatient cancer drug treatments and increased subsidies and granular claim limits for patients. These revisions will enter in force in September 2022.
Taiwan	IRPMA	No major updates are provided
Thailand	PReMA	Thailand pharmaceutical market in 21 was not much different from the previous year. The focus of public healthcare are COVID-19 situation. The situations of cost containment, rational drug use and support of local pharmaceutical industry are still the same. There were new list of NLEM and median prices for biologics announced in 2021. The big changes of Thailand pharmaceutical market in 2021 still came from COVID-19 situation as follows: •continuing to expand telemedicine and telepharmacy to avoid patients to visit the hospitals •stockpiling for essential medicines: COVID-19 medicines, medicines for non-communicable diseases •local research and development of COVID-19 vaccines
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. In 2020, the success of the Vietnam Government and healthcare system in the combat against COVID-19 pandemic helps the economy to be forecasted to make a strong come back. Vietnam is also racing to produce its own COVID-19 vaccine, which could provide it with health security and export opportunities. Today, the pharmaceutical market in Vietnam is growing at a rapid pace and has increased from USD2.7 billion in 2015 to a forecast of USD7.7 billion in 2021 (according to the statistics of the Drug Administration Vietnam) 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. At the end of 2020, 90.85% of the population is now covered by the SHI system, and the target for coverage in 2021 has been raised to 91%. 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: Drug Administration Vietnam's statistics, Vietnam Minister of Health's statement at the Conference to assess and conclude the year 2020 on 6 January 2021, 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	1,412.12 million people (2020), Source: National Bureau Statistics of China https://data.stats.gov.cn/search.htm?s=%E4%B8%AD%E5%9B%BD%E4%BA%BA%E5%8F%A3	7394.7 million (mid 2021) Source – Census & Statistics Department HKSAR	1,380.04 Million [2020] [Source: http://data.un.org/en/iso/in.html]	267.67 million people (2018), Source: United Nations Statistics, https://www.un.org/en/ Forecast : Indonesia's population is increasing at 0.8% per annum and will total 277.5 million by 2024, an increase of 8.7 million over the 2020 level. Although the 0-14 years age group will decline by 0.66 million from 2020-2024, those aged 15-64 years will grow by 6.3 million, at an average 0.9% annually, adding substantially to the workforce over the outlook period. The 65+ years cohort will grow fastest, at an average rate of 4.5%, rising by 3.1 million, and will account for 6.7% of total numbers by 2024. Source :IQVIA Market Prognosis	125.63 million people (2021) [Source: United Nations Statistics]	51.84 million people (2020), Source: Korean Statistical Information Service (KOSIS)	32.675 million people (Jan 6 2022), Source: Department of Statistics Malaysia	109 Million (as of 2020) Philippine Statistics Authority https://psa.gov.ph/content/2020-census-population-and-housing-2020-cph-population-counts-declared-official-president	5.453.6 million (2021) https://www.singstat.gov.sg/find-data/search-by-theme/population/population-and-population-structure/latest-data	23. 394 million [Source: Ministry of the Interior, Nov 2021]	70,029,542 people [2021 https://worldpopulationreview.com/]	97.339 million people (2020) , Source: United Nations, http://data.un.org/en/iso/vn.html
	Elderly population ratio (≥ 65 yrs)	190.6 million people (2020), Source: National Bureau Statistics of China https://data.stats.gov.cn/search.htm?s=%E4%B8%AD%E5%9B%BD%E4%BA%BA%E5%8F%A3	1.434 Million (19.3%) Source – Census & Statistics Department HKSAR	Population ages 65 and above (% of total) in India was reported at 6.378% in 2019 according to World Bank collection of development indicators, compiled from officially recognized sources [Source: https://data.worldbank.org/indicator/SP.POP.65UP.TO.ZS?locations=IN]	6.3% (2020) Source Link : http://www.bps.go.id/publication; World Data Atlas - Demographics	28.8% (2021) ["Demographic forecast," Bureau of Statistics of the Ministry of Internal Affairs and Communications]	15.7% (2020) Source: Korean Statistical Information Service (KOSIS)	≤ 14 y/o, 23.04%; 15-64 y/o, 69.6%; ≥ 65 y/o, 7.37% (Q3 2021) [Department of Statistics, Malaysia] Life expectancy at birth: male: 73.2 years; female: 78.3 years (2021) [Source: Department of Statistics, Malaysia]	6 Million (6%) (as of 2020) World Bank https://data.worldbank.org/indicator/SP.POP.65UP.TO?locations=PH	639,000 (2021: Singapore citizens and permanent residents) https://www.singstat.gov.sg/find-data/search-by-theme/population/population-and-population-structure/latest-data	16.80% [Source: Ministry of the Interior, Nov 2021]	11.3% [2021 https://worldpopulationreview.com/]	7.554% (male 2,863,034 / female 4,423,377) (2019) [World Bank]
	No. of physicians (per 1,000 people)	2.90 (2020)- Source: Source: China Statistical Yearbook 2021 http://www.stats.gov.cn/tjsj/ndsj/2021/indexch.htm	Total and healthcare professionals to Population Doctors: 15,298 (1:489) Registered Chinese medicine practitioners: 7,919 (1:944) Dentist: 2,651 (1: 2,819) Nurses: 61 295 (1:122) Pharmacists: 3097 (1: 2413) Source: Health Facts of Hong Kong 2021 Edition	0.857 [2018] [Source: https://data.worldbank.org/indicator/SH.MED.PHYS.ZS?locations=IN]	0.72 doctors 0.15 dentist Total : 234,329 (Doctors: 151,456; Dentists: 35,219; Doctors Specialist: 43,110 ; Dentists Specialist: 4,544) 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.	2.59 (2018) ["Survey of Physicians, Dentists and Pharmacists," Ministry of Health, Labour and Welfare]	2.08 107,976 (2020) Source: Korean Statistical Information Service (KOSIS)	2.2 or 1 doctor for every 454 Malaysians (Galen Centre for Health and Social Policy)	0.6 per 1,000 population (as of 2017) World Bank https://data.worldbank.org/indicator/SH.MED.PHYS.ZS?locations=PH	3.13 (2020) [Source: Statistics of Medical Care Institution & Hospital Utilization 2020, Department of Statistics, Ministry of Health and Welfare]	N/A	0.919 [2019 World Bank]	0.88 (2019) [Statistical Yearbook of Vietnam 2019]

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	No. of hospitals	1022922 (2020)- Source: Source: China Statistical Yearbook 2021 http://www.stats.gov.cn/tjsj/ndsj/2021/indexch.htm	Public Hospitals: 43 [2022 Hospital Authority] Private Hospitals: 12 [2022 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 : 2,925 (private & public) -Public : 1071 (36.61%) -Private : 1,854 (63.39%) Source Link : http://sirs.yankes.kemkes.go.id/rsonline/report/ - 2020 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: 179,416 (2019) Public hospitals (National/public medical institutions): 5,848 (2019) Private hospitals (Others): 173,568 (2019) *National/public medical institutions ["Survey on Medical Institutions (dynamics) and Hospital Report," Ministry of Health, Labour and Welfare]	Total: 96,742 (2020) (Tertiary hospital: 42 / General hospital: 319, Hospital: 1,515 / Healthcare Institute: 1,582 / Clinic: 33,115 / Dental hospital: 235/ Dental clinic: 18,261 / Midwifery clinic: 18 / Hospitalized health center: 15 / Health center: 241 / Health subcenter: 1,317 / Primary Health care post: 1,903 / Oriental hospical:410 / Oriental clinic: 14,464 /Pharmacy: 23,305) Source: Korean Statistical Information Service (KOSIS)	1. Total number of Government Hospitals- 145 (Source-MOH as of 10/1/2022) 2.Total number of Government Hospital Beds- 41995 (Source-data.gov.my as of 8 February 2021) 3.Covid-19 Hospital Bed Capacity - ICU Beds-1,596 beds - Non ICU Beds-18659 beds (Source-covid-19.moh.gov.my) 4.Total number of Government Health Clinics-2838 (Source-MOH as of 10/1/2022) 5. Total number of Private Clinics- 8196 (Source-medicalprac.moh.gov) 6. Total number of Private Hospitals: 208 (16,469) (Source: Health Facts 2020 and medicalprac.moh.gov)	1,385 hospitals (as of February 2022) National Health Facility Registry https://nhfr.doh.gov.ph/Philippine_health_facility_statuslist.php	Ministry of Health Singapore – Health Facilities 2020 Total number of hospitals 28 Acute hospitals 18 (public 10, not-for-profit 1, private 7) Psychiatric hospitals 1 (public) Community hospitals 9 (public 5, not-for-profit 4) Public polyclinics 20, private general practitioner clinics 2343 Public dental clinics 245, private dental clinics 862 Pharmacies 259 (public 66, private 193) Source: 2020, Department of Statistics, Singapore https://www.moh.gov.sg/resources-statistics/singapore-health-facts/health-facilities	479 (2020) [Source: Statistics of Medical Care Institution & Hospital Utilization 2020, Department of Statistics, Ministry of Health and Welfare]	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) [GENERAL STATISTICS OFFICE Vietnam]
	Hospital beds (per 1000 people)	6.46 (2020)- Source: China Statistical Yearbook 2021 http://www.stats.gov.cn/tjsj/ndsj/2021/indexch.htm	Total number of hospital beds: 42, 291 Public Hospitals: 29, 902 (Hospital Authority) Private Hospitals: 5,050 [End 2020 Department of Health] Nursing Homes: 6,465[End 2020 Department of Health] Under Correctional Institutions: 874 [End 2020 Department of Health]	0.53 [2017] [Source: https://data.worldbank.org/indicator/SH.MED.BEDS.ZS?locations=IN]	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]	13.0 (2018)【Hospital beds (per 1,000 people), The World Bank】	13.8 (2020) Source: Korean Statistical Information Service (KOSIS)	2.01 beds (2020) (Source: The SunDaily)	1.2 (as of 2016) WHO-OECD https://iris.wpro.who.int/bitstream/handle/10665.1/13982/9789290618485-eng.pdf	3.5 (Total hospital beds 15564 according to MOH statistics 2020) https://www.moh.gov.sg/resources-statistics/singapore-health-facts/beds-in-inpatient-facilities-and-places-in-non-residential-long-term-care-facilities	7.21 (hospital beds + clinical beds; 2020) [Source: Statistics of Medical Care Institution & Hospital Utilization 2020, Department of Statistics, Ministry of Health and Welfare]	2.41 [2019 export.gov]	2.85 beds/1,000 population (est. 2019) [Statistical Yearbook of Vietnam 2019]
	GDP (Current USD, Billion)	USD 15954.56 billion (RMB 101598.62 billion, 1 USD≈6.368RMB) - Source: National Bureau Statistics of China https://data.stats.gov.cn/easyquery.htm?cn=C01&zb=A0208&sj=2020	344,7 billion (2020 Hong Kong TDC data)	USD 2,869 Billion [2019] [Source: https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=IN]	1,119 Billion [2019] (current US$, World Bank Website] Source: https://www.worldbank.org/	5,397 Billion (2020) ["International Comparison of GDP," Cabinet Office]	1,651 Billion (2020) Source: Korean Statistical Information Service (KOSIS)	GDP (nominal) USD 387.094 billion GDP (PPP) USD 978.78 billion World Economic Outlook Database, IMF (2021 estimates)	361.5 billion (as of 2020) World Bank https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=PH	339.998 billion [World Bank 2020] https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=SG	669.3 billion (2020) [Source: National Statistics, Taiwan]	502 billion [Dec/20 Tradingeconomics.com]	261.921 Billion (2019) [World Bank]
	GDP Growth Rate (annual %)	2.3%, Source: National Bureau Statistics of China https://data.stats.gov.cn/easyquery.htm?cn=C01&zb=A0208&sj=2020	2020: -6.5% 2021: +6.4% in real terms over 2020 https://research.hktdc.com/en/article/MzIwNjkzNTY5	4.181 [2019] [Source: https://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG?locations=IN]	4.91% (from 2000 - 2020 y/y) Source : Statistic Indonesia (BPS) Supported Link : https://www.tradingeconomics.com Forecast : 5.2%(from 2022 - 2021 y/y) ▪Real GDP is forecast to increase by just 0.2% in 2020, with measures to contain COVID-19 curtailing growth, before recovering to grow by an annual average of 5.3% in 2021-2024. Private consumption is expected to contract by -1.0% in 2020, owing largely to preventative measures in place to limit the spread of COVID-19, but will recover from 2021 and grow at an average of 5.3% annually to 2024, as long as the virus is brought under more effective control. Inflation will slow to 2.2% in 2020, largely due to weaker domestic demand, and will rise again from 2021 as demand recovers, to average 3.7% over 2021-2024, although it will be kept in check by low global oil prices. The rupiah will remain vulnerable to bouts of volatility, but is forecast to slightly appreciate against the US dollar to reach an annual average of US$1:Rp13,691 in 2024. A significant worsening of the COVID-19 outbreak could reduce growth prospects, however. Source :IQVIA Market Prognosis	FY2020 Real △ 4.5% (year-on-year) FY2019 Nominal △ 3.9% (year-on-year) ["GDP Statistics," Cabinet Office]	-0.9 %(2020) Source: Korean Statistical Information Service (KOSIS)	-5.6% (2020) [World Bank] 3.0% (First 9 months of 2021- Ministry of Finance)	-9.5% (2020); Q3 2021 at 7.1 Philippine Statistics Authority https://psa.gov.ph/content/philippine-gdp-posts-83-percent-fourth-quarter-2020-95-percent-full-year-2020 https://psa.gov.ph/content/gdp-posted-growth-71-percent-third-quarter-2021	-5.4% [World Bank 2020] https://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG?locations=SG	3.70% (Q3 2021) [Source: National Statistics, Taiwan]	-1.1% [Sep/21 Tradingeconomics.com]	7.017% (2019) [World Bank]

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Economic status	Consumer prices (annual %)	2.5% (2020), Source: National Bureau Statistics of China https://data.stats.gov.cn/easyquery.htm?cn=C01&zb=A0208&sj=2020	+ 1.6% https://www.censtatd.gov.hk/en/web_table.html?id=52	7.66% [2019] [Source: https://data.worldbank.org/indicator/FP.CPI.TOTL.ZG?locations=IN]	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	-0.02%（2020 年） Inflation rate, average consumer prices *Inflation rate based on the Consumer Price Index (CPI)【IMF】	0.5% (2020) Source: Korean Statistical Information Service (KOSIS)	-1.0 (2020) [World Economic Outlook Database]	4.5% Philippine Statistics Authority https://psa.gov.ph/statistics/survey/price/summary-inflation-report-consumer-price-index-2012100-december-2021	-0.2% [2020, Department of Statistics, Singapore] https://www.singstat.gov.sg/modules/infographics/consumer-price-index	2.84% (Nov 2021) [Source: National Statistics, Taiwan]	2.17% [Dec/21 Tradingeconomics.com]	3.23% (2020) [GSO Vietnam]
	Unemployment, total (% of total labor force) (national estimate)	4.2% (2020), Source: National Bureau Statistics of China https://data.stats.gov.cn/easyquery.htm?cn=C01&zb=A0208&sj=2020	3.9 % (10/2021 - 12/2021) https://www.censtatd.gov.hk/en/web_table.html?id=6	Unemployment Rate in India increased to 5.399 percent in 2020 from 3.52 percent in 2017 [World Bank Modeled ILO estimate] [Source: https://data.worldbank.org/indicator/SL.UEM.TOTL.ZS?locations=IN]	Indonesia Unemployment Rate increased to 7.07 % in Aug 2020, from the previously reported number of 5.28 % in Aug 2019. Source: //tradingeconomics.com/Indonesia[/ unemployment-rate	2.8% (2020) [Harmonized Unemployment Rates (HURs), OECD]	4.0% (2020) Source: Korean Statistical Information Service (KOSIS)	4.7% (October 2021) [Department of Statistics Malaysia]	6.5% (November 2021) Philippine Statistics Authority https://psa.gov.ph/content/unemployment-rate-november-2021-estimated-65-percent	2.6% [As of Sep 2021, Department of Statistics, Singapore] https://www.singstat.gov.sg/find-data/search-by-theme/economy/labour-employment-wages-and-productivity/latest-data	3.66% (Nov 2021) [Source: National Statistics, Taiwan]	2.25% [Sep/21 Tradingeconomics.com]	2.022% (2020) [World Bank]

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Pharmaceutical distribution	Pharmaceutical market size	271,545 million USD (2021, 1 USD≈6.368RMB) Source: Frost &Sullivan https://baijiahao.baidu.com/s?id=1720382031882243016&wfr=spider&for=pc	1,884 million USD (2021, Ex-Manufacturer, 1USD=7.8 HKD, IQVIA Constant rate) Source: IQVIA	19,059 million USD (2020, 1USD=73.7 Local currency) Source: IQVIA	2,866 million USD (2018, Ex-Manufacturer, 1USD=14,788.5 IDR, IQVIA Constant rate) Source: IQVIA	7,335.2 Billion JPY (2018) "According to the Ministry of Health, Labor and Welfare, it is estimated that this figure deviates from the actual situation because a considerable number of companies including major companies are missing from the aggregation target. Therefore, we do not recommend posting the data."	KPBMA only have market data of 2020 at this moment. But since JPMA kindly put that data in last year's report, we would like to ask if it's possible to get updated one here again.	USD 2,020 million (MAT Q3 2021) Source: IQVIA	4,373 million USD (2020, Ex-Manufacturer, 1USD=51.43 PHP, IQVIA Constant rate) Source: IQVIA	986 million USD (2020, Ex-Manufacturer, 1USD=1.3 SGD, IQVIA Constant rate) Source: IQVIA	7,812 million USD (2021, 1USD=27.65TWD) [Source: IQVIA]	6,891 million USD [2021 IQVIA]	4,259 million USD (2020, Ex-Manufacturer, 1USD=23,164.2 VND, IQVIA Constant rate) Source: IQVIA
	Generic ratio in the market	63% (2020) https://www.huaon.com/channel/trend/756281.html	N/A	89.3% (2020) Source: IQVIA	"BPJS Health still have a challenge to manage their operational efficiency and how to make the JKN more stable in terms of long-term profitability, so the generics will definitely increase through 2021 and 2022…Now that BPJS are positive [budget surplus], they'll use the budget properly to increase and push generic drug consumption further." (Local Company Executive) Source :IQVIA Market Prognosis	N/A	N/A	47% (volume, MAT Q3 2021) Source: IQVIA	72.0% (2020) Source: IQVIA	39.3% (2020) Source: IQVIA	43% [Source: 2020-11-20 press release, Ministry of Health and Welfare]	51% [2021 IQVIA]	72.4% (2020) Source: IQVIA

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Pharmaceutical distribution	Overview of pharmaceutical distribution	N/A	N/A	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 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 distributor, 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. The pandemic has cemented the advantages of the leading players. Many smaller wholesalers have been forced to cease trading completely in the face of staffing and cash flow problems. This has enabled remaining players to reduce discounting levels, helping them to offset increases in the cost of doing business during the pandemic. [Source: MP India]	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 60,000 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. In addition, a revised version of the guideline was issued in November 2021 and has been applied since January 2022 in light of the fact that the trading environment for ethical drugs has changed significantly and the need for efforts to improve business practices for many years has increased. https://www.mhlw.go.jp/content/10800000/000861022.pdf	・Drugs distributed to medical institutions in 2020 were worth 30.3 trillion won which was up by 4.8% compared to 28.9 trillion won the year before. Among these, prescription drugs accounted for 89% or 27 trillion won. - By medical institution, general hospitals accounted for 6.6 trillion won (21.8%), hospitals for 1.8 trillion won (5.8%), clinics for 2.3 trillion won (7.7%), pharmacies for 19.3 trillion won (63.7%), and others for 0.3 trillion won (1.0%). - Drug sales price in total for each distribution stage were: 2.8 trillion won from manufacturers/importers to medical institutions, 23.6 trillion won from manufacturers/importers to wholesaler, 20.9 trillion won between wholesalers, and 27.6 trillion won from wholesalers to medical institutions. ・As of the end of December, the number of finished drug product distributors was 3,654, and Among them, 3,170 (86.8%) were wholesalers, 484(13.2%) were drug manufacturers / importers. ・Companies that account for the top 5% of annually supply account for 71% of the drug distribution market. - By business type, manufacturers accounted for 85% followed by 76% of importers and 63% of wholesalers. ・There were 13 items of OTCs sold at convenience stores as of 2020 and their total sales amount were 45.7 billion won. Source: 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	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: • 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 Philippine Competition Commission, 2018 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: • 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 Philippine Competition Commission, 2018	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. For 2020, 90,85% of the population is now covered by the SHI system. 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 licence grant but still need implementation	N/A	The Indian Government has issued a consolidated paper through Central Drugs Standards Control Organisation (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 11rganization 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 11rganization 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 11rganizationa. 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, 11rganizati by the management. Various jobs in the distribution chain will be detailed and will require an 11rganizational 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	Real GDP is forecast to increase by 3.9% in 2021, after a contraction of -2.0% in 2020 that was caused by the COVID-19 pandemic. Stringent social restrictions and uncertainty around the pandemic will weigh on consumer demand for the remainder of 2021, thereby slowing the near-term recovery. Economic growth will average 5.6% growth in 2022-2025, with the uptick in 2022 being supported by the loosening of restrictions, which will boost domestic demand and private consumption. Inflation will rise to 2.4% in 2021 as the global prices of key commodities increase, although prices will be kept in check by weak domestic demand. Inflation will average 3.4% over 2022-2025. Although the rupiah is expected to strengthen in 2021, the local currency is projected to weaken throughout the forecast period to reach an annual average of US$1:Rp17,030 in 2025.	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.)	NPRA is the regulatory authority for certifications of GDP and GMP. According to the Controls of Drugs and Cosmetics Regulations 1984, any company that intends to manufacture, import or wholesale any registered product needs to have the following types of licenses respectively - Manufacturer's License, an Import License or a Wholesale License. https://www.npra.gov.my/index.php/en/guidelines-for-compliance-licensing/1608-licensing-manufacturer-importer-and-wholesaler.html	The FDA implements WHO GDP and GSP as part of the licensing requirements for distributors and retailers. In addition, a local cold chain management standard is implemented. (Administrative Order No. 2013-0027, Bureau Circular No. 2007-003)	The Health Sciences Authority (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. The amendment of Article 53-1, Pharmaceutical Affairs Act had been approved by The Legislative Yuan and issued on June 14, 2017. Article 53-1 defined the companies who wholesale, import or export the medicinal products (including cold chain products) shall comply GDP. TFDA has also announced in 2019 (TFDA official letter No. 1081102318) that companies distributed, imported, or exported the medicinal products (including cold chain products) must apply for the evaluation of GDP and meet the standards of the good distribution practice for western medicines before 31 Dec 2021	Thai FDA plans to implement GDP (Good Distribution Practice) as regulatory requirement in 2022. 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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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMa	PReMA	PG
Pharmaceutical distribution	Central logistical management requirement (e.g.Serialization/barcode requirement)	NMPA issued Basic Dataset of Drug Traceability for Marketing Authorization Holders and Manufacturers, Basic Dataset of Drug Traceability for Distributors, Basic Dataset of Drug Traceability for Medical Organizations, Basic Dataset of Drug Traceability for Consumer Inquiry, and Basic Technical Requirements for Drug Traceability Data Exchange, which will be valid from March 11st, 2020. Source: NMPA https://www.nmpa.gov.cn/yaopin/ypggtg/20200311085301898.html	N/A	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 "parentchild" 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, the "Law for Partial Revision of the Law Concerning Quality, Effectiveness, and Safety of Pharmaceuticals and Medical Devices" promulgated on December 4, 2019 enacted the bar code display. It will be put into effect in December 2022. Moreover, labeling of JAN code (GTIN) is required for OTC drugs.	1. The HIRA entrusted research on the effectiveness analysis and improvement plan of the serialization currently in effect, and is also considering a plan to expand the serialization in effect for ETC to OTC.	The MOH Pharmaceutical Services Program is progressing with plans on the Pharmaceutical Track & Trace System under a Malaysian National Medicines Policy initiative for strengthening regulatory capacity & standards. In 2021 a Vaccine Management System (VMS) was implemented in the National COVID-19 Immunization Program (PICK) based on the concept of Track & Trace and served as a pilot project for the Track & Trace system. Engagement sessions for all relevant stakeholders have been planned in 2022.	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. (FDA Circular No. 2016-011)	Plans in place to implement the Central Fill Warehousing Pharmacy to supply to the public healthcare institutions through ALPS.	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.

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
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) 2014 2.The Code of Pharmaceutical Practices, 2012 by Organisation of Pharmaceutical Producers of India (OPPI) 3.Drugs & Cosmetics Act, 1940 4.Drugs & Magic Remedies (Objectional advertisement) Act, 1954 (DMRA) 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 However, 2 most followed codes are: 1)Uniform Code of Pharmaceuticals Marketing Practices, 2014 ("UCPMP Code") 2)The Code of Pharmaceutical Practices, 2012 by Organisation of Pharmaceutical Producers of India (OPPI) UCPMP is a voluntary code issued by the Department of Pharmaceuticals (DoPrelating 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.	IPMG CODE OF PHARMACEUTICAL MARKETING PRACTICES September 2019 Revision IPMG's latest Code of Ethics is now aligned with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) standards and have been socialized in September 2019. Reference: https://cms.ipmg-online.com/material/pages/resources/documents/IPMG%2020CoC_ENG_Sept_19_1.pdf	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, a part of the JPMA Code of Practice was formulated in January 2013 and revised in October 2019. It was subsequently revised based on the revision of the IFPMA in June 2018 Code, and based on the "Guidelines on Information Provision in Connection with Promotional Activities for Ethical Drugs" in September 2018. 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 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)	PhAMA Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products 21st Edition continues to remain in force. There is a separate code that regulates over the counter (OTC) products. https://www.pharma.org.my/index.cfm?&menuid=10	The DOH, through the FDA implements a code of ethics 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 DOH-FDA policy 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. (Administrative Order No. 2015-0053, PHAP Code of Ethics)	In addition to SAPI Code of Conduct 2022 (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 the current version was published in May 2021 and can be accessed through the IRPMA website	There is a new Ministry of Public Health notification: Ethics on Drug Procurement and Promotion effective in May 2021. The 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.	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 Amended for the third time by the Pharma Group General Assembly on 7 August 2020, effective 1 October 2020 https://www.eurochamvn.org/sites/default/files/uploads/Sector%20Committees/PG/PG%20Code%20of%20Ethical%20Practices_approved%207%20Aug%202020_effective%201%20Oct%202020.pdf

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Promotion	Hospital visit regulations	N/A	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 corporate hospitals and some State Governments in respect of Government hospitals have totally stopped allowing Medical Representatives.	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)	YB Khairy Jamaluddin in his capacity as the Minister of Health, had announced on November 26, 2021 that MOH will allow caretakers and visitors to visit certain categories of patients. These types of patients include those who are elderly, severely fatigued and the less abled. The objective here is to reduce the exposure of medical professionals and patients to Covid-19. (https://www.bharian.com.my/berita/nasional/2021/11/892261/penjaga-pelawat-dibenarkan-lawat-pesakit-di-hospital-kkm)	Hospital visits are allowed, provided the engagements with healthcare professionals are ethical and focuses on the provision of medical information. (Administrative Order No. 2015-0053)	•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. •Some restriction imposed during the Covid-19 pandemic control in place. •Specified in detail in SAPI Code of Conduct 2022	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, e.g., 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; f) 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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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Promotion	Advertising regulations	N/A	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	In India, promotion of medicines is regulated by the Drug and Cosmetics Act, 1940 (DCA) and the Drugs and Cosmetics Rules, 1945 (DCR) and DMRA Amendments to the Drugs and Cosmetics Act were published in draft form by the MOHFW in June 2019 and notified by the ministry in February 2020 Moves to tighten advertising and promotion rules are also in the pipeline. The scope of existing advertising regulations – and penalties for contravention of the rules – would be increased by provisions outlined in draft amendments to the Drugs and Magic Remedies (Objectionable Advertisements) Act tabled in 2020. The bill expands the list of diseases covered by the rules from 54 to 78, with AIDS among the proposed additions. [Source: MP India Q3 2020]	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/	After industry-wide discussions and based on agreements within the industry, KPBMA, KRPIA, KMDIA has announced a Temporary Guideline for Online Conferences (“Guideline”) under the COVID-19 pandemic situation with the approval of the Fair Trade Commission. Under the Guideline, maximum of 6M KRW/company is allowed for online ads and booths when a conference is held “online”. This Guideline is effective until the end of June 2022, and is highly likely to be extended considering current COVID-19 situation.	. There are 4 guidelines and or circulars which have been made available pursuant to the Medicines (Advertisement & Sales) Act 1956. These guidelines are as described below. 1. Guidelines on Advertising Medicines and Medicinal Products to the Public. The objective of this regulation is to serve as a guide to ensure that advertisers do not take undue advantage of potential customers and to ensure that advertisements contain a high standard of information, and its contents are proper and reliable. The Medicine Advertisements Board (MAB) has been given the authority to amend and or delete parts of this Guideline from time to time by order. 2. Advertising Guidelines for Healthcare Facilities and Services These Guidelines are intended to complement the provisions of the Medicines (Advertisement and Sale) Act 1956 (Revised 1983) and the Medicine Advertisements Board Regulations 1976. The purpose of these Guidelines is to provide information to private hospitals, clinics, radiological clinics and medical laboratories regarding the regulations governing advertisements of healthcare services offered by these facilities that are disseminated to the general public. The information provided in the advertisements must be factually accurate and capable of being substantiated. It must not be exaggerated, false, misleading, or deceptive. Unless exempted as laid out in section 3.0 of this guideline, advertisements shall only be publicized upon approval by the Medicine Advertisements Board. 3. Medicines Advertisement Board and Policy Decision (Product) 4. Medicines Advertisement Board and Policy Decision (Service) The purpose of both the above guidelines (No 3 and 4) is to stipulate clear rules on the prerequisites of an advertisement.	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. (Administrative Order No. 65 s. 1989)	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 Authority (HSA)’s "GUIDE ON ADVERTISEMENTS AND SALES PROMOTION OF MEDICINAL PRODUCTS", "EXPLANATORY GUIDANCE TO THE HEALTH PRODUCTS (ADVERTISEMENT OF THERAPEUTIC PRODUCTS) REGULATIONS 2016".	The advertising regulations are defined and regulated in Article 24, and 65 to 70 of *Pharmaceutical Affairs Act* and more detail regulations are in Article 44 to 47 of *Pharmaceutical Affairs Act Enforcement Rules*.	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 licence 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)

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
Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	-	In 2020, the Basic Medical Insurance for Employees Combined Maternity Insurance	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).	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. Initially the scheme was designed for BPL families, but later it included 11 other categories of Unorganized Workers (UOWs) (MGNREGA workers, construction workers, domestic workers, sanitation workers, mine workers, licensed railway porters, street vendors, beedi workers, rickshaw pullers, rag pickers and auto/taxi drivers). The scheme has now been transferred to the Ministry of Health & Family Welfare on an "as is where is" basis with effect from 01.04.2015. 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/- a year for up to 5 family members, 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 annually while Central and State Government pays the premium to the insurer selected by the State Government on the basis of a competitive bidding.The RSBY has now been largely overtaken by the rollout of the PMJAY. 2.Employment State Insurance Scheme (ESIS) Covers around 31 million workers and their families, equating to a total beneficiary population of approximately 133 million. Provides health, sickness, disability and maternity benefits for workers in the formal economy who earn up to Rs21,000 a month and are employed by businesses with a staff of more than 10. Funded by employee and employer contributions equivalent, respectively, to 1.75% and 4.75% of gross salaries. Provides a degree of outpatient as well as inpatient cover, but treatment is almost exclusively in public facilities. At just under Rs69 billion in 2018, ESIS spending on medical benefits was equivalent to just Rs516 per capita, according to the 2019 National Health Profile. That figure has declined in recent years, despite continued increases in premium income. The scheme's revenues were more than two-times higher than its expenditure in the year to March 2018. 3.Central Government Health Scheme (CGHS) Covers around 4.5 million senior civil servants and their families, who enjoy comprehensive benefits, including outpatient cover and treatment in private as well as public health facilities. The scheme provides primary healthcare and medicines to its beneficiaries through its network of 329 Allopathic Wellness Centers spread in 72 cities Payroll-based contributions range from Rs250 to Rs1,000 a month, but cover only a fraction of the scheme's costs, which are funded predominantly by the central government. CGHS expenditure reached Rs29.8 billion in 2018-2019, when per capita expenditure exceeded Rs9,000, according to the 2019 National Health Profile. 4.State Government sponsored programs Cashless schemes funded out of state healthcare budgets, often supplemented by local 'sin' taxes (on alcohol or tobacco, for example). While population coverage and benefit schedules vary, most schemes are restricted to families living below the poverty line (BPL), cover inpatient treatment only, and cap the annual value of cover available to individual families 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 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. According to Insurance Regulatory and Development Authority of India (IRDAI) the health Insurance coverage has been witnessing a reasonable growth both in terms of number of persons covered and premium collected. As per the data available with IRDAI, during the FY 2017-18 there were 48.20 crore persons covered under health insurance policies (excluding Personal Accident and Overseas and domestic travel policies) offered by both General and Health Insurers. http://loksabhaph.nic.in/Questions/QResult15.aspx?qref=3648&lsno=17 https://www.nhp.gov.in/national-health-insurance-schemes_pg Ayushman Bharat Scheme 2018; Established in 2018, a national scheme providing hospital treatment worth up to Rs500,000 a year for around 100 million of the country's poorest families (approximately 500 million individuals), with costs split between central (60%) and state (40%) governments. Health cards issued to eligible families entitle patients to treatment in any public or private hospital contracted under the scheme. The scheme covers all pre-existing conditions. AB PM-JAY is an	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. •The process of including products from the FORNAS in the e-catalogue has been delayed due to the COVID-19 pandemic. The latest round of e-catalogue drug procurement contracts were negotiated between the Ministry of Health (MOH) and the drug industry in the second half of 2019, and have been repeatedly extended throughout 2020.	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+	N/A	mySalam(Social Health Insurance for B40): 1. As of 30 September 2021, the mySalam insurance scheme for the B40 community has paid out claims relating to hospitalization and critical illness of more than RM180 million to 125,000 patients. In addition, 229,000 individuals have also received compensation due to COVID-19 with a total value of RM115 million. 2. In 2021, the scope of mySalam has been expanded to cover the cost of medical devices such as stents for the heart. 3. The mySalam scheme will be expanded in the year 2022 to cover eligible BKM recipients and claims for medical device benefits will also be extended to dependents of eligible mySalam recipients. (Source: MOF- 2022 Budget Speech)	N/A	On 14 Sep 2021, the Government announced further revisions to enhance MediShield Life coverage for cancer that will come into effect **in September 2022**: •Creation of a positive list of clinically proven and cost-effective outpatient cancer drug treatments that will be claimable under MediShield Life •Patients will be able to make claims of between S$200 and S$9,600 per month under this list that will cover 90 per cent of existing cancer drug treatments used in the public sector. The more granular claim limits is meant to provide better coverage based on the cost of each treatment •There will also be separate claim limits for outpatient drug services (such as scans, blood tests and doctor consultations) of up to an additional S$1,200 to be claimable. •The Medication Assistance Fund will be extended to more Singaporeans by raising the eligible income criteria. •55 more cancer drugs will be added under the Standard Drug List and Medication Assistance Fund (raising the support to around 150 treatments now). **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 high-cost hospital bills for all Singapore citizens and Permanent Residents no change to inclusivity of elderly and severely ill persons) 3. Medifund (voluntary insurance for people in need) 4. CareShield Life, basic long-term care insurance scheme for people become severely disabled, the scheme is implemented in 1st October 2020 for Singapore citizen and Permanent Residents who turn age 40 in 2020 or 30 in 2020, whichever is later. https://www.careshieldlife.gov.sg/eldershield/about-eldershield.html 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 is a severe disability insurance scheme that aims to provide basic financial protection to Singaporeans who need long-term care at an old age 7. ElderFund (a new discretionary assistance scheme targeted at assisting severely disabled lower-income Singapore citizens aged 30 and above who are not able to benefit from CareShield Life, ElderShield and the Interim Disability Assistance program for the Elderly and have low Medisave balances and inadequate personal savings to meet their long-term care needs).	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. [Source: Handbook of Taiwan's National Health Insurance 2020–2021]	Universal Health Coverage Scheme (UCS) Civil Servants Medical Benefit Scheme (CSMBS) Social Security Scheme (SSS) 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

					entitlement-based scheme, all the eligible beneficiary families are covered from day one of the implementation of the scheme in the State/UT. AB PM-JAY does not require enrolment, however, beneficiary verification process is being undertaken to verify the genuineness of the beneficiary. Under Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), a total of 1592 Health Benefit Procedures have been defined. Health Benefit Packages under AB-PMJAY includes all the expenses incurred for the following components of treatment including investigations: • Medical examination, treatment, and consultation • Pre-hospitalization • Medicine and medical consumables • Non-intensive and intensive care services • Diagnostic and laboratory investigations • Medical implant services (where necessary) • Accommodation benefits • Food services • Complications arising during treatment • Post-hospitalization follow-up care up to 15 days AB PM-JAY is being implemented in 32 States and UTs across India apart from West Bengal, NCT of Delhi, Odisha and Telangana. The scheme is implemented across the country through a three-tier model. National Health Authority, an attached office of the Ministry of Health and Family Welfare, has been provided with full autonomy, accountability and mandate to implement AB PM-JAY across the country. For effective implementation of AB PM-JAY at States/UTs level, State Health Agencies (SHA) have been established. District Implementation Units (DIUs) have been setup across all district for ensuring on-ground coordination between scheme stakeholders and smooth implementation. AB PM-JAY is completely funded by the Government and costs are shared between Central and State Governments in the ratio as per the extant directives issued by Ministry of Finance, from time to time. The States/UTs have been given provided with the flexibility to implement the scheme in the operational model best suited to the local conditions. Thus, AB PM-JAY is being implemented in Insurance mode, Mixed mode and Trust mode. In NITI Aayog estimated that the PMJAY would cost Rs120 billion a year when fully operational. The central government allocated Rs64 billion to the scheme in its 2019-2020 budget. That was the first full year in which the PMJAY While in the Union Budget 2021-22, the allocation for MoH was raised to Rs 73,931.77 crore from last year's Rs 69,000 crore, allocation for Ayushman Bharat remained same as last year. http://loksabhaph.nic.in/Questions/QResult15.aspx?qref=17237&lsno=17 [https://www.businesstoday.in/top-story/modi-ayushman-bharat-scheme-health-care-socio-economic-caste-census-pandit-deendayal-upadhyay-modicare-prajaa/story/281504.html MP India Q3 2020]	•The next round of negotiations is expected to take place by the end of 2020 and responsibility will be handed back to the National Public Procurement Agency (LKPP). The LKPP will guide public sector purchasing through 2021 and 2022, although this could be delayed if there are additional outbreaks of COVID-19. Source :IQVIA Market Prognosis					8. Vaccination and Childhood Developmental Screening Subsidies (from 1 Nov 2020 MOH will enhance subsidies for vaccinations recommended under the National Childhood Immunisation Schedule and National Adult Immunisation Schedule at all CHAS CP clinics and polyclinics) 9. 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. 10. Polyclinic drug subsidies 11. Public specialist Outpatient Clinics (SOCs) service and drug subsidies [MOH Healthcare schemes & subsidies: https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies]			

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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 Ayushman Bharat Scheme: National Health Authority	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: Control overall drug pricing and reimbursement policy. 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) ・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	UCS: National Health Security Office (Independent agency affiliated with the Ministry of Public Health) CSMBS: Comptroller General’s Department, Ministry of Finance SSS: Social Security Office, Ministry of Labor Private insurance: Insurance companies	1. Vietnam Social Security 2. Private corporation
		Insurance coverage	95% population (1.36 billion) covered by basic medical insurance: Basic Medical Insurance for Employees (344 million) Basic Medical Insurance for Urban & Rural Residents (1017 million) http://www.gov.cn/xinwen/2021-03/08/content_5591551.htm	Some 3 587 900 persons (50.8%) were entitled to medical benefits provided by employers/companies or were covered by individually purchased medical insurance or had both kinds of medical protection. Among them, 1 146 900 persons (32.0%) were entitled to medical benefits from employers/companies only, including 328 400 persons entitled to medical benefits provided by civil service/Hospital Authority only. While another 1 353 000 persons (37.7%) were covered by individually purchased medical insurance only, the remaining 1 087 900 persons (30.3%) had both kinds of medical protection Thematic Household Survey Report - Report No. 74 Census and Statistics Department	37% of Indian population possessed health insurance cover in March 2019, according to IRDAI Govt Schemes (National and State) 76% Group schemes 9% Individual policies 15% [Source: MP India Q3 2020]	Target Universal Healthcare Coverage 2019: 257.6 million participants Achievement per 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]	Under 70% for all healthcare services, drugs, and devices(2021) 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] Expansion of MySalam for 2020 includes for medical devices and to Malaysian middle 40% income (M40) group.	100% population coverage (S1 2021) PhilHealth https://www.philhealth.gov.ph/about_us/statsncharts/snc2021_1stSem.pdf	MediShield Life & Integrated Shield Plan covers all Singapore Citizen & PRs ~ 2.83 million people (2020) Eldershield – covers 1.39 million seniors (2020) https://www.moh.gov.sg/resources-statistics/singapore-health-facts/government-health-expenditure-and-healthcare-financing	99.8% (2018) [Source: National Health Insurance Administration, Ministry of Health and Welfare]	100%. Under the system, all citizens are covered by public insurance (UCS, ,CSMBS, and SSS)	According to the Vietnam Minister of Health’s statement at the Conference to assess and conclude the year 2020 on 6 January 2021, at the end of 2020, the percentage of population joining social health insurance is 90,85%. Source: https://moh.gov.vn/tin-noi-bat/-/asset_publisher/3Yst7YhbkA5j/content/bo-truong-bo-y-te-nguyen-thanh-long-nam-2021-nganh-y-te-tiep-oi-moi-manh-me-toan-dien-e-phuc-vu-nguoi-dan-tot-hon

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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Target population	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	All	**Type of insurance** / **Target Population Covered** Rashtriya Swasthya Bima Yojna (RSBY): Below Poverty Line (BPL) families included in the district BPL list prepared by State government Employees State Insurance Scheme (ESIS): All the employees from Any establishment having more than 10 employees who earn up to Rs 21000 per month + Their dependants. Central Governme nt Health Scheme: Central government employees+ Certain autonomous, semiautonomous and semi – government Organisations. + Members of parliament, governors, Accredited journalists. Private Health Insurance: Pan India Mostly urban population with minimal reach in rural area AB PMJAY: 100 million of the country's poorest families, or around 500 million individuals	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 **Continuing roll-out of the NHI system:** The NHI program, the JKN, overseen by BPJS Health, provides access to both inpatient and outpatient services and covers any treatment deemed medically necessary free of charge, including drugs listed on the national formulary. There was a reported slowdown in JKN expansion during 2020 as a result of the COVID-19 pandemic. A total of 225.9 million people had been enrolled into the JKN by the end of August 2021 (~84% of the population), a slight increase from the total of 222.1 million participants in February 2021. While efforts to complete the enrolment process are being stepped up, the target for coverage of 98% of the population by 2024 will be even more challenging as a consequence of the pandemic-induced financial fallout. Source :IQVIA Market Prognosis	1.General employees and family members (69.30 million) 2. Seamen and family members (117,000) 3. National and local government officers, etc., and teaching faculty of private educational institutions and family members (8.55 million) 4. Farmers, self-employed and other retirees of employees' insurance (29.32 million) 5.Persons aged 75+, etc. (18.03 million) [As of the end of March 2020]	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. The major source of financing is general tax of local government but review and payment process is handling by HIRA and NHIS. ・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.	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 3. Middle 40% income group. *Bantuan Sara Hidup* recipient aged between 18 – 65 years old who earned less than MYR24,000 annually also qualified for the scheme.	All Filipinos (employed, overseas Filipinos, informal/self-earning, indigents, Senior Citizens) https://www.philhealth.gov.ph/about_us/statsncharts/snc2021_1stSem.pdf	1. Medisave (Employees and their families. Compulsory enrolment): personal medical account. 2. Medishield Life (Compulsory insurance that supplements part of the high-cost inpatient treatment that is not completely covered by Medisave, all Singapore citizens and Permanent residents are eligible regardless of age and health condition). 3. Medifund (endowment fund set up by government to help needy Singaporeans with their remaining bills after receiving prior government subsidies, eligibility includes being a Singaporean, a subsidized patient who has received or will be receiving treatment from a MediFund-approved institution) 4. CareShield Life, basic long term care insurance scheme for people who are severely disabled, eligibility for Singaporeans born in 1980 or later (aged 30 to 40 in 2020) and Singaporeans born in 1979 or earlier who are insured under the ElderShield 400 scheme, the scheme is implemented in 1st October 2020. https://www.careshieldlife.gov.sg/eldershield/about-eldershield.html 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) eligibility includes elderly who are unable to perform 3 or more of the 6 activities of daily living 7. ElderFund, a new discretionary assistance scheme targeted at assisting severely disabled lower-income Singapore Citizens aged 30 and above, eligible for Singaporean elderly who are unable to perform 3 or more of the 6 activities of daily living, Singaporeans aged 30 and above and residing in Singapore, Household monthly income per person is S$1,200 or less and Medisave balance of less than S$10,000. 8. Vaccination and Childhood Developmental Screening Subsidies, eligible to all Singapore Citizens who meet all criteria stipulated in the latest NCIS, NAIS or CDS guidelines 9. 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. https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies	All citizens with official residency or foreign national citizens with Alien Resident Certificate. At the end of 2020, there were 23,987 thousand beneficiaries. [Source: National Health Insurance Annual Statistical Report 2020]	UCS: approx. 48 million people For citizens not covered by the 2 aforementioned insurance schemes CSMBS: approx. 5 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. 16 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.	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

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Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Financing of Healthcare	In 2020, Per capita government subsidies for Urban & Rural Residents were not less than 550 yuan. Source: Ministry of Finance of the People's Republic of China http://www.gov.cn/xinwen/2021-03/06/content_5590913.htm	Analysed by financing scheme, 53% of the current health expenditure was paid via the government schemes, 30% was by household out-of-pocket payment in 2019/20. Payment via privately purchased insurance schemes and employer-based insurance schemes taken together accounted for 16% in 2019/20. Over the past decade or so, the share attributed to privately purchased insurance schemes had shown a distinct uptrend. [Domestic Health Accounts, Food & Health Bureau] https://www.fhb.gov.hk/statistics/en/dha/dha_summary_report.htm#:~:text=The%20public%20share%20in%20total,54%25%20in%202019%2F20.&text=Analysed%20by%20financing%20scheme%2C%2053,pocket%20payment%20in%202019%2F20.	**Type of insurance** / **Target Population Covered** Rashtriya Swasthya BiMayojna (RSBY): 75% by Central Government, 25% by state government And Nominal 30 Rs annual payment by family Employees State Insurance Scheme (ESIS): Funded by employee and employer contributions equivalent, respectively, to 1.75% and 4.75% of gross salaries. Central Government Health Scheme: Payroll-based contributions range from Rs250 to Rs1,000 a month, but cover only a fraction of the scheme's costs, which are funded predominantly by the central government. Private Health Insurance: Self-Paid State schemes: Often supplemented by local 'sin' taxes (on alcohol or tobacco, for example) PMJAY: costs split between central (60%) and state (40%) governments. [IQVIA Research – MP India Q3 2020]	[1] PBI: Government funded (national treasury). Covers poor and near poor people of 96.6 million members at Rp 42.000/pm/capita (premium is all subsidizedby the government for poor and near poor or PBI member) [2] Non-PBI: Civil servants and 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 July 1, 2020 (PresDecree 64/2020) Class 3 Rp 25.500 Rp 42.000 (Rp 35.000 paid by member and Rp 7.000 subsidized by the Government) Class 2 Rp 51.000 Rp 100.000 Class 1 Rp 80.000 Rp 150.000 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 collected by the insured and government subsidy. ・Insurance Premium account for 84% and government subsidy is 12.3% ・Government subsidy is comprised of general tax(79.6%) and surcharge on tobacco(20.4%). (Source: NHIS Statistical Yearbook, 2020)	1. Malaysia's health spending was expected to reach 5 per cent of the gross domestic product (GDP) or RM72.7 billion in 2021. 2. The amount - comprising both public and private spending - represents an increase in the country's health expenditure, which has been steadily increasing from 4.2 per cent of GDP in 2016 to 4.7 per cent of GDP or RM63.8 billion in 2020. Source: Codeblue 3. The Ministry of Health has been given a budget allocation of RM 32.4 billion for the year 2022. (Source: MOF- 2022 Budget Speech)	1. Public Health Financing (Central Govt, State/Regional Govt, Social security and Social Health insurance) 2. Private Financing (commercial insurance and other corporations (HMOs)) 3. Household out-of-pocket Philippine Statistics Authority https://psa.gov.ph/pnha-press-release/node/165216	·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 wage which will supplement both Medisave and Medishield Life. oMediShield Life is a basic health insurance plan, administered by the Central Provident Fund (CPF) Board, which helps to pay for large hospital bills and selected costly outpatient treatments, such as dialysis and chemotherapy for cancer. It is structured so that patients pay less MediSave/cash for large hospital bills. oMedifund: Entire endowment fund set up by national treasury ·ElderShield: provides monthly payouts of $300 or $400 per month for up to 5 or 6 years, insurance premiums are still paid from Medisave up until the age of 65 CPF Contribution Website on Medisave https://www.cpf.gov.sg/member/faq/healthcare-financing/medisave CPF contribution website on EldersShield https://www.cpf.gov.sg/member/healthcare-financing/eldershield CPF contribution website https://www.cpf.gov.sg/member/cpf-overview	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.	UCS: general tax 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. 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 Source: Hospital Authority https://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=10045&Lang=ENG&Dimension=100&Parent_ID=10044&Ver=HTML	**Type of insurance** / **Coverage of healthcare expenses** Rashtriya Swasthya BiMayojna (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, Permanentdisablement 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: AB PMJAY: Hospital treatment in any public or private hospital contracted under the scheme, worth up to INR 500,000 a year. It covers all pre-existing conditions. In its second phase, rolled out from October 2019, the scheme covers 1578 procedures in 872 treatment packages. These include immediate pre- and posthospital costs as well as surgery, diagnostics and drugs administered during hospital stays. The MOHFW published a draft national policy for rare diseases in January 2020. The draft does not attempt to establish threshold prevalence rates, which would be impossible given the paucity of data on the incidence of rare diseases. Instead, it classifies rare diseases into three groups on the basis of treatment options and costs, Group 1: diseases for which a one-time curative treatment is available Group 2: diseases requiring long-term or lifelong treatment, where interventions are relatively low-cost and have a documented benefit Group 3: diseases for which treatment is available but at very high cost and over the long term – subdivided into (1) diseases where there is evidence of good long-term treatment outcomes; and (2) diseases for which treatment costs are very high, and for which outcomes data are available in a small number of patients. • The draft says the government will encourage and support efforts by states to screen for and prevent rare diseases and will provide patients with funding of up to Rs1.5 million for the treatment of Group 1 diseases, which will be available in specialist public hospitals for ABPMJAY affiliates [MP India Q3 2020]	Different premium scheme is applied for PBI and 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 : 2,925 (private & public) -Public : 1071 (36.6%) -Private : 1,854 (63.4%) 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 (97.2%): -Medical Benefits (95.5%) -Physical check-ups costs (2.5%); Cash Benefits (2.8%): -Medical care costs (7.7%) -Benefits for the appliances of the disabled (5.9%) -Reimbursement in the co-payment ceiling system (75.9%) -Prenatal care costs (10.5%) •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. Type / Inpatient / Outpatient Tertiary hospital: 20%: 60% General hospital: 20%: 45-50%* Hospital: 20%: 35-40%* Clinic: 20%: 30% Pharmacy: -: 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): RM1 Outpatient treatment (specialist consultation) : RM5 Admission for third class ward: RM500, higher charges for 2nd class and 1st class wards. For non-Malaysians, the deposit payable admission to 3rd class ward is RM600. Private medical institutions: Consultation fees: RM30-RM200 [Source: IQVIA Market Prognosis Report 2019-2023)	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. 5. Eldershield: 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. https://www.careshieldlife.gov.sg/eldershield/benefits.html [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. ・Basic co-payment: A fixed amount for each hospital category. ・Drug co-payment: A fixed amount for each drug price category, and the burden rate is about 20% but upper limit is 200NTD/time. Inpatient co-payment: 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.	UCS: 3,798 THB/person (2022) •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. 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: 3,959 THB/person (2021) •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.	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.

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
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 persons aged 65 or above are eligible to receive and use the vouchers to pay for private primary healthcare services. At present, the annual voucher amount for each eligible elderly person is $2,000 while the accumulation limit of vouchers is $8,000. Elderly persons are provided with their annual amount of vouchers that will be automatically deposited in their voucher account on 1 January from the year in which they become eligible under the Elderly Health Care Voucher Scheme. 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.	<table><tr><td>Healthcare expenditure (Per capita) in USD</td><td>~ 22 USD</td></tr><tr><td>Healthcare expenditure as % of GDP</td><td>3.5% OF GDP</td></tr><tr><td>PUBLIC Health Expenditure</td><td>1.28 %</td></tr></table>[Source: MP India Q3 2020, PHE and PHE per capita is for 2017-2018 (BE)]	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.	UCS: Capitation, DRG and special schemes CSMBS: Fee for service, IPD - DRG. No charge for medical fees at public hospitals. Partial coverage of medical fees at private hospitals SSS: Capitation, DRG	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)	806.96USD, (1CNY=0.16USD) 5146.4 （RMB,2020） Source： China National Health Commission http://www.nhc.gov.cn/guihuaxxs/s10743/202107/af8a9c98453c4d9593e07895ae0493c8.shtml	Total expenditure on health amounted HK$189,624 million (2019/20), with annual per capita total expenditure on health at HK$25,258. (Health Facts of Hong Kong 2021 edition)	~ 22 USD Assuming 1 USD = 76 INR [Source: MP India Q3 2020, PHE per capita is for 2017-2018 (BE)]	112 USD [World Bank 2018]	2,999 USD (335,000 yen (920,000 yen for 75+) [FY2020] 1 USD=111.71-yen TTS as at March 2021) 【Materials released by the Ministry of Health, Labor and Welfare "Recent trends in medical expenses"】	3,406.3 USD PPP [OECD Health Statics 2021] (OECD Average 4,087.5 USD)	531.01 USD (2021) (Estimate figure derived from dividing total healthcare spending in 2021 by Malaysia's current population.)	159.76 USD (PhP 8,216.42 as of 2020; 1USD=51.43 PHP) Philippine Statistics Authority https://psa.gov.ph/pnha-press-release/node/165216	2,823.65 USD [The World Bank 2018]	1,585 USD (2019) [Source: Department of Statistics, Ministry of Health and Welfare]	276 [2018 World Bank] *Latest data available	According to World Bank: -Domestic general government health expenditure per capita (current US$): 69.019 (2018). Link: https://data.worldbank.org/indicator/SH.XPD.GHED.PC.CD?end=2018&locations=VN&start=2000&view=chart -Domestic general government health expenditure per capita, PPP (current international $): 200.541 (2018) Link: https://data.worldbank.org/indicator/SH.XPD.GHED.PP.CD?end=2018&locations=VN&start=2000&view=chart
		Healthcare expenditure (% of GDP)	7.12% (2020) Source： China National Health Commission http://www.nhc.gov.cn/guihuaxxs/s10743/202107/af8a9c98453c4d9593e07895ae0493c8.shtml	6.8% (2019/20) (Health Facts of Hong Kong 2021 edition)	3.5% [Source: MP India Q3 2020]	2.9 % [World Bank 2018]	7.00% [FY2020]	8.2 % [OECD Health Statics, 2021] (OECD Average 8.8%)	4.73% (2020) [MOH Health Facts 2021]	5.6% (as of 2020) Philippine Statistics Authority https://psa.gov.ph/pnha-press-release/node/165216	4.46 % [The World Bank 2018]	6.1% (2019) [Source: Department of Statistics, Ministry of Health and Welfare]	3.79% [2018 World Bank] *Latest data available	6% (2018) [World Bank]

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			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Insurance & drug pricing system/Public healthcare system	Current status of medical insurance system	Public Health expenditure, (% of GDP)	4.72% (2019) Source: National Bureau Statistics of China	Public expenditure on health was 53.5% of total expenditure on health while it is 15.7% of total public expenditure. (Health Facts of Hong Kong 2021 edition)	1.28% (2017-2018 BE) [Source: MP India Q3 2020]	1.4% [2016 – knoema.com]	38.3% (State 25.4%, Regional 12.8%（FY2019）	5.0% [OECD Health Statics, 2021] (OECD Average 6.6%) * Reference Government and compulsory health insurance schemes, % of current expenditure on health: 61.0% (OECD Average 74.1%)	2.1 (Based on the figures in Budget 2022) (Source: TheEdgeMarkets)	2.23%(45.7% public share of current health expenditure, current health expenditure as a share of total health expenditure 89.2%, total health expenditure as a share of 5.6%, as of 2020) Philippine Statistics Authority https://psa.gov.ph/pnha-press-release/node/165216	2.1% [FY 2018] https://www.moh.gov.sg/resources-statistics/singapore-health-facts/government-health-expenditure-and-healthcare-financing	3.91%	2.42% [2018 World Bank] *Latest data available	2.696% (2018) [World Bank]
		Others	N/A	Private expenditure on health was HK$88,097 as 46.5% of total expenditure on health (Health Facts of Hong Kong 2021 edition)	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 regulate price of medicines through external reference pricing. The Pharmaceutical Industry and healthcare sectors concerned are expressing opposition to the regulation. 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.	N/A	N/A	N/A	Percentage in new drug makers' sales UCS: Less than 10% CSMBS: 85-90% SSS: Less than 10%	N/A
	Overview of pharmaceutical reimbursement	Overview of pharmaceutical reimbursement	The National Reimbursement Drug List (NRDL) was updated by China's National Health Security Administration (NHSA) in 2021. 74 new medications have been added to NRDL, with prices of 67 medicine types slashed by an average of 61.71 percent. 7 drugs for rare diseases, tumors, chronic diseases, anti-infection treatment and those specifically for women or children, are among the additions to NRDL. 11 medications with low clinical value and low demand have been removed from NRDL. A total of 507 medications have been added to the NRDL since the inauguration of the NHSA in 2018, bringing the list to 2,860 items. Source: National Healthcare Security Administration http://english.www.gov.cn/statecouncil/ministries/202112/03/content_WS61aa017ac6d0df57f98e5fd9.html http://www.nhsa.gov.cn/art/2021/12/3/art_14_7430.html	In line with the Government's public healthcare policy to ensure that no one is denied adequate medical treatment due to lack of means, the Hospital Authority provides medical services and drugs or medical items to patients at highly subsidised rates based on their clinical needs and in accordance with the HA's treatment guidelines. Guided by the principles of evidence-based medical practice, targeted subsidy and opportunity cost consideration, the standard fees and charges in public hospitals and clinics do not apply to designated Privately Purchased Medical Items (PPMIs) and SFIs. While patients who need these items/drugs and have the ability to pay for their costs have to purchase at their own expense, financial assistance is provided through the Safety Net to subsidise the medical expenses of patients who have financial difficulties in purchasing PPMIs or specified SFIs listed on the HADF at their own costs.	India lacks a pharmaceutical reimbursement system comparable to systems seen in developed countries. Most people have no form of drug cover and must pay for their medicines out-of-pocket – or go without treatment. While some form of drug cover is provided for beneficiaries of public-sector employer or voluntary schemes (or private alternatives) living in urban areas, the level of coverage offered by these schemes varies. [PPR Country Guide India Q1]	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 Workplace 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. Implement of selective reimbursement system for drugs which is not proven in cost-effectiveness with different co-payment rate(30%,50%,80%)	Drug expenses: 8.74% of government's total annual expenditures. (2018) [Pharmacy Practice and Development Division]. 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.	Only drugs listed in the Philippine National Formulary (PNF) shall be considered for reimbursement. With the enactment of the UHC Act, the government institutionalized HTA as the process used to evaluate medicines for inclusion in the PNF	•A Standard Drug List system has been established. •Expansion of Medication Assistance Fund (MAF) subsidies to more Singaporeans by raising the eligible income criteria. •MAF subsidies will be enhanced with subsidies of up to 50% extended to Singaporeans with per capita household income (PCHI) between $2,800 and $6,500 per month List of drugs (as of 1 February 2022) https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies/drug-subsidies-schemes	Reimbursement will be applied with reimbursement price approved drug by National Health Insurance (NHI) Administration. Although NHI is a universal service, various expending control schemes, e.g., DET, MEA, etc., are in place: ・Drug Expenditure Target (DET): 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. ・Price Volume Agreement (PVA): 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. Managed Entry Agreement (MEA): A voluntary scheme in principle and 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: UCS: benefit in kind. According to NLED. CSMBS: NLED and non-NLED (with conditions) medicines, restrictions on some of high cost anticancer/hematologic drugs SSS: 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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			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
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 The National Health Commission issued an announcement to solicit public opinions on the Measures for the Administration of the National Catalogue of Essential Drugs (Revised Draft). Source: National Health Commission of China https://mp.weixin.qq.com/s/HyzU3Wmqbevp5TtxtYjmtA	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 province3. 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) and must be covered by BPJS-Keshatan. NDEL is reviewed by a ForNas Committee at least every 2 years using several criterias such as efficacy, safety, marketing authorization, risk-benefit ratio and comparative cost effectiveness	The NHI Drug Price Standard specifies the drug items that can be used for insurance-covered medical care.	Essential Drug List is managing by MFDS(Positive Listing) Drug Reimbursement List is updated and managed by HIRA(Positive Listing) 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 5th edition of NEML dated 26 December 2019 is available. The 5th edition contains 359 chemical entities within 27 therapeutic groups. The sub-division of therapeutic group remained the same. [National Essential Medicines List 5th Edition]. 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. 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. WHO-OECD https://iris.wpro.who.int/bitstream/handle/10665.1/13982/9789290618485-eng.pdf	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 oIt is modelled on the WHO Essential Drug List oIt applies to patients who receive assistance for public medical care oDrug access is not linked to listing in the SDL list oProviders of medical services are not limited to drugs listed in the SDL oThere 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%. [https://www.who.int/medical_devices/02_keng_ho_pwee.pdf] •A positive list of clinically proven and cost-effective outpatient cancer drug treatments has been established by the Ministry of Health (MOH). oList of drugs: https://www.moh.gov.sg/cost-financing/healthcare-schemes-subsidies/drug-subsidies-schemes •The positive list will be implemented in September 2022 o More granular claim limits ranging from $200 to $9,600 per month for cancer drug treatments on the positive list oAdditional$1,200 per year for cancer drug services (cancer screening, diagnostics etc.) 55 more cancer drugs will be listed under the SDL/MAF	•Necessary Drugs: Defined by Articles 4, 34, and 35 of National Health Insurance Drug Benefit Items and Payment Criteria. Essential Drugs List: Based on Article 27-2 of Pharmaceutical Affairs Act, which was established by TFDA.	**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 31 May 2021	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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			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Insurance & drug pricing system/Public healthcare system	Overview of pharmaceutical reimbursement	Out of pocket expenses and/or ratio of medicines	NHC announced that average individual out-of-pocket(OOP) medical expenses reduced to below 30% in 2018. The OOP per capita in extreme poverty area fell to below 10% in the first half year of 2019. Source: National Health Development Research Center National Health Commission http://news.cctv.com/2019/07/09/ARTINHJChqkezFUI6b68dIrY190709.shtml	N/A	Out of pocket medical expenses are over 70% of all healthcare costs in India [Source: MP India Q3 2020]	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 and 31.9% in 2018 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.	The Share of out-of-pocket medical expenses is 32.5%.(2019) (OECD Average 21.4%)	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. 35% is out-of-pocket (2018) [MNHA]	There is no direct data available from government on this. However, there is data for the %private share for current health expenditure at 54.3%, 44.7% of which is out-of-pocket expenses. The %private share of expenses on medicines is at 85%. Philippine Statistics Authority https://psa.gov.ph/pnha-press-release/node/165216 WHO-OECD https://iris.wpro.who.int/bitstream/handle/10665.1/13982/9789290618485-eng.pdf	Patients will be able to draw from MediSave and/or cash to pay the balance of costs after insurance claim limits are reached.	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 co-payment from allowed. 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	National Healthcare Security Administration issued new NRDL, with 74 new drugs added and an average price fall of 61.7% for the newly-added drugs. http://www.gov.cn/xinwen/2021-12/03/content_5655774.htm The NHC revised of the Measures for the Administration of National Essential Medicine List (issued in 2015) and formed the Draft of the Measures for the Administration of National Essential Medicine List, that is now under the phase of seeking public opinion. http://www.nhc.gov.cn/yaozs/s7656/202111/068c31b85cb7486b9f77057b3e358aae.shtml	N/A	NA	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.	The Share of out-of-pocket medical expenses is 32.5%.(2019) (OECD Average 21.4%)	N/A	PhilHealth will only reimburse cases with medicines that are included in the formulary. However, in the benefit packages (composed of hospitalization, professional fees, and medicines), there is no explicit allocation for how much goes to medicine.	Yes	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	4.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. 5.The Organisation is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. 6. 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.	NHIS: Payer and negotiate drug price and volume with pharmaceutical companies. HIRA: Set reimbursement guideline and decision making for reimbursement with cost-effectiveness evaluation 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.	There are no specific organizations that monitor the medicines price for now. However, the organization involved in conducting medicines price study is Pharmaceutical Services Programme (PSP), while Ministry of Health is the one who makes the decision. PSP release manual guidelines known as Recommended Retail Prices and Consumer Price Guide as public reference.	For government procurement: DOH and HTA Unit/Council For private sector medicines that meets certain criteria: Pharmaceutical Division and Drug Price Advisory Council 1. Drugs that address health priorities of the general public, especially those for the leading causes of morbidity and mortality 2. Drugs that have high price differentials/arbitrage compared to international prices 3. Drugs that have limited competition in terms of lack of generic counterparts or lack of market access to these products Drugs where the innovator product is the most expensive yet most prescribed and/or dispensed in the market	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 ALPS. Since 2015, Cost-effectiveness assessments recommendations for some specific innovations have led to price capping at public sector. ALPS, previously known Group Procurement Office (GPO) is responsible in executing a national-level, end-to-end supply chain blueprint, in partnership with all Public Healthcare Institutions, to ensure access to appropriate and affordable treatments and medications at the 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	For Public Hospitals, there are mainly two approaches: 1. Centralized Drug Procurement Program. Competitive bids shall be used to purchase medications and be carried out by local governmental authorities on a province-by-province basis under the central coordination of NHC. The “zero-mark-up” policy has been implemented since 2017 (the drug price that a hospital charges the patient should be the same as it pays to the drug suppliers). 2. Volume-Based Procurement. The NHSA directly negotiate with pharmaceutical companies about drug supply for public hospitals and strive to get favorable terms by insisting on bulk purchasing. The participant with the lowest tender price will be the bid winner. By securing the purchase price at the terminal end, the cost at each distribution phase upwards will be reduced, which ultimately leads to an end lower price. http://www.nhsa.gov.cn/art/2020/7/31/art_37_3387.html http://www.nhc.gov.cn/tigs/s3581/201704/0563e06eff4441ffa9772dc30b487848.shtml	N/A	The DPCO provides for ceiling or retail prices to be set for all active ingredients listed in Schedule I of the Order, based on the wholesale price of all brands and generics (including imported products) with a market share of at least 1%. The wholesale price is calculated as follows: (the sum of the [wholesale] prices of all brands and generics with at least 1% share) divided by (the total number of brands and generics). A 16% mark-up for pharmacies is taken into account in the ceiling/retail price. The Order states that a maximum retail price (MRP) is formed on the basis of the ceiling/retail price, plus any applicable local taxes (i.e. state or municipal sales taxes, which have been replaced by the goods and services tax [GST] The wholesale price is calculated on the basis of dosage and delivery forms listed in Schedule I; the ceiling/retail price of a pack is extrapolated from this. If a dosage unit for a formulation is not in the schedule, the ceiling or retail price is based on the lowest pack size for that category of medicine Non DPCO drugs Manufacturers are permitted to increase the prices of drugs which are not included in the DPCO schedule/NLEM, by up to 10% per year (see ‘Changes in Price: Branded Drugs’ in ‘Lifecycle Events’). Otherwise the prices of non-DPCO drugs are largely free from control Generics Generics and biosimilars are subject to the same controls affecting the pricing of other drugs – including the provisions of the Drugs (Prices Control) Order 2013 and the Drugs (Price Control) Amendment Order, 2016 [Source: PPR country guide Q1 2020]	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.	HTA is the process used by the government to determine products that will be procured and reimbursed by government. For the private sector medicines, the Maximum Retail Price (MRP) is imposed for medicines that meet the abovementioned criteria.	Singapore’s national HTA agency, Agency for Care Effectiveness (ACE), is responsible for annual review of the list of drugs approved under the SDL or MAF listing. ACE conducts HTAs to support subsidy decisions by the respective MOH advisory committees for two main technology streams: 1.Drugs: Drug Advisory Committee (DAC) 2.Medical technologies (including devices, diagnostics and medical services): Medical Technology Advisory Committee (MTAC). •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 2020 that, from November 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. oThis decision reflects the persistently low uptake rate for certain vaccines as well as the government’s aim to reduce the incidence of preventable diseases. oAs part of the efforts to better protect Singaporeans from vaccine-preventable diseases and to reduce the risk of outbreaks in the community, the Ministry of Health (MOH) will enhance subsidies for vaccinations recommended under the National Childhood Immunisation Schedule (NCIS) and National Adult Immunisation Schedule (NAIS) at all Community Health Assist Scheme (CHAS) General Practitioner (GP) clinics and polyclinics from 1 November 2020. Varicella, influenza and pneumococcal polysaccharide vaccines are included into the NCIS. oAll eligible Singaporean children will also receive full subsidies for childhood developmental screening at all CHAS GP clinics and polyclinics, so that they may receive the necessary developmental assessments together with their childhood immunisations from their family doctor. [IQVIA], [MOH https://www.moh.gov.sg/news-highlights/details/enhanced-subsidies-for-nationally-recommended-vaccinations-and-childhood-developmental-screening]	For NDA-approved drugs, reimbursement submissions will be accepted, evaluated by CDE (Center for Drug Evaluation) for HTA (Health Technology Assessment), and reviewed by Expert Committee. Finally, a PBRS meeting will be held to reach a resolution on NHI drug listing and pricing.	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”.	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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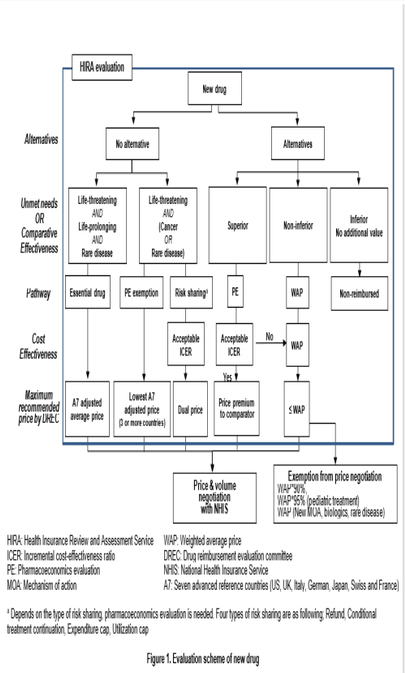
Insurance & drug pricing system/Public healthcare system	Overview of pharmaceutical reimbursement	Pricing rules/methods	For exclusive drugs, the pricing method is negotiation. For non-exclusive drugs under the government procurement, the price is set according to the procurement regulation. For other non-exclusive drugs, the price is set by bidding. For habitforming drugs and spirit drugs, the price is set by government. http://www.nhsa.gov.cn/art/2020/7/31/art_37_3387.html	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) For the generics pricing system, MoHW announced new system to improve drug quality. Generic price will be set upon how many criteria they have satisfied among i)independent BE(Bioequivalence) test instead of BE test done by consortium of many pharmaceutical companies, ii) In-house manufacturing, iii) DMF listing If satisfied all criteria, generic price will be 53.55% of original, two items met – 43.3%, one item met – 33.3%, none of criteria met – 30%. Until reassessment of generic price, 2 years of preparation period will be provided. 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.	There are no mechanisms for medicines price in Malaysia at present. However, Pharmaceutical Services Program (PSP) published manual guide known as Recommended Retail Prices and Consumer Price Guide as public reference to purchase medicines. (https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/recommended-retail-price-rrp-nedl-2011.pdf) In addition, Ministry of Health indirectly controls and reduces medicine prices with bulk purchase. The three procurement methods are 1) Supply by Concession Company 2) National Tender and 3) Local purchase. As for now, government is planning to regulate medicine prices using external reference pricing to benchmark drug prices against 8-12 countries. (https://codeblue.galencentre.org/2020/01/21/moh-hopes-to-control-medicine-prices-by-year-end/)	Cost-effectiveness is used as the primary method for HTA. External Reference Pricing from a basket of countries, with the lowest price plus adjustments is used for MRP.	•ALPS was established on 1 July 2018 to replace the former Group Procurement Office, as a new supply chain agency in support of the three healthcare clusters to achieve system-wide gains and support care transformation through greater economies of scale, new capabilities and innovations in procurement and supply chain management. •ALPS 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	Optional	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 was formed in 2014 and has a responsibility to give recommendations to the MoH regarding the list of healthcare services, including medicines, which are covered by the BPJS-Kesehatan. This implies the HTA committee is responsible for advice regarding the National Formulary (NF or ForNas). However, HTA 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 •Additions to the national formulary (FORNAS) in 2020 have been minimal, with recent amendments largely consisting of new usage restrictions to previously-listed drugs. This trend is likely to continue for high-cost drugs in particular, as opposed to de-listing from the FORNAS. Future amendments to the FORNAS are expected to leverage health technology assessment (HTA) more frequently in reimbursement decisions. Source :IQVIA Market Prognosis 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 : Presention 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	The cost-effectiveness analysis system started in April 2019. Drugs and medical devices with large market sizes or extremely high unit prices are evaluated, and the evaluation results are not used to judge whether or not insurance can be reimbursed, but are once listed in insurance and then used for price adjustment. However, rare diseases for which there are not enough treatment methods for designated intractable diseases and drugs and medical devices used only for children are excluded. Hereafter, the evaluation system will be enhanced, cases will be collected, and the ideal system and utilization method will be examined.	HIRA disclosed final reports on the contracted research for HTA guideline renewal by Jan 22nd, 2021. Upon this, pre-notification is under progress and main changes are, 1) Time horizon, 2) Consistent analysis on target population (especially for the subgroup), 3) Model structure appropriateness (AdviSHE), 4) Uncertainty analysis, 5) Diagnostics to be included if necessary, 6) Adjustment of cross-over impact, 7) Discount rate 5% -> 4.5%.	ntroduced 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 guidelines for HTA were recently released (Q4 2020). The HTAU/HTAC is currently reviewing existing products in the PNF, as well as the benefit packages.	•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. •From 1 January 2021, under a new company-led process, pharmaceutical companies can request for their oncology drugs to be evaluated for funding consideration. The pilot process under ACE enables parallel regulatory and funding submissions to allow cancer drugs to be evaluated closer to the anticipated date of regulatory approval and expedite funding considerations to improve patient access to clinically necessary treatments. •ACE was also responsible for establishing the positive list for oncology treatments that will take effect in September 2022. [ACE official website: http://www.ace-hta.gov.sg/our-process-and-methods.html]	The current reimbursement review process includes a comprehensive evaluation of the therapeutic and pharma-economic aspects of a new drug by CDE using the HTA. This evaluates the efficacy and/or effectiveness as well as the comparative safety of a new drug. Other aspects of the assessment include budgetary impact, as well as related ethical, social and political issues. The HTA process involves several government agencies to collect evidence and finalize the assessment report. The categorisation of the drug is also determined during this stage. The 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 assess and appraise health interventions and technologies efficiently and transparently. 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 Organisation 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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Insurance & drug pricing system/Public healthcare system	Pharmaceutical reimbursement	Others	N/A	N/A	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/	N/A	N/A	N/A	N/A	N/A	N/A	NHIA's Horizon Scanning Implementation began on Sept. 26, 2020, requiring manufacturers to register their planned products and expected prices for the next 2 years, which should be considered in NHIA's budgeting process.	N/A	N/A

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
Insurance & drug pricing system/Public healthcare system	Other	Procurement of medicines (Tendering/bidding)	In 2020, the total amount of online purchase orders through the provincial centralized drug purchase platform was 931.2 billion yuan, a decrease of 60.1 billion yuan over 2019. Among them, chemical drugs (chemical medicine and biological products) was 752.1 billion yuan and TCMs was 179.1 billion yuan, down 59.4 billion yuan and 700 million yuan respectively compared with 2019. Drugs in the NRDL accounted for 86.5% of the total amount of purchase, with an amount of 805.2 billion yuan. In 2020, three Volume-Based Procurements were carried out by the provincial level, involving 112 drug varieties, with an average price reduction of 54%. The actual procurement volume of bid drugs was 2.4 times the agreed procurement volume. http://www.nhsa.gov.cn/art/2021/6/8/art_7_5232.html Source: 2020 Statistical Bulletin of the National Healthcare Security Development-NHSA	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.	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, disitribution, and use processes. See also the above drug procurement process	The cost-effectiveness analysis system started in April 2019. Drugs and medical devices with large market sizes or extremely high unit prices are evaluated, and the evaluation results are not used to judge whether or not insurance can be reimbursed, but are once listed in insurance and then used for price adjustment. However, rare diseases for which there are not enough treatment methods for designated intractable diseases and drugs and medical devices used only for children are excluded. Hereafter, the evaluation system will be enhanced, cases will be collected, and the ideal system and utilization method will be examined.	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 produce	nclusion in MOH Medicines Formulary (Blue Book) and bidding the MOH. There are three medicine procurement methods, 1) Supply by Concession Company 2) National Tender and 3) Local Purchase	Similar to reimbursement, 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.	•ALPS was established on 1 July 2018 to replace the former Group Procurement Office, as a new supply chain agency in support of the three healthcare clusters to achieve system-wide gains and support care transformation through greater economies of scale, new capabilities and innovations in procurement and supply chain management. •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. Under the Procurement Act, three main procurement methods must be used, in accordance with the conditions stipulated: 1. General invitation method: A government agency may invite general entities that have the qualifications specified by the government agency, to submit a proposal. 2. Selection method: A government agency may invite at least three particular entities that have the qualifications specified by the government agency, to submit a proposal, unless there are fewer than three entities that meet the qualifications. This method can be used if there are special circumstances or conditions – for example, an article being procured that has special characteristics or is especially complex, or must be manufactured, sold, constructed, or serviced by a highly skilled person, or which, by the nature of its use, or technical specifications, must be of a brand name. 3. Specific method: A government agency may invite one specific entity that has the qualifications specified by the government agency, to submit a proposal, or to directly negotiate a price matter that has a small budget. This method can be used if there are special circumstances or conditions – for example, if there is only one qualified entity, or an article is to be purchased due to a disaster or epidemic, and the other two methods would lead to a delay and severe damage. 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)	*The Patent Law* comes into force in June 2021 with the following new contents. 1. Introduction of "Drug Patent-term Compensation System" and "Patent Disputes Early Resolution Mechanism" 2. Increase the scope of infringement damages compensation The Patent Law https://www.cnipa.gov.cn/art/2020/11/23/art_97_155167.html	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, importation is considered as meeting local working requirement) – Article 20 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. 3, 2019 (Promulgated on May 17, 2019) Effective date: October 1, 2020 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)	[KRPIA Note] ☐ Links to the Patent Act and Enforcement Decree remains the same ☐ Added key changes on the Patent Act below: Key changes on the Patent Act (Enforcement Date: April 10th, 2022) - The period for requesting a trial against rejection has been extended from the current 30 days to 3 months, so that the period an applicant can prepare a request for trial has been extended. - In the event that the right is extinguished due to the overdue for document submission or payment of fees, the requirement for recovery was previously as "causes that cannot be held responsible" but the revised Act has relaxed it to "reasonable cause" - If there is a priority claim in the earlier application, under the amended Act, unnecessary administrative procedure is avoided by omission of process of the priority claims and the submission of evidential documents when filing a divisional application for the earlier application. - If the shared patent right, design right, and trademark right are transferred to another due to a request for division by some co-owners, the remaining co-owners have a non-exclusive license (non-exclusive license). - The amended Act allows separate applications for registrable claims without taking them as grounds for rejection in the trial procedure, whereas under the existing Act if a trial against decision of rejection proceeds, the entire patent was rejected even if it was possible to register a part of it. ☐ - Under the current Act, if an earlier application was quickly registered, it was impossible to file a patent application because it was impossible to claim priority while applying for an improved invention. However, under the revised Act, it is expected to become possible to apply for improved inventions even after a patent registration decision is made before the establishment registration.	The Intellectual Property Corporation of Malaysia (MyIPO) is the office responsible for handling patents. 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) Key takeaways of the Patent (Amendment) Bill 2021: 1. The Patent (Amendment) Bill 2021 contains 69 amended clauses that have included Malaysia's commitments in the TRIPS Agreement on public health, the Regional Comprehensive Economic Partnership Agreement (RCEP) and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). 2. The formal recognition of patents as an asset class which can be the subject of a security interest in the same way as a movable property. This legal recognition can be found at Section 39 of the amended Patent Act.	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", https://www.jpo.go.jp/e/system/laws/gaiko ku/ •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. Taiwan *Pharmaceutical Affairs Act* has incorporated a new chapter of "Patent Linkage of Western Pharmaceuticals" since the end of 2017 and this amendment was promulgated by presidential order on Jan 31, 2018 and implemented from Aug 20, 2019. Under the patent linkage system, a new drug marketing approval holder may complete listing and reporting of the patent information with respect to the pharmaceutical patent. On the other hand, a generic drug approval applicant who seeks grant of drug approval for the generic drug shall make relevant certification or declaration in regard to the patent listed by the new drug approval holder with the competent authority, and the competent authority will stay issuance of drug approval for a period of 12 months to clear relevant patent disputes. The first applicant of generic drug approval to successfully challenge patent validity or make non-infringement declaration against the new drug and to have produced complete in full the materials required of the application for approval of the generic drug will be granted an exclusive marketing term of 12 months. Regulations regarding drug patents are defined and set forth in Article 40-2, 40-3, 100-1 and 48-3 to 48-22 of *Pharmaceutical Affairs Act*	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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			RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Intellectual property rights/IP	Overview of Intellectual property right system	Trademark law	N/A	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. 42, 2021 (Promulgated on May 21, 2021) Effective date: May 21, 2022 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	[KRPIA Note] -Links to the Patent Act and Enforcement Decree remains the same -Added key changes on the Patent Act below: Key Changes on the Trademark Act (Enforcement Date: April 10, 2022) If an examiner discovers an obvious reason for rejection before a trademark application that has been decided to be registered, it has been amended to cancel the decision to register and allow for a reexamination ex officio so that the grant of rights with grounds for invalidation can be blocked in advance.	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) MyIPO had issued the guidelines of trademarks (as updated on January 6 2020) to facilitate the transitions of trade mark applications filed under Trade Marks Act 1976 to the new Act. [Conventus Law] The principal legislation governing Trademark Law in Malaysia remains unchanged. However, there have been slight changes to the regulatory guidelines governing Trademarks in Malaysia. This is due to the issuance of the Trademarks Act 2019 Practice Direction 1/2021 on the 3rd of November 2021. These guidelines have been issued pursuant to the power conferred on the Registrar of Trademarks through Sections 160 and 183 of the Trademarks Act. Source : Intellectual Property Corporation of Malaysia	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/docs/default-source/resources-library/trade-marks/infopacks/tminfopack_apr2017.pdf	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

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Intellectual property rights/IP	Overview of Intellectual property right system	Patent linkage	In July 2021, China National Intellectual Property Administration, National Medical Products Administration and Supreme People's Court successively issued the “Implementing the Measures for Patent Disputes Early Resolution Mechanism”, “Implementing the Measures for Administrative Adjudication System of Patent Disputes Early Resolution Mechanism”, “Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drugs Applied for Registration”, marking the formal establishment of China's drug patent-term compensation system. As of November 2021, relevant departments have received 23 administrative adjudication requests on drug patent disputes filed by patentee or MAH, and formally registered 12 requests that meet the acceptance conditions. In December 2021, the Beijing Intellectual Property Court issued the “Guidelines on Filing Civil Cases on Drug Registration Related Patent Disputes”. Implementing the Measures for Patent Disputes Early Resolution Mechanism https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210703223942131.html Implementing the Measures for Administrative Adjudication System of Patent Disputes Early Resolution Mechanism https://www.cnipa.gov.cn/art/2021/7/5/art_2073_166516.html Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drugs Applied for Registration http://www.court.gov.cn/fabu-xiangqing-311791.html Guidelines on Filing Civil Cases on Drug Registration Related Patent Disputes https://bjzcfy.chinacourt.gov.cn/article/detail/2022/01/id/6468073.shtml	Generics proven to infringing patent rights could be delisted the drug registration by the application of patent owner.	Generics proven to infringing patent rights could be delisted the drug registration by the application of patent owner.	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)	N/A	At present Malaysia does not have any patent linkage system. However, this could change since Malaysia has signed the Comprehensive and Progressive Agreement for Transpacific Partnership (CPTPP) in March 2018, which imposes an obligation on the Drug Control Authority (DCA) to implement a patent linkage system. The reason Malaysia presently does not have a patent linkage system is due to the CPTPP not having been ratified yet. Source: The Law Reviews	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. There was a starting collaborative action among public ad private sectors on patent linkage.	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.

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Intellectual property rights/IP	Overview of Intellectual property right system	Regulatory data protection	In September 2021, “Outline of Strengthening Intellectual Property Construction” proposed to complete digital intellectual property protection regulations. http://www.gov.cn/zhengce/2021-09/22/content_5638714.htm	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, subsequent applicants are able to obtain marketing authorizations using the original applicant’s regulatory data resulting in unfair commercial use of the innovator’s 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). [KRPIA Note] · No update on relevant law but added a clarification concerning our previous report on re-examination of pediatric use	By virtue of the Directive on Data Exclusivity, which was issued by the Director of Pharmaceutical Services and came into force on 1 March 2011, undisclosed, unpublished and non-public domain pharmaceutical test data of the following is protected under the data exclusivity regime: - New drug products containing a new chemical entity. - Second indication of a registered drug product. - The period of data exclusivity cannot be more than: o Five years for a new drug product containing a new chemical entity. o Three years for data concerning the second indication of a registered product. The data exclusivity period runs from the date the new drug product, or the second indication is first registered/granted marketing authorization/first approved and granted data exclusivity/test data protection in the country of origin or any country recognized by the Director of Pharmaceutical Services. Data exclusivity protection does not extend to situations where compulsory licenses have been issued and does not prevent the government from taking any necessary action: - To safeguard public health or national security. - For the purposes of non-commercial public use. - During a national emergency or public health crisis. - During any other urgent circumstances as may be declared by the government. Source: Thomson Reuters Practical Law DE Directive Feb 2011	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: ⅰ) Safety, efficacy information submitted to obtain marketing approval, ⅱ) 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*. 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.

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 eligibility for secondary use, salt, polymorph, formulation, etc.	In August 2021, "The Guidelines for Patent Examination (Draft for Comment)" defined the scope of drug eligible for patent-term compensation. In chemicals category 2.1, the drugs with known active ingredients as esters, or as salts, and in chemicals category 2.4, the drugs with new indications containing known active ingredients, are eligible for patent-term compensation.	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.	N/A	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	In June 2021, the Patent Law officially came into force, in which Article 42 stipulated the drug patent-term compensation system "The Rules for Implementation of the Patent Law (Draft for Comments)" in November 2021 and "The Guidelines for Patent Examination (Draft for Comments)" in August 2021 further refined the patent-term compensation system for drugs. The Rules for Implementation of the Patent Law (Draft for Comments) https://www.cnipa.gov.cn/art/2020/11/27/art_75_155294.html The Guidelines for Patent Examination (Draft for Comments) https://www.cnipa.gov.cn/art/2021/8/3/art_75_166474.html	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." [KRPIA Note] • Updated the revised KIPO regulations effective as of March 2019	As of 2021, there is no provision for the extension of a patent term in Malaysia. However, new drug products containing a new chemical entity and second indication of a registered drug product are eligible for data exclusivity. Source: Thomson Reuters Practical Law	N/A	5 years https://www.ipos.gov.sg/docs/default-source/resources-library/patents/infopacks/patents-formalities-manual_1-nov-2018.pd	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	N/A	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, however, importation is now considered already as fulfilling this obligation (see above) 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.	The Patent (Amendment) Bill 2021 introduces a few important amendments to the rules on compulsory licensing in Malaysia. The summary of the key amendments are as follows: 1. The amendments under Part X of the Patent act seek to empower the Registrar to grant a compulsory license. 2. Amending parts of the Patent Act to comply with the obligation under Article 31bis of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"). The objective here is to allow the grant of a compulsory license to produce a pharmaceutical product in Malaysia and to export that pharmaceutical product to an eligible importing country to address its public health problems. 3. Allowing anyone to apply to the Registrar of Patents for a compulsory license where the products produced in Malaysia under the patent for sale in the domestic market are sold at unreasonably high prices without any legitimate reason. Giving the Registrar authority to grant a compulsory license notwithstanding an exclusive license contract between the licensor and a licensee. The amendments will also protect the licensor from any action for breach of contract by the licensee resulting from the granting of the compulsory license by the Registrar.	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 license 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 license, 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 license 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.

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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 circulation, 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[https://www.yakubutsu.mhlw.go.jp/]," 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. [https://www.jpma.or.jp/globalhealth/fake_measures/index.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.	1. Malaysia does have a raft of legislative provisions that were designed to combat counterfeiting. A brief list of such legislative provisions can be found below: 2. List of provisions - **Part VII of the Copyright Act 1987 and Part XVI of the Trademarks Act 2019** These provisions empower enforcement officers with a whole host of powers to arrest persons suspected of infringement and to search for and seize infringing goods. - **Section 44 of the Copyright Act 1987** This section provides for a warrant of search and seizure where there are reasonable grounds to suspect a party of possessing infringing copies. - **Part XV of the Trademarks Act 2019** These provisions criminalize the act of counterfeiting trademarks.	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 set up special groups, e.g., Allied Control Group (聯合緝查小組) and Expert Group of Illicit Drugs Control (打擊不法藥物專案會報), to make efforts to control counterfeit drugs.	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	Anti-monopoly Law of the People’s Republic of China (Draft Amendment) (October 2021) Data Security Law (June 2021) http://www.npc.gov.cn/npc/c30834/202106/7c9af12f51334a73b56d7938f99a788a.shtml Personal Information Protection Law of the People's Republic of China full translation (August 2021) http://www.npc.gov.cn/npc/c30834/202108/a8c4e3672c74491a80b53a172bb753fe.shtml	N/A	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. Form 27 has been recently amended & simplified. Pregrant 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 exists 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,	N/A	N/A	N/A	1. There have been two other new bills so far which have been passed in late December 2021 by the Dewan Negara (Upper House of Malaysia’s Parliament). These bills and their objectives are as follows: - **The Copyright (Amendments) Bill 2021** The copyright law amendments serve to provide efficient and effective protection of intellectual property in line with current demands and to fulfil, the needs of the business community and stakeholders. The amendment is also to prepare Malaysia to join the Marrakesh Treaty to Facilitate Access To Published Works For Persons Who Are Blind, Visually Impaired Or Otherwise Print Disabled (Marrakesh Treaty) - **Geographical Indications Bill 2021** This bill was enacted in line with the need to protect registered or unregistered geographical indications in Malaysia, in line with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement which were effective on 1st January 1995. **2. Malaysia Intellectual Property Strategy 2021 – 2025** The Kick-off Consultation Session for the Malaysia Intellectual Property Strategy 2021 - 2025 was held jointly by MyIPO & WIPO on 29 January 2021. This policy is to support the Shared Prosperity Vision 2030 to change Malaysia’s economic model to be more progressive, knowledge-based and high-valued, and to attract more R&D investments, the Malaysian IP ecosystem needs to be effective in safeguarding the R&D outputs	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.	N/A	N/A	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.	N/A

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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, pharmacies, distribution need relevant licenses from Department of health	The FDI n 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. In Pharmaceuticals, 100 % FDI is allowed in greenfield projects under automatic rule. For brownfield projects, it is automatic route upto 74% and beyond that is through Government route. OTHER CONDITIONS (i) 'Non-compete' clause would not be allowed in automatic or government approval route except in special circumstances with the approval of the Government. (ii) (The prospective investor and the prospective investee are required to provide a certificate along with the application for foreign investment (iii) Government may incorporate appropriate conditions for FDI in brownfield cases, at the time of granting approval. (iv) FDI in brownfield pharmaceuticals, under both automatic and government approval routes, is further subject to compliance of following conditions: (a) The production level of National List of Essential Medicines (NLEM) drugs and/or consumables and their supply to the domestic market at the time of induction of FDI, being maintained over the next five years at an absolute quantitative level. The benchmark for this level would be decided with reference to the level of production of NLEM drugs and/or consumables in the three financial years, immediately preceding the year of induction of FDI. Of these, the highest level of production in any of these three years would be taken as the level. (b) R&D expenses being maintained in value terms for 5 years at an absolute quantitative level at the time of induction of FDI. The benchmark for this level would be decided with reference to the highest level of R&D expenses which has been incurred in any of the three financial years immediately preceding the year of induction of FDI. (c) The administrative Ministry will be provided complete information pertaining to the transfer of technology, if any, along with induction of foreign investment into the investee company. Consolidated FDI Policy 2020 Department for Promotion of Industry and Internal Trade (d) The administrative Ministry (s) i.e. Ministry of Health and Family Welfare, Department of Pharmaceuticals or any other regulatory Agency/Development as notified by Central Government from time to time, will monitor the compliance of conditionalities FDI up to 100%, under the automatic route is permitted for manufacturing of medical devices. The above mentioned conditions will, therefore, not be applicable to greenfield as well as brownfield projects of this industry Incentivization of Local API Production • Supply chain disruptions during the initial phase of the COVID-19 crisis underlined the local industry's heavy dependence on API imports from China. Policymakers had already introduced measures designed to encourage an increase in local API manufacturing, but these were stepped up during the first half of 2020 • The government has set aside almost Rs100 billion to incentivize local production of more than 50 APIs, and to fund the establishment of pharmaceutical parks where investors in API manufacture will benefit from substantial government funding. Around 70% of funding (Rs69.4 billion) has been earmarked for spending on rewards for manufacturers that increase production of critical APIs over the next six years [Source: MP India Q3 2020]	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. When a foreigner establishes a 100% foreign-capital hospital, it is necessary to obtain a Malaysian doctor's license.	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 availa

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Healthcare and Pharmaceutical industry policy	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, 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 license for therapeutic products (TPIL) and a wholesaler's license for therapeutic products (TPWL) are required to import and wholesale therapeutic products respectively. Companies must comply with the GDP standard. •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's Therapeutic 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 license for therapeutic product (TPIL). An importer's license 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 have 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.

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Healthcare and Pharmaceutical industry policy	Industry development policy	N/A	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. The Government has made unprecedented strides to promote I&T development by investing more than $130 billion over four years. Hong Kong's I&T industry is flourishing at the moment, and the interaction among the Government, industry, academia and research sectors has also been strengthened significantly. https://www.policyaddress.gov.hk/2021/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 centres 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	Pharmaceutical Industry Vision 2021 (Developed in Sep., 2021) Formulated by the Ministry of Health, Labor and Welfare for the first time in eight years in light of changes in the environment surrounding the pharmaceutical industry. Promote industrial policies from the perspective of the 4 main pillars. 1.Innovative Drug Discovery ・Public support to reduce investment risk and improve the investment environment, promotion of external capital investment and joint development, human resource development and employment, support for overseas expansion ・Development of medical information infrastructure such as genome and promotion of its utilization ・Building a global network with academia and venture companies ・Improvement of clinical trial environment such as regulatory harmonization in Asia and construction of clinical trial network ・Ensuring transparency and predictability in National Health Insurance drug price scheme, etc. 2.Generic Drug ・Strengthen responsibility for stable supply and management system ・Support for overseas expansion ・Improving transparency by disclosing the status of efforts to ensure stable supply and quality assurance ・Promotion of the use of generic drugs including biosimilars ・Promotion of self-care and self-medication 3. Pharmaceutical distribution ・Improvement of commercial distribution function (market price formation) through business practices ・Obtaining information on supply instability at an early stage and examining distribution schemes 4. Economic security ・Risk analysis of pharmaceuticals that should be secured stably and strengthening of the supply chain ・Ensuring profitability and predictability of vaccines and therapeutic products (including AMR) To contribute to the follow-up of this vision, we will set KPIs and continuously carry out public-private dialogue and information dissemination at the practical level.	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	The government's industry development policies can be broken down into the following categories. 1. **Pro-business policies** These policies revolve around the Government's intention to increase the ease of setting up a business in Malaysia. These include making sure the cost of setting up a business is low. Based on Section 562 of the Companies Regulations 2017, the fee for the registration of a foreign company with a share capital of not more than RM1,000000.00 is RM 5000.00. Pro-business policies also include policies that improve access to basic utilities and immigration policies that are conducive for investment. **2. Attractive tax and other incentives** The Malaysian government has maintained and improved upon its tax and incentive policies to remain an attractive destination for foreign investment. The following is a list of tax rates applicable to the pharmaceutical industry in Malaysia - Corporate tax rates Resident and non-resident companies- 24 percent Resident companies with paid-up capital of RM2.5 million and less at the beginning of the basis period for a year of assessment on the first RM500,000 (USD162,337.67) chargeable income- 17 percent On subsequent chargeable income-24 percent - Personal Income tax rates 0%-30% The following is a list of all the incentives that can be applicable to the pharmaceutical industry - Incentives for Manufacturing Companies Pioneer Status with income tax exemption of 70% of statutory income for 5 years, or Investment Tax Allowance (ITA) of 60% of qualifying capital expenditure incurred within a period of 5 years (to be offset against 70% of statutory income for each assessment year.) - Incentives for High Technology Companies Pioneer Status with full income tax exemption of statutory income for 5 years, or ITA of 60% on qualifying capital expenditure incurred within a period of 5 years (to be offset against 100% of statutory income for each assessment year.) - Incentives for Strategic Projects Incentives for Strategic Projects are dependent on: i) Level of investment ii) High technology/technology transfer ii) Linkages with local ecosystem/vendor development iv) High income employment/technical skills v) Level of R&D undertaken locally (a) Pioneer Status with full income tax exemption of statutory income for 10 years, or (b) ITA of 100% of qualifying capital expenditure incurred within a period of 5 years (to be offset against 100% of statutory income for each assessment year.) - Incentives for Research & Development (R&D) (i) Contract R&D company (a) Pioneer Status with 100% income tax exemption of statutory income for 5 years, or (b) ITA of 100% of qualifying capital expenditure incurred within 10 years (to be offset against 70% of the statutory income in each year of assessment.) (ii) R&D Company ITA of 100% of qualifying capital expenditure within 10 years and to be offset against 70% of the statutory income for each year of assessment (iii) In-house Research Investment Tax Allowance of 50% of qualifying capital expenditure incurred within 10 years and to be offset against 70% of statutory income for each year of assessment - Guidelines for Incentive for Manufacturers of Pharmaceutical Products Including Vaccines Under the 2021 Budget The incentive is for both new and existing companies: (i) Income tax rate of 0% to 10% for a period of 10 years (ii) Income tax rate of 10% for the subsequent period of 10 years **3. Intellectual property protection (IP Protections)** Malaysia has strong IP protections in place and is committed to safeguarding IP on inventions. To ensure IP protection in Malaysia is in line with international standards and provides protection for both local and foreign investors, Malaysia is a party to the following treaties: - World Intellectual Property Organization (WIPO), 1967; - Paris Convention for the Protection of Industrial Property 1883; - Berne Convention for the Protection of Literary and Artistic Works (1886); - Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement; - Patent Cooperation Treaty (PCT) 1970	The Board of Investments is leading the crafting of a pharmaceutical industry roadmap, in light of the supply security challenges with COVID-19.	The Singapore government actively supports the growth and development of the biopharmaceutical industry through various investments. Singapore has over 60 manufacturing facilities across a wide range of products, including bulk active pharmaceutical ingredients, bulk biologics, drug products and nutritionals. A new 10-year plan was announced in Jan 2021 to grow Singapore's manufacturing sector by 50 per cent and maintain its share of about 20 per cent of gross domestic product (GDP) - the Manufacturing 2030 plan. The biomedical cluster is central to Singapore's vision and to achieve its target, the government is committed to: •Step up efforts to attract the best global and local companies in niche areas such as innovative technologies that will help Singapore remain a critical node in global value chains. •Offer tailored support to grow the size and capabilities of employees advanced manufacturing. These investments in Singapore's capabilities aim to equip Singapore for end-to-end production of many biomedical products, including vaccines. The government will continue efforts to attract frontier investments in the biopharmaceutical industry, and build strong partnerships between public and private sectors, as well as between companies and academia to upskill talent in the sector. The government will continue to build strong capabilities within the biopharma sector, in areas of medical technologies such as gene therapy, stem cells treatment, cancer immunotherapy and personalised/precision medical treatments. Singapore continues to enhance the working environment in biopharma and biomedical parks for businesses to ensure infrastructure will support expansion of the industry. •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.	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. 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 to digital platforms 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. However, currently such figure is at around 50%. In 2021, the Ministry of Health aims to submit the National Strategy on pharma sector development to 2030, vision 2045 for approval. 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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Healthcare and Pharmaceutical industry policy	Medicine Price Controls	N/A	N/A	N/A	N/A	N/A	N/A	1.As of January 2022, the planned Medicine Price Control Policy has yet to be implemented. This policy was mooted in 2019 as a proposed solution to rising drug prices. The initial plan was to implement this policy through the Price Control and Profiteering Act 2011. 2.To identify the real impact and harms of this policy, a specific Cost-Benefit Analysis (CBA) was conceived via collaboration between the Malaysian Productivity Corporation (MPC), a statutory body under the Ministry of International Trade and Industry (MITI), and several other government bodies, economists, and private industry groups such as the Pharmaceutical Association of Malaysia (PhAMA), the Malaysian Organisation of Pharmaceutical Industries (MOPI), the Association of Private Hospitals of Malaysia (APHM), the Malaysian Medical Association (MMA) and the Pharmaceutical Research & Manufacturers of America (PhRMA). 3.There have been pockets of criticism against the Cost Benefit Analysis (CBA) over potential conflicts of interests and that the public was not given adequate time to respond to the findings in the CBA.	N/A	N/A	N/A	N/A	N/A
	Procurement of Medicines	N/A	N/A	N/A	N/A	N/A	N/A	Malaysia's public sector procures medicines using three mechanisms that are subject to public procurement regulations stipulated by the Ministry of Finance (MOF). These mechanisms along with the explanations on how they work are below. 1. National Concession Agreement with One Designated Supplier The national concession agreement was with Pharmaniaga Logistics Sdn Bhd, a government-linked company (GLC) that took over the functions of the government central procurement service, including warehousing and distribution, in a form of privatization in the early 1990s. At present, public facilities can procure approximately 350 medicines, which are listed in the Approved Product Purchase List (APPL), directly from Pharmaniaga Logistics Sdn Bhd through the concession agreement at prices negotiated by MOH 2. National Tenders This procurement mechanism involves MOH facilities ordering medicines via tenders managed centrally by the Procurement Division with technical support from the Pharmaceutical Services Programme. These centrally negotiated tenders on behalf of all public facilities are required for products where the annual purchase value exceeds MYR 500,000.00 3. Direct Purchases by Health Facilities For items, whose annual purchase value is between MYR 50,000.00 and MYR 500,000.00, health facilities can directly purchase the items themselves, but must obtain a minimum number of quotations from suppliers registered with the government prior to procurement. For purchases less than MYR 50,000.00 the facilities are permitted to make direct purchases at their discretion Source: BMC Health Services Research	N/A	N/A	N/A	N/A	N/A

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Healthcare and Pharmaceutical industry policy	Government counterpart	N/A	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)	The Department of Trade and Industry and the Board of Investments https://boi.gov.ph/tag/dti/	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)	N/A	Various pharmaceutical associations are in place. The government has established various consultative groups: • For Health, there is an Advisory Council • For Trade, the Pharma Technical Working Group For FDA, Pharma Industry Working Group	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 Frost & Sullivan's data, in 2020, China's domestic CRO market scale was US $8.3 billion, of which the clinical CRO market scale was US $6 billion and the preclinical CRO market scale was US $2.3 billion. It is expected that the compound growth rate in the next 3 years will be 27.49%, higher than the growth rate of the global market. https://www.sohu.com/a/490039242_120106660	N/A	N/A	Quintiles, Prodia, Pacific Bridge Medical, PAREXEL etc	N/A	N/A	International CROs (https://ichgcp.net/cro-list/country/malaysia) include: • Quintiles • PAREXEL • IQVIA • INC (formerly MDS) • Covance • Pharmanet • PPDi • The George Institute for International Health · Novotech Locally incorporated CROs include Info Kinetics Sdn Bhd	Several Contract Research Organisations 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, ICON, PAREXEL International, Novotech, Intellim and more	N/A	Non-exhaustive list of active CRO's in Thailand IQVIA Parexel Acriles Covance PPD Asia Global Research	N/A

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Healthcare and Pharmaceutical industry policy	Contract manufacturing Organization	According to Frost & Sullivan's data, the market scale of China's CMO industry was only US $900 million in 2014, and then rapidly increased to US $4 billion in 2020. As to the global proportion, China's CMO industry has grown rapidly in recent years, from 5.6% in 2014 to 12.4% in 2020. https://baijiahao.baidu.com/s?id=1715917898352551253&wfr=spider&for=pc	N/A	N/A	Combiphar, Dexa Medica, Bernofarm, Sanbe Farma, Kalbe Farma, and other local pharmaceutical companies	N/A	N/A	In 2020, a total of 265 facilities were licensed by the Drug Control Authority (DCA), Ministry of Health Malaysia. (NPRA annual report 2020) This cover facilities that produce pharmaceuticals, health supplements, traditional medicine, and veterinary products, including contract manufacturing organizations. A List of all Licensed Manufacturers in the QUEST System is available on https://www.npra.gov.my/index.php/en/informationen/quest-list-of-manufacturers-wholesalers-importers/quest-list-of-manufacturers.html	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.

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Pharmaceutical industry groups	Name of main Organization (Please insert weblink if available)	N/A	The Hong Kong Association of the Pharmaceutical Industry (HKAPI) www.hkapi.hk	▪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	KRPIA (Korea Research-based Pharmaceutical Industry Association): https://www.krpia.or.kr/ KPBMA (Korea Pharmaceutical and Bio-pharma Manufacturers Association): https://www.kpbma.or.kr/ KoBIA (Korea Biomedicine Industry Association): https://www.kobia.kr/ KoreaBIO: https://www.koreabio.org/	Pharmaceutical Association of Malaysia (PhAMA): Innovative R&D-based pharmaceutical companies. (http://www.phama.org.my/) Malaysian Organisation of Pharmaceutical Industries (MOPI): local manufacturers of generic drugs. (https://mopi.org.my/) Malaysian Association of Pharmaceutical Suppliers (MAPS): importers of generic drugs (http://www.i-maps.my/1.asp)	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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	Access & Medical Services	N/A	The government has been drafting medical device regulations. The basic concept is voluntary listing.	India's health care sector provides a wide range of quality of care, from globally acclaimed hospitals (India is home to global leaders in innovation in and quality of health care such as the Narayana Hospitals, known for providing high-quality cardiovascular surgery at low cost, and the Arvind Eye Care System, whose hospitals provide a high volume of cataract surgery, as well as globally renowned medical teaching institutions such as the All India Institute of Medical Sciences, in New Delhi). to facilities that deliver care of unacceptably low quality. Nine out of ten doctors in India work in the private sector. But the fact remains that for nearly 600 million rural and urban poor, quality, affordable healthcare is beyond their reach. India caters to at least 1,511 people, much higher than the World Health Organization's norm of one doctor for every 1,000 people. The shortage of trained nurses is even more dire, with a nurse-to-population ratio of 1:670 against the WHO norm of 1:300. Efforts to improve the quality of care are particularly challenged by the lack of reliable data on quality and by technical difficulties in measuring quality. Ongoing efforts in the public and private sectors aim to improve the quality of data, develop better measures and understanding of the quality of care, and develop innovative solutions to long-standing challenges Key challenges for access & medical services are : Reducing out-of-pocket expenditure According to the Ministry of Health, nearly 63 million people are faced with poverty every year due to "catastrophic" expenditure they incur over healthcare. In addition to this, only a very small percentage of Indians have health insurance policies in India. And until the right mechanisms are put in place, ensuring that out-of-pocket healthcare expenditure incurred by people comes down, the OOP expenditure will continue to disengage all the economic progress made by the Indians. The Economic Survey 2020-21 has strongly recommended an increase in public spending on healthcare services from 1 percent to 2.5-3 percent of GDP, as envisaged in the National Health Policy 2017. It notes that this can significantly reduce the Out-of-Pocket-Expenditure (OOPE) from 65 per cent to 35 per cent of the overall healthcare spend. The Survey also underlines that OOPE for health increases the risk of vulnerable groups slipping into poverty because of catastrophic health expenditures. The life expectancy in a country correlates positively with per-capita public health expenditure. Significantly, it also observes that from a financial perspective, India has one of the highest levels of OOPE in the world, contributing directly to the high incidence of catastrophic expenditures and poverty. Lack of resources Despite being a rapidly growing economy, India spends meagre resources on its healthcare needs. In fact, the overall expenditure on public healthcare in India has contracted over the time given that India spends only about 1 percent of its GDP on public health. In fact, if experts are to be believed India must spend a substantial funds to reach the global acceptable levels of child and maternal mortality rates. The government may raise the resources in numerous ways right from reallocating subsidies to optimizing welfare budgets and in particular, by working in harmony with the state governments. As per the Economic Survey, the expenditure on health increased from 1.2 per cent to 1.5 per cent during the during the period 2014-15 to 2020-21. Recognizing the importance of skills The lesser number of skilled and well-learned medical graduates, in particular in rural India is turning out to be the biggest roadblock facing the healthcare system in India. In fact, its effect has been such that no fresh graduates are inclined to serve the rural community thanks to abject living conditions. At the same time, this is the area where investments by government can do wonders. Dedicating resources towards training and education of skilled workforce, competitive pay and creating standard living conditions will make sure that public healthcare in India is in the hands of well-qualified people. The issue of quacks and traditional healers treating patients at the grass root level is a serious concern. This is connected to the poor availability of healthcare services and service providers in rural areas. The government has not formulated any Bill to curb these malpractices. The extent of harm, morbidity and mortality resulting from such treatments is devastating https://www.tribuneindia.com/news/comment/challenges-of-health-coverage-in-india/569722.html	• Differences in status of doctor deployment depending on the region: There is still a shortage of doctors, but the pattern of deployment is a bigger problem that the number of doctors. Fifty percent of the hospitals in eastern Indonesia have a doctor shortage, whereas the hospitals in western Indonesia have more doctors than they need. This regional difference in the deployment of healthcare professionals is a major problem. • Necessity of disease countermeasures including measures to reduce HIV/AIDS and lifestyle disease countermeasures against diabetes, etc. • Correction of regional differences in medical services (correction of uneven distributions of doctors and nurses) • Expansion of facilities that accommodate medical tourism (accommodating tourists going overseas) ["Report on the survey and analysis of medical needs overseas and the status of Japanese companies' entry into foreign markets": http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000074947_3.pdf]	N/A	N/A	N/A	• The UHC Act has generated much hope and expectation for Filipinos. However, several hurdles must be addressed before UHC can be truly felt in the country. For example, there is still very limited health facilities and healthcare professionals in the country, especially in the primary care setting. This is coupled by patient perception that in case of illnesses, a hospital is the first place to visit. This results to flocking at tertiary level hospitals, even for cases that can be handled in primary care facilities. Another is the very limited funding and subsequently, government support/subsidy • Health facilities and healthcare workers are maldistributed, with large concentration in urban areas • Health information system is also lacking, making data-driven decision making difficult. There is also no central patient information system. • Infrastructure for pooled procurement, price negotiations are being built, but need further improvement. Central pooled procurement and multi-year obligations provide opportunities to leverage on greater volumes to bring down prices. The implementation of quarantine measures, as well as the requirement for COVID testing prior to accessing hospitals had made severe impact to the healthcare industry, with data showing that 72% reduction in hospital visits, low elective surgery and prescription census. These effectively meant contractions in the prescription market, as well as the medical device industry.	Alongside battling the ongoing Covid-19 pandemic, MoH's key objectives and challenges are - Singapore's rapidly ageing population, boosting healthcare infrastructure to continue delivering better healthcare, and ensure that Singaporeans have access to good and affordable healthcare for all their healthcare needs from primary healthcare at the local GP to long-term community or residential care. • The Ministry of Health (MoH) completed the reorganization of the former six regional health systems (RHSs) into three integrated clusters in early 2018, with the aim of facilitating the provision of multidisciplinary, patient-centric care across different settings. The new structure is also expected to achieve better integration between the providers in each region, as well as help optimize resources. • To help patients cope with rising healthcare costs, the government will continue to enhance subsidies for medical services and outpatient drugs in public healthcare institutes. The Community Health Assist Scheme (CHAS) will be extended to all Singaporeans with chronic conditions, regardless of their incomes, while the Merdeka Generation Package will be rolled out to some 500,000 Singaporeans born in the 1950s at an early stage of the forecast period. • Developing the primary care sector will remain a key focus for the MoH during the forecast period in order to alleviate demand for hospital care, as well as ensure seamless patient care across sectors. To this end, the government is pursuing several strategies, including: investing in the Primary Care Network (PCN) scheme, establishing additional polyclinics and strengthening the role of the family practitioner. Meanwhile, the government is also continuing to invest in large scale out-patient and day-care facilities, as well as adding further to existing bed capacity by building new hospitals.	N/A	No new significant issue	Prior to the Pharma Law, Decree 54 and recently issued Registration Circular, access to medicines in Vietnam is slow with only 6% of new molecules available in 3-7 years of launch. Another obstacle: the long-time lag can be attributed to difficulty of drug registration and limited reimbursement assurance. Poor access to treatment is one of the drivers of patients seeking care abroad. 40,000 Vietnamese citizens spent $2 billion in healthcare facilities abroad • Most travel to Singapore or Thailand, where costs can be 8x those in Vietnam • Poor access to new medicines could be one of the key drivers • Other drivers include the perception of inferior local facility quality, and overcrowding of existing institutions (IMS) The Registration Circular 32/2018/TT-BYT has positive developments to improve the process for drug registration in Vietnam. Further attention and support from the Government is needed to ensure the regulation itself and the implementation phase can ensure (i) quality assurance for patient safety, (ii) harmonization of regulatory requirements, (iii) reduction of unnecessary administrative burden, and (iv) fair and equal access to the market.

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	Generic Policy and advance	N/A	N/A	Most medicines sold in India are the branded generics (Indian pharma) & branded generics & patented products by MNCs. Branded generics dominate the prescription pharmaceutical market in India, accounting for around 80% of sales by value. 'Trade generics' (also called 'generic generics' even though they are branded) are estimated to account for 4-8% of the market by value [Source: MP India Q3 2020] Read more at: http://timesofindia.indiatimes.com/articleshow/60752490.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst The push towards generic drugs began with Prime Minister Narendra Modi declaring that the government will bring a legal framework to get doctors to prescribe generic names. Soon after the Medical Council of India (MCI) directed doctors to write generic names inprescriptions or face disciplinary action. The push to get the doctors to prescribe generic names, is one of the many steps the government has been taking to reduce medical costs in India. The key ones has been 1) Expansion of National list of Essential Medicines (NLEM) bringing them under price cap, 2) push by the government to increase awareness of generic drug prices and 3) increase access through Jan Aushadhi programme. "A shift to a generic-generic model (similar to US) from the branded generic model currently in India, requires confidence among doctors, pharmacists and patients on the quality of drugs available in market." [https://health.economictimes.indiatimes.com/news/pharma/government-policy-would-succeed-if-generic-drug-quality-improves-jefferies/58350022	N/A	[KPBMA] The MFDS revised the Pharmaceutical Affairs Act to restrict joint use of BE test to prevent the issue of excessive number of identical generic drugs flooding the market. According to the newly established bill on July 20, 2021, the number of items that may be approved by using previously submitted BE test or clinical trial data shall be limited to three.	N/A	Major players in the Malaysian generic market include Pharmaniaga, Duopharma Biotech, Kotra Pharma, Xepa Soul-Pattinson, and Y.S.P.	• The DOH advocates the use of generics. While market reports already confirmed the dominance of generics as a whole, the DOH pushes for the use what they call as "true generics", ie generic medicines without brand names. DOH continue to claim that generics (true generics) is still not widely available in the country, and uses this as justification for their policy recommendations such as: ○ The use of maximum retail price (mandatory price cuts). DOH sees that there is little/lack of competition in the market, making medicines prices high. Due to market failure, DOH believes that MRP should be used. ○ Mandatory carry of retailers of generic equivalents of drugs in their Primary Care Formulary List The FDA deferred the implementation of bioequivalence (BE) evidence as requirement for renewal of registration of drug products (FDA Circular No. 2016-019). As such, pharmaceutical products for automatic Certificate of Product Registration (CPR) will be granted full renewal validity even without the BE requirement. The BE ensures that a generic product is similar with the innovator reference with regards to quality, safety and efficacy. The deferred implementation may have a public health repercussion and sends a negative signal to companies that are fully complying with FDA requirements.	• A consortium between regulators in Australia, Canada, Singapore and Switzerland has selected generic drug review as a priority area for collaboration. This consortium, ACCESS has included UK since October 2020. • The fast-track registration process for generic drugs imported from India (the verification-CECA evaluation route) was set up under a Memorandum of Understanding (MoU) on economic cooperation between Singapore and India. This obviates the need for Indian manufacturers to obtain clearances to export drugs to Singapore, provided that the generic has been approved by at least one of the five international agencies referenced by the HSA. The process does not guarantee automatic market entry, as it is also subject to certain qualification criteria. • Branded products dominate the generic market, Indian manufacturers are expected to increase their foothold in Singapore's generics market, with more companies following the lead of Ranbaxy Laboratories, Strides Arcolab, Intas and Dr Reddy's by taking advantage of the fast-track approval system for Indian generics. • Chinese manufacturers do not enjoy a particularly good reputation in Singapore, and Chinese generics companies are unlikely to play a major role in the market during the next five years. [IQVIA]	N/A	COVID-19 Primary Care system Telemedicine and telepharmacy	"National Strategy for the Development of the Pharmaceutical Industry up to 2020 and Vision up to 2030", which was approved in January 2014, proclaims a policy of concentrating efforts on investment and development to expand and strengthen production of high-quality generic pharmaceuticals, and promoting a switch from imported drugs to domestically produced ones. [New-S SECURITIES_Vietnam Weekly Report_April 20, 2015]

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	Health insurance system challenges	N/A	Voluntary Health Protection Scheme	India has one of the lowest per capita healthcare expenditures in the world. Government contribution to insurance stands at roughly 32%. The high out-of-pocket expenses in India, as we detailed earlier, stem from the fact that 63% of Indians do not have health insurance [2019], according to data from the Insurance Regulatory a Development Authority. Government insurance covers also sometimes limit of expenses to be incurred on individual per year & process to avail these insurance seeking reimbursement is sometimes challenging. Key challenges for growth of Private Medical Insurance are ·Indian population is yet to accept Health insurance as a financial vehicle for medical treatment ·Private Insurance majorly covers cost of hospitalization & not the cost of medications ·Poor understanding of the Medical Insurance products ·Higher claim ratio specially in the corporate Health business [MP India Q3 2020	• Universal health insurance: The plan is to sequentially unify all services into a universal health insurance system by 2019. The due date for mandatory enrollment of company employees in BPJS is January, 2015, but it will be a matter of waiting for results to see how far enrollment has progressed. • Increase in enrollee coverage rate in universal health insurance system. • Under the new system that came into force in January, 2014, coverage of all citizens by 2019 was established as the goal, and it is gradually being implemented. Other challenges include securing financial resources, enrollment of the self-employed and farmers, the greater part of the "uninsured" who make up about 40% of the population, and the lack of medical facility infrastructure development, and the shortage of healthcare personnel. • Securing financial resources . . . A fund of 1.3 to 1.6 trillion is necessary for full-scale operation of a PBI for low-income people, and this is a burden on government resources. • Promotion of the e-catalog system (electronic procurement system that supports the universal health insurance system)	N/A	[KRPIA] As the health care environment changes due to aging society, health insurance expenditure continues to increase. In response, the government has sought to stabilize the cumulative finance by continuously pursuing spending efficiency measures through streamlining the ratio of the medical fee structure, adjusting the copayment rate, and reducing drug prices, and improving the tax system. Nevertheless, the financial condition of health insurance is expected to deteriorate due to the continuous increase in the elderly population and the expanding of coverage. Accordingly, the government keeps up the scrutiny to secure fundamental sustainability of the health insurance system through social consensus as well as the fundamental system improvement plan such as reform of payment system, drug price system and financing for stabilization of health insurance.	Government expanded the MySalam scheme to cover 45 types of critical illnesses and polio, and also for medical devices and to Malaysians in Middle 40% income group (M40).	• Financial protection from PhilHealth is limited, resulting to high level of household OOP (out of pocket) in the country. While the benefit packages are purported to cover from diagnosis to treatment, there is no specific allocation for each component of the package. Since the value/support is limited and most medicines are taken outside the hospital, medicines are excluded in the benefit and paid for by patients OOP. The establishment of health technology assessment (HTA) as a prerequisite for PNF inclusion, as well as the concurrent review of all existing products in the PNF has put the process in a transition phase, halting the nomination process for new products. The process and requirements described in the HTA process could take as long as two years and undermine patient access to innovative medicines. Given the importance of PNF inclusion for government procurement and product inclusion in benefit packages, it is imperative that a fit-for-purpose and a transparent and efficient PNF listing process be put in place by the government.	•On 21 Dec 2020, the Government announced that it accepted all the recommendations of the MediShield Life Council and that it will provide about $2.2 billion for premium subsidies and support over the next three years, including a one-off COVID-19 subsidy for all Singapore Citizens for two years. Premium payment was deferred until end Dec 2021 for those who have insufficient MediSave balances and are unable to pay their premiums due to the economic impact from COVID-19. The annual MediSave top-ups for Pioneer Generation seniors were also enhanced from 2021. The key changes that came into effect on 1 March 2021 include: oHigher yearly annual claim limit would be increased from $100,000 to $150,000. oIncrease claim limits for daily ward claim limit (of additional claim limit of $200 per day for the first two days of hospitalization stay), sub-acute care at community hospitals, outpatient treatments and radiotherapy for cancer treatment, oLower deductibles for day surgery and removal of exclusions for attempted suicide, intentional self-injury, drug addiction and alcoholism. oLower subsidy for private hospital coverage. •Demographic and epidemiological trends will drive up demand for medicines, while broader MediShield Life's coverage and expansions under CHAS will also boost pharmaceutical consumption. •On 14 Sep 2021, the Government announced further revisions to enhance MediShield Life coverage for cancer: oCreation of a positive list of clinically proven and cost-effective outpatient cancer drug treatments that will be claimable under MediShield Life oMore granular claim limits ranging from $900 to $2,000 a month to provide better coverage based on the cost of each treatment oSeparate claim limits for outpatient drug services (such as scans, blood tests and doctor consultations) •While new product launches in the public sector will boost market value, overall market growth rates will be limited by which drugs are available on the positive list as patients undergoing treatment will not be able to claim for products not on the positive list with effect from April 2023 (with the exception of policy holder with riders). Patient affordability issues and the proliferation of generic prescribing to adhere to the new rules may serve to limit market growth rates further.	.Because payment to individual medical facilities is on a fee-for-services basis, there are problems with excessive treatment and the so-called 3-minute consultation. They are experimenting with a number of systems, including a total budget control system, but these remain problems.	No significant issue	Government policy seeks to broaden access to healthcare and improve the quality of provision. This will involve further investment in expansion and restructuring of the public hospital sector and efforts to strengthen primary care provision. Both are sorely required, as major city hospitals continue to battle chronic overcrowding, but effective implementation of healthcare reforms could be hampered by funding issues, staff and equipment shortages, and poor management. Pressure on the healthcare system will intensify as social health insurance (SHI) coverage increases. 90,85% of the population is now covered by the SHI system, and the target for coverage in 2021 has been raised to 91%. Most uninsured patients are poor, and funding coverage for this segment of the population will drive up public health expenditure. While the network of hospitals, composed of both branch, provincial level and national level facilities, provides the country with a high number of beds per inhabitant, it still has not solved the issues of high bed occupancy rate and Vietnam continues to far exceed the 80% threshold occupancy rate recommended by the WHO. Having too many patients in higher level hospitals has become an urgent problem in recent years, with two to three patients sharing a bed becoming common in many central and provincial hospitals. Bed occupancy rates have reached 120–160%, especially in the central hospitals of some large cities. Overcrowding in higher level healthcare facilities may have several causes, including limited healthcare quality in lower level facilities in districts and communes, and even in provincial hospitals; increasing expectations of service quality; improvement in convenience of transportation from remote areas to central areas; and limited differences in hospital fees at different administrative levels. This may lead to a drain on resources in higher level hospitals and subsequent wastage at lower levels. Beyond the inequality of care, the overall quality of services provided is the major reason for the high occupancy rate. The average length of stay is significantly longer on average in Vietnam than in other South-East countries. The outdated medical equipment, combined with the limited access to the latest drugs in Vietnamese public hospitals (and specifically in the small provincial level hospitals) are commonly cited as the major challenges to improving the quality of care in Vietnam.

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	Reimbursement or payment system challenges	N/A	N/A	Most of the private medical insurance companies provide cashless hospitalization for the patient in designated hospitals but the amount for the same is limited to an extent & cost of medicines is often not covered, critical illness like cancer are omitted from some insurance offering ·Government insurance covers also sometimes limit of expenses to be incurred on individual per year & process to avail these insurance seeking reimbursement is sometimes challenging. For the medicines which are not in formulary patients have to purchase the medicines and seek reimbursement	• Until the new system is complete, the uninsured bear all costs themselves. • Generic drug prescriptions are expected to increase with the introduction of the universal health insurance system, and prescribing of generic drugs is in fact increasing. • The government legally obligates public medical institutions to use low-cost generic products. • In many cases, new drugs are not covered by public insurance, and since non-branded generics are listed under public insurance to begin with, it is assumed that the importance of having their products listed in insurance drug lists will increase for pharmaceutical companies that sell branded generics. INA-CBG reimbursement system The INA-CBG reimbursement system for the provision of JKN inpatient services is accompanied by clinical guidelines, which encourage doctors to reduce drug costs by prescribing cheaper alternatives to help manage capped budgets. Together with the e-catalogue, it places the burden of cost-containment on the shoulders of hospitals and their physicians. The regulation of prescribing in public hospitals has been tightened and treatment guidelines enforced more strictly, requiring adherence to the FORNAS and clinical pathways in order to secure reimbursement. Prescribers have a little more leeway for the treatment of some serious conditions, reflecting the fact that certain flat-sum tariff calculations exclude drug costs. The limited nature of JKN coverage and the financial status of patients can affect drug choice and the duration of prescriptions, however, while moves to limit coverage for some cancer drugs have affected physician choice (see National Drug Formulary). Source :IQVIA Market Prognosis	N/A	[KRPIA] Under the RDRG, a growing number of healthcare institutions are applying the scheme. -RDRG was applied to 27 private hospitals in two stages in August 2018 and January 2019. As of April 2020, based on HIRA data, the total number of medical centers which implement RDRG system turned out 98 across the nation, including both public hospitals and private hospitals.	All drugs need to be listed in the MOH formulary before they are purchased by public hospitals for supply to patients. Patients' access to new drugs at public medical institutions is delayed. Moving toward HTA (CEA and BIA) with limited budget. (https://www.ispor.org/docs/default-source/conference-ap-2018/2018_ispor_tokyo_jp15_current_practices_and_prospects_in_managing_reimbursement_in_asia_pacific_and_europe-final.pdf?sfvrsn=2e9adeb4_0) Innovative medicines are unlikely to be included in formulary listing due to government's preference on cost-effectiveness and generic medicines.	Hospitals have threatened to cut ties with the PhilHealth for its continuing delays in payment. The latest amount is around P25.45 billion (486 Million USD) which the state insurer promises to pay in 6 months. Past reports of fraudulent claims, with the organization facing several investigations on corruption allegations, were identified as a reason for careful disbursement process	•Since its establishment in 2015, Singapore's national health technology assessment (HTA) agency, the Agency for Care Effectiveness (ACE) has become increasingly active, particularly as it makes up part of the ministry's Beyond Healthcare 2020 plan. ACE is responsible for drug evaluations and recommendations that feed into MoH decision-making on drug subsidy listings. •MoH subsidies will continue to be enhanced with support from the Agency for Care Effectiveness (ACE). While the drug subsidy listing process remains opaque, greater stakeholder engagement between ACE, the MoH and industry players will result in improved transparency over the long term. •Drug evaluation and decision-making procedures for subsidy listing were reformed in May 2017. This has seen the national HTA agency (Agency for Care Effectiveness; ACE) take on a pivotal role in the SDL and MAF listing procedures, working with the DAC on evaluations and the development of recommendations to the MoH. ACE's involvement has driven the gradual expansion of the subsidy list, fulfilling the MoH's aims of improving patient access to medicines. Reports indicate that the government intends to undertake a further review of the MAF subsidy process in a bid to make it more efficient. •There is no formal price control system for pharmaceuticals in Singapore, with price dictated by purchasing practices, market competition and patient affordability. Prices in the public sector are controlled indirectly by the tender system operated by ALPS. In addition, cost-effectiveness assessments carried out by ACE for specific innovative therapies has led to price capping for selected drugs at public institutions. [IQVIA]	The average time required from regulatory approval of a new drug to price listing is 427 days [2016 MOHW New Drug Control Summary]. It takes that long because there must be HTA evaluation and a meeting of an expert committee (corresponds to Central Social Insurance Medical Council of Japan). Moreover, Manage Entry Agreement negotiations must be conducted between the corporation and the MOHW for drugs whose annual projected sales within the 5 years after price listing exceed NTD 200 million, and this leads to delays in reimbursement.	Even more patients visited hospitals, but as of budget limitation there were various new policies announced and implemented to limit the cost mainly for CSMBS for example OCPA for oncology treatment and will be expanded to other high-cost medicines.	Under current practice, once a pharmaceutical product is granted an MA/visa number, it is still not eligible for reimbursement, as it has to be enlisted into the National Reimbursement List (NRL). The new Circular 30/2018/TT-BYT promulgation of List of modern medicines, biologicals, radiopharmaceuticals and tracers covered by health insurance, insurance coverage ratio and payment conditions thereof removes the provision of 2-year timeline for NRL to be reviewed and updated, meaning the timeline now could be longer or shorter than 2 years, during which time no new information or newly-licensed products can be considered for reimbursement. Altogether, with current practice, new pharmaceuticals may have to wait several years for MA and inclusion in the NRL thereafter, effectively causing considerable delay in bringing new reimbursed treatments to Vietnamese patients and contributing to medical tourism. In order to ensure faster access to new, innovative pharmaceuticals, it is recommended that reimbursement should be possible as soon as they receive MA, in line with other ASEAN markets.

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	Drug price and pricing system challenges	N/A	N/A	The Indian market is highly competitive in bringing the cheapest brand to people. It is noteworthy that doctors always relate the quality of the drugs to the cost of the drugs. The brand leader sells the highest priced medicines. National Pharmaceutical Pricing Authority (NPPA) makes decisions on drug pricing in India. Currently, the prices of over 400 essential medicines are capped by the NPPA Tender pricing for Government Procurement The tender prices are about 1–3% of the retail market prices. In Tamil Nadu, Albendazole 4oomg is bid at Rs.0.35 per tablet by the Government but in the market it is sold for rs.12 per tablet. , and for all other medicines companies are allowed to hike prices by a maximum of 10% annually. For any further increase, companies have to seek permission from the NPPA. Majority of State & Central Government Health Schemes go for annual tender or rate contract for medicines for their respective estimated purchase quantities	Self-estimated price (HPS) is currently used as one of the references in the drug procurement system and selection process in e-catalogue. Challenge is, this HPS system is thought to have restricted the tender and negotiation process and lack of explanation and transparency of the calculation. ・ The economic fallout from the COVID-19 pandemic will intensify pressure on drug prices. The MOH is attempting to extract savings through the widespread procurement of unbranded generics, while branded generics and innovative drugs face tough negotiations for e-catalogue drug procurement contracts. However, more price flexibility could be awarded to manufacturers of essential medicines that are in short supply due to pandemic-related disruptions. ・ The MOH's cost conscious approach to drug procurement, which is handled by the National Public Procurement Agency (LKPP), will continue to favor unbranded generics in e-catalogue tenders. Existing e-catalogue procurement contracts were repeatedly extended through 2020 as a result of the COVID-19 pandemic, before a backlog of agreements was negotiated during the fourth quarter of 2020 through to April 2021. These will guide public sector purchasing until 2023. Source :IQVIA Market Prognosis	N/A	[KRPIA] 1.Long review process -By regulation, new drug listing process should complete in 240 – 270 days but in practice it takes much longer time. In 2017, based on what HIRA reported, it took 348 days for new oncology drugs however, if all days for Reply-To-Question submission counted, it went up to 757 days in total from the initial submission to the final listing. More than 3 folds of what's written in regulation. -Similarly, reimbursement coverage expansion review process becomes much longer as well in 2020. 2.Lack of value recognition for innovation (1)Low flexibility with ICER application The government is said to grant reimbursement for new drugs which fall in 1 – 2 times GDP per capita range as the ICER evaluation threshold however the government keeps applying U$ 20,000 – 45,000 based on GDP per capita back in 2010. Korea's GDP per capita was U$23,087 in 2010 but U$31,846 in 2019. ICER threshold should be updated properly along Korea's economic growth. (2)Limited scope with RSA system It is true that the government made improvement with target scope of RSA system in 2020 where a follower drug to initial RSA drug may also be granted RSA eligibility, but overall RSA target therapeutic areas still limited to only life-threatening cancer/rare diseases. The government should open up RSA system for other diseases including chronic diseases. (1)CEA waiver products to be subject of RSA refund Upon newly revised regulation as of '20 Oct 8th, CEA waiver products will be mandated not only for expenditure cap as previous but also for refund. 3.Ongoing scrutiny for cost-containment Cost containment efforts including drug price reduction should go hand in hand with funding efforts for access to innovation, but the government keeps focusing on the former. (1)Evidence-based reevaluation of drug benefits -Part of the task of reinforcing the pharmaceutical benefits scheme through revaluation of insurance benefits -Plan full-fledged implementation of re-evaluation system based on drug clinical efficacy following a pilot program (choline alforscerate) in 2020 -Differentiation and gradual application of evaluation methods by type of listing process are being prepared. Based on the results of the reevaluation, follow-up measures such as adjustment of drug prices, reimbursement standard, and determination of whether to maintain health insurance benefits will be implemented. (2)Finance-based reevaluation of drug benefits -Part of the task of reinforcing the pharmaceutical benefits scheme through revaluation of insurance benefits -Plan to introduce 'regular re-pricing system' in 2021, where drug reimbursement prices are adjusted based on overseas drug prices from IRP basket countries, as another post-listing price control measure. -Methodology and details of re-pricing system are to be drafted during 1H 2021.	**The MPC 2.0 Cost Benefit Analysis** The CBA 2.0 was coordinated by the Malaysian Productivity Corporation (MPC) with the collaboration of several government bodies, economists and private industry groups. A single public consultation document summarizing the preliminary findings of the CBA has been put online for consideration. A public webinar was also organized by the MPC on December 1st 2021 where a reading of the CBA was held followed by a Q&A session. The findings of the CBA can be distilled into the following a. The costs of the MPC are expected to outweigh the benefits resulting in RM206 billion in losses over the next 15 years. b. Decreased medicine accessibility in the long-run especially among the B40 community c. Employees in the private healthcare sector stand to lose up to RM31 billion in wages over the next 15 years. d. MPC may also reduce Malaysia's attractiveness as a priority market for new and innovative drugs e. Potentially poorer public health outcomes due to reduced access to innovative drugs (Source: Comprehensive Cost Benefit Assessment on the Medicine Pricing Policy-Preliminary Findings)	On February 2020, the government imposed draconian price cuts through the MRP. Under Executive Order No. 104, an initial list of 133 drug formulations was covered with a mandatory price reduction of up to 50 percent from prevailing market prices. Another set of 72 drug formulations were covered, with price reduction proposals ranging up to 96 percent, in spite of calls to suspend such measures due to the impact of COVID-19 on the industry. The combined list includes molecules for hypertension, diabetes, cardiovascular disease (CVD), chronic lung diseases, neonatal diseases, major cancers, chronic renal disease, psoriasis and rheumatoid arthritis, among others. [Executive Order No. 104: https://doh.gov.ph/sites/default/files/health_advisory/EO%20No.%20104.pdf and Executive Order No. 155: https://www.officialgazette.gov.ph/downloads/2021/12dec/20211207-EO-155-RRD.pdf] These policies are the start of further price regulations in the future, as the DoH intends to cover 1,154-2,394 preparations or 26-54 percent of the medicines available in the market, which is estimated to reduce industry's annual revenues by approximately PHP 57 billion or almost USD 1.1 billion if fully implemented. To fully institutionalize the MRP policy, the DoH released its guidelines containing the: (1) constitution of a Drug Price Advisory Council, responsible for drug price evaluations and for recommending which drugs will be under price regulation and at what level; (2) the medicine review process, including the basket of countries for external reference pricing, medicine selection algorithm (incorporating public nomination of medicines for MRP), and formula for calculating MWP and MRP; (3) implementation guidelines, including exhaustion of inventory, publication and posting requirements; and (4) monitoring and evaluation (impact assessment). In addition, the DoH also proposed a legislation for the creation of a Drug Price Regulatory Board (DPRB) to oversee the MRP mechanism, with the sole task of regulating medicine prices. The MRP policy has contributed to a contraction in the prescription medicine market by as much as 18.2 percent (Q3 2020 vs. Q3 2019). Three products covered in the first wave of MRP were also withdrawn from the market, as the price cuts were unsustainable to maintain. Insulin Degludec 100 Units/mL, 3mL Pre-filled pen ・Amlodipine + Hydrochlorothiazide + Olmesartan medoxomil 37.5 mg film-coated tablet ・Lenograstim 263 mcg/ mL, 1 mL vial An industry study found the following regarding the MRP policy: ・Spending on medicine remains burdensome for patients because it is mostly sourced out-of-pocket. ・MRP has a negative impact to health & economy, affecting medicine availability & launches, patient support programs, workforce, and investment appetite of companies. ・Majority of doctors did not observe improved access despite improved affordability. ・There are alternative tools that can improve access sustainably. Another policy is being reviewed by the DOH to further control pricing in the private sector. This is through the issuance of suggested retail prices. While "suggested" on paper, policies provide potential investigation and enforcement action should there be deviations from the "suggested" retail prices.	•While pharmaceutical prices remain free from explicit regulatory control, prices in the public sector are controlled indirectly by government bulk-purchasing practices (via ALPS) and policies designed to favor the use of generics or lower-cost products. Price also plays a role in determining which therapies are subsidized by the government. •Since 2016, the Agency for Care Effectiveness (ACE), Singapore's national health technology assessment (HTA) agency, has officially taken on the role of drug evaluation and recommendation in the MoH's subsidy listing decisions. Whilst multinational originators welcome the publishing in February 2018 by ACE of its Drug Evaluation Methods and Process Guide as a first step towards greater transparency, concerns remain regarding the lack of opportunity for dialogue with the agency during the evaluation process. Indeed, price negotiations appear to be the only interaction that companies have with ACE, and some industry observers assert that a novel drug's likely budget impact is the only criteria which ultimately determines recommendation for listing. •Discounting will remain widespread in both the public and private sectors, driven by ALPS purchasing strategies and discounting/bonusing programs offered to private dispensing doctors, respectively. •According to industry estimates, the average mark up on drugs purchased by providers and passed on to patient, lies in the region of 20% to 25%. Providers claim that these margins are necessary to cover dispensing and other operating costs, but they remain controversial and are seen as a further barrier to patient access to medicines. It is likely that over time, margins will be harmonized, at least within the new regional clusters. •There is no formal price control system for pharmaceuticals in Singapore, with price dictated by purchasing practices, market competition and patient affordability. Prices in the public sector are controlled indirectly by the tender system operated by ALPS. In addition, cost-effectiveness assessments carried out by ACE for specific innovative therapies has led to price capping for selected drugs at public institutions.	Because the previous year's drug expenditures are not taken into account when setting the DET target price, they calculate it by establishing the growth rate on the basis of the preceding year's target, and for this reason, there have actually continued to be negative revisions since DET trial calculation was introduced. DET will continue to be used on a trial basis until 2019. Officials are intended to officially implement the DET system in 2020. However, due to the COVID-19 situation, the pilot run will last for one more year to minimize the admin burden and focus the resources and manpower for the COVID-19 challenges, which means DET mechanism is expected to be implemented officially in 2021. The industry is still communicating with the officials on the implementation time and details.	Median Price	The Law on Pharmacy lays the foundations for the negotiation of prices for some drugs procured for use in the public sector. It also calls for an increase in levels of price transparency and stability. New regulations regarding price negotiation mechanism are now issued (Tender Circular 15/2019/TT-BYT). The next step will be ensuring effective, fair and transparent implementation of price negotiations, as well as other price-related measures including price declaration, price referencing.

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	Intellectual property rights challenges	N/A	No patent linkage	India joined WTO (World Trade Organization) and became a signatory of the TRIPS (TradeRelated Aspects of Intellectual rights) agreements in the year of 1995. With this, all the signatories were supposed to align their IP rules in conformation with the TRIPS agreement. However, developing countries like India were granted a window period of 10 years (5- compulsory +5 extended) to comply with the rules put forth by the agreement. Though India had aligned its rule in accordance to TRIPS in the year 2005, still, there are many challenges and issues, that needs to be addressed to maximize the benefits. Thus, getting and granting IP rights in India has become a matter of contention since 2005 and various stakeholders are interested in knowing India address these issues. This article is an attempt to underline those challenges and issues that India is facing in offering IP rights to companies in Indian jurisdiction. Though, there are many challenges we will list only the top 6, that are of utmost importance. 1# From Process to Product Patents- One of the binding point in TRIPS agreement is that all member countries are required to shift their patent regime from “Process Patent” to “Product Patent.” The fundamental difference between a Process Patent regime and a Product Patent regime lies in the fact that the former protects for processes only while the latter products. It becomes a contentious issue when it comes to getting IP rights on pharmaceuticals and food products. Unlike developed countries where Capitalist Economic Model is working India has adopted a mixed development model striking a balance between Capitalism and Socialism. This approach was taken to safeguard the interest of ordinary people those are struggling for their basic needs including food and medicines. Developed countries are accusing countries like India and Brazil being protectionist when it comes to granting patents in pharmaceuticals and food sectors. 2# Section 3(d) of the Indian Patent Act- Another challenge that it is facing is the condemnation of section 3(d) of the Indian Patent Act. This section prevents multinational companies evergreening their patents simply by making minor changes. Implementation of 3(d) was exercised in challenging the patent of Novartis Glevac drug. The Court rules that multinational companies can’t evergreen their patents simply by making minor changes in earlier patents and they need to show considerable “Therapeutic Efciency” to get patent protection in already existing patents. 3# Compulsory licensing- With the provision of compulsory licensing, the Govt of India can compel the owner company or other companies to mass produce some drugs in emergency irrespective of who got the patent. Multinationals are accusing India of being opportunistic in their stand and are asking to abrogate this provision. However, Indian Govt is not willing to cancel this provision to safeguard the interests of mass. 4# Provision of Drug Price Control Order- With this provision companies can’t charge an unfair price for drugs that they are producing. The price has to be justied regarding investments, and if someone plays foul, then the Govt has the right to intervene. 5# Food security and IPR- India is a land of farmers wherein most of the people are engaged in doing farming for their livelihood. In such a country Govt offers many subsidies to farmers. India’s domestic support schemes are generally in the form of “minimum support price” for major agricultural commodities and “input” subsidies provided to farmers in the types of electricity, fertilizers, seeds, etc. However, for complete implementation of TRIPS agreements, these subsidies will have to be reduced or eliminated. Thus, the Indian Government is struggling to create a balance between food security and providing IP rights in India. 6# IPRs, Community property rights, & Indigenous knowledge- Traditional knowledge gives ready-made leads for pharmaceutical companies and then simply come up with the new formulation to show the efficacy of the general traditional understanding. The Indian Govt is bound to protect the rich source of traditional knowledge by not allowing multinationals to get patents on traditional culture. As a defensive mechanism, the Govt has created TKDL (Traditional Knowledge Digital Library) to challenge patenting traditional Indian understanding. Multinationals and developed countries are also opposing this move. https://yourpatentteam.com/top-challenges-issues-intellectual-property-rights-india/	• They have little experience with reviews, and there are disparities in the quality of reviews. • Reviews take time and are slow (throughout ASEAN). • Only the native language is recognized as the language for use in applications, and the burden of translation costs is large. • Movement to invoke compulsory licenses. • Drug inventions that could be subject to patented inventions are limited.	N/A	[KRPIA] • Unlike when prosecuting a patent application, an applicant for a Patent Term Extension (PTE) application who receives a Notice of Final Rejection does not have any further opportunity to amend the PTE application. In addition, if KIPO issues a Preliminary Rejection, and even if KIPO agrees that most of the requested PTE term is allowable, if the PTE applicant fails to completely overcome the Preliminary Rejection, KIPO will issue a Final Rejection as to the entire PTE request. Since there is no way at that point for a PTE applicant to appeal only the specific portions of the PTE request found not allowable, a PTE applicant facing a Preliminary Rejection is usually forced to simply accept KIPO's initial determination of allowable PTE, rather than making an argument to support its PTE calculation and thereby risk the issuance of a Final Rejection. Therefore, there is clearly a need to adjust the PTE application procedure to allow PTE applicants to appeal only the specific portions of the PTE request that are finally rejected, while still being granted the PTE found allowable by KIPO. • Under the patent-regulatory approval linkage system in Korea, if multiple generics seek approval for generic versions of the same original drug, the originator must seek a sales stay against all such generics (generally by first filing a patent infringement action against the generics), or else forfeit the right to seek a sales stay against any of them. However, a problem can easily arise because a given patent may not necessarily cover all drugs that might be considered the "same" under the Korean Pharmaceutical Affairs Act. For example, different crystalline forms or different hydrates of an active ingredient compound are considered to be the "same" active ingredient by the MFDS, but different salts would be considered different active ingredients. However, the relevant listed patent may only cover one specific crystalline form of the active ingredient (and therefore there would be no basis to file an infringement action against a different crystalline form). Since a patentee must sue a generic for infringement in order to request a sales stay, under a situation where there are multiple generics but only some are covered by the listed patent, the current system forces a listed patentee either to forfeit any sales stay against any generic (even infringing generics), or risk antitrust enforcement by filing suit against a clearly non-infringing generic product in order to maintain its right to a sales stay. This unfairness in the current patent linkage system should be addressed.	Compulsory Licensing Challenges Malaysia’s federal legislature has passed the Patent (Amendments) Bill which strengthens the ability for individuals and corporate entities to apply for compulsory licensing in situations where the price of pharmaceuticals are much higher than what the general public can afford. The concern here is that this could weaken the intellectual property rights of the pharmaceutical companies in the long term.	・There is a need for a more effective patent encement in the Philippines. In the past FDA would check the patent status of products, preventing the registration of follow-on products if patent is still valid. However, this was revised when a 2005 DOH Administrative Order (A.O. No. 2005-0001) took effect, effectively allowing applicants of follow-on products to continue with their registration and put the responsibility of monitoring patent validities to applicants and patent holders. This meant that patent holders if follow-on products passed FDA evaluation but the innovator still had patent validity, patent holders must pursue costly and time-consuming legal remedies to protect products from patent infringement. [A.O. No. 2005-0001: https://ww2.fda.gov.ph/attachments/article/15853/ao%201%20s%202005.pdf] A coordinated effort between the Intellectual Property Office of the Philippines (IPOPHL) and the FDA should be in place to prevent the FDA registration of a follow-on product until the expiration of the patent of the innovator product, or a sufficient time for the resolution of a patent infringement dispute. ・In May 2021, a revised joint policy was issued by the DOH, DTI, FDA, and IPOPHL covering the issuance of Special Compulsory Licenses (SCLs). While the policy provides certain protection to patent holders (e.g. the requirement to negotiate first prevention of re-exportation, additional labeling requirements), concerns arise with the immediate granting of SCLs. According to the policy, failure to file an answer will warrant the immediate issuance of the SCL, notwithstanding the non-satisfaction of the requirements. This should not be the case,as the SCL must only be issued upon finding of the existence of a valid ground, in accordance with international rules, only in exceptional circumstances, and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options. https://pharma.doh.gov.ph/2021/08/12/supplemental-guidelines-to-joint-doh-dti-ipo-bfad-administrative-order-no-2008-01-the-implementing-rules-and-regulations-of-republic-act-9502-otherwise-known-as_the-universally-accessible-c/	Singapore was ranked top in Asia and second worldwide in the World Economic Forum’s Global Competitiveness Report 2019 for having the best IP protection. Singapore was also ranked third on the International Property Rights Index 2020, which reflects the strength of the country’s property rights regime in attracting and retaining foreign investment. Separately, the Intellectual Property Office of Singapore (IPOS) was ranked the most innovative office in the world for the first time in 2020 and subsequently third in 2021 under the World Trademark Review (WTR)’s IP Office Innovation Ranking as a reflection of IPOS’ tools and services in supporting a robust regulatory environment in Singapore. https://www.worldtrademarkreview.com/enforcement-and-litigation/singapore-ranked-worlds-most-innovative-ip-office-in-exclusive-research Singapore is also involved in the ASEAN Patent Examination Co-operation program, which reduces the cost and time required to obtain a patent in the ten member countries (Brunei, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Viet Nam). Outstanding issues of concern for originators include data exclusivity periods (currently five years) and the modest nature of patent term extension provisions. The EU-Singapore Free Trade Agreement, signed in October 2018, could deliver improvements in these areas. [IQVIA]	N/A	Patent situation is the same and based on new Drug Act in 2019, the application for registration of a drug formula will require disclosure of the all patent or petty patent application numbers which went through the publication process according to the patent law.	Current legal instruments are expected to provide more effective protection to IPR holders in the industry. However, even with the new regulations, IP infringement in the pharmaceutical sector remains a significant challenge in Vietnam, and IP enforcement activities continue to play an important role. In practice, IP infringement in the pharmaceutical industry often involves patents. Administrative enforcement bodies tend to be reluctant to get entangled with the complexity of patent disputes; as a result, there has been a noticeable movement toward civil action, and a growing number of patent litigation cases are being handled by local courts. At least a half-dozen major pharmaceutical companies from Europe and the United States have filed civil cases against local infringers in Vietnam. Patent litigation cases often encounter prolonged legal proceedings in court due to a number of factors, such as the defendants’ filing of invalidation procedures against the registered patents in question, or constant requests from the court for expert opinions on infringement. Another challenge facing IPR holders in the pharmaceutical sector recently is that the new Law on Pharmacy (effective January 1, 2017) does not provide legal grounds for the withdrawal of Marketing Authorization (MA) licenses. As a result, the Drug Administration of Vietnam often hesitates to withdraw MAs of infringing generics even after there is confirmation of patent infringement from competent authorities such as the Ministry of Science and Technology (MOST) Inspectorate and/or local courts. In addition, among the authorities, there appears to be a general tendency to advocate for narrowing the scope of pharmaceutical patent protection in Vietnam rather than expanding it, which could pose challenges for global innovator companies if and when the patent prosecution guidelines are revised. [Vietnam Pharma Update 2017, Tilleke & Gibbins]

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	Challenges on government policy for pharmaceutical industry promotion, etc.	N/A	Most of the domestic makers are producers of generics. In particular, drugs imported from the EU and the US make up a large share of the market. 23 local licensed manufacturers.	The Indian government has taken many steps to accelerate the pharmaceutical sector in India. The approval time for new facility reduced and NOC for export licenses will be issued within two weeks. Signing of MoUs with USFDA, Health Canada, WHO and other bodies in the world is going to benefit the Indian pharmaceutical sector. For the technology up gradation, zero duty applicable to the pharmaceutical sector through the Export Promotion Capital Goods (EPCG) Scheme. The government is planning further relaxation in FDI norms in the Pharmaceutical sector. Customs duties and excise duty exempted for the HIV/AIDS drugs and diagnostic kits supplied under the National AIDS Control Program funded by the Global Fund to fight AIDS, TB and Malaria (GFATM). The Department of pharmaceuticals of Indian government aims at making India as a major hub for end-to-end discovery under Pharma Vision 2020 Key Challenges: The contribution from the government in the areas of health care is not satisfactory, which is only 1.28 percent of the GDP and healthcare infrastructure development not up to the expectation in India. The pharmaceutical companies expect the government to improve the systems in the public health care administration, so as to reach the medicines to the needy people, which will improve overall health care of the country India needs mere structured and matured regulations on clinical trial policies. More expectations are from pharmaceutical companies, as a compensation, for the person injured during clinical trials. Presently, the regulations in clinical trials are uncertain, which may hinder the clinical research environment in India and have an impact on the availability of new treatments and vaccines to Indian patients. Other challenges arising from recent government decisions The government is trying to cut healthcare costs by forcing doctors to prescribe cheaper unbranded generic medicines and extending the range of drugs that are subject to price controls. It is also discouraging high-margin combination drugs and phasing out loan licensing (a form of contract manufacturing that increases pharmaceutical industry capacity) for safety reasons. The government also proposes to raise import duties on active pharmaceutical ingredients, the key elements of drugs, to boost the domestic industry and reduce India's over-dependence on imports from China for bulk drugs and APIs. This will likely increase manufacturers' costs for finished products. India Pharma's export prospects have been dampened by a strong rupee and a series of nontariff trade barriers in importing countries that either raise the costs of compliance, or -- in extreme cases -- lead to a denial of market access International Journal of scientific research and management (IJSRM) ||Volume||4||Issue||06||Pages||4287-4302||2016| [https://asia.nikkei.com/Business/Business-Insight/India-s-pharmaceutical-prescription-is-unhealthy2] [MP India Q3 2020]	1.Local Content Requirement (TKDN) 2.Halal Law Please refer explanation to challenges in pharmaceutical industry	N/A	[KPBMA] Out of the R&D budget of 15.7218 trillion KRW by government ministries (MSIT, MoHW, and MOTIE) in 2022, the R&D budget in the bio sector was only 1.7896 trillion KRW, accounting for 11.4%. The industry suggested to the government that a strong control tower should be installed for efficient and continuous execution of the budget distributed by ministries.	No new challenges	The UHC Act requires all manufacturers to document, maintain records, and make publicly available information on covered financial relationships with healthcare professionals and providers in accordance with existing laws, including the Data Privacy Act. The law also requires manufacturers to report the same to the DOH. In 2021 the DOH and FDA released the implementing guidelines for the abovementioned requirement. In the policy, the DOH and FDA requires companies to report financial disclosures quarterly to the FDA. https://dmas.doh.gov.ph:8083/Rest/GetFile?id=689659	From January 2019, SAPI members will no longer be able to engage in direct sponsorship following an amendment to SAPI's Code of Conduct. This development means that the industry's code is aligned with the code of the Singapore Medical Council, revised in 2016. The revision removes the ability of pharmaceutical company to form a direct relationship with an individual physician in the context of medical education. Instead, companies will be able to sponsor hospitals or other healthcare providers, who can in turn select the doctors that can benefit from such sponsorship. In the private sector, third party agencies may be approached to do such independent selection. With the increasing importance of ACE evaluations in determining the cost-effectiveness of novel therapies, companies have begun to expand their market access personnel. Some are also recruiting more health-economists in order to conduct internal HTAs, despite the fact that they are not required to provide ACE with such evaluations.	In particular, at large hospitals, which have a major impact on drug expenses, there is fierce price competition for many kinds of drugs, and there is a need to promote "separation of dispensing from medical practice" as well as "measures to reduce drug price differentials" as means of eliminating this. There is also a need for revision of the OTC monograph (examination standards for designated drugs), including the relaxation of restrictions on ingredients and amounts thereof so that import and sale of drugs that are already on the market in the EU, US, and Japan will be possible, as well as a need to expand the list of Switch OTC ingredients with reference to Switch OTC products that have a track record of sales in Japan.	New Ministry of Public Health notification: Ethics on Drug Procurement and Promotion in May 2021.	.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. Conscious of the huge challenges the country is currently facing, the Vietnamese government has set up a comprehensive roadmap to 2020 (which is being reviewed with new vision to 2035) to improve all major aspects of the country healthcare system. Several master plans have thus been issued since 2012 addressing key areas such as public health insurance, hospital services or access to drugs. Yet growth in these segments is subject to the evolution of regulations related to pharmaceuticals. The modernization of the Vietnamese healthcare system will require better and faster access to drugs and will need to go hand in hand with a simplification of the current regulatory environment and bidding processes.

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	Challenges of pharmaceutical industry	N/A	N/A	Challenges faced while operating in global market Slowdown of US generic market US generic drugs market expanded at a compounded annual growth rate (CAGR) of 15% in 2010-15, but is expected to slow down to 5% CAGR in 2016-20 due to the lower value of patented drugs expiring during this period. Annual price erosion in generic drugs in the US is likely to increase to 10-12% from 7-8% currently. Chinese firms moving from APIs to formulation export Historically, the Chinese cornered the API (active pharmaceutical ingredients) market, but they are getting stronger in formulations. India has had language and other skills advantage in terms of ANDA filings and regulatory process, but China is gradually importing talent and they are very good at squeezing cost Compliance issues and good manufacturing practices More scrutiny of manufacturing facilities by USFDA due to Generic Drug User Fee Act US FDA in year 2009, found severe lapses at the manufacturing units of erstwhile Ranbaxy (now merged with Sun Pharma). With India accounting for 40% of US generic drug filings, FDA decided to ensure the drugs from India are of top quality. Inspections rose from 108 in 2009 to 290 in 2015. India has the highest number of US FDA-approved plants outside the US, with the total at 572 currently, compared with 433 in 2013. The rise in inspections is also due to the 2012 Generic Drug User Fee Act (GDUFA) in the US, which sought to speed up generic approvals and eliminate disparity in inspections of US and foreign manufacturing facilities. Minimal presence in regulated Biosimilar market In branded formulation space now, biologics constitutes nearly 50% of drugs by value. Biologics/Biosimilar have huge potential in emerging markets and a lot of Indian companies are looking at it; but as far as regulated markets are concerned. https://www.livemint.com/Industry/FsuFVKI1dNC30O4TyWeOGO/Fading-glory-Indian-pharma-industry-in-uncharted-terrain.html Challenges in domestic market I. High 'Out of Pocket (OoP)' expenditure limiting access to medicines: While India is making reasonably rapid strides in its economic growth, the country is increasingly facing constraints in providing healthcare benefits to a vast majority of its population with ballooning 'Out of Pocket (OoP)' expenditure of over 70% and 72 percent of which is the cost of medicines (Source: HLEG Report). This is mainly because of the following key reasons: • Low public spending on healthcare at around just 1.1 percent of the GDP • Fragile healthcare infrastructure • Very low penetration of health insurance system for all strata of society • Poor healthcare delivery system • Absence of 'Universal Health Coverage' Government Share in Total Healthcare Spend is One of the Lowest in the World Country Brazil China Mexico South Africa Pakistan Bangladesh Sri Lanka India % of Healthcare Spend 41.9 56.7 50.5 42.8 33 34 45 27.5 (Source: data compiled) Changing disease pattern increases healthcare expenditure, further limiting access As the disease pattern is undergoing a shift from acute to non-infectious chronic illnesses, requiring longer duration of treatment, OoP expenditure on healthcare will increase even more, bringing greater misery to the population in general and creating even greater access barrier, if no action is taken immediately. It is worth acknowledging that one finds some good initiatives though, especially for the population Below the Poverty Line (BPL) and hears about the success of 'Rashtriya Swasthya Bima Yojna (RSBY)' and other health insurance schemes through rural micro health insurance units. It has been reported that currently around 40 such schemes are active in the country, which is far from enough. II. Public and government pressure to make drug prices more affordable: Pharmaceutical companies in India have been constrained to live with continuing focus of the government and also of the civil society on 'reasonably affordable medicines' irrespective of the fact whether they are generic or patented. The Department of Pharmaceuticals has reportedly started comparing Indian drug prices with their international equivalents in terms of the 'purchasing power parity' and 'per capita income' and not just their prevailing prices in various developed markets converted into rupees. With such comparisons the government has already started voicing that prices of medicines in India are not the cheapest but on the contrary one of the costliest in the world Thus, one of the critical challenges of the Indian Pharmaceutical Industry continues to be delivering affordable medicines for a large section of the population of the country, as expected by the government. Reported high profitability, at least, of the listed pharmaceuticals companies gives an impression to the stakeholders, including the government, that there is a scope for further reduction of pharmaceutical prices in India. Pharmaceuticals being covered under the 'Essential Commodities Act', empower the government to announce the 'administered price' for essential medicines. Current debate and deliberations on the New Drug Policy both by the Supreme Court and the Group of Ministers is a case in point. Be that as it may, the proposed pricing methodology and the span of price control in the long overdue New Drug Policy have just been announced by the Group of Ministers (GoM) on September 27, 2012, which is in line with what I had recommended in my article of May 21, 2012 in this blog. In my view, the new proposal of the GoM is expected to improve both the availability and affordability of the essential medicines, significantly. III. Inadequate penetration of current health insurance schemes: Health insurance coverage is still very low in India as compared to, among many other countries, Brazil and South Africa and at-par with our neighboring island state Sri Lanka. The details are as follows: Country Brazil South Africa Sri Lanka India % of Healthcare Spend 21 39 10 10 (Source: data compiled) Moreover, currently health insurance schemes only cover expenses towards hospitalization. Ideally, medical insurance schemes in India should also cover domiciliary or in-patient treatment costs and perhaps loss of income too, if India wants to bring down the OoP expenditure for its population or at least till such time the ambitious 'Universal Health Coverage' project gets translated into reality. IV. Pricing of Patented Drugs: Innovative pharmaceutical products patented in India are expected to facilitate access to latest modern medicines to the country's population to meet their unmet needs, if available at a reasonably affordable price. To respond to this important need of the patients, many innovator companies like, Merck, GlaxoSmithKline (GSK) have already announced a differential pricing mechanism for their patented medicines in India. Recent grant of compulsory license of Bayer's Nexavar to Natco, among other reasons on Thus, one of the critical challenges of the Indian Pharmaceutical Industry continues to be delivering affordable medicines for a large section of the population of the country, as expected by the government. Reported high profitability, at least, of the listed	1.Halal Law : Bill on Halal Product Assurance (called UU Jaminan Produk Halal No. 33/2014) contains mandatory of halal certificates & labels for pharma products. Action taken : To exclude pharma products from halal requirements. Status: Pharma products (ethical) have to be certified in 2034 at the latest (Religious Affairs Minister's decree No 26/2019) 2.Local Content Requirement as stipulated in the presidential regulation on government procurement No.16/2018 (prioritization on local pharmaceutical & medical device products in the e-procurement system) – the Minister of Industry's decree is yet to be issued 3.Drug procurement in JKN (National Health Security) : Sustainable healthcare financing; late payment from the hospital to the pharma industry; guarantee & quality of drug services; focus on price. Adoption of MCDA (Multi Criteria Decision Analysis) as a tool / solution for multi-criteria (no more focus solely on price), multi-winner and multi-year policy implementation 4.Patent Law (Article 20, Bill No.13/2016 stipulating the requirement of domestic processing for patented products). Current status : Ministerial regulations (MoLHR) No.15/2018 about patent implementation stipulating 5 (five) years postponement and can be extended under certain reasons	N/A	[KPBMA] In 2021 too, the Korean pharma industry, which has a high proportion of imports of raw materials and a large number of generic drug items, could not be free from impurity issues such as NDMA, AZBT, etc. Concerns about impact on human body were very low for AZBT found in sartans and impurities found in varenicline, but concerns over the constant issue of impurities did not disappear. Regulatory authorities and industries are discussing ways to improve the quality of raw materials used in Korea in various ways such as increasing the self-sufficiency rate of domestic raw materials.	1. Malaysia has extended compulsory licensing for Sofosbuvir after the government-use license expired in 2020. (Source: CodeBlue) 2. The passing of the Patents Amendment Bill 2021	Slow regulatory processes remain a major hurdle in providing access to innovative medicines. Current committed turnaround time for Certificate of Product Registration (CPR) is 254 calendar days. In practice, turnaround time ranges from two to four years. While another government agency, the Anti-Red Tape Act has been monitoring FDA performance, the industry is yet to see improvements in the process.	• Although demographic trends will continue to drive demand for pharmaceutical products, patient affordability issues and government efforts to curb drug spending will act as constraints on market value growth. Innovative therapies face lengthy delays to formulary listings as well as to inclusion on the SDL/MAF and, despite improved benefit coverage under MediShield Life, most drugs are predominantly financed out-of-pocket. • Pharmaceutical companies will continue to benefit from the country's efficient healthcare infrastructure, ambitious healthcare policies, as well as world-class biomedical sciences and research facilities. Strong government support, low corporation tax and low unit labor costs will also continue to entice multinationals to invest in manufacturing and R&D activities. • The Singaporean generics market is largely a branded market, which is dominated by Indian manufacturers. Pro-generic policies will drive the use of generics, but low prices will limit value growth, particularly in the public sector, where generics have to compete on price to win ALPS tenders. • Industry spending on R&D will continue to rise, supported by government incentives that aim to see the country rival leading international research hubs. Under the Research, Innovation and Enterprise 2020 (RIE2020) plan, the government plans to invest S$4 billion over five years (2016-2020) to support research into the health and biomedical sciences.	There are 9 associations in existence, but a good cooperative relationship has not been established because of the underlying competition of interests between the original makers in Japan, EU, and US and the local generic makers, and a consolidation of opinions for the industry as a whole has not been achieved.	•Cost Containment •Median Price •Regulatory changes from COVID-19	1.Legal Entity: the pharmaceutical industry is going through a major change, companies are reconsidering their business models in Vietnam following new regulations (i.e. opportunity to establish FIEs), in order to ensure viable and sustainable model for business operations. 2.Speed of access for new drugs: currently slow compared to neighboring countries, but the industry is positive that new regulations regarding registration will speed up the access time. 3.Government procurement: there is a need for a sustainable environment that encourages investment and sector development while addressing short-term State budget concerns. IPR protection

				pharmaceuticals companies gives an impression to the stakeholders, including the government, that there is a scope for further reduction of pharmaceutical prices in India. Pharmaceuticals being covered under the 'Essential Commodities Act', empower the government to announce the 'administered price' for essential medicines. Current debate and deliberations on the New Drug Policy both by the Supreme Court and the Group of Ministers is a case in point. Be that as it may, the proposed pricing methodology and the span of price control in the long overdue New Drug Policy have just been announced by the Group of Ministers (GoM) on September 27, 2012, which is in line with what I had recommended in my article of May 21, 2012 in this blog. In my view, the new proposal of the GoM is expected to improve both the availability and affordability of the essential medicines, significantly. III. 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The details are as follows: Country Brazil South Africa Sri Lanka India % of Healthcare Spend 21 39 10 10 (Source: data compiled) Moreover, currently health insurance schemes only cover expenses towards hospitalization. Ideally, medical insurance schemes in India should also cover domiciliary or in-patient treatment costs and perhaps loss of income too, if India wants to bring down the OoP expenditure for its population or at least till such time the ambitious 'Universal Health Coverage' project gets translated into reality. IV. Pricing of Patented Drugs: Innovative pharmaceutical products patented in India are expected to facilitate access to latest modern medicines to the country's population to meet their unmet needs, if available at a reasonably affordable price. To respond to this important need of the patients, many innovator companies like, Merck, GlaxoSmithKline (GSK) have already announced a differential pricing mechanism for their patented medicines in India. Recent grant of compulsory license of Bayer's Nexavar to Natco, among other reasons on hospitals. In India the demand for these services has outstripped supply. There is a huge short fall in 'Healthcare Manpower' of the country as demonstrated in the following table: Target Actual Shortfall % Doctors 1:1000 Doctor-Population Ratio: 0.77:1000, Over 1 Mn Doctors [2018] 76 Specialists 58,352 6,935 88 Nurses 1,38,623 20,48,979 [2017] 53 Radiographers 14,588 2,221 85 Lab Technicians 80,308 16,208 80 Source: Rural Health Statistics 2011 in 12th Plan draft chapter Besides above, other key challenge faced by the pharmaceutical industry in this area is dearth of industry-specific employable work force in important areas like, R&D, clinical research, pre-clinical and clinical studies, manufacturing, quality assurance, besides sales and marketing. VIII. Requirement of Stringent Regulatory Practices: In the increasingly globalized economy, strict conformance to high regulatory standards like, Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) pose another major challenge for the pharmaceutical industry in India. Those pharmaceutical companies who are involved in manufacturing and export of drugs and pharmaceuticals are required to meet standards set up not only by the Drug Controller General of India (DCGI) and/or the State Drug controllers, but also of the regulatory authorities of the respective countries, where their products will be exported. IX. Ethics and Compliance: Concerns spanning from clinical trials to ethical marketing practices, are hugely bothering a large section of the stakeholders are assuming greater proportion, as the pharmaceutical industry is increasingly facing stringent regulatory and media scrutiny in gradually expanding areas of business operations. Thus, to overcome this challenge, there is a dire need for the industry to move beyond its usual bottom-line centric model to a transparent, comprehensive and implementable 'Ethics and Compliance Models', which are well meshed with all other business processes. http://www.tapanray.in/nine-major-challenges-constraining-indian-pharmaceutical-industry-from-taking-a-quantum-leap/					• Market value will also be boosted by new product launches and greater patient access to innovative therapies – notably oncology medicines – in the public sector, though patient affordability issues and generic prescribing will act as constraints on overall growth rates.			

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	Foreign Investment Restriction/trade barrier	N/A	N/A	Tariffs, Taxes & Duties Tariff barriers moreover constitute a significant trade barrier. Tariffs in India vary from sector to sector and between product groups. Tariff rates have been reduced over the past years, but are still quite high compared to other countries. Additional duty is generally applied to the import tariff, which means the total import duty often adds up to 30 pct. or more. Corporate tax for foreign companies is approx. 30 pct. Import duties, which were previously prohibitively high at levels of 180% or more, have been rationalised to conform to international levels, albeit in the high end. Duties have been used as means for anti-dumping at several occasions in previous years. Technical Barriers to Trade The liberalization of the Indian economy since the 1990s has had a very palpable impact on India's trade policy vis-à-vis foreign trade. Import regulations have been progressively eased - both in terms of quantitative restrictions and import duties and almost all items are now allowed to be imported into India. However, some import restrictions still remain for certain goods. There are import prohibitions and restrictions on some goods for sanitary reasons and for other goods testing and certification is required. Bureau for Indian Standards (BIS) demands that certain products fulfil the Indian BIS-quality standards which have gradually come closer to ISO-standards. In particular import of foodstuff is subject to Intellectual Property (IP) is administered by a few central ministries who formulate the business rules which differs from sector to sector. A number of other ministries and departments are also involved in regard to enforcement or commercialization of IP Trade Barriers Any restriction imposed on the free flow of trade is a trade barrier. Trade barriers can either be tariff barriers (the levy of ordinary negotiated customs duties in accordance with Article II of the GATT) or non-tariff barriers, which are any trade barriers other than tariff barriers. Import Licensing: One of the most common non-tariff barriers is the prohibition or restrictions on imports maintained through import licensing requirements. Though India has eliminated its import licensing requirements for most consumer goods, certain products face licensing related trade barriers. For example, the Indian government requires a special import license for motorcycles and vehicles that is very restrictive. Import licenses for motorcycles are provided to only foreign nationals permanently residing in India, working in India for foreign firms that hold greater than 30 percent equity or to foreign nations working at embassies and foreign missions. Some domestic importers are allowed to import vehicles without a license provided the imports are counterbalanced by exports attributable to the same importer. Standards, testing, labeling & certification: The Indian government has identified 109 commodities that must be certified by its National Standards body, the Bureau of Indian Standards (BIS). The idea behind these certifications is to ensure the quality of goods seeking access into the market, but many countries use them as protectionist measures. For more on how this relates to labeling requirements, please see the section on Labeling and Marking Requirements in this chapter. Anti-dumping and countervailing measures: Anti-dumping and countervailing measures are permitted by the WTO Agreements in specified situations to protect the domestic industry from serious injury arising from dumped or subsidized imports. India imposes these from time-to-time to protect domestic manufacturers from dumping. India's implementation of its antidumping policy has, in some cases, raised concerns regarding transparency and due process. In recent years, India seems to have aggressively increased its application of the antidumping law. In the first half of the calendar year 2006 India topped the list of countries initiating new anti-dumping investigations with 20 new initiations. Export subsidies and domestic support: Several export subsidies and other domestic support is provided to several industries to make them competitive internationally. Export earnings are exempt from taxes and exporters are not subject to local manufacturing tax. While export subsidies tend to displace exports from other countries into third country markets, the domestic support acts as a direct barrier against access to the domestic market. Procurement: The Indian government allows a price preference for local suppliers in government contracts and generally discriminates against foreign suppliers. In international purchases and International Competitive Bids (ICB's) domestic companies gets a price preference in government contract and purchases. Service barriers: Services in which there are restrictions include: insurance, banking, securities, motion pictures, accounting, construction, architecture and engineering, retailing, legal services, express delivery services and telecommunication. Other barriers: Equity restrictions and other trade-related investment measures are in place to give an unfair advantage to domestic companies. The GOI continues to limit or prohibit FDI in sensitive sectors such as retail trade and agriculture. Additionally, there is an unpublished policy that favors counter trade. Several Indian companies, both government-owned and private, conduct a small amount of counter trade. https://www.globaltrade.net/f/business/text/India/Trade-Policy-Trade-Barriers-in-India.html	• Preferential tax treatment under the law exists as a business incentive for making inroads into Indonesia, but this incentive is not actually functioning, because the taxation authorities sometimes will not permit preferential treatment. ["Report on the survey and analysis of medical needs overseas and the status of Japanese companies' entry into foreign markets": http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000074947_3.pdf] • New entrants to the Indonesian market must select a partner, because investment is restricted to 85% by the negative list. • Moreover, foreign businesses must have their manufacturing facilities inside Indonesia.	N/A	Challenges for pharma-related companies • Shortening time to market investment Establish a clinical development schedule wherein new drug licenses could be obtained at the same time as in the country where the drug was first developed. Acquire skills for obtaining drug price approval in the shortest possible time. • Dealing with drug prices Frequency of drug price calculation rule revision is high. Insurance drug price for new drug approval is low compared to other foreign countries. There are various systems for drug price adjustment, and major drops in drug prices. Challenges for companies associated with medical devices • Regulatory review The regulatory review period is long. The regulatory review criteria are unclear. • Insurance system Since product prices are determined by the insurance system, the products cannot be provided at appropriate prices. Fall in insurance prices. Limitations on the scope of insurance coverage. • Competition with local companies and Chinese companies Under the South Korean government's FTA, products are imported at low Customs duties or zero Customs duties from China and other signatories, and price competition is fierce. Once new entrants have formed a market for their products, the local companies start providing similar products at somewhat lower prices, which makes for tough competition. (See World Business Associates Co., Ltd.: "Report on the survey and analysis of medical needs overseas and the status of Japanese companies' entry into foreign markets (2015)	No new challenges	N/A	The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) came into force on 30 December 2018 and serves to eliminate tariffs for 94% of Singapore's exports to CPTPP markets. On 1 Oct 2019, Singapore signed several components of a free trade agreement (FTA) with the Russia-led Eurasian Economic Union (EAEU), paving the way for greater business links between Singapore and EAEU markets. The Framework Agreement, Non-Services and Investment Agreement, as well as the Armenia-Singapore Services and Investment Agreement, all form part of the EAEU-Singapore FTA. The agreements are significant in promoting trade liberalization and economic cooperation against the tide of protectionism. Under the trade deal, EAEU member states will reduce tariffs on 90 per cent of goods exported by Singapore to their markets, and over a 10 year period, this will increase to 97 per cent. The FTA will also increase certainty for businesses and facilitate operations by protecting investments and intellectual property, and promoting e-commerce. The United Kingdom-Singapore Free Trade Agreement (UKSFTA) came into force on 11 February 2021 and provides Singapore and UK companies with certainty and clarity in trading arrangements between both countries. Under the UKSFTA, Singapore and UK companies enjoy the same benefits that they have been receiving under the European Union-Singapore Free Trade Agreement (EUSFTA). At COP26 in November 2021, Singapore agreed to the final text of the Glasgow Climate Pact and also signed up to several partnership coalitions: The Powering Past Coal Alliance, the Global Coal to Clean Power Transition Statement, the Global Methane Pledge, the Greening Government Initiative (GGI) and the Agriculture Innovation Mission for Climate (AIM4C). The country also agreed to join the Glasgow Leaders' Declaration on Forests and Land Use. On 29 Dec 2021, Singapore and China signed 14 agreements at the annual 17th Joint Council for Bilateral Cooperation (JCBC) meeting, ranging from strengthening cooperation in finance, exchange of trade and customs information, competition law, urban governance and planning, nature conservation to maritime safety. The 2021 JCBC meeting also introduced public health as a new pillar of partnership. The Regional Comprehensive Economic Partnership (RCEP) entered into force on 1 Jan 2022 and is a free trade agreement among the Asia-Pacific nations of Australia, Brunei, Cambodia, China, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, New Zealand, the Philippines, Singapore, Thailand, and Vietnam. The RCEP is expected to eliminate about 90% of the tariffs on imports between its signatories within 20 years of coming into force, and establish common rules for e-commerce, trade, and intellectual property.	The following have been cited as challenges. 1. Re proper use of medical financial resources (eliminating the large price differentials) This means "promoting separation of dispensing from practice" and "measures to reduce price differentials", but in order for promotion of the separation of dispensing from practice to lead to elimination of price differentials, it will be necessary to promote this chiefly at large hospitals, which have a major impact on drug expenditures. 2. Re promoting the introduction of new drugs The criteria for Category 1 (epoch-making new drugs) are strict, and the criteria for price calculation are also low, in addition to which prices are markedly decreased by the existing PVS or DET. This situation must not delay accessibility for patients or become a factor inhibiting the introduction of new drugs. Efforts need to be made to obtain speedy price approval so that expenditure on new drugs can be properly recovered. 3. Re revision of OTC monographs Since there are many regulations on ingredients and quantity, drugs that have already been marketed in Japan, EU, or US cannot be imported and sold. Another issue is the continuing growth in the number of Switch OTC ingredients in Taiwan with reference to Switch OTC products that have been sold in Japan.	-	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.

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	Counterfeit medicines, etc.	N/A	N/A	Approximately 10.5% of medicines in low and middle income countries including India are sub-standard and falsified, a report released by World Health Organization (WHO) on Tuesday showed. While counterfeiting is a global issue, it is much more prevalent in low and middle income countries with an estimated 10 to 30 per cent of medicines in these countries being counterfeit, compared to just one per cent of medicines in high-income countries https://blogs.deloitte.co.uk/health/2018/04/tackling-counterfeit-medicines-in-india.html https://www.livemint.com/Industry/6i5W6D4n07yGwmZDV2JalN/India-among-countries-where-10-of-drugs-are-substandard-WH.html	BPOM develops counterfeit and substandard drug reporting applications-based through smartphone devices due to the increasingly widespread circulation of counterfeit drugs Thorugh this application, healthcare practitioners in hospital and health center can report directly if they find any suspicious of counterfeit drugs practice Based on the report by MIAP (Indonesian Anti-Counterfeiting Society), counterfeit drugs problem continues to increase due to increased recommendation for license revocation by BPOM, as first quarter 2018 BPOM has issued 230 recommendations for revocation of licenses.	N/A	The pharmaceutical serial number system is a mechanism where a serial number is assigned to allow tracking of drugs throughout the manufacture, import, distribution and use stages. This prevents counterfeit or illegal drugs from entering the market and allows those with issues to be recalled before reaching patients, leading to improved drug safety. With clearer distribution paths that can block potential prescription drug kickbacks, pharmaceutical distribution has become more transparent. (Source: “This is how, ‘Pharmaceutical Serial Number system will be implemented,” Pharmaceutical Management General Information Center, November 2015)	No new challenges	According to a report from the United Nations Office on Drugs and Crime report, the Philippines leads in the number reported cases of pharmaceutical crime in Southeast Asia. The report said that the Philippines accounted for 193 of the 673 incidents reported from 2013 to 2017. The current pandemic has highlighted the issue of counterfeiting, and the proliferation of unauthorized online sellers of prescription medicines and vaccines, which may also be counterfeit. Counterfeit medicines were reported at the height of the lockdown, with some claiming to be used for the treatment of COVID-19. Unregistered COVID-19 vaccines were also reported to be smuggled in the country.	N/A	N/A	No significant issue	Despite recent improvements to the IP environment, illegal copying remains commonplace, partly due to the lax enforcement of legislation. Part of the problem is the fact that the government has little scope to tackle the problem, given that the majority of drug sales in Vietnam are achieved not through regulated pharmacies but through private dealers. In addition, the country has long, poorly monitored borders with countries such as Laos, China and Cambodia, where the counterfeit drug trade is active. Furthermore, many IP-infringing pharmaceuticals are imported via fast-tracked special import quotas. There is rarely any public information available on the application or decision to grant the SIQ. As a result, the rights holder cannot take action until the market has already been flooded by the infringing product, thus adding to the damages to the rights holder. Further transparency is needed. Recent patent infringement cases in Vietnam’s pharmaceutical sector have revealed the ambiguity of competent authorities’ roles in determining whether a patent has been infringed. Such vagueness has caused unexpected delays in legal proceedings.
	Other Market access challenges	N/A	N/A	Population: India has the world's second-largest population & existing healthcare infrastructure is just not enough to meet the needs of the population. The central and state governments do offer universal healthcare services and free treatment and essential drugs at government hospitals. However, the hospitals are, as we said, understaffed and under-financed, forcing patients to visit private medical practitioners and hospitals Insurance: India has one of the lowest per capita healthcare expenditures in the world. The high out-of-pocket expenses in India stem from the fact that 63 percent of Indians do not have health insurance [2019]. Rural-urban disparity: Speciality & super speciality healthcare in India is concentrate in Urban Areas anf rural patients often have to travel long distance to avail these healthcare services [https://www.firstpost.com/india/indias-healthcare-sector-a-look-at-the-challenges-and-opportunities-faced-by-81-3-billion-industry-3544745.html] [MP India Q3 2020]	Single winner policy that affects sustainability of pharma industry in Indonesia; BPJS is constantly plagued with deficit (estimated > 2 billion USD) created late payment from hospital to pharma companies	N/A	none	No new challenges	• The Philippines imposes a mandatory discount scheme, wherein the pharmaceutical industries pay for the discount of certain population groups such as Senior Citizens, Persons with Disability, National Athletes, and proposals to include Solo Parents. The unclear formula and inequitable sharing has led to the higher burden of cost being carried by the manufacturers with no contribution from the government, adversely impacting the pharmaceutical industry.	•Multinational pharmaceutical companies will continue to strengthen their internal market access teams, given ACE’s remit to evaluate the cost-effectiveness of treatments. While this is more feasible for larger companies, it will prove challenging for smaller players with more limited resources. •Drugmakers in Singapore will continue to develop their internal HTA teams and dedicated market access teams in order to strengthen their engagement with ACE. Greater regulation of sales and marketing activities, notably the 2019 amendment to SAPI’s Code Conduct, will necessitate a more strategic approach in the key promotion of brands. [IQVIA]	N/A	-	N/A

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HKAPI	**The Hong Kong Association of the Pharmaceutical Industry** Sabrina Chan Karen Yuen
IPMG	**International Pharmaceutical Manufacturers Group** Parulian Simanjuntak Khairilisani Destita
IRPMA	**International Research-Based Pharmaceutical Manufacturers Association** Heather Lin Linda Wu Cindy Chou Stally Lee
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** Chorong Kim
OPPI	**Organisation of Pharmaceutical Producers of India** Nitika Garg Kedar Suvarnapatki,
PhAMA	**Pharmaceutical Association of Malaysia** Alice Chee Long Siew Mei Stephanie Ong
PHAP	**Pharmaceutical and Healthcare Association of the Philippines** Teodoro Padilla Richard Simon Binos Paul Marvin quizon Rose Anne Evangelista
PhIRDA	**China Pharmaceutical Innovation and Research Development Association** Lu Xiaoti Ruan Xinxin Yang Yuanlin
PReMA	**Pharmaceutical Research & Manufacturers Association** Pitchapon Noonbhakdi
RDPAC	**China Association of Enterprise with Foreign Investment R&D-based Pharmaceutical Association Committee** Wu Tong Sara Wang Zhu Bo
SAPI	**Singapore Association of Pharmaceutical Industries** Christina Teo Kum Cheun Wong Regulatory Affairs Committee & Public Policy Committee
PG	**Pharma Group (Vietnam)** Thuy Nguyen Thach Do Xuan Thuy Nguyen Hieu Ho
RA-EWG	**Regulations and Approvals Expert Working Group**

With many thanks from PMRE Task Force:

PMRE Publication Team

Hirokazu Matsukami (TF Lead)
Regulatory Affairs: Jun Hirao, Kazuhiro Kaneko
Market Environment: Megumi Yoneyama, Osamu Kagawa
Secretariat: Kazuharu Matsuoka, Erina Yamada

PMRE Review Team

China : Volunteers of the China team / Korea : Kim, Iwamoto
Taiwan : Koyama, Ikegami
Thailand : Okamoto, Yoneyama / Indonesia : Kanno, Nakamura
Malaysia : Kihara / Vietnam: Higashiyama, Hosokawa, Matsuda
Philippines : Fujii, Chiba / India : Kuwahara
Singapore : Katsukawa, Rikukawa / Hong Kong : Kagawa, Kaneko