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Identification and Clarification of the Differences in Regulatory Environment between Asian Economies

APAC PMRE Task Force

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Abbreviation

Abbreviation	Description
ACRA	Accounting and Corporate Regulatory Authority (Singapore)
ACTD	ASEAN Common Technical Document
ADME	Absorption, Distribution, Metabolism and Excretion
ADR	Adverse Drug Reaction
AE	Adverse Event
AF	Application Form
ALD	Audit & Licensing Division (Singapore / HSA)
API	Active Pharmaceutical Ingredient
ASEAN	Association of South-East Asian Nations
ASTT	Administration of Science, Technology and Training
ATMPs	Advanced Therapy Medicinal Products
AVG	ASEAN Variation Guideline
BA	Bioavailability
BE	Bioequivalence
BLA	Biologics License Application
BP	British Pharmacopoeia
BPOM	Badan Pengawas Obat dan Makanan (Indonesian national agency of drug and food control)
BSE	Bridging study evaluation (Taiwan)
CDE	Center for Drug Evaluation
CDFS	Council on Drug and Food Sanitation (Japan)
CDL	Central Drugs Laboratory (Kasauli)
CDRR	Center for Drug Regulation and Research (Philippines)
CDSCO	Central Drugs Standard Control Organization (India)
CEP	Certification of suitability to the monographs of the European Pharmacopoeia
CFDA	China Food and Drug Administration
CFDI	Center for Food and Drug Inspection
CHPTA	Center for Health Policy and Technology Assessment (Taiwan)
CIOMS	Council for International Organizations of Medical Sciences
CIRB	Centralised Institutional Review Board (Taiwan, Singapore)
CLA	Central Licensing Authority (India)
CMC	Chemistry, Manufacturing and Control
CMO	Contract Manufacturing Organization
CNIPA	China National Intellectual Property Administration
COVID-19	Coronavirus Disease 2019
CPO	Contract Pharmaceutical Organization
CPP	Certificate of Pharmaceutical Product
CRC	Clinical Research Centre
CREC	Central Research Ethics Committee (Thailand)
CRF	Case Report Form
CRIS	Client Registration and Identification Service
CRM	Clinical Research Materials Notification
CRO	Contract Research Organization
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Application
CTC	Clinical Trial Certificate
CTD	Common Technical Document
CTGTP	Cell, Tissue and Gene Therapy Products
CTIL	Clinical Trial Import License (Malaysia)
CTN	Clinical Trial Notification
CTRI	Clinical Trials Registry of India
CTW	Clinical Trial Waiver
CTX	Clinical Trial Exemption
CUHK	Chinese University of Hong Kong

Abbreviation	Description
CV	Curriculum Vitae
Cat.	Category
ChP	Chinese Pharmacopoeia
ChPC	Chinese Pharmacopoeia Commission
Co-I	Co-Investigator
CoA/COA/CA	Certificate Of Analysis
CoPP	Certificate of Pharmaceutical Product
DAV	Drug Administration Department of Vietnam
DCA	Drug Control Authority (Malaysia)
DCGI	Drugs Controller General of India
DLP	Data Lock Point
DMC	Data Matrix Code
DMF	Drug Master File
DMR	Drug Manufacturing Regulation
DMSC	Department of Medical Sciences
DNA	Deoxyribonucleic Acid
DOH	Department of Health
DP	Drug Product
DRGD	Drug Registration Guidance Document (Malaysia)
DRR	Drug Registration Regulations (China)
DS	Drug Substance
DSRB	Domain-Specific Review Board (Singapore)
DSUR	Development Safety Update Report
EC	Ethical/Ethics Committee
eCTD	Electronic Common Technical Document
EC-MOPH	Ethics Committee - Ministry of Public Health
EFTA	European Free Trade Association
EMEA/EMA	European Medicines Agency
ENG	English
EP	European Pharmacopoeia
EU	European Union
FDA	Food and Drug Administration
FERCIT	Forum for Ethical Review Committees in Thailand
FIH	First-In-Human (Clinical Trials)
FP	Final Product
FRP	Facilitated Regulatory Pathway
FSC	Free Sale Certificate
G	Generic
GACP	Good Agricultural and Collection Practices
GBAICTI	Greater Bay Area International Clinical Trial Institute (Hong Kong)
GCP	Good Clinical Practice
GDA	GMP Desktop Assessment
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GMP CE	GMP CErtificate
GPIN	Global Product Identification
GPP	Good Pharmacy Practice
GS1	Global Standard One
GTIN	Global Trade Item Number
GVP	Good Pharmacovigilance Practices
HA	Health Authorities
HBRA	Human Biomedical Research Act (Singapore)
HGR	Human Generic Resources
HGRAC	Human Genetic Resource Administration of China

Abbreviation	Description
HIV	Human Immunodeficiency Virus
HK	Hong Kong
HKAPI	Hong Kong Association of the Pharmaceutical Industry
HKD	Hong Kong Dollar
HKU	University of Hong Kong
HSA	Health Sciences Authority (Singapore)
HTAin	Health Technology Assessment in India
HeFTA	Health Financing and Technology Assessment unit (India)
Hep C	Hepatitis C
IB	Investigator's Brochure
IBD	International Birthday
IC	Informed Consent
ICF	Informed Consent Form
ICH	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDR	Indonesia Rupiah
IEC	Independent Ethical Committee
IL	Import License
IMCT	International Multi-Center Clinical Trial
IMP	Investigational Medical Product
IMPD	Investigational Medicinal Product Dossier
IND	Investigational New Drug
IP	Indian Pharmacopoeia
IPMG	International Pharmaceutical Manufacturers Group (Indonesia)
IRB	Institutional Review Board
IRPMA	International Research-Based Pharmaceutical Manufacturers (Taiwan)
IVPT	In Vitro Percutaneous Transmission
IVRT	In Vitro Release Testing
JP	Japanese Pharmacopoeia
JPMA	Japan Pharmaceutical Manufacturers Association
KGMP	Korea Good Manufacturing Practice
KOL	Key Opinion Leader
KOMNAS	The Indonesian Human Rights National Commission (Komnas HAM)
KP	Korean Pharmacopoeia
KPBMA	Korea Pharmaceutical and Bio-Pharma Manufacturers Association
KRPIA	Korean Research-based Pharma Industry Association
LPLV	Last Patient Last Visit
LTO	License to Operate
LoA	Letter of Authorization
LoQ	List of Questions
MA	Marketing Authorization
MAA	Marketing Authorization Applicant
MAH	Marketing Authorization Holder
MAV	Major Variation Application
MF	Master File (Japan)
MFDS	Ministry of Food & Drug Safety (Korea)
MFR	Manufacturer
MHLW	Ministry of Health, Labour and Welfare (Japan)
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
MIDR	Million Indonesia Rupiah
MIIT	Ministry of Industry and Information Technology (China)
MOH or MoH	Ministry of Health (Malaysia) (Vietnam)
MOPH	Ministry of Public Health (Thailand)
MOST	Ministry of Science and technology (China)
MRCT	Multi-Regional Clinical Trials

Abbreviation	Description
MREC	Medical Research and Ethics Committee (Malaysia)
MTA	Material Transfer Agreement
MiV	Minor variation
MoHFW	Ministry of Health and Family Welfare (India)
N/A	Not Applicable
NADFC	National Agency for Drug and Food Control (Indonesia)
NATCM	National Administration of Traditional Chinese Medicine （China)
NBE	New Biological Entity
NCE	New Chemical Entity
NCO	New Combination
ND	New Delivery system
NDA	New Drug Application
NDCT	New Drugs and Clinical Trial (India)
NDOS	New Dosage form of Approved New Drug
NF	National Formulary
NG	New Generic
NHC	National Health Commission (China)
NHG	National Healthcare Group (Singapore)
NI	New Indication
NIBIO	National Institute of Biomedical Innovation, Health and Nutrition (Japan)
NICVB	National Institute for Control of Vaccines and Biologicals (Vietnam)
NIFDC	National Institutes for Food and Drug Control (China)
NME	New Molecular Entity
NMPA	National Medical Products Administration (China)
NMRR	National Medical Research Register (Malaysia）
NOC	No Objection Certificate
NPRA	National Pharmaceutical Regulatory Agency (Malaysia)
NR	New Route of administration
NS	New Strength of Approved New Drug
NSAE	Non Serious Adverse Event
NSWS	National Single Window System (India)
NUHS	National University Health System (Singapore)
NeeS	Non-eCTD Electronic Submission (Thailand)
ODD	Orphan Drug Designation (Taiwan)
OECD	Organisation for Economic Cooperation and Development
OPPI	The Organisation of Pharmaceutical Producers of India
OTC	Over-The-Counter
PBRER	Periodic Benefit Risk Evaluation Report
PD	Pharmacodynamics
PG	Pharma Group (Vietnam)
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PHREB	Philippine Health Research Ethics Board
PI	Package Insert
PIC/S or PIC/s	Pharmaceutical Inspection Co-operation Scheme
PIL	Patient Information Leaflet
PK	Pharmacokinetics
PMD Act	Pharmaceuticals, Medical Devices and Other Therapeutic Products Act （Japan)
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMF	Plant Master File
PMS	Post-Marketing Surveillance/Study
PNDF	Philippine National Drug Formulary
PQM	Product Quality Monitoring (Malaysia)
PRH	Product Registration Holders (Malaysia)
PRISM	Pharmaceutical Regulatory Information System (Singapore)
PROMISE	A priority regulatory review pathway in Singapore (HSA)

Abbreviation	Description
PReMA	Pharmaceutical Research and Manufacturers Association (Thailand)
PSAR	Pandemic Special Access Route (Singapore)
PSM	Pre-submission Meeting (Malaysia)
PSUR	Periodic Safety Update Report
PTTS	Pharmaceutical Track & Trace System (Malaysia)
PV	Process Validation
PhAMA	Pharmaceutical Association of Malaysia
PhIRDA	China Pharmaceutical Innovation and Research Development Association
PhP	Philippine Peso
PvPI	Pharmacovigilance Program of India
QC	Quality Control
QOS	Quality Overall Summary
QP	Qualified Person
QR	Quick Response
R&D	Research and Development
r-DNA	recombinant DNA
RC	Registration Certificate
RDPAC	R&D-based Pharmaceutical Association Committee
REMS	Risk Evaluation and Mitigation Strategy
RFID	Radio Frequency Identification
RMP	Risk Management Plan
RNA	Ribonucleic Acid
RRC	Research Review Committee
RTF	Refuse-To-File (Taiwan)
RWE	Real-World Evidence
SADR	Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SAKIGAKE	"Breakthrough Therapy"-type priority review system (Japan)
SAMR	State Administration for Market Regulation (China)
SAPI	Singapore Association of Pharmaceutical Industries
SARS-CoV-2	Severe Acute Respiratory Syndrome COronaVirus 2
SAS	Special Access Scheme
SDL	Subsidies for Drugs on the Standard Drug List (Singapore)
SEC	Subject Expert Committee
SHARE	Singapore Health Product Access and Regulatory E-System
SKAI	Competency Standards of Indonesian Pharmacists
SLS	Stakeholder-Led Submission (Indonesia HTA) / Statement of Licensing Status (Singapore HSA)
SMF	Site Master File
SMP	Safety Monitoring Program (Thailand)
SMPC/SmPC	Summary Product Characteristics
sNDA	supplemental New Drug Application
SODA	Sale of Drugs Act (Malaysia)
SODIP	Sale of Drugs (Investigational Products for Clinical Trials) Regulations (Malaysia)
SOP	Standard Operating Procedure
SPARK	Support Anti-Tumor Drugs R&D for Kids (China / NMPA)
SRA	Stringent Regulatory Authorities
SSR	Site Summary Report
SUSAR	Suspected Unexpected Serious Adverse Reaction
TACTA	Taiwan Alliance for Clinical Trial Association
TCTC	Taiwan Clinical Trial Consortium
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration (Australia)
THB	Thai Baht
TP	Therapeutic Products
TPI	Taiwan Package Insert

Abbreviation	Description
Thai-FDA	Thailand Food and Drug Administration
USA	United States of America
USADRs	Unexpected Serious Adverse Drug Reactions
USD	United States Dollar
USFDA	US Food and Drug Administration
USP	United States Pharmacopoeia
VN	Vietnam
VNM	Vietnamese
WD	Working Day
WHO	World Health Organization
XDR TB	eXtensively Drug-Resistant TuBerculosis

EXECUTIVE SUMMARY 2026

China	RDPAC/PhIRDA	1.National-level Policy 1）Opinions of the General Office of the State Council on Deepening the Reform of Drug and Medical Device Regulation in an All-Round Way and Promoting the High-Quality Development of the Pharmaceutical Industry https://www.gov.cn/zhengce/content/202501/content_6996115.htm 2）Policy Interpretation of the Opinions on Deepening the Reform of Drug and Medical Device Regulation in an All-Round Way and Promoting the High-Quality Development of the Pharmaceutical Industry https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdzh/20250103173228104.html 3）Regulations on the Administration of Clinical Research and Clinical Translation Application of Biomedical New Technologies (Decree of the State Council of the People's Republic of China No. 818) https://www.gov.cn/zhengce/content/202510/content_7043790.htm 4）Announcement of the National Medical Products Administration on Matters Concerning the Optimization of the Review and Approval of Clinical Trials for Innovative Drugs (No. 86, 2025) https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20250912092255131.html 5）Notice of the Center for Drug Evaluation of the National Medical Products Administration on Issuing the Requirements for Application Documents of Innovative Drug Clinical Trial and Other Related Documents (No. 40, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/2dcbc56bb4d53be01fb362e3e6d31725 2.Regional-level Policy 1）Shanghai Municipal Regulations on Drug and Medical Device Administration https://yjj.sh.gov.cn/dfxfghgz/20250610/9bf2c2bab61f4063bb55b22bd61b0ad0.html 2）Several Measures of Beijing Municipality on Supporting the High-Quality Development of Innovative Pharmaceuticals (2025) https://ybj.beijing.gov.cn/zwgk/2024zcwj/202504/t20250407_4058418.html 3.Notification by the NMPA and the affiliate 1）Announcement of the National Medical Products Administration on Matters Related to the Import of Commercially Scaled Batches of Overseas Marketed Drugs Prior to Marketing Approval in China (No. 96, 2025) https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20250930090453177.html 2）Policy Interpretation of the "Announcement of the NMPA on Matters Related to the Import of Commercially Scaled Batches of Overseas Marketed Drugs Prior to Marketing Approval in China" https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdyp/20250930090850112.html 3）Notice of the National Medical Products Administration on the Pilot Program for Optimizing the Review and Approval Procedures for Supplemental Applications of Overseas Manufactured Drugs https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20251107104752156.html 4）Notice of the National Medical Products Administration on Issuing the Application Procedures and Documentation Requirements for the Re-registration of Domestically Manufactured Drugs (No. 38, 2024) https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20241011180912117.html 5）Announcement of the National Medical Products Administration on Matters Concerning the Implementation of the 2025 Edition of the Pharmacopoeia of the People's Republic of China (No. 32, 2025) https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20250325184202175.html 6）Announcement of the National Medical Products Administration on Issuing the Appendices for Pharmaceutical Excipients and Drug Packaging Materials of the Good Manufacturing Practice for Drugs (2010 Revision) (No. 1, 2025) https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20250102142249169.html https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20250102144532189.html 7）Announcement of the National Medical Products Administration on Expanding the Implementation Scope of Electronic Common Technical Document (eCTD) for Drugs (No. 10, 2025) https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20250123164542175.html 8）Notice on the Cancellation of Submitting Clinical Trial Databases via CD and the Update of the Electronic Application Dossier Preparation Software https://www.cde.org.cn/main/news/viewInfoCommon/d7e02d507a9feff923637cebbefded07 9）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Requirements for Preparing Module 2 Quality Documents in Abbreviated New Drug Applications for Chemical Generic Drugs (Trial) (No. 32, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/8173832d915fc5c592ff840651f4bd38 10）Announcement of the National Medical Products Administration on Issuing the Administrative Provisions for the Experimental Research of Narcotic Drugs and Psychotropic Substances (No. 51, 2025) https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20250530115105182.html 11）Notice of the National Institute for Food and Drug Control on Issuing the Standard for Drug Registration Testing Procedures and Technical Requirements (2025 Revision) https://www.nifdc.org.cn/nifdc/xxgk/zcfg/flfg/20250714141242164112 8.html 12）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Questions and Answers on Pharmaceutical Similarity Studies of Biosimilars (No. 30, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/74ec4ee60f06e4a3fc98f04e5e8b0e1c 13) Notice of the Center for Drug Evaluation of the National Medical Products Administration on the Release of the Technical Guidance Principles for the Preparation of Biosimilar Product Labels (No. 12 , 2025) https://www.cde.org.cn/main/news/viewInfoCommon/02c265536d59d0ec97d81a23627afa37 14) Notice of the General Affairs Department of NMPA on Printing and Distributing the Guidelines for the Inspection of Appendices of Pharmaceutical Excipients and the Guidelines for the Inspection of Appendices of Pharmaceutical Packaging Materials (No. 67, [2025]) https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20251121174208105.html 15) Announcement of the National Medical Products Administration on Issuing the Provisions on the Administration of Inspection and Export Certification of Export Drugs by Drug Manufacturers (No. 113, [2025]) https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20251121163558131.html 4.General 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Safety Surveillance of Drugs https://www.cdr-adr.org.cn/tzgg_home/202508/t20250819_51233.html 7）Notice on Issuing the Guidance for the Management of Bioanalytical Laboratories in Drug Clinical Trials https://cfdi.org.cn/cfdi/resource/newsmobile/16488.html 5.Technical Guidelines (General) 1）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Vaccine Clinical Trials (No. 16, 2025) https://www.cde.org.cn/zdyz/opinioninfopage?zdyzIdCODE=3e23108aa065ae187ffb353794f7b1d4 2）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Multivalent Vaccine Clinical Trials (No. 48, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/2da6292c736d146129c0a07a80f99541

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https://www.cde.org.cn/main/news/viewInfoCommon/0889d723de12de0bb82f616ef34376e3 7）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Studying the Shelf Life of Intermediate Products of Oral Solid Dosage Forms of Chemical Drugs (No. 6, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/4d8e5e1508c0a144ce4b38c91327015d 8）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Pharmaceutical Research on Oral Soluble Film Preparations of Chemical Drugs (Trial) (No. 17, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/e9ca411c6e11df700933b13e3764f783 9）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Model-Informed Drug Development for Rare Diseases (No. 25, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/6af9e335e63bbcfc762a3d191ff8b719 10）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical 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Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Clinical Trials of Drugs for Alzheimer’s Disease (Trial) (No. 19, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/7ac4dac8345a94018570294031541f1d 13) Notice of the Center for Drug Evaluation of the National Medical Products Administration on Issuing the Technical Guidance Principles for Research on Production Site Changes for Marketed Blood Products (Trial) (No. 20, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/e13aa3a6b482a06e6980763617375a08 14）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Guiding Principles for Clinical Resistance Studies and Data Submission of Anti-HIV Infection Drugs (No. 23, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/1fad6e10fcf3f314abbba9442b1dc4f0 15）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Clinical Trials of Antibacterial Drugs for Serious Bacterial Infectious Diseases with 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		20）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Common Issues and Technical Requirements for Marketing Application of Recombinant Adeno-Associated Virus Vector-Based In Vivo Gene Therapy Products (No. 39, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/2676e243499c7d7bf4bf18e355a6f40e 21）Notice of the Center for Drug Evaluation of the National Medical Products Administration on the Release of the Technical Guidance Principles for Clinical Trials of Herpes Zoster Vaccines (No. 42, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/3eeee237e4b3e78b157815bcf4bb993e 22）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines Principles for Pharmaceutical Research and Evaluation of Recombinant Glycoprotein Hormone Products (No. 47, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/11fc6ef8418697ad269a89937eb29b5e 23）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guidelines for Clinical Development of New Drugs for Osteoarthritis (No. 33, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/8dc23b0ff119f65929481514344eb993 7. Specific Theme ●Pediatric Drugs 1）Notice of the Center for Drug Evaluation of the NMPA on Launching the “Support Anti-Tumor Drugs R&D for Kids (SPARK)” https://www.cde.org.cn/main/news/viewInfoCommon/40fda4373a2a7b55fa7b16f61bb04c52 2）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Technical Guiding Principles for Safety Information Evaluation and Reporting in Pediatric Drug Clinical Trials (Trial) (No. 21, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/d3762909c55ef21c7fc533d8ba826d40 3）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Common/General Issues and General Responses in Pediatric Drug Research and Development https://www.cde.org.cn/main/news/viewInfoCommon/bccd09f6a6a311ffb5827be1e0389df0 ●Aging Friendly 1）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Key Points for Writing Medication Information for the Elderly Population in Drug Package Inserts (Trial) (No. 43, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/ba056d1147d71784407288123b07a414 2）Notice of the Center for Drug Evaluation of the NMPA on Issuing the Key Elements and Trial Design Points for the Participation of the Elderly Population in Innovative Drug Clinical Trials (Trial) (No. 44, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/37737625304556df59e4ab29e9711da1 3）Notice of the Center for Drug Evaluation of the NMPA on Issuing the General Principles and Considerations for Age-Friendly Design in Innovative Drug Research and Development (Trial) (No. 45, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/145b8545564e4553f94a8ab4256fa111 ●OTC 1）Notice on Issuing the “Principles for Determining the Indication Scope of Nonprescription Drugs” (Revised Draft) http://www.cdr-adr.org.cn/tzgg_home/202508/t20250808_51223.html 2）Notice on Issuing the Guiding Principles for the Application Scope of Prescription to Nonprescription Drug Switch http://www.cdr-adr.org.cn/tzgg_home/202508/t20250808_51222.html 7. Others 1）2024 Annual Drug Review Report https://www.cde.org.cn/main/news/viewInfoCommon/54538c67b7e764fc51666567fc620241 2）Annual Report on the Progress of Clinical Trials for New Drug Registrations in China (2024) https://www.cde.org.cn/main/news/viewInfoCommon/d0bc4836cfc4cb7c9ecf29ddaa7be6ea
Hong Kong	HKAPI	Update the special pathway (“1+ mechanism”), the scope now extends to the change of indications, dosage and route of administration, effective on 29 Nov 2025. Also, pre-NDA meeting can be requested for applications under “1+ mechanism”. Primary evaluation (without requirement of CPP) will be implemented in phases in the period between 2026 and 2030. Guidelines and requirements to be confirmed. Certificate holders should allow and facilitate GCP inspection to be conducted by inspectors of the Drug Office at all relevant premises related to the trial may start from Q4 of 2026.
India	OPPI	No major updates are provided.
Indonesia	IPMG	In 2025, regulatory environment in Indonesia observed this changes: -BPOM issued some new regulations, such as BPOM Regulation No. 2 Year 2025 regarding the Guideline of Vaccine Batch/lot Release Certification (enacted on Jan 9, 2025), BPOM Regulation No. 7 Year 2025 concerning the amendment of BPOM Regulation No.7 Year 2024 regarding Standard of Good Manufacturing Practices (enacted on Mar 4, 2025), BPOM Regulation No. 8 Year 2025 concerning Evaluation Guideline for Advance Therapy Evaluation (enacted on Mar 6, 2025), BPOM Regulation No. 9 Year 2025 concerning Guidance for Risk Assessment for Safety and/or Quality of Drug and Drug Materials (enacted on Apr 23, 2025), BPOM Regulation No 12 Year 2025 concerning Certain Drugs that are Often Misused (enacted on Apr 23. 2025), BPOM Regulation No. 19 Year 2025 concerning Amendment of BPOM Regulation No. 9 Year 2024 regarding Guidelines for Follow-Up Actions on the Results of Supervision of Drugs, Drug Ingredients, Narcotics, Psychotropics, Precursofrom 120 rs, and Addictive Substances (enacted on Jun 24, 2025), BPOM Regulation No. 20 Year 2025 Concerning Standard of Good Distribution Practices (enacted on Jun 24, 2025), BPOM Regulation No. 23 Year 2025 Regarding Fifth Amendments for BPOM Regulation BPOM Regulation No 24 Year 2017 concerning Criteria and Procedure of Drug Registration (enacted on Aug 1, 2025), BPOM Regulation No 24 Year 2025 concerning Procedure of New Drug Development Approval (enacted on Aug 13, 2025) -Several draft regulations also being discussed, such as Draft BPOM Regulation concerning Drug promotion and advertising, GMP standards for excipients used in pharmaceutical production, Evaluation of Compliance with Good Manufacturing Practices Requirements in Imported Drug Manufacturing Facilities, PV Guideline and Biosimilar guideline -BPJPH issued new regulation No 221 Year 2025 concerning Registration of Foreign Halal Certificates, that was aligned with Presidential Decree No. 42 of 2024 on Halal Product Assurance. -Halal/non-Halal Labeling: BPOM issued draft regulation concerning Guidance for Halal/non-Halal labeling as mandated in Presidential Decree No.6 Year 2023 concerning Halal Certification for Medicine, Biological Products, and Medical Devices. However, according to more recent Presidential Decree No. 42 of 2024 on Halal Product Assurance, BPJPH, in coordination with relevant stakeholders, is responsible for determining non-Halal regulations. In 2026, we expect the following developments: -BPJPH Draft Regulation concerning Form and Procedures for Inclusion Of Non-Halal Information as mandated in Presidential Decree No. 42 of 2024 on Halal Product Assurance, which is to establish the form and procedures for including non-halal information on products in Indonesia, aiming to ensure consumer rights to clear and honest information about product halal status. It applies to products derived from prohibited materials or produced through non-compliant halal processes in food and beverage products, medicine, biological product and cosmetics, chemical products and medical devices. -Revision of the Drug Registration Guideline (BPOM) ◦ E-labeling ◦ DP multi-source ◦ Joint-Assessment
Japan	JPMA	The revised Pharmaceutical and Medical Device Act was announced in May 2025, and ministerial ordinances and related notifications are being prepared in preparation for its enforcement in May 2026. The main changes planned are the development of a clinical trial environment aimed at strengthening drug discovery capabilities, the obligation to make efforts to establish development plan of pediatric drugs, reviewing the conditional approval system, and renovating GCP.
Korea	KPBMA/KRPIA	Starting January 1, 2025, the new drug application fee was substantially increased (approx. KRW 8M → KRW 410M). The pre-submission consultation system, previously operated under an MFDS administrative notice, was formally established as an official regulation in 2025. Updates were made to the GMP certification renewal system, clarifying 3-year validity and 2-year extension rules when on-site inspection is waived. The number of MFDS-certified clinical trial sites was updated (208 sites as of Nov 2025). The integrated RMP system continues to replace the Re-Evaluation system following the 2025 reform.

Malaysia	PhAMA	Developments in the regulatory landscape in Malaysia for 2025 include the following: **1. Change in NPRA's Top Management** The NPRA Director, Dr. Azuana Ramli, was promoted to Deputy Director-General for Pharmaceutical Services on 08 April 2025. Mdm Wan Noraimi binti Wan Ibrahim was appointed as the new NPRA Director on 21 August 2025. **2. Site-Specific Stability** Site-Specific Stability revisions/updates have been included in the DRGD January 2025 release on the NPRA website. https://www.npra.gov.my/index.php/en/drug-registration-guidance-documents-drgd-e-book.html **3. Proposed amendments to the Sale of Drugs Act (SODA) 1952.** The SODA amendments will also impact the CDCR (Control of Drug & Cosmetics Regulations) which are regulations under this Act. When these amendments are passed in Parliament, and come into effect legally, it will empower the NPRA to implement various new activities including: **- Patent Linkage** **- Pharmaceutical Track and Trace System (PTTS)** **- GVP Inspections (Pharmacovigilance)** **- Risk-Based PQM (Product Quality Monitoring)** **- Sale of Drugs (Investigational Product) Regulations - for Investigational New Drug (IND) Applications in clinical trials** **- Fee changes** **4. E-Labelling** The scope of current e-labelling implementation was extended to OTC products from 1 August 2025**.** The E-Labeling Guidelines & FAQ have since been updated on 14 July for expansion to OTC and for direct submission for e-labelling variation of pack. https://www.npra.gov.my/index.php/en/directive-general/1527741-direktif-berkenaan-peluasan-skop-produk-yang-melaksanakan-electronic-labelling-e-labelling-kepada-kategori-produk-generik-bukan-racun-berjadual-over-the-counter-products-otc.html **5. Screening Requirements** Following the Screening Practices Workshop organized by PhAMA in collaboration with NPRA on 16 April, the NPRA provided the Screening Package for New Drug Products and Biologics on 03 June 2025, which included a letter template, Screening Checklist, and relevant forms. (https://npra.gov.my/index.php/en/component/content/article/466-english/announcement-main/announcement-2025/1527729-screening-package.html?Itemid=1391) **6. Drug Shortage Reporting** The Ministry of Health has issued a Directive on Implementation of Reporting of Medicine Shortage and Discontinuation in Malaysia in July 2025. Directive on Implementation of Reporting of Medicine Shortage and Discontinuation in Malaysia: https://www.npra.gov.my/index.php/en/directive-general/1527740-direktif-berkenaan-pelaksanaan-pelaporan-gangguan-dan-pemberhentian-bekalan-ubat-ubatan-di-malaysia-berdasarkan-guideline-on-reporting-of-medicine-shortage-and-discontinuation-in-malaysia.html Guideline on Reporting of Medicine Shortage and Discontinue In Malaysia: https://www.npra.gov.my/easyarticles/images/users/1153/DCA/Direktif/Guideline-on-Reporting-of-Medicines-Shortage-in-Malaysia_August-2025.pdf **7. Track & Trace Implementation plans:** The Ministry of Health (MOH) has appointed the vendor for the PTTS (Pharmaceutical Track & Trace System for Registered Pharmaceutical Products) in October 2025. The tender contract was awarded to the same contractor for the PTTS and the hologram supply to facilitate a seamless implementation for T&T, which will be in phases to transition from the current hologram security labels to the T&T system. The MOH is targeting for T&T implementation in 3 years when the system and stakeholders are ready. The plans cover the development of a Repository for the PTTS and a 6-months Pilot focusing on scheduled Poisons (prescription & pharmacy products). It is anticipated to commence roll-out from 2027 (with hologram and T&T during the transition period), and targeting full implementation of PTTS by 2029. **8. Sale of Drugs (Investigational Products for Clinical Trials) Regulations (SODIP)** A public consultation was held in October 2025 to seek feedback from stakeholders and interested parties on the Draft Sale of Drugs (Investigational Products for Clinical Trials) Regulations. At present, there is no specific act or regulation that governs clinical trials involving both registered and unregistered products in Malaysia. Regulatory oversight of clinical trial activities has been limited to the importation and manufacturing of unregistered products intended for clinical trials, as provided under the Control of Drugs and Cosmetics Regulations (CDCR) 1984. Specifically, CDCR 1984 regulates the following: i) Importation of investigational products (Regulation 12(1)(c)) through the Clinical Trial Import Licence (CTIL); and ii) Manufacturing of investigational products (Regulation 15(5)) through the Clinical Trial Exemption (CTX). The overall goal of this consultation was to obtain opinions, suggestions, and recommendations to strengthen the draft regulations before they are finalized and enforced. **9. Multiple Drug Product Manufacturing Sites under a Single License** NPRA initiated a pilot project for Registration of Multiple Drug Product Manufacturing Sites under a Single License starting 16 June 2025 to assess the complexity of assessment, particularly in terms of manpower and additional regulatory requirements. This pilot will also help evaluate the feasibility of using the current Quest 3+ system for multisite assessment, as a step towards the development of Quest 5. The pilot will cover one product from the New Drug Product, Biologics, and Generic Medicine categories. **10. CGTP Guideline Revision** A Directive on the revision of the "Guidance Document And Guidelines For Registration Of Cell And Gene Therapy Products (CGTPs) In Malaysia (Second Edition)" was issued on 19 September 2025 https://www.npra.gov.my/index.php/en/directive-general/1527767-pekeliling-berkenaan-pengemaskinian-guidance-document-and-guidelines-for-registration-of-cell-and-gene-therapy-products-cgtps-in-malaysia-second-edition.html **11. FIH Clinical Trials with CGTPs** NPRA issued a Directive regarding the expansion of the scope of First-In-Human (FIH) Clinical Trial Products for Applications for Clinical Trial Import License (CTIL) and Authorization to Manufacture Unregistered Products for Clinical Trial Purposes (CTX) to Cell and Gene Therapy Products (CGTP). https://www.npra.gov.my/index.php/en/directive-general/1527703-direktif-berkenaan-peluasan-skop-produk-kajian-klinikal-first-in-human-fih-untuk-permohonan-lesen-import-percubaan-klinikal-ctil-dan-kebenaran-untuk-mengilang-produk-tidak-berdaftar-untuk-tujuan-percubaan-klinikal-ctx-kepada-cell-and-gene-therapy-product-cgtp.html **12. Draft Revisions:** NPRA shared the following draft revisions for consultation with industry to enhance reliance in post registration space and eliminate country specific requirements: **13. Proposed Revision of Timelines for Variation Applications of Registered Products (Pharmaceuticals and TMHS), Including Reliance (Pharmaceuticals Only), Following Pilot Study Implementation (7 October 2025)** **14. Proposed Revision of New/Additional Indication (AI) Applications, Including Reliance, Following Implementation of Pilot Study (7 October 2025)** **15. Proposed Revision of Animal DNA Testing Circular (13 September 2025)**
Philippines	PHAP	The Philippine FDA focused in the crafting of operational guidelines to implement the 3 policies released in Q4 2024. The implementation of the new schedule of fees were halted through a Moratorium, and industry is awaiting the official release sometime Q2 2026. We are yet to see the impact of the new operational guidelines, which aim to incorporate many international best practices – including multiple sites in a single MA, do and tell, elabeling, among others.

Singapore	SAPI	**1. Issuance of Verification Electronic Certificates for Exporters from 01 June 2025** The Health Sciences Authority / Audit & Licensing Division (ALD) will no longer issue hard copy certificates for Certificate of Pharmaceutical Product (CPP), Certificate of Free Sales (FSC), and Statement of Licensing Status (SLS). HSA will be utilising TrustDocs, a digital platform developed by the Government Technology Agency of Singapore (GovTech), to issue electronic certificates which are secure and verifiable. There will not be any changes to the application process, regulatory requirements and application fees for these certificates. Each electronic certificate will be sent to the applicant via email as a PDF attachment. This PDF file contains a unique Quick Response (QR) code and a preview of the certificate. Authenticity of the document can be verified at the TrustDocs website. This initiative is part of HSA's ongoing digital transformation to improve work efficiency and address industry's needs. **2. Updates to ACCESS NASWI operational procedure** Main updates to PROMISE pathway including: • PROMISE pathway extends to include new indication applications. • Access agencies should submit one scientific data package and justification when requesting priority review. • No change to the eligibility criteria for PROMISE pathway • Technical pre-submission meeting to be held after decision of priority request instead of before submission of priority request. **3. Regulatory Updates for Therapeutic Product Registration (effective 30 July 2025)** i. **Enhancement of application checklists for NDA, GDA and MAV submission** The application checklists for NDA, GDA and MAV submissions (Appendix 2A, 2B, 3A, and 3B) have been revised to improve usability for applicants, serving as submission aids to ensure completeness of application dossiers and reduce screening queries. The new checklists in MS Excel format are now available for use in application submissions. The MS Word format will continue to be accepted during the transition period until 31 October 2025. The new format, which will fully replace the MSWord format from 1 November 2025. ii. **Clarification on prerequisite documents for acceptance of application for screening** Applications will not be accepted for screening if any of the prerequisite documents is omitted: • Module 3/Part 2 Drug Substance dossier • Module 3/Part 2 Drug Product dossier • Module 4/Part 3 Non-Clinical dossier (if applicable) • Module 5/Part 4 Clinical dossier • Drug Master File (DMF) and its accompanying Letter of Access (if applicable) • Assessment report from Reference Agencies (for verification route) • Duly completed Application Checklist in MS EXCEL format • Duly completed Patent Declaration Form iii. **Updated acceptable proof of GMP compliance for drug product manufacturing sites** The GMP documentary evidence has been updated to align with the latest version of the guidance on "GMP Conformity Assessment of An Overseas Manufacturer, version December 2024". The acceptable proof of GMP compliance issued by a competent authority may be in the form of Valid PIC/S GMP Certificate (Certificate of GMP Compliance) or Establishment Inspection Report (EIR) and close out letter issued by US/FDA. Proof of compliance must be valid at the time of submission and not less than 6 months before expiry. This applies to NDA, GDA and MIV-1/2 applications. iv. **Introduction of a new online form for DMF submission** The DMF submission process has been streamlined, and DMF holders can now notify HSA and obtain a DMF reference number for submission of the dossier using a new online form. Applicants are no longer required to submit a separate DMF receipt acknowledgement issued by HSA in their product registration application. v. **Streamlining of dossier requirements for MAV-1 verification evaluation route** Complete assessment reports obtained from the public domain for the primary reference agency are now acceptable to support MAV-1 applications via verification evaluation route. vi. **Enhancement of criteria for forensic classification of TPs (POM/P/GSL)** The regulatory considerations for POM, P and GSL, have been enhanced to facilitate and provide clarity on the criteria for reclassification. vii. **Other revisions** The relevant sections of the Guidance documents listed below have been updated with minor amendments and editorial changes for better clarity: • Definition of abridged evaluation route for Biosimilar applications • RMP requirements for GDAs • Requirements for documents in PDF format • PRISM submission requirements • Conditions for MIV-1 checklists B16 (Appendix 13A) and B6 (Appendix 14A) **4. HSA Update on eCTD implementation** HSA announced the launch of eCTD Portal for test submission, effective 30 September 2025. The test submission phase will be open for six months from 30 September 2025 to 27 March 2026. During this period, companies are encouraged to submit test submission to familiarize themselves with the new system. All submissions made during this test phase will not be processed for regulatory review and will be removed from the system upon completion of the test period. Actual dossier submission in eCTD format will be accepted from 1 April 2026 onward. **5. HSA Issuance of Verifiable Electronic Licences for Import and Export of Controlled Drugs, Psychotropic Substances and Restricted Substances** From 01 October 2025, the Health Sciences Authority will be utilising TrustDocs , a digital platform developed by the Government Technology Agency of Singapore (GovTech) to issue electronic licences/authorisations for the import and export of Controlled Drugs, Psychotropic Substances and Restricted Substances. This initiative is part of HSA's ongoing digital transformation to improve work efficiency and address industry's needs. There will not be any changes to the application process, regulatory requirements and application fees for these licences/authorisations. Upon the implementation of electronic licences/authorisations, HSA will no longer issue printed hard copy of these licences/authorisations. The electronic licence/authorisation which is secured and verifiable, will be issued to the applicant in PDF format, with a unique Quick Response (QR) code for verification of the authenticity of the document at the TrustDocs website. **6. HSA Introducing "SHARE" For CTGTP CPP and FSC** Launch of SHARE (Singapore Health Product Access and Regulatory E-System) for Cell, Tissue and Gene Therapy Products (CTGTP) Certificate of a Pharmaceutical Product (CPP) for Class 2 CTGTP and Free Sales Certificate (FSC) for Class 1 CTGTP from 17 Dec 2025. This will be applicable for application of CTGTP CPP or FSC, tracking or withdrawal of applications, view and download of certificates.
Taiwan	IRPMA	No major updates are provided. However, there are some updates on the pages: 6, 7, 9, 11,14, 15, 17, 18, 19, 20 which are highlighted in yellow for your convenience. The major updates are provided on page 8 regarding the Clinical Report / CMC summary /CMC report for the IND/CTA application because the answer provided last year was likely inaccurate and misleading in the context of IND/CTA requirements; as well as a new subject enrollment network on page 16.

Thailand	PReMA	The Thai FDA is driving digital modernization and regulatory transformation through several key 2026 initiatives: • **E-Labeling Paperless** is voluntary and restricted to Injectable dosage forms, Products for medical facilities that are not sold in pharmacies. Exclusions: Self-administered injectables, human/animal vaccines, and injectables for food-producing animals. Thai FDA Notification Re: Guidelines for the Evaluation of Modern Medicine Registration Submitted via Electronic Methods B.E. 2568 (cited 2025 DEC 12 media.php). • **GMP Clearance** in parallel is permitted only for urgent public health needs. Public Manual: Registration of Modern Drug Formulations for Humans and Animals, and Traditional Drugs for Animals (Electronic Submission) (Medicines) (cited 2025 DEC 12 media.php). • **Renewal & Reference SmPC**: Increased regulatory focus on aligning local labeling with the Reference SmPC/PIL during renewal of product certificate. Access to published Reference SmPC/PIL is provided through a dedicated section on the Medicines Regulation Division website https://drug.fda.moph.go.th/drug-information/category/medicine-for-people-and-professional (cited 2025 DEC 12). • **Pharmacovigilance (PV)**: The regulatory scope of Good Distribution Practice (GDP) is being extended to formally include PV requirements. Ministerial Notification Re: Criteria, Methods, and Conditions for the Distribution of Modern Medicines B.E. 2568 (cited 2025 DEC 12 media.php). • **Clinical Trial Authorization evaluation timelines** are significantly accelerated: Low/Intermediate risk trials are processed within 1–2 working days, while High-risk trials take 25–30 days (excluding ATMPs) or 70 days for ATMPs. Public Emergency authorizations are prioritized at 20 working days. Public Manual: Assessment for Approval of Clinical Research Studies Applications and Applications for Amendments to Clinical Research Studies (Drugs) (cited 2025 DEC 11 media.php). Collectively, these reforms signal the Thai FDA's progression toward a more digitally enabled regulatory framework. By significantly accelerating Clinical Trial Authorization timelines, Thailand is strengthening its national R&D ecosystem and shortening the path to market for innovative therapies. Simultaneously, leveraging the Pharmacovigilance (PV) system to align with global safety benchmarks fosters a sustainable environment for pharmaceutical innovation in 2026 and beyond.
Vietnam	PG	In 2025, the pharmaceutical sector saw important legislative reforms coming into effect with the revised Pharmaceutical Law and Circular 12/2025/TT-BYT on drug registration, both effective from 1 July 2025. These changes are broadly welcomed by the industry as they address long-standing gaps in the regulatory framework, streamline administrative procedures, and reduce unnecessary administrative burdens while placing greater responsibility on companies to submit high-quality and compliant dossiers. From the perspective of the innovative industry, key improvements include the introduction of Regulatory Reliance to shorten registration timelines (stipulated at 9 months) for products approved by stringent regulatory authorities (SRAs), the establishment of recognition mechanisms, maintain simplification of the Marketing Authorization Renewal process to prevent supply disruptions (replacing Circular 55/2024/TT-BYT) and new incentives to support sector-development activities such as local manufacturing and clinical trials. Nonetheless, concerns remain regarding the implementation of regulations, including MA Renewal and other administrative processes that can result in supply disruption.

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IND/CTA	Requirements to be the IND/CTA applicant	Sponsor (Companies) or regulatory agency (CRO) or institute.	• A local company holding relevant licence(s) such as Wholesale Dealer Licence, Antibiotics Permit and Wholesale Dealer's Licence to supply Dangerous Drugs, whenever applicable, or • the principal investigator who conducts the trial; or • the sponsor-investigator who initiates and conducts the trials should be the applicant	As per online portal requirement user i.e. any person, a company or an institution or an organization need to register themselves on the National Single Window System (NSWS) portal by providing requisite set of documents for the registration purpose. Application in CT-10, CT-12, CT-13 & CT-16 require to be submitted through NSWS portal effective from 16.01.2024 Ref- File no. IT-13011(11)/1/2023-e Office dtd 16 Jan 2024. cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA4NDk=	CRO, Companies and doctors who can follow standards of GCP. Sponsor or CRO If CRO from other country, they should stay in ID during the clinical trial. If sponsor from other country, they should delegate some or all functions to CRO in Indonesia.	GCP applies to clinical trials conducted by companies and investigators. CROs are able to submit the Clinical Trial Notification (CTN) if they serve as the in-country caretaker.	The company or CRO, etc. who are registered in Korea	An investigator, or an authorised person from a locally registered pharmaceutical company/ sponsor/ Contract Research Organisation (CRO) with a permanent address in Malaysia can make the application. Malaysian Guideline for Application of CTIL and CTX 8.1th Ed (Effective on 30 April 2025) (#4.1) Notes: Applications for CTIL/ CTX containing "poison/drug" should be made by Poison License Type A Holder in a private sector or Annual Retention Certificate Holder by public pharmacist. The holder of CTIL/CTX for a particular product does not need to conduct the clinical trial himself/herself.	FDA-licensed Sponsors and Contract Research Organizations (CROs) A license to operate (LTO) is required for a CRO and its Sponsor, prior to the conduct of the clinical trial. (Administrative Order No. 2024-0015)	Yes, CRO is possible, however the sponsor should be a locally registered business entity registered with the Accounting and Corporate Regulatory Authority (ACRA) in Singapore. In order for the sponsor to carry out electronic transactions with HSA on the sponsor company's behalf, the sponsor should apply for a Client Registration and Identification Service (CRIS) account to access PRISM.	The applicant is the pharmaceutical license owner or local legal entity with a pharmaceutical sponsor's delegation in Taiwan. CRO can be an applicant if the CRO – provided that (1) the CRO holds a valid pharmaceutical business license in Taiwan, and (2) they submit a formal power-of-attorney/ sponsorship delegation from the lincensed drug owner (sponsor). In addition, Hospitals qualified under the relevant health lwas may also serve as applicants when they meet criteria to act as sponsors.	Drug manufacturing/ import license holder or government (applicant can be sponsor or CRO)	Sponsor companies, CROs and doctors who can follow GCP standards CPO or CRO
	Clinical trial consultation system If consultation system exists, input "yes" and describe the details such as consultation timing or procedures.	Yes During R&D process, communication and consultation can be conducted for traditional Chinese medicines, chemical medicines and biological products, including Type I (the meeting held on the purpose to address the major safety issues encountered during the clinical trials of drugs, and the major technical issues in the R&D process of the breakthrough therapeutic drugs), Type II(pre-IND meeting, meeting at the end of Phase II/pre-clinical meeting of Phase III, and pre-NDA meeting), and Type III (all meeting aside from Type I and Type II). For detailed requirements, may refer to Measures for Administration of Communication for Drug R&D Activities and Technical Review (No.48 of 2020) and NMPA Announcement of China National Drug Administration on Adjusting Review and Approval Procedures for Drug Clinical Trial (No. 50 of 2018) and Notice of the Center for Drug Evaluation, National Medical Products Administration on Issuing the "Reference Materials for Applying to Drug Development and Technical Review Communication Meetings" (No. 48, 2024)	No	Yes, the New Drugs and Clinical Trials Rules, 2019 (NDCT Rules 2019) in India do provide a consultation system for clinical trials. Specifically, Rule 34 of the NDCT Rules allows sponsors or applicants to request a pre-submission meeting with the Central Licensing Authority (CLA) to seek guidance on regulatory requirements and procedures related to clinical trials. This meeting aims to facilitate clarity and streamline the approval process for clinical trial applications. While specific timelines for the consultation meeting are not detailed in the NDCT Rules 2019, it is advisable for sponsors to plan ahead and request the consultation at least a few weeks before submitting the clinical trial application to allow for sufficient time for the meeting and subsequent preparations.	Yes The consultation with Head of evaluator & Assistant Director by email, face to face, live chat and appointment before discussed.	Yes Various clinical trial consultations are offered by PMDA on new drugs and biological products (e.g., pre-PhI/Pre-PhIIa/Pre- PhIIb/End of PhII study, Pre-application, Quality, Safety, etc.).	Yes Pre-submission consultation is available for sponsors to receive regulatory advice on requested review items. Eligible product categories include: - New drugs - Advanced biopharmaceuticals (e.g., cell therapy, gene therapy, and tissue-engineered products) - Priority-review products for serious or rare diseases Public-health emergency products, including: - Products targeting drug-resistant pathogens - Products targeting novel or previously unaddressed pathogens - Medical products intended for pandemic preparedness or biodefense	NPRA has issued the Guidance Document for Pre-Submission Meeting (PSM) First Edition (February 2020). The main objective of PSM is to provide regulatory advice (with regards to quality, safety and efficacy aspects) to applicants prior to the submission of an application to register a product. Scope of product categories: -New chemical entities -Biologics including biosimilars -Natural products with therapeutic claim Health supplement products with disease risk reduction claim	Yes Consultation is done through official letters. Currently, there is no provision for face-to-face consultation, but FDA is looking at establishing a "limited contact" discussion with applicants.	No, but company can always write in to HSA to request for a meeting.	Yes Regulation consultation service is available for all phases of product development. In 2018 the reasonable consultation fee will be charged to the applicant and the consultation result would be recognized as formal record during NDA review. For more detailed information, please refer to the following website. Link to Consultation Service **A formal consultation system exists in Taiwan for IND/CTA.** The system is maintained by Center for Drug Evaluation (CDE), under Taiwan Food and Drug Administration (TFDA). ◆ **What is covered** •The consultation services cover **all phases of drug development**, including pre-clinical, IND prior-assessment, and clinical trial design (Phase I through IV). •There are also "regulatory strategy consultations" for later-stage planning (e.g., NDA, bridging studies, or marketing authorization strategy). ◆ **When and how to request consultation** •Applicants submit a "Consultation Service Application Form" via the CDE website. •Once accepted (Day 0), a designated consultation team is assembled for your case. •For a "Clinical Trial Consultation," the standard timeline is: CDE issues a written response by **Day 56**, a consultation meeting around **Day 60** (or mutually agreed date), and final meeting minutes by **Day 70** (or within 10 days after the meeting). •For "IND Prior Assessment" (pre-submission quality/nonclinical or full package check), there is a similar mechanism: written response by about Day 30, meeting around Day 34, and final minutes by Day 44 (or 10 days after meeting) — depending on the schedule. ◆ **Fees & subsidization** •The consultation services are generally **fee-charging** ("paid consultations"). •There is a "strategic discussion fee" (currently **NT$30,000**) payable at the start; this fee may be **deductible** from the second-stage consultation fee (one deduction per case). •For certain applicants — e.g., academic institutions, public research institutes, or medical institutions — consultations for Phase I (including preclinical) and Phase II clinical trial may be **fully subsidized** (i.e., no fee). ◆ **Importance of including consultation record in formal submission** •If you used consultation, you are expected to **reference the consultation history / case number** in your formal IND/CTA application to TFDA, and **attach the written consultation response and meeting minutes** as part of the submission package. This helps the regulator see that pre-submission issues have been resolved.	Yes Can consult at FDA (Such as direct contact, telephone, official letter)	No There is no official consultation in place; however, sponsors can send letters to the Administration of Science Technology and Training under the Ministry of Health in order to request consultation.

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IND/CTA	Flow of clinical trial notification, IND application and IRB permission	· Communication and exchange meeting for new drugs can be applied before 1st IND submission in principle, except some special conditions which listed in the guidance of No.48 of 2020. · No mandatory requirement to complete IRB review prior IND submission · IRB review should have been completed before clinical trial started, Products apply for the 30-day pathway for drug clinical trial applications must complete IRB prior to submitting the clinical trial application (https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20240731184417109.html).	Parallel submission to Department of Health (DH) and Ethics Committee. Both approvals needed.	Clinical trial on new drug shall be initiated after approval by CDSCO in Form CT-06 (NOC: No Objection Certificate from DCGI) after positive opinion from Subject Expert Committee (SEC) or by IND Committee in case of IND application and approval of respective Institutional/ Independent Ethics Committee (EC). In case of parallel applications, CDCSO & respective EC will grant conditional approval and note that the trial should only start after CDSCO and EC approval. Vide Notice dated October 27, 2025, CDSCO made a provision for filing Post Approval Changes pertaining to Clinical Trials (Form CT-06) for cell and gene therapeutic products through the SUGAM Online portal system. The same has also been made functional.	Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval Refer to BPOM regulation No 24 Year 2025 for 1st CTA under IND Approval Process	A clinical trial is conducted based on the notification, and not based on an application. Contracts with clinical sites should be signed after 30 days from the date of clinical trial notification (14 days from the second trial onwards).	IRB approval is required before or after MFDS approval. In addition, parallel application is allowed. Clinical trials can be initiated after both of MFDS and IRB approvals.	A CTIL from the Drug Control Authority (DCA) authorising the licensee to import a product for purposes of clinical trials is required. All the clinical trials that require CTIL/ CTX must be registered with NMRR (National Medical Research Register). NPRA will only accept favorable opinion/ approval issued by EC that is registered with the DCA. Malaysian Guideline for Application of CTIL and CTX 8.1th Ed (Effective on 30 April 2025) [§ 5.1 and S5.2]. Note: The process flow also includes First-In-Human Clinical Trials (S5.2). History of Minor Revision Malaysian Guideline for Application of CTIL and CTX 8.1th Ed	In March 2020, FDA issued a streamlined process in obtaining approval for Clinical trials. The process begins with the screening of application by FDA for completeness. If accepted, FDA forwards it simultaneously to Regulatory Reviewers and the Scientific Advisory Committee; FDA makes the final decision based on their recommendations. Ethical review approval is not a prerequisite for FDA application, and may be done in parallel with FDA review. (Administrative Order No. 2020-0010)	Under the Health Products Act and its subsidiary legislation, the Health Products (Clinical Trials) Regulations, and require either Clinical Trial Authorization (CTA) or acceptance of Clinical Trial Notification (CTN) prior to initiation of the clinical trial. There are three clinical trial submission routes (CTC, CTA and CTN) Clinical trials of therapeutic products (e.g. pharmaceutical drugs and biologics) require Clinical Trial Authorization (CTA) or acceptance of Clinical Trial Notification (CTN) before the trial can be initiated or conducted. Such clinical trials must be conducted in compliance with the Health Products (Clinical Trials) Regulations and the ICH E6 Good Clinical Practice guidelines. Clinical trials of medicinal products (e.g. cell, tissue and gene therapy products or complementary health products) require a Clinical Trial Certificate (CTC) before the trial can be initiated or conducted. Such clinical trials must be conducted in compliance with the Medicines (Clinical Trials) Regulations and ICH E6 Good Clinical Practice guidelines. For clinical trials that require Clinical Trial Authorization (CTA) or a Clinical Trial Certificate (CTC), the clinical trial application may be submitted concurrently to HSA and the relevant IRB. For clinical trials that require Clinical Trial Notification (CTN) to HSA, the submission should be made only after having received IRB approval for the clinical trial.	Flow of Clinical Trial Application: https://www.cde.org.tw/drugen/25797/26014/26039/26041/26043/normalPost IRB permissions are posted onto the individual IRB website. Flow will vary among different IRBs. For instance, the IRB process of China Medical University Hospital is posted on https://www.cmuh.cmu.edu.tw/Department/CustomPage/530. However, there is no English version of the flow. In summary: the process involves **preparing the application (CMC/ nonclinical/clinical protocol), submitting to CDE/TFDA (online), obtaining IRB (or c-IRB) approval in parallel, and then — once both regulatory and ethics approvals are in hand — the trial can commence**. However, some sites request a fully executed contract with the institution to be one of the required document to start a clinical trial.	Clinical Trial Authorization: There are flexible GMP requirements For example: - For drugs registered abroad, evidence like the NRA website page can be used with GMP certificate not required, but it must be verified that the registration is for the same strength, form, and manufacturing source as the drug used in the clinical study - QP Declaration is accepted for Phase 1 clinical studies. Refer to Thai FDA Notification Re: Standard, Application Submission and Reporting to drugs for Clinical Research Studies to provide data for drug registration, dated 8 Jan 2025. (cited 2025 FEB 3 media.php) Submission Fee: Refer to Ministerial Notification, dated 8 Nov 2023 (cited 2025 FEB 3 media.php) Initial review fee: 1,000 THB Expert review fee: 30,000 THB (Initial application) 2,000 (Amendment) Consultant fee: 2,000 THB per hour	In short: Clinical trial notification, then Hospital IRB permission, IND application and MOH IRB approval. Clinical trial should be submitted to Site level first. After receiving IRB/ EC approval at site level (For some Hospitals under Department of Health, the hospital should get approval from MOH and People's Committee before submitting it to HA), we can continue submission to health authority (HA). The CT can be initiated after getting HA's, in this case the Ministry of Health's, approval. Import License (IL) in only obtained after having HA approval.

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IND/CTA	Time required for clinical trial notification, IND application and IRB permission obtainment Official timeline (working days) if it is announced.	Implied permission system for clinical trial: -If no comments from CDE since IND submission accepted in 60WDs, clinical trial can be started. -If any queries from CDE, response should be submitted within 5WDs. Otherwise, another round of 60WDs is needed. The NMPA implements pilot to complete the review and approval of innovative drug clinical trial applications within 30WD. The pilot work started from August 2024 and completed in July 2025. Source: National Medical Products Administration on Issuing the Pilot Work Plan for Optimizing the Review and Approval of Clinical Trials of Innovative Drugs https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20240731184417109.html Based on the experience of the above-mentioned pilot work, the NMPA implemented 30 working days for eligible innovative drugs from Sep 2025. Source: Announcement of the National Medical Products Administration on Optimizing the Clinical Trial Review and Approval of Innovative Drugs https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20250912092255131.html	**IND application**: "stop-clock mechanism" Not require consideration by Committee:45 working days for DH processing and cumulative 45 working days maximum for response by applicant Require consideration by Committee: 60 working days for DH processing and cumulative 60 working days maximum for response by applicant **IRB permission:** 30-60 days. Hospital Authority streamlines clinical research approval to promote medical research development https://www.info.gov.hk/gia/general/202507/31/P2025073100376.htm	EC review – 14 to 60 days (depending on the Institutional EC meetings timelines, industry experience). NDCT Rules 2019 has provisions on deemed approval if no communication is received from Central Licensing Authority within 30 working days for drugs discovered, researched, and manufactured in India and 90 days for drugs developed outside India (already approved and marketed in specified countries).	CTA: Timeline for evaluation is 20 working days for protocol & amendment of clinical trial after NADFC stated the protocol & amendment complete IND: Timeline for evaluation is 100 working days (first CTA approval). For protocol & amendment of clinical trial refer to CTA regulation.	The from the first clinical trial notification" rule applies for drugs containing new active ingredients, new ethical combination drugs and drugs with a new administrative route. Clinical trials can be started 14-days after the clinical trial notification from the second trial onwards (for the same product).	In principle, the review of an IND application takes 30 working days. Queries can be given by MFDS up to 2 times. In case of queries given, it would take 2-3 months or more. - The deadline for answering first queries is basically 30 calendar days and can be extended up to 2 times if there are proper reasons. (the deadline is 30 calendar days at a time). - The deadline for answering second queries is 10 calendar days IND approval by MFDS and IRB review can be got in parallel. Based on individual application (level of document), the requirements of query, expected period and additional document can vary.	Official Timeline for CTIL/CTX: * Normal: 45 working days for FIH clinical trials, as well as clinical trials involving biologics, CGTPs and herbal products with unapproved claim. For FIH clinical trials, this timeline includes the review time taken by external Panel of Expert(s). • 30 workings days for all products except those products mentioned above. **Fast Track: • 22 working days for clinical trials involving biologics, CGTPs, and herbal products with unapproved claim. • 14 working days for all products except those products mentioned above.Malaysian Guideline for Application of CTIL and CTX 8.1th Ed (Effective on 30 April 2025) [§ 5.2]. The IRB/IEC should review a proposed clinical trial within a reasonable time. MalaysianGuidelineforGoodClinicalPractice.pdf § 3.1.2 (GCP 4th Edition) IRB/IEC approval: Complete submission without queries can be approved within 4 to 8 weeks. In Malaysia, regulatory and ethical submissions are done in parallel. Regulatory approval takes approximately 30 business days while MREC ethics approval takes about 50 business days. Ethical review and approval can be as short as one month from the time of application if there are no issues/ queries. On average, it takes about four months to obtain regulatory and ethics approval. **• https://www.crc.gov.my/general-clinical-trial/** **• https://clinicalresearch.my/establishing-clear-procedures-and-improving-start-up-timeline-in-malaysias-clinical-research-ecosystem/** **1.** Notes: * Does not include review time by external panel of reviewers for First-In-Human Clinical Trials. ** For treatment/ prevention in pandemic/ endemic /public health interest. Does not include First-In-Human Trials	The purported timeline is 40 days for the whole process. https://www.fda.gov.ph/wp-content/uploads/2023/08/K.pdf	The timing will depend on which of the three clinical trial submission routes (CTC, CTA and CTN). Clinical Trial Certificate (CTC) and Clinical Trial Authorisation (CTA): 30 working days. Note: 60 working days for cell, tissue, and gene therapy products Clinical Trial Notification (CTN): 5 working days. Clinical Research Materials Notification (CRM): Immediate Reference: GN-IOCTB-04 Rev. No. 004 REGULATORY REQUIREMENTS FOR NEW APPLICATIONS AND SUBSEQUENT SUBMISSIONS Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pdf	For the case of standard IND application, the review timeline is 45 calendar days after submission. For the protocol with same protocol number is submitted in A10 countries simultaneously, accelerate review (Fast track system is not applicable for First in Human Study) is available and the review timeline is 15 calendar days after submission. IRB review timeline depends on each IRB review meeting frequency. The approval time may take around 1-4 months. Link to IND Review Time and Process Process / Official Timeline / Regular process for most trials Standard IND Review / 45 calendar days / Regular process for most trials Accelerated A10 IND Review / 15 calendar days / Simultaneous submission in A10 countries required. If the FIH protocol is submitted in the US and Taiwan at the same time, it is eligible for accelerated review. c-IRB Main Review / 20 working days / For multi-center trials c-IRB sub-IRB review / 10 working days / After main IRB approval Institutional IRB Review / Not fixed (1-3 months) / Depends on each hospital	Clinical Trial Authorization official evaluation timeline (Initial) **Type of Clinical Research Studies** / **Timeline (WD)** Study category A (low risk or no greater risk than standard care) / 1 Study Category B (intermediate risk or higher risk than standard care) / 1 Study Category B (intermediate risk or higher risk than standard care) with Reliance - Assessment Report from SRA / 2 Study Category C (high risk or substantially higher risk than standard care) with Reliance - Assessment Report from SRA / 25 Study Category C (high risk or substantially higher risk than standard care) for Phase 3 research for all types of drugs, which attached Phase 1 and 2 research information and researcher certification regarding ethnic factors (excluding ATMP) / 30 Study Category C for Phase 1 and 2 research for all types of drugs (excluding ATMP) / 50 Study Category C for ATMP / 70 Public Emergency / 20 Amendment of Clinical Trial Authorization (Sor Yor 2) / 30 Time for the sponsor to respond to the inquiry (excluded from the evaluation timeline): • Screening process: 14 days • Evaluation process: 7+7 days Refer to Public Manual: Assessment for Approval of Clinical Trial Studies Applications and Applications for Amendments to Clinical Research Studies (Drugs) (cited 2025 DEC 11 media.php) and Thai FDA Notification Re: Standards, Licensing Requirements, and Reporting Obligations Related to Drug Research Conducted to Support Drug Registration (cited 2025 DEC 11 media.php) IRB: (each study site or EC of MOPH) - Institute EC 2-3 months - Central EC: CREC 5-6 months EC-MOPH 7-8 months.	**Registering a clinical trial**: -5 working days for ASTT to verify legality of the application -60 days for applicant to respond if needed to further complete application -5 working days after receipt of eligible application, for ASTT to grant written approval **Approving a clinical trial**: -5 working days for ASTT to verify legality of application -60 days for applicant to respond if needed to further complete application -25 days after receipt of eligible application, ASTT to meet with National Biomedical Ethics Committee and a record on clinical trial outline assessment shall be made -5 working days after receipt of record by National Biomedical Ethics Committee, ASTT submits complete application to MOH Minister for approval (if clinical trial needs correcting, applicant has 90 days)

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IND/CTA application materials	Application form If application form is needed, input “Yes” and describe country specific requirements (if any) and its language	Yes (in Chinese)	Yes, in English. PIs refer to below link for full requirements: Guidance Notes on the Application for Certificate for Clinical Trial/ Medicinal Test Version September 2025 https://www.ppbhk.org.hk/eng/doc/guidelines_forms/Guidance_Notes_en_Version.pdf?v=y921tf	Yes, Application form is in English language and is called Form CT-04	Yes There is a checklist requirement CTA: Refer to BPOM regulation No.8 Year 2024 about Procedure of Clinical Trial Approval, annex I IND: Refer to BPOM regulation No 24 Year 2025 for CTA under IND Approval Process, annex 2	Since September 2022, the new form, including the description of Drugs used in the Clinical Trial, has been fully implemented.	Yes IND application can be made through “nedrug web site (https://nedrug.mfds.go.kr/index).” The format of Application form should be written in Korean.	Yes Application form must be filled in English or Bahasa Melayu. (The documentation/ requirements details are provided in the Malaysian Guideline for Application of CTIL and CTX.)	Yes Form is available in the FDA website. It is in English.	Application for Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate to HSA through PRISM.	Yes Yes. In Taiwan, the official IND/ CTA application form is issued in Chinese. However, applicants may complete the content of the form in English, and TFDA accepts English entries within the Chinese-format application.	Yes Local form (in Thai) The Application form is available to complete via e-submission system. Form is changed from NorYorMor1 to Sor Yor1	Yes, in Vietnamese or in English (Article 11, Circular 12/2025/TT-BYT)
	A statement regarding the reason why the sponsoring of the proposed clinical trial is scientifically justified	Yes (in Chinese)	Not required	Yes	Yes Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval Using Indonesian or English language	Yes (in Japanese)	Yes (in Korean)	Yes (in English or Bahasa Melayu)	Yes in English	No	Yes The official letter to indicate the sponsoring of proposed clinical trial is needed.	No	No
	Protocol If protocol submission is needed, input “Yes” and describe its language	Yes (in Chinese) Protocol or draft protocol is needed	Yes, in English	Yes (in English)	Yes Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval Using Indonesian or English language	Yes (in Japanese)	Yes The protocol must be written in Korean. The protocol written in English, however, is acceptable in case of phase 1 study.	Yes (in English or Bahasa Melayu)	Yes in English	Yes, in English	Yes Either the Chinese or English version is acceptable. The Chinese synopsis is required	Yes Guideline available, can be in Thai or English	Yes Protocol is mandatory in VNM and ENG. MOH EC members refer to ENG version to verify information.
	IB if IB is needed in the CTA/IND application, input “Yes” and describe its language	Yes (in Chinese)	Yes (in English) For Phase IV trials, HK registered pack insert can be used.	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval	Yes (in Japanese)	Yes. (in Korean) In case of foreign language, the original document can be required to translate in Korean (not mandatory)	Yes (in English or Bahasa Melayu)	Yes in English	Yes, in English	Yes Either the Chinese or English version is acceptable.	Yes Guideline available (for unregistered drug in Thailand)	Yes In Vietnamese Or in English accompanied by a summary in Vietnamese
	CRF (sample) if CRF template (blank form) is needed in CTA/ IND application, input “Yes” and describe its language	No	CRF sample is per individual IRB requirement. This is not required by Department of Health.	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval	If the items to be described in the CRF can be read in the protocol, it is not required.	No CRF template is not necessary for MFDS IND approval.	Yes (in English or Bahasa Melayu)	Yes in English	CRF is not included in submission dossier. It is not a requirement as per HSA guidance document.	Yes Either the Chinese or English version is acceptable.	No requirement	Yes In Vietnamese or in English
	Informed Consent Form (ICF) If sample of Informed Consent Form is needed in the CTA/IND application, input “Yes” and describe its language	Yes (in Chinese)	Either in both English and Chinese, or in Chinese only.	Yes (in English) or vernacular language (as per New Drugs & Clinical Trial Rules, 2019)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval	Yes (in Japanese)	Yes. ICF template must be written in Korean. For foreign subjects, ICF templates written in foreign languages can be used.	Yes (in English or Bahasa Melayu)	Yes in English and Filipino; IC in regional/ vernacular language required as applicable	Yes, in English	Yes (https://www.fda.gov.tw/TC/newsContent.aspx?cid=3&id=30810) In Taiwan, the ICF is generally expected to be provided in Chinese, and CIRB/IRBs typically use Chinese-language templates for review. Regarding ICF amendments, TFDA announced on 14 November 2024 that 41 IRBs are authorized to review and approve ICF amendments for new drug clinical trials from 1 January 2025 to 31 December 2028. For trials reviewed by these authorized IRBs, ICF amendments do not need to be submitted separately to TFDA for approval. Therefore, for the CTA/IND application, the ICF is usually submitted in Chinese, unless the reviewing IRB accepts an English version.	Yes Local form (in Thai)	Yes, in Vietnamese and English (both are mandatory)
	Investigator’s CV	No	English CV of PI.	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval	No	No Information of investigational sites, investigators are required. But, CV itself is not necessary.	Yes (in English or Bahasa Melayu)	Yes in English	CV of PI, in English	Yes For both the Principal Investigator (PI) and any Co-Investigators (Co-I), an investigator’s résumé (CV) may be submitted in either Chinese or English. In Taiwan, the application must also include evidence of GCP and ethics-related training (i.e. the required training hours) to qualify the investigators to conduct clinical trials..	No requirement	Yes, in Vietnamese or English

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IND/CTA application materials	Overall requirement on content if “list of content” or “check list” form is needed in the application, input “Yes”	Yes (in Chinese) Adopt to ICH M4 Module1	Yes	Yes, as described in 5th Schedule of NDCT-19	Yes Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval Using Indonesian or English language	No	Yes The check list form for r equired documents is pr ovided from “nedrug we b site **(https://nedrug. mfds.go.kr/index).”**	Yes (in English or Bahasa Melayu)	NO	No	Yes The check list form for required documents is provided in Chinese. Link to Application Instruction	Yes Checklist form is required in the application	No Application for approval for clinical trial consists of: a) Application form b) Documents containing information about the drug for clinical trial: - Drug trial documents: composition, manufacturing process, quality standard and drug test report (in the case of a modern drug, herbal drug or traditional drug, it is required to have a drug test report of the state-owned drug-testing facility that complies with GLP or provider of drug/medicinal ingredient testing services that complies with GLP within its scope of operation or of the manufacture that complies with GMP; in the case of a vaccine, it is required to have a quality test report of the National Institute for Control of Vaccine and Biologics or Certification of analysis in the case of a batch of vaccines and biologics); - Documents about pre-clinical trial of the drug that needs to be tested: reports on pharmacological effects, toxicity, safety, proposed dose, administration route and directions for use; - Documents about the clinical trial in previous phases (if the trial facility applies for permission for clinical trial in the next phases and the drug is not exempt from clinical trial in previous phases). c) Legal documents about the drug for clinical trial: - A copy of the written approval for registration of the clinical trial granted by the Administration of Science Technology and Training, the Ministry of Health. - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the application form for permission for phase 4 clinical trial submitted by the competent pharmacy authority if the drug is requested to undergo phase 4 clinical trial; - Package insert of the drug licensed for free sale if the drug is requested to undergo phase 4 clinical trial; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the trial facility’s certificate of eligibility for pharmacy business; - A confirmation of participation provided by the trial centers if a multicenter trial is conducted in Vietnam; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the written approval for participation in the trial granted by the People’s Committee of the province or central-affiliated city if a field trial is conducted; - A clinical trial agreement between the organization/ individual that has the drug for clinical trial and the provider of clinical trial services; between the organization/individual that has the drug for clinical trial and the trial assistance organization (if any). d) A clinical trial outline and its description: - A description of the clinical trial outline - A Case Report Form (CRF); dd) Principal investigator’s academic résumé and copy of the certificate of completion of GCP training course which is issued by the Ministry of Health or GCP training institution; e) Participant information sheet and volunteer letter g) A record on scientific and ethical assessment prepared by the internal Biomedical Ethics Committee; h) Label of the drug
	Non-clinical summary if non-clinical reports are needed in the IND/CTA, input “Yes”	Yes (in Chinese)	No	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 8Year 2024 about Procedure of Clinical Trial Approval Using Indonesian or English language	No Non-clinical information is included in the IB.	Yes. (in Korean) In case of foreign language, the original document should be attached to the Korean document. GLP data should be acquired from GLP laboratories in OECD member countries. GLP data from non-OECD member countries would be recognized if the results of the inspection from OECD member countries(include Korea) meet the GLP criteria.	Yes Non-clinical information is required in the Investigator’s brochure, in English or Bahasa Malaysia	Yes in English	No	No A separate non-clinical summary document is not required. Non-clinical information should be provided via the Investigator’s Brochure (IB).	No including in IB	No Not applicable (often included in IB) If provided, Vietnamese/English

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IND/CTA application materials	Non-clinical report	Yes (in Chinese)	No	Yes (in English)	Yes	Yes The final non- clinical safety reports are needed in the CTN of First-in-Human, if there are no clinical data on overseas. Language is in English or Japanese.	No If necessary, full report (Korean) can be requested by MFDS.	No	Yes in English	No	No A separate nonclinical report is not required for the IND/CTA application. Nonclinical data are appropriately submitted via the Investigator's Brochure (IB).	No including in IB	No Not applicable (often included in IB) If provided, Vietnamese/ English
	Clinical summary If clinical summary is needed, input "Yes" and describe its language	Yes (in Chinese), if there was any clinical data.	No	Yes (in English)	Yes	No Clinical information is included in the IB.	Yes. (in Korean) In case of foreign language, the original document should be attached to the Korean document.	Yes (in English or Bahasa Melayu)	Yes in English	No	No A separate "Clinical Summary" document is not required for a standard IND/CTA application in Taiwan. The required submission package should include the trial protocol (with Chinese and/or English summary), but there is no separate standalone clinicalsummary document mandated.	No including in IB	No NA If provided, Vietnamese/ English Clinical summary is often included in Protocol and IB.
	Clinical report	Yes (in Chinese) If there was any previous clinical date, or conduct clinical trial in other countries or the products has been marketed, the applicant should provide the whole clinical trial date, including the original and Chinese translation materials. After being approved to conduct clinical trials of drugs, the applicant shall submit regularly updated reports on safety during the period of clinical research to CDE.	Not required	Yes (in English)	Yes	No	No If necessary, full report (Korean) can be requested by MFDS.	No	Yes in English	Yes, HSA would require local sponsor to submit the final CSR 1 year from local LPLV, unless otherwise aligned. Sponsors also need to submit trial status report of the trial to HSA every 6 monthly, and whenever there is a change of study status (e.g. trial initiation, temporary suspension of recruitment, resumption of recruitment etc.); for IRB usually annually) Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pd	**No.** A formal *clinical report* is **not required** for IND/CTA applications in Taiwan. **Explanation:** At the IND/CTA stage, the Taiwan Food and Drug Administration (TFDA), with technical review by the Center for Drug Evaluation (CDE), requires submission of the **clinical trial protocol, investigator's brochure, nonclinical data, and CMC information**. These documents demonstrate the scientific rationale, patient safety considerations, and trial feasibility. A *clinical report* only becomes relevant **after the trial is completed**, when results are submitted as part of later regulatory filings such as a New Drug Application (NDA).	No including in IB	No NA. it is often included in IB
	CMC summary	Yes (in Chinese)	Not required	Yes (in English)	Yes	No	Yes. (in Korean) In case of foreign language, the original document should be attached to the Korean document.	Yes (in English or Bahasa Melayu)	Yes in English	CMC information is included in the submission dossier, only if requested by HSA (only for CTA and CTC applications) Specifically for CTGTP, if requested by HSA, IMPD of CTGTP IND needs to fulfil the requirements stipulated in Appendix 8: Chemistry, Manufacturing and Controls Requirements for Cell, Tissue or Gene Therapy Products for Clinical Trials and Product Registration. cmc-requirements-for-ctgtp-for-clinical-trials-and-product-registration.pdf	**Yes.** A **CMC (Chemistry, Manufacturing, and Controls) summary is required** as part of IND/CTA applications in Taiwan. **Explanation:** For IND/CTA submissions, the Taiwan Food and Drug Administration (TFDA), with technical review by the Center for Drug Evaluation (CDE), requires applicants to provide sufficient information to demonstrate the **quality, safety, and consistency of the investigational product**. This includes a **CMC summary** covering drug substance and drug product manufacturing, control methods, stability data, and packaging. The CMC section ensures that the investigational drug can be reliably produced and is suitable for use in clinical trials. Without this summary, TFDA cannot adequately assess whether the investigational product meets regulatory and patient safety standards.	Yes See detail in guideline (for NCE)	Yes (IMPD, CoA, SmPC, label…) English/Vietnam
	CMC report	Yes (in Chinese)	Not required	Yes (in English)	Yes	No	No If necessary, full report (Korean) can be requested by MFDS.	Yes (in English or Bahasa Melayu)	Yes in English	No	**No.** A formal *CMC report* is **not required** for IND/CTA applications in Taiwan. **Explanation:** At the IND/CTA stage, the Taiwan Food and Drug Administration (TFDA), with technical review by the Center for Drug Evaluation (CDE), requires submission of a **CMC summary**, not a full CMC report. The summary must cover essential information on the **drug substance and drug product manufacturing, analytical methods, stability data, and packaging** to demonstrate that the investigational product can be consistently produced and is suitable for clinical use. A detailed *CMC report* is only expected at later stages of development (e.g., NDA/MAA), when comprehensive quality documentation is needed to support marketing authorization.	Yes See detail in guideline (for NCE)	Same as CMC summary

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IND/CTA application materials	GMP certificate of the investigational drug	For IND of IMCT which import drug isn't marketed abroad, GMP certificate is not required, GMP statement is acceptable. For CTA of 5 category of import drug, GMP certificate is required. CDE Guidelines for Acceptance and Review of Chemical Drug Registration (No.10, 2020)	Yes, also need to have GMP cert of placebo if applicable	Yes	Necessary	No	Yes GMP certificate is necessary. If GMP certificate is not acquired or available, QP (Qualified Person) declaration letter should be submitted instead of GMP certificate.	Yes (Copy of Certificate of GMP Compliance for the manufacturer of drug product and/or final/ batch releaser only should be submitted.)	Yes in English	GMP certificate required for CTA and CTC applications. The requirements differ as per the local registration and sourcing of the product, also if its Biological and biotechnology product and Class 2 CTGTP, additional GMP certificate is required to certify that the manufacture of the drug substance is in compliance to GMP standards. Reference: GN-IOCTB-04 Rev. No. 004 REGULATORY REQUIREMENTS FOR NEW APPLICATIONS AND SUBSEQUENT SUBMISSIONS Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pdf	**Yes.** A **GMP certificate of the investigational drug is required** as part of IND/CTA applications in Taiwan. **Explanation:** The Taiwan Food and Drug Administration (TFDA), with technical review by the Center for Drug Evaluation (CDE), requires applicants to submit documentation demonstrating that the investigational product is manufactured in compliance with **Good Manufacturing Practice (GMP)** standards. This ensures the **quality, consistency, and patient safety** of the drug product used in clinical trials. The GMP certificate (or equivalent documentation) is part of the **CMC section** of the IND/CTA dossier, alongside manufacturing process descriptions, analytical methods, and stability data. Without this certificate, TFDA cannot verify that the investigational drug meets the regulatory requirements for trial use.	Yes, but in case of Phase 1 clinical studies, they are exempt from GMP inspection. A self-declaration letter by the Qualified person who is responsible for the quality assurance system can be accepted. (cited 2025 FEB 3 media.php)	Yes Necessary
	Sample of the investigational drug (for IND review) if the sample of the investigational drug is needed in the IND/CTA application, input "Yes"	Not mandatory requirement, depends on if CDE has further requirements of sample testing	Sample not required, but a sample certificate of analysis of the drug and/or placebo is required.	Samples are requested only for Vaccine CTA applications. Samples are requested only at the time of IND application for other pharmaceutical products	No Product Information of investigational drug, CoA of investigational drug, Summary Batch protocol (Three consecutive batches)à only for Vaccine, Lot release only special for vaccine.	No	No The sample of investigational product is not required.	No Sample NOT required, but a sample certificate of the analysis of the drug is required.	NO	No	**No.** A **sample of the investigational drug is not required** as part of the IND/CTA application in Taiwan. **Explanation:** For IND/CTA submissions, the Taiwan Food and Drug Administration (TFDA), with technical review by the Center for Drug Evaluation (CDE), requires applicants to provide **documentation**—including the clinical trial protocol, investigator's brochure, nonclinical data, and a **CMC summary with GMP certificate**—to demonstrate the investigational product's safety, quality, and consistency. However, **physical samples of the investigational drug are not part of the standard IND/CTA dossier**. TFDA reviews the submitted data rather than testing the product itself at this stage. Drug samples may be requested later in the development process (e.g., during inspections or marketing authorization review), but they are **not a routine requirement for IND/CTA review**.	No No requirement	No Minimal required is label mockup. Dossier still can be submitted without pictures.

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NDA	Requirement for MAH, applicant for import drugs	According to new issued Drug Administration Law, -Drug Marketing Authorization Holder (MAH) refers to enterprises or R&D institutions which hold a drug approval license. -Where the MAH is an overseas enterprise, the enterprise legal person within the territory of the People's Republic of China shall be designated to fulfill the obligations of the MAH and assume the joint liability of the MAH together.	The local subsidiary can be the MAH, while foreign company cannot be the MAH.	MAH is to be defined at the time of Import License application	Multi- National company and domestic pharmaceutical company having manufacturing license can register. Imported drug that will be registered as NDA in Indonesia is prioritized for national health program, new active substance and drug which can't be produced locally	Only the marketing authorization applicant (MAA) / holder (MAH) of pharmaceutical products may submit an NDA.	The MAH must be a locally incorporated company, corporate or legal entity in Korea. It should have importation business license from MFDS according to Article 42 of "Pharmaceutical Affairs Act"	The Product Registration Holder (PRH) must be a locally incorporated company, corporate or legal entity, with permanent address and registered with Companies Commission of Malaysia (with the scope of business related to the health/ pharmaceutical product). [DRGD § 5.1]	FDA-licensed Drug Manufacturers, Traders, Distributors Any establishment that intends to import, distribute, sell, or offer for sale any imported drug product must first secure a License to Operate (LTO) as Drug Importer. (Administrative Order No. 2024-0013 (https://app.doh.gov.ph:1024/Rest/GetFile?id=791578) and 2024-0015 (https://app.doh.gov.ph:1024/Rest/GetFile?id=810956))	MAH holder must be a Company which is based and registered in Singapore.	**Yes.** For **imported drugs in Taiwan**, the **Marketing Authorization Holder (MAH) / applicant must submit a New Drug Application (NDA)** in order to obtain product registration and market approval. **Explanation:** •In Taiwan, the **MAH is the legal entity responsible for drug registration and postmarketing obligations**. For imported drugs, the MAH must be a locally registered company or its designated representative. •To place an imported drug on the Taiwan market, the MAH must file an **NDA with the Taiwan Food and Drug Administration (TFDA)**. This NDA includes comprehensive documentation: quality (CMC), nonclinical, and clinical data, along with GMP certificates and labeling information. •The NDA requirement applies regardless of whether the drug is developed domestically or imported. IND/CTA approval alone only permits clinical trial conduct; it does not grant marketing authorization. •Therefore, for imported drugs, the **MAH/applicant must complete the NDA process** to secure TFDA approval before the product can be sold or distributed in Taiwan.	The local subsidiary can be the MAH and a foreign company cannot be the MAH. (Drug Act, B.E. 2510 Section 14)	The following entities may register drugs/medicinal ingredients: a) Any establishment having a license for manufacturing, wholesaling, exporting, importing drugs/medicinal ingredients in Vietnam; b) Any foreign establishment having a license for manufacturing, wholesaling, exporting, or importing drugs/medicinal ingredients in local country and having a representative office license in Vietnam.
	Acceptance of CTD format	ICH CTD format is mandatory for NDA application of both chemical drug and biological products since 1st Oct,2020	CTD is needed for registration of NCE.	Currently applications need to be submitted through online SUGAM portal and CTD sections can be uploaded as is under respective checklist as per the Sugam checklist.	ACTD (article 27 Drug Registration Guideline No. 24 year 2017) In practical, Both ICH-CTD format and ASEAN CTD (ACTD) format are acceptable by BPOM.	ICH-CTD format V4.0 was implemented on April 1, 2025	According to Article 6 of "Regulation for Approval, Notification and Review for Drugs," CTD format for MA is acceptable for any drug approval. For prescription drugs which includes new drugs, and drugs that require safety & efficacy review, CTD format is mandatory	The online product registration application is based on the ASEAN CTD format. ICH format accepted with some reformatting for uploading into the online system which is structured in ACTD format (presently no change of title/ numbering required)	FDA accepts NDAs following ASEAN and ICH CTD format. However, certain sections in the ICH-CTD should still comply with the ASEAN harmonized requirements. (Administrative Order No. 2013-0021, FDA Circular No. 2020-026, Registration of Pharmaceutical/Drug Products Frequently Asked Questions (FAQs) Version 3.0)	ACTD or ICH-CTD	**Yes.** The **Common Technical Document (CTD) format is required** for NDA submissions in Taiwan. **Explanation:** •The Taiwan Food and Drug Administration (TFDA) has formally adopted the **ICH CTD format** for New Drug Applications (NDA). •Applicants must structure their dossiers according to the **five CTD modules**: ◦ Module 1: Administrative and prescribing information (Taiwanspecific requirements). ◦ Module 2: Summaries (quality, nonclinical, clinical). ◦ Module 3: Quality (CMC). ◦ Module 4: Nonclinical study reports. ◦ Module 5: Clinical study reports. •This harmonization aligns Taiwan with international standards (ICH guidelines), facilitating regulatory review and global development strategies. •While **Module 1 is countryspecific**, the overall dossier must follow CTD formatting. TFDA will not accept NDA submissions outside of CTD structure.	Effective from 15 Feb 2023, all applications must be in eCTD or NeeS format.	ACTD and ICH-CTD format (however, currently online registration system only allows structure in ACTD format for NDAs)

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NDA	Implementation of eCTD format (timing, required or optional)	As of 29 December 2021, marketing authorization applications for Category 1 and Category 5.1 chemical drugs, as well as Category 1 therapeutic biological products and Category 1 preventive biological products, may be submitted in the eCTD (electronic Common Technical Document) format. To ensure the steady implementation of the eCTD system and to minimize potential impacts on regulatory submissions, applicants for the above-mentioned registration applications may still opt to use the existing submission formats for registration applications. — Announcement of the National Medical Products Administration on the Implementation of Electronic Common Technical Document (eCTD) Submissions for Drugs (Announcement No. 119 of 2021) https://www.cde.org.cn/ectd/news/viewInfoCommon/4e7e33b3bad573245871870861a8537f As of 27 Jan 2025, the eCTD scope is expanded to IND of chemical drug Categories 1 to 5, NDA of chemical drug Categories 2, 3, 4 and 5.1, IND of biological product Categories 1 to 3, and NDA of biological product Categories 2 and 3, all of which are optional implementation. Source: Announcement of the National Medical Products Administration on Expanding the Implementation Scope of Electronic Common Technical Documentation for Drugs (No. 10, 2025) https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20250123164542175.html NMPA issued Announcement on the Full Implementation of eCTD Submissions for Chemical Drugs and Biological Products, which was published on January 15th, 2026, and takes effect as of March 1st, 2026. https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20260115150651145.html	Not required. No timeline for the implementation of eCTD	Not required	BPOM has their own system (New Aero) for electronic submission, no requirement for eCTD format. As long as it is electronic files it is acceptable as New Aero has specific arrangement (will still need each section uploaded in the system).	eCTD has been implemented since 2005, and v.3.2.2 became mandatory in 2009. V4.0 is scheduled to become mandatory from April 2026 onwards.	Yes. The eCTD format is available for regulatory submissions in Korea. eCTD v3.2.2 has been implemented since 2016, and its use is currently optional. MFDS also plans to introduce eCTD v4.0 with a voluntary period starting in 2027, with the mandatory implementation date yet to be announced.	NPRA has no plans for implementation of eCTD format currently.	There is no legislation implementing the use of eCTDs yet.	1 April 2026 (targeted implementation), Optional	**Yes.** 2020 onward: TFDA published eCTD technical specifications and validation guidelines, with industry consultation and pilot use. January 1, 2026: For new drug applications (new substances, biologics, new indications, new dosage forms, new combinations, new strengths / dosages), electronic submission becomes mandatory. TFDA accepts either eCTD or transitional eSubmission. Paper dossiers are no longer accepted. July 1, 2027: For those same categories, only eCTD format is accepted. The transitional eSubmission option is discontinued. Other submission (variations, renewals): TFDA may allow transitional acceptance for a limited time, but the long-term direction is full eCTD compliance. In short: Mandatory electronic submission begins January 1, 2026; mandatory eCTD format begins July 1, 2027. [Additional background] 2014-2019: TFDA did not yet implement eCTC. This period was focused on planning, studying international practices (FDA, MEA), and preparing technical frameworks. 2020: TFDA officially released eCTD specifications and validation guidelines, initiating pilot use and stakeholder consultation. 2026: Mandatory electronic submission begins (eCTD or eSubmission). 2027: Mandatory eCTD format only.	Effective from 15 Feb 2023, all applications must be in eCTD or NeeS format.	No plan for implementation

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NDA	Category of NDA	The registration classification of chemical drugs includes ・Cat.1: Innovative drugs that are not marketed overseas and domestically; ・Cat.2: Modified new drugs that are not marketed overseas or domestically; ・Cat.3: Generic drugs applied by domestic applicant, with a drug that has been marketed overseas but not marketed domestically; ・Cat.4: Generic drugs applied by domestic applicant, with an innovative drug that has been marketed domestically. ・Cat.5: Domestic applications for drugs overseas marketed. Refer to Registration Classification and Requirements for Application Dossiers of Chemical Drugs (2020 No.44) for details. The registration classification of biological products includes ・Preventive biological products ・Cat.1: Innovative vaccines; ・Cat.2: Modified vaccines; ・Cat.3: Domestically or overseas marketed vaccines ・Therapeutic biological products ・Cat.1: Innovative biological products; ・Cat.2: Modified biological products; ・Cat.3: Domestically or overseas marketed biological products Refer to Registration Classification and Requirements for Application Dossiers of Biological products (2020 No.43) for details.	Four categories: 1. New Chemical Entity (NCE) including new biological entities 2. Generic (i.e. drug substance already registered at Department of Health (DOH) 3. Biosimilar 4. Advanced Therapeutic Product (ATP)	New Drug: 1) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent has not been approved as safe and efficacious by DCGI with respect to its claims; or 2) a drug approved by the CLA for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or 3) a fixed dose combination of two or more drugs, approved by CLA separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or 4) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by DCGI; or 5) a vaccine, r-DNA derived product, living modified organism, monoclonal antibody, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug; NOTE: The drugs, other than drugs referred to in sub- clauses (4) and (5), shall continue to be new drugs for a period of four years from the date of their permission granted by the DCGI and the drugs referred to in sub- clauses (iv) and (v) shall always be deemed to be new drugs; Ref: Rule 2 (w) - NDCT Rules, 2019 [Gazette Notification G.S.R 227(E) dated March 19, 2019]	Article 5 ,Drug registration Guideline No.24 year 2017: New Registration consist of : a. Category 1: New Drug and Biological Product registration including Biosimilar Product. b. Category 2: branded generic / generic product. c. Category 3: Registration of other dosage form with special technology, example transdermal patch, implant and beads.	For New Drugs: New Drug Application (NDA) and supplemental New Drug Application (sNDA), Generic drug application.	For New drugs, Biologics, Advanced biopharmaceutical drugs, Drugs for Safety & Efficacy Review and Generics drugs application.	**1. New Drug Products** **a. New NCE** **b. Hybrid NCE** **2. Biologics** **a. Vaccines** **b. Blood products** **c. Monoclonal Antibodies** **d. Recombinant proteins** **e. Cell and gene therapy** **3. Generics** **4. Health Supplements** **5. Natural Products** **6. Veterinary Products** [DRGD Section A.3]	In the recently released new drug registration guidelines, FDA has recategorized its NDA into New Pharmaceutical Product Application (NPPA) to cover the following: New pharmaceutical product application (NPPA) / New biological pharmaceutical product application (NBPPA) (1) NPPA/NBPPA-1: For the first strength of a product containing a new chemical or biological entity. This means the entity is currently not registered in the country or with any reference drug regulatory authority (RDRA). (2) NPPA/NBPPA-2: For the first strength of a product containing: (a) New fixed-dose combination of registered chemical or biological entities. This means the fixed-dose combination is currently not registered in the country or with any RDRA. (b) Registered chemical or biological entities with any of the following conditions or changes not previously approved for any reference pharmaceutical product and do not fall under post-approval changes/ variations: (i) in new dosage forms, such as tablets, capsules, and injectables; (ii) in new presentation, such as single-dose vials and pre-filled syringes; (iii) in new formulation, such as preservative-free; (iv) for use by a new route of administration; and (v) for a new indication, dosage recommendation, or patient population. (c) For products that do not fall under NPPA/ NBPPA-1, NPPA/ NBPPA-3, or generic pharmaceutical product application (GPPA). (3) NPPA/NBPPA-3: For subsequent strengths of a product that has been registered through an NPPA/NBPPA-1 or NPPA/NBPPA-2. The product name, dosage form, presentation, indication, dosing regimen, and patient population should be the same as that for the NPPA/NBPPA-1 or NPPA/NBPPA-2 submission. (Administrative Order No. 2024-0013)	NDA-1 for the first strength NCE and biological entity. NDA-2 for new combination, new dosage form, new route of administration or new indication of registered chemical and biological entities. NDA-3 for subsequent strengths of a new drug product. GDA-1 for the first strength of a generic chemical product. GDA-2 for subsequent strengths of the generic chemical product.	New Drug I: (1) New chemical entity (2) New therapeutic area (3) New combination (4) New administration route New Drug 2 (1) New dosage form (2) New usage dose (3) New unit dose Biological products: genetically engineered drugs (including biosimilars), vaccines, drugs derived from human blood and plasma, allergenic products, others. Radiopharmaceuticals https://www.cde.org.tw/drugen/25797/26014/26084/26086/26092/normalPost Link to NDA Application Instruction	Modern Medicine 1.1) New Drug 1.1.1) Biologics 1.1.2) Radioactive 1.1.3) New Chemical Drug NCE = New Chemical Entity, NI = New Indication, NCO = New Combination, ND = New Delivery system, NR = New Route of administration, NDOS = New Dosage form of Approved New Drug, NS = New Strength of Approved New Drug 1.2) Generic Drug 1.2.1) required bioequivalent 1.2.2) not required bioequivalent	(Law 105/2016/QH13 and 44/2024/QH15 and Decree 163/2025, Circular 12/2025/ TT-BYT) New registration of drug/ drug material: 1. Chemical drug (new drug, generic) New drug: drugs containing new pharmaceutical substances (new chemical entities), medicinal materials, which for the first time are used for drug manufacturing in Vietnam; drugs involving a new combination of pharmaceutical substances that have been marketed or medicinal materials that have been already used in drug manufacturing in Vietnam 2. Biologics (reference biologics and Biosimilars) 3. Vaccines 4. Herbal medicines 5. Drug materials (API, herbal semi-product, excipients, capsule shell used for manufacturing of medicines)

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
NDA	Requirement of CPP	Yes 1) Category 1 and 2 Products A CPP is not required for NDA submission. However, a CPP should be provided as a reference if the product has been approved overseas during China NDA review. 2) Category 5.1 (Chemical Drugs) and Category 3.1 (Biologicals) Generally, A CPP from MAH country is required at the time of CTA and NDA submission. 3) Post-Marketing Variations In some certain situations (e.g., MAH change), a CPP is needed. Otherwise, Approval Letter or No Approval Statement is enough. 4) Renew application CPP is request. According to CDE announcement on Nov.27 2020 (https://www.cde.org.cn/main/news/viewInfoCommon/6b83ff7946a07d0b01a0d65c22308f29), in view of the FDA policy adjustment on CPP issuance, it is agreed that for FDA-approved products exported to the USA from countries outside of the USA, the CPP can no longer be provided when registration applications are submitted in China and the applicant can provide the screenshot of the FDA website or other certified documents etc to support filing of the registration application. Convention on the Cancellation of Legalization Requirements for Foreign Official Documents Will be effected in China since Nov.7th 2023 was issued by Ministry of Foreign Affairs of the People's Republic of China and effected on Nov.7th 2023. On January 23, 2024, the CDE issued the Notification on Issues Related to Supporting Documents for Medicines Manufactured Overseas (《关于境外生产药品证明文件有关事宜的通知》). With the issuance of this notification, certificates issued by countries that are signatories to the ``Convention Requiring Authentication of Foreign Public Documents'' will no longer require authentication procedures, and will only require an apostille. https://www.cde.org.cn/main/news/viewInfoCommon/aadd7317832f15b8bae6a7d6d7bef81d	Marketed CPP to be submitted at the time of application. No. of CPP required: **NCE and ATP:** • Conventional pathway: 2 of the following reference countries: US, EU, UK, Australia, Canada, Japan, Switzerland, China, Brazil, Singapore and South Korea (including source country) • Special pathway (1+ mechanism): 1 reference country (source country) **Generic:** 1 (source country only) **Biosimilar:** 1 (source country) from US FDA, EMA, Japan MHLW, Australia TGA or Health Canada	CPP or Free sale certificate (FSC) issued by country of origin is required at NDA. The CPP and FSC should be notarized and apostilled or legalized	Yes. Copy of CPP or e-CPP for pre-registration and registration is accepted since currently NDA registration is performed by online electronic registration. Annex , Drug Registration Guideline No. 15 year 2019 One CPP could be utilized as supporting docs for Path 90 WD (reliance) and 300 WD. For Path 90 WD (reliance), BPOM refer to reference countries : EU, US, Australia, Canada, UK Japan, Switzerland Applicant can choose 1 country as reference. Several requirements are necessary, eg. unredacted assessment report from reference countries, same quality document with reference country, etc.	No	No, CPP is not mandatory. However, if the imported drug product is manufactured at a facility that has not undergone KGMP evaluation by the Ministry of Food and Drug Safety, or if the product name, composition, manufacturer and location, and manufacturing contractor are not confirmed, a CPP must be submitted.	Yes A CPP is required at the point of submission for imported products, i.e. CPP from the competent authority in the country of origin (country of manufacture) in the format of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce or by the authorized body. If a CPP from the country of origin is not available, for example when the product is manufactured under contract for a product owner from another country and the product is not licensed for sale in the manufacturing country, the following alternatives may be considered: **i. CPP from the country of the product owner; OR** **ii. CPP from the country of release or CPP from DCA reference country, if CPP from the country of the product owner is not available.** Alternative documents in lieu of CPP to support registration applications for imported products **a. If a CPP cannot be provided at the point of submission, the following documents can be considered as alternatives** **i. An official approval letter or document by the competent authority that states the registration status of the product; AND** **ii. Certificate of Free Sale (CFS) or proof that the product is marketed in the exporting country. If the product is not marketed in the exporting country, the manufacturer declares in the declaration letter the reason for not marketing the product in the country. The acceptance of the reason for not marketing the product in the country is subject to NPRA's discretion; AND** **iii. The Summary of Product Characteristics (SmPC) or Package Insert (PI) approved by the competent authority** **b. For non-scheduled poison (OTC), health supplements and natural products (excluding natural product with therapeutic claim and health supplement with disease risk reduction), a Certificate of Free Sale (CFS) and Good Manufacturing Practice (GMP) certificate from the relevant competent authorities are required as alternative documents.** For product not registered in any other country: **a. Submission of a product registration without a CPP due to the fact that the product has not been previously approved in any country can be considered on a case-by-case basis depending on the country's need.** **b. Prior to submitting the dossier, the applicant should submit an exemption request letter with justifications to the Director of NPRA. Subsequently, the applicant may request a pre-submission meeting to provide an overview of the product and regulatory submission plan in other countries (if any).** **c. This requirement is not applicable for non-scheduled poison (OTC) products, health supplements and natural products.** [DRGD Appendix 29] CPP is optional for Facilitated Registration Pathway (Revision 1, November 2023) Direktif Berkenaan Pengemaskinian dan Pelaksanaan *Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023* Lampiran A - *Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023*	Yes One CPP is required to be submitted from the source or any reference country. Must indicate that it is registered and freely sold in that country	No Submission of CPP is not compulsory as a form of proof of approval. The proof of approval must come in the form of an official approval letter or equivalent document (e.g. CPP) issued by the National Medicine Regulatory Authority which certifies the registration status of the product (not provincial/ territory/ or state agencies). CPPs that indicate that the product is not licensed in the exporting country (including the scenario where the product is licensed "solely for export only") are not acceptable proof of approval.	Yes CPP(s) are required before drug license issuance. The detail is as the same as 2022. Amendments of "Regulations for Registration of Medicinal Products" for A10 CPP legalization exemption in 2020. Please refer to Article 38, 38-1, 38-2, 38-3, 38-4, 38-5 and 39 in this link: Regulations for Registration of Medicinal Products	CPP can be provided any time after application submission but must be before obtaining registration approval. eCPP is accepted. (cited 2025 FEB 3 media.php and media.php) 1 CPP from any country with marketed status. The product detail has to be supplemented to the CPP: • Required Trade name • Must include sales statement • Manufacturing sites at least DP manufacturer and primary packager Product formula at least active ingredient and in percentage display	**Requirements for a CPP** (Art. 22, Circular 12/2025/TT-BYT) 22.2. Requirements for a CPP: a) A CPP must be issued by the competent authority and cover all the information required in the WHO-model CPP published on WHO's web page (https://www.who.int/) b) A CPP shall be issued by competent authority of the manufacturing country or by reference regulatory authorities (listed below), confirming that the drug is licensed and marketed in that country. c) In case of meeting the need for prevention and treatment of infectious diseases of group A that have been declared epidemics according to the provisions of law on prevention and control of infectious diseases, CPP may be replaced by another document issued by a competent authority, which confirms that the drug is licensed for marketing and marketed in the home country, and fully includes information regarding the name, address of the manufacturer and licensing conditions. d) In case provided CPP does not meet requirements in point a, b above, the Minister of Health shall review the case based on the advices from the Advisory Council providing that such a drug product has been licensed for marketing by at least one regulatory authority in the world and falls into one of the categories: - Drugs, vaccines, biologics to meet emergency requirements in national defense, national security; for the prevention, combatting of epidemics, diseases, for the mitigation of consequences of natural disasters, calamities drugs for the service of health programs of the states; - Vaccines for the use in national expanded immunization programs, for which there are no substitutable vaccines readily available in the market in terms of quantity, quality, safety, efficacy or cost of use; - Other specific cases covered by agreements, mutual recognition between competent authorities regarding the conditions for manufacturing and marketing of drugs, vaccines, biologics. đ) Information recorded on a CPP must be consistent with relevant information in the registration dossier of the drug. Where information recorded on a CPP is not consistent with the administrative documents of the registration dossier, the registrant shall submit an explanatory letter along with supporting documents. **Reference regulatory authority** (Art. 2, clause 9 Circular 12/2025/TT-BYT) 9. European Medicines Agency (EMA) and the Stringent regulatory authorities (SRA) are: a) The European Medicines Agency (EMA); b) The Stringent regulatory authorities (SRA) are authorities categorized by the World Health Organization (WHO) as belonging to the SRA list, which are: - Members of the ICH before 23 October 2015, comprising: US Food and Drug Administration (FDA), the pharmaceutical regulatory authorities European Union countries, the UK Medicines and Healthcare products Regulatory Agency (MHRA) Japan Pharmaceuticals and Medical Devices Agency ((PMDA) - Observer members of ICH before 23 Oct 2015, comprising pharmaceutical regulatory authorities of European Free Trade Association (EFTA) and Swiss regulatory authority (Swiss medic), and Canada Health Ministry (Health Canada). - Regulatory authorities associated with an ICH member through a legally-binding, mutual recognition agreement before 23 Oct 2015, including Australia, Iceland, Liechtenstein, and Norway.

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NDA	Acceptance of foreign clinical trial data. (Can approval be obtained by utilizing foreign clinical trial data?)	To support NDA approval in China, data obtained from clinical studies are required to demonstrate sufficient efficacy and safety in Chinese population. In principle, foreign clinical trial data is acceptable as a source of supportive documents, therefore, it may not be utilized as the direct evidence to obtain NDA approval in China as a routine practice. Exceptional considerations may be allowed for life threatening situations where no available therapies existed etc. If the drug is assessed to be safe and effective and non-racial sensitive, it may be considered to be exempted from domestic clinical trials, according to the Clinical Technical Requirements for Drugs Marketed Overseas but Not Marketed in China. http://english.nmpa.gov.cn/2020-11/18/c_568155.htm For some cases of orphan drugs, in most cases Chinese clinical trial data is required, and foreign clinical trial data can be acceptable as the supportive data.	The overseas clinical trial data is acceptable. Bridging data (e.g. selected information from the Complete Clinical Data Package that is relevant – i.e. Asian data, including pharmacokinetic data, and any preliminary pharmacodynamic and dose-response data) will also be required for Special pathway ("1+" mechanism).	NDCT Rules (Rule 101) update – Vide Order dated August 7, 2024, The Drugs Controller General of India (DCGI)/ The Central Licensing Authority (CLA) specified six countries under the Rule 101 of the NDCT, for considering local clinical trial waiver during the approval process of five categories of new drugs. The names of the countries specified through an order now include US, United Kingdom, Japan, Australia, Canada and European Union. The notification of the countries is expected to help faster decisions on the waiver of the requirement of local clinical trials, with consistency and predictability. New drugs from these countries, including orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situation, new drugs used for special defense purpose, and new drugs having significant therapeutic advance over the current standard care, will be considered for clinical trial waiver. Waiver of local phase III CT data is yet to be implemented uniformly. Ref: CDSCO le no. DC-DT—15011 (11)/85/2024 dated 07.08.2024; cdsco.gov.in/ opencms/opencms/system/modules/ CDSCO.WEB/elements/ download_file_division. jsp?num_id=MTE1ODI=	Yes Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guideline. Local regulatory trials are required for TB program and drug for family planning program	Yes The data from overseas clinical trial is accepted in accordance with ICH E5. The drugs approved using global clinical trial data have increased. On the other hand, if the safety and tolerability can be explained and the safety is clinically acceptable and manageable, additional phase 1 studies in Japanese people are not necessary, in principle, before MRCT. However, information on pharmacokinetics in Japanese patients should be collected as much as possible.	Yes For new drugs, bridging data is needed For generics, bioequivalence data from Koreans is generally used. In the case of OTC drugs, in principle, bridging data is exempted.	Yes Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guidance, and accepted by the major reference countries. Local clinical trial data in diseases of public health interest may be considered to support priority review. Priority Review may be granted for: New Chemical Entity (NCE) or biologics product with a phase III global, multicentre pivotal clinical trial conducted locally in Malaysia for the treatment of diseases of public health significance (e.g., hepatitis, HIV, COVID-19, etc.). A minimum of 5% of the total number of randomised subjects are subjects in the clinical studies conducted at study sites in Malaysia. [DRGD Appendix 12]	Yes There is no requirement for local clinical trial data (Phases I-III) for registration.	Yes Overseas clinical trial data is acceptable.	Yes, foreign clinical trial data is acceptable. However, BSE is mandatory for NDA and BLA. Drugs received Designation Request of Medications for Pediatric Population or the Minority Patients with Serious Diseases from the central health authority, cellular and gene therapy products are exempted from the BSE according to the amendment of the "Regulations for Registration of Medicinal Products" announced on 14th Sep 2021.	Yes. Overseas clinical trial data is acceptable.	Yes (Art. 18&19, Circular 12/2025/TT-BYT) Full clinical data refer to research that has been conducted, documented, and evaluated in accordance with the guidelines issued by the Ministry of Health or by other organizations recognized by Vietnam (including the ICH, WHO, EMA, international organizations of which Vietnam is a member, or regulatory authorities specified in Clause 9, Article 2 of this Circular) Clinical research data provide adequate information for analyzing and interpreting the impact of Asian ethnic factors on the drug's safety and efficacy, in accordance with ICH-E5 guidelines
	Implementation of ICH E17 guideline.	CDE released the draft guideline for comments on Dec. 13 2024. Source: https://www.cde.org.cn/main/news/viewInfoCommon/196f2d48912515aa6ca3175f545ebee8	Not announced	While India is not a member of ICH and ICH E17 guideline is not yet implemented, however, the global clinical data is accepted in lieu of the local CT data waiver.	Yes	Yes The guideline was issued in June 2018.	Yes Implemented; Date: 12 October 2018	-	Yes, no specific issuance on implementing ICH E17 but AO 2020-0010 adopts all ICH Safety and Efficacy guidelines, including E17. MRCT applications are accepted	ICH E17 guideline is adopted by HSA. Ref: https://www.hsa.gov.sg/clinical-trials/regulatory-guidances	Yes, the ICH E17 guidelines were announced on October 22, 2021 by the TFDA. (https://www.fda.gov.tw/TC/siteListContent.aspx?sid=9354&id=38817)	ICH E17 guideline has been adopted. However, no official announcement can be found.	-
	Application fees	New standard for drug registration fee was published by NMPA, refer to link for details. https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggt/20200630211101986.html	Application fee: HKD 1100 License fee: HKD 1370 Renewal fee (every 5 years): HKD 575	As per Sixth Schedule of NDCT Rules, 2019 (FEE PAYABLE FOR LICENCE, PERMISSION AND REGISTRATION CERTIFICATE)	Annex, President Regulation No. 32 year 2017 on type & tariff for drug registration: Application fee : Pre-Registration : 1 Million IDR (MIDR) Registration fee for : Category 1 : new product & Biological Product : 30 MIDR, new indication : 20 MIDR Category 2: Branded generic product: 7.5 MIDR, Branded generic product with BA/BE data: 12.5 MIDR, Generic product: 2 MIDR, Generic product with BA/BE data: 7 MIDR Category 3 : other product: 7.5 MIDR On site Inspection IDR 50 Mio (excluding transportation & accommodation of inspector)	The application fee was revised on May 20, 2022. Application fees for drugs containing new active ingredients (in case of non- orphan drug) are: To Government: 533,800 yen To PMDA: for review: 36,538,400 yen for paper-based compliance inspection: 10,363,300 yen for GCP inspection: domestic 4,302,300 yen, and overseas 4,758,500 yen +travel expenses for GMP inspection: domestic 1,008,700 yen, and overseas 1,272,900 yen + travel expenses	Application fee are defined in the Annex 1 of the "Regulation of Fees for Approval of Medical Products" Starting January 1, 2025, the application fee for new drugs was increased substantially, rising from approximately 8 million KRW to about 410 million KRW.	Fees are required and details are given in the DRGD Appendix 9: Fees. These are according to product categories, number of active ingredients, types of applications etc.	In the recently released new FDA schedule of fees and charges, here are the new fees, depending on the product type. Product Type / Fees per year New Chemical Entity/ Biological/Vaccine: 43,000.00 Generic Drug Rx: 18,000.00 Non-Prescription Drug / Household Remedy: 17,000.00 Medical Gas: 9,000.00 Traditional Medicine: 14,500.00 Herbal Medicine: 17,000.00 (Administrative Order No. 2024-0016 (https://app.doh.gov.ph:1024/Rest/GetFile?id=813327))	For therapeutic products HSA website: https://www.hsa.gov.sg/therapeutic-products/fees revised-fees-2024.pdf For CTGTP HSA website: https://www.hsa.gov.sg/ctgtp/fees-and-turnaround-time	"Standards of Review Fees for the Registration of Western Medicines" was amended in 2020 and became effective in 2021.On September 2, 2024, the TFDA announced a draft amendment, which is currently in the public commentary period. "Standards of Review Fees for the Registration of orphan drug" was amended and became effective on 1 Jan 2022. Link to application fee	Effective 2 Dec 2023, new fee is applied with the exceptions: A) A new drug that is researched, developed and manufactured locally or imported for national security, to resolve shortages, or as targeted drugs in accordance with Thai FDA Notification. B) An orphan drug that is listed in accordance with the Thai FDA Notification. C) A registered drug that needs revision in accordance with the Ministry of Public Health Notification or Thai FDA Notification stipulations regarding quality and safety problems. D) Company License and Product Registration certificate required for address change in accordance with the requirements of the Administrative Department or Thailand Post Co., Ltd. E) A new drug that is researched, developed and manufactured locally by a charitable and non-profit organization designated by the Minister of Public Health. (cited 2025 FEB 3 media.php)	NDA: 11,000,000 VND (450 USD) Renewal (So-called extension): 4,500,000 VND (185 USD) Variation 1,500,000 VND (61 USD) Circular 41/2023/TT-BTC

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
NDA	Other requirements	Simultaneous development and registration of vaccine is opened Optimize registration process: Change sequential process to parallel, e.g., pre-NDA QC testing and GCP Inspection Since Jul.1st, 2021 for imported drugs, the repackaging process has been updated to 1)NDA submission and approved by NMPA/CDE, receive drug approval license, 2)CDE filing for large package, 3)CDE filing for repackage. On Jul.18 2023, NMPA published the feedback to Shanghai MPA (Order.388) (https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20230718164249177.html) on related issues of re-pack sales of imported drugs, indicated that, once overseas manufactured drugs complete the filing process, the re-packed imported drugs could be sold by re-pack enterprises. Additionally, NMPA issued Announcement on Implementing Electronic Application of Drug Registration (2022, No. 110) on Nov.30, 2022, indicated that since Jan.1 2023, the drug registration applications reviewed and approved by NMPA and the supplementary dossiers during the review shall be adjusted to be submitted in electronic form, and the applicants no longer need to submit paper application dossiers. Existing working procedures remain unchanged. Upon the implementation of this Announcement, if the applicant makes drug application by eCTDs, paper application dossiers are no longer needed, and other requirements shall still be implemented in accordance with the Announcement on Implementing the Application with Electronic Common Technical Documents for Drugs (No. 119 [2021]). CDE published the pilot version of e-submission materials editing software on ,Jul.7 2023. (https://www.cde.org.cn/main/news/viewInfoCommon/bf55bfc7eec61d9716506a5f186d753a) The eSubmission requirements will be updated from Mar 1, 2024, as the Notice on Updating the Technical Requirements of Electronic Disc Submission of Application Dossiers and Other Files by the CDE, National Medical Products Administration in Dec 2023. (https://www.cde.org.cn/main/news/viewInfoCommon/2969c293179bd697dbb64c454926dd80) The CDE has established Electronic Submissions Gateway（ESG）to provide applicants with multiple options for submitting electronic submission dossier. (https://www.cde.org.cn/main/news/viewInfoCommon/2969c293179bd697dbb64c454926dd80)	Primary evaluation (without requirement of CPP) will be implemented in phases in the period between 2026 and 2030. Guidelines and requirements to be confirmed.	Import License is required after marketing approval and Registration Certificate. India has a mandatory testing requirement at the time of import of first commercial shipment. After first shipment, testing is conducted as per following schedule1. Vaccines- Every Imported Batch 2. Plasma Derived Products- Every Imported Batch 3. Biologicals-Once every 6 months Small Molecules-At port officers discretion	Specific country requirement on product labeling on product package, example: font type and size of the generic name, retail price, symbol of prescription drug, the name of importer. Site Master File, Established Inspection Report within 2 years, GMP certificate and Manufacturing License are requested for site involved in DP manufacturing (for chemical) and DP and DS (for biological) in NDA or transfer site submission. Inspection may be conducted against overseas factories if necessary RMP is required for NDA, new indication and/or posology, etc as per BPOM Regulation No 15 year 2022 regarding PV implementation. Labeling format refer to BPOM regulation No. 279 year 2024 regarding Product Information Standard.	-	-	Other requirements are as noted in the DRGD.	•Reference Standard Sample (at least 300 mg; subject to FDA advise when to submit) •Compliance to foreign GMP requirements (before submitting NDA, applicants must first secure a Certificate of GMP Compliance from FDA for each foreign manufacturing site involved in the final product [Administrative Order No. 2013-0022 and FDA Circular No. 2014-016]) •Local generic labeling requirements (Administrative Order No. 2016-0008) •Registration sample/s mocked-up in the proposed commercial and sample labeling presentations, including the corresponding Certificate of Analysis (subject to FDA advise when to submit)	For GDA, the reference product must be the registered product with Singapore HSA Batch numbering system is required for registration of generics and branded innovators Singapore-Specific Annex may be required for submission of risk management plan in support of NDA, GDA and MAV applications.	Not applicable.	In case of biological products, local laboratory testing by DMSC will be required typically in parallel with registration.	Online submission via the MOH Public service portal Labeling, Package Insert, COA for Drug Substance and Drug Product, AF, LoA, legal documents of applicant, RMP (chemical drug, biologics, vaccine). And for vaccines, antiserum, blood extracts and human plasma below document is requested: a) The batch release certificate issued by a competent authority of the country in which the CPP is issued; b) The test report, specifications and test method certified by VN National Institute for Control of Vaccines and Biologics (NICVB); *: Evaluation on good manufacturing practice (GMP) compliance of MFR (Decree 163/2025/ND-CP; TT48 on the online system of DAV: https://dichvucong.dav.gov.vn/): GMP certificate/GMP inspection report/Manufacturing license of finished product manufacturer; site master file and some documents depending on specific cases. Legal documents proving compliance with GMP submitted by a manufacturer of active ingredients, excipients, capsule shells, semi-finished herbal ingredients and herbal ingredients (for manufacture of herbal drugs) may be any of the following documents: a) The GMP certificate; b) The manufacture license that certifies GMP compliance; c) The CPP if the active ingredient is conformable with GMP; d) The Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP). đ) Other legal documents issued by competent authorities including at least the following contents: name and address of the manufacturer, confirmation of GMP conformity, and name of the active ingredients, herbal materials, excipients, and capsule shells e) With regard to excipients in registration dossiers for finished drug products, drug raw materials being semi-finished products: If manufacturers of excipients cannot provide certificate of a, b, d, đ, the manufacturer can provide Self-declaration as Form 05/TT 12/2025 GMP Principles and Standards for production of pharmaceuticals have been applied by administration of country or other international organization. (Article 22, Circular 12/2025/TT-BYT)
NDA application materials	CMC summary	Yes (in Chinese)	For NCE/ Biosimilar/ATP only (document in English).	Yes, in English	Yes (in Indonesian or English as in part II Quality) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VII	Yes Only Japanese as M2.3 in CTD	Yes M2 in CTD in principle should be Korean, but Tables, etc. may be written in English.	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	YES ACTD Part II in English	Yes (in English)	Yes (In English as M2.3 in CTD)	Yes	Yes QOS of DS, DP Vietnamese or English
	CMC report/ body of data	Yes (in Chinese)	For NCE/ Biosimilar/ATP only (document in English).	Yes (English is acceptable as M3 in CTD)	Yes (in Indonesian or English as in part II Quality) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VII	Yes English is acceptable as M3 in CTD	Yes M3 in CTD: English is acceptable.	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	YES ACTD Part II in English	Yes (in English)	Yes (In English as M3 in CTD)	Yes In addition to ACTD on Quality Part II (or ICH CTD Module 2.3), the Certificate of Analysis for Finished product (3 batches), API (for at least 2 batches from API manufacturer and DP manufacturer), Excipient (at least 1 batch).	Yes Vietnamese or English Quality dossier shall be prepared in conformance with the guidelines of ACTD - Part II or Module 2 and 3-ICH-CTD and relevant guidance. - Drug substance (S): General Information (S1); Manufacture (S2); Characterization (S3) and Control of Drug Substance (S4), Reference Standards or Materials (S5); Container Closure System (S6) and Stability (S7); - Drug product (P): Description and Composition (P1); Pharmaceutical Development (P2); Manufacture (P3); Control of Excipients (P4); Control of Finished Product (P5); Container Closure System (P7). Reference Standards or Materials (P6); Stability (P8) and Product Interchangeability Equivalence evidence (P9) if applicable For vaccines, antibody-containing sera, blood derivatives and plasma from human, following documents shall be required: a) Batch release certificate issued by the competent authority of the CPP-issuing country according to applicable regulations or by one of the regulatory authorities stipulated in Clause 9 Article 2 of Circular 12/2025/TT-BYT b) Test certificate, quality specification and test method certified by the National Institute for Control of Vaccines and Biologics or by a state drug testing laboratory authorized by the Ministry of Health to test, evaluate, and monitor vaccines and biologics. (Clause 3, Article 27, Circular 12/2025/TT-BYT)

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NDA application materials	Non-clinical summary	Yes (in Chinese)	For NCE/Biosimilar/ATP only (document in English).	CDSCO has decided to accept the preclinical toxicity data already generated and accepted by regulatory authorities of other countries for review of new drugs, subsequent new drugs (SNDs) and fixed dose combinations (FDCs), subject to certain conditions. According to the NDCT Rules, 2019, the regulator noted that, a repeated dose toxicity study in India may not be mandatory in certain cases including when a data on animal toxicity as per the specifications in the rule, has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug. The animal toxicity data generated in other countries may be accepted and may not be asked to be repeated in India on a case to case basis depending upon the quality of data and the credentials of the laboratory where such data has been generated, noted the regulator pointing to the Schedules of the NDCT Rules, 2019. However, the animal toxicity data needed in certain cases such as new claims namely, indications, dosage, dosage form or route of administration etc., should be determined on case by case basis depending on the nature of new claims as well as the mechanism of action etc., and the non-clinical data already generated with the drug in the approved claim. Use of unapproved excipients in the formulation also will require relevant safety data. Besides, as per the NDCT Rules, 2019, sub-acute animal toxicity studies for intravenous infusions and injectables data is still required to be submitted by an applicant for grant of permission to import or manufacture such new drug as mentioned in the Second Schedule of the Rules. Ref: CDSCO F. No. 12-01/24-DC (Pt-104) dated 29.07.2024 cdsco. gov.in/opencms/ opencms/system/ modules/CDSCO.WEB/ elements/download_file_ division.jsp?num_ id=MTE0OTA=	Yes (in Indonesian or English as in part III Non Clinical Data) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VIII	Yes Only Japanese as M2.4, M2.6 in CTD	Yes M2 in CTD in principle should be Korean, but Tables, etc. may be written in English.	Yes (Part 3 in ACTD) - in English or Bahasa Malaysia	YES ACTD Part III in English	Only for full dossier, in English	Yes (In English as M2 in CTD)	Yes ACTD on Non-Clinic Part III or ICH CTD Module 2	Yes Vietnamese or English The non-clinical document shall be prepared in conformance with the guidelines of ACTD - Part III or Module 2 and 4-ICH-CTD and relevant guidance or guidance in Annex III of Circular 12/2025/TT-BYT.
	Non-clinical report	Yes (in Chinese)	For NCE/Biosimilar/ATP only (document in English).	Yes, (English is acceptable as M4 in CTD)	Yes (in Indonesian or English as in part III Non Clinical Data) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VIII	Yes English is acceptable as M4 in CTD	Yes M4 in CTD: English is acceptable	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part III in English	Only for full dossier, in English	Yes (In English as M4 in CTD)	Yes ACTD on Non-Clinic Part III or ICH CTD Module 4	Yes for new chemical drugs, vaccines, and biologics Online submission via the MOH Public service portal The non-clinical document shall be prepared in conformance with the guidelines of ACTD - Part III or Module 2 and 4-ICH-CTD and relevant guidance or guidance in Annex III of Circular 12/2025/TT-BYT. Vietnamese or English The content of Non-clinical report includes: 1. Pharmacology 1.1 Primary Pharmacodynamics 1.2 Secondary Pharmacodynamics 1.3 Safety Pharmacology 1.4 Pharmacodynamics Drug Interactions 2. Pharmacokinetic 2.1 Analytical Methods and Validation Reports 2.2 Absorption 2.3 Distribution 2.4 Metabolism 2.5 Excretion 2.6 Pharmacokinetic Drug Interactions 2.7 Other Pharmacokinetic Studies 3. Toxicology 3.1 Single dose toxicity 3.2 Repeat dose toxicity 3.3 Genotoxicity 3.4 Carcinogenicity 3.5 Reproductive and Development Toxicity 3.6 Local Tolerance 3.7 Other Toxicity Studies
	Clinical summary	Yes (in Chinese)	For NCE/Biosimilar/ATP only (document in English).	Yes, in English	Yes (in Indonesian or English as in part IV Clinical Data) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex IX	Yes Only Japanese as M2.5, M2.7 in CTD	Yes M2 in CTD in principle should be Korean, but Tables, etc. may be written in English	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part IV in English	Yes (in English)	Yes. (In English as M2 in CTD)	Yes ACTD on Clinic Part IV or ICH CTD Module 2	Yes for vaccines, biologics, and generics which origin has not registered in VN The clinical trials shall be prepared in conformance with the guidelines of ACTD - Part IV or Module 5-ICH-CTD.

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NDA application materials	Clinical report	Yes (in Chinese) According to newly issued Guidelines for Acceptance and Review of Chemical Drug Registration (For Trial Implementation) (2025 No.14) https://www.cde.org.cn/main/news/viewInfoCommon/caba883106101c3f121bd028076e31d7 and Guidelines for Acceptance and Review of Biological Products Registration (2025 No.15) https://www.cde.org.cn/main/news/viewInfoCommon/4ad85c95f2158d8eab911b263a92b3e2, it is no necessary to provide site summary report (SSR) for the submission in Clinical Study Report (CSR)	For NCE/Biosimilar/ATP only (document in English).	Yes, (English is acceptable as M5 in CTD)	Yes (in Indonesian or English as in part IV Clinical Data). Indonesia required full clinical study report Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex IX	Yes English is acceptable as M5 in CTD	Yes M5 in CTD: English is acceptable	Yes (Part 3 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part IV in English	Yes (in English)	Yes. (In English as M5 in CTD)	Yes ACTD on Clinic Part IV or ICH CTD Module 5	Yes for vaccines, biologics and generics which origin has not registered in VN Clinical dossier shall be prepared in accordance with the guidelines in Part IV of the ACTD or the guidelines in Modules 2 and 5 of the ICH-CTD and other relevant guidelines or the guidelines provided in Annex III of Circular 12/2025/TT-BYT
	Other required documents	CDE Announcement on M4 Module 1 Administrative Documents and Drug Information (2020 No.6) effected since July.1st According to NMPA Announcement on Implementation of Drug Common Technical Document Electronic Submission (No. 119, 2021) issued by NMPA on Sep.30, 2021, since Dec. 29, 2021, for Cat.1 and Cat 5.1 of chemical drugs, Cat. 1 of therapeutic biologicals and Cat.1 of preventive biologicals, may follow eCTD for the NDA submission. The Applicant may follow eCTD technical documents to prepare and submit eCTD submission dossier CD. eCTD Technical Specification V1.0, eCTD Verification Standard V1.0 and eCTD Implementation Guideline V1.0 were issued as well. According to the CDE announcement in July 2024 (Notification on Trial of Submission of Drug Registration Electronic Declaration by Internet Transmission Method), online submissions are also permitted. The CDE released the announcement of Soliciting Public Comments Regarding the Correspondence Table for Technical Documents and Submission Material Directories Related to the eCTD (https://www.cde.org.cn/main/news/viewInfoCommon/564d3aba1ec4620c9ab5aaea18c2af7c)	All documents in English. About general requirements and generic, please refer "Guidance Notes on Registration of Pharmaceutical Products/ Substances" (Nov 2022) https://www.ppbhk.org.hk/eng/files/Guidance_on_Reg_of_Pharm_Prod_Sub_en.pdf?v=kwop3l7 About NCE or biological entity and special pathway ("1+ mechanism"), please refer "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity" (Nov 2024) https://www.ppbhk.org.hk/eng/files/Guidance_on_Reg_of_Pharm_Prod_Containing_New_Chem_or_Bio_Entity_en.pdf?v=8xag5 About Biosimilar guideline, please refer "Guidance Notes for Registration of Biosimilar Products" (Aug 2021) https://www.ppbhk.org.hk/eng/doc/guidelines_forms/Biosimilar_guidelines_revised_Final_ENG.pdf?v=f4vd1 About ATP guideline, please refer "Guidance on Application of Certificate of Drug/Product Registration – Advanced Therapy Products" (1 Nov 2024) https://www.ppbhk.org.hk/eng/files/PPB_Guidance_Reg_ATP_en.pdf?v=m3gdv About labelling of pharmaceutical products, please refer "Guidelines on the Labelling of Pharmaceutical Products" (Aug 2021) https://www.ppbhk.org.hk/eng/doc/guidelines_forms/Label_GI_en.pdf?v=hqpnvn About labelling of ATP, please refer "Guidance on Labelling Requirements of Product Code, Unique Donation Identifier and Unique Recipient Identifier for Advanced Therapy Products" (1 Aug 2021) https://www.ppbhk.org.hk/eng/files/PPB_Guidance_Code_ATP_en.pdf?v=zpc4hf	As described in Chapter X (IMPORT OR MANUFACTURE OF NEW DRUG FOR SALE OR FOR DISTRIBUTION) of New Drugs and Clinical Trial Rules, 2019 The Module 1 of NDA in Sugam expects submission of multiple legalized documents including Power of Attorney, CPP, GMP certificate etc.	See BPOM Regulation No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration See BPOM Regulation No. 15 Year 2019 on amendment to regulation of BPOM Regulation No.24 Year 2017	CTD M1 and M2 are acceptable only in Japanese. CTD M1: 1.1 Table of Contents 1.2 Approval application (copy) 1.3 Various certificates 1.4 Patent information 1.5 Data concerning the origin or background of development 1.6 Information on the use of the drug in foreign countries 1.7 List of similar products from the same therapeutic category with similar efficacy 1.8 Package insert 1.9 Documents pertaining to the non-proprietary name of the drug 1.10 Summary of data pertaining to the designation as a toxic drug, etc. 1.11 Master plan for post-marketing surveillance 1.12 List of attached data 1.13 Other data	Module 1 1.1 Table of contents of Module 1 1.2 Application form or approval application(Copy) 1.3 Statement and Signature of the person in charge of preparation of CTD, His/Her information(career) 1.4 Statement and Signature of the translator 1.5 Status of the product usage in foreign countries 1.6 Information on properties of the product including comparison with similar products that were approved in Korea. 1.7 Various documents related to Regulations on Safety of Pharmaceuticals Article 4 (1) 1.7.1 Bioequivalence test data/ Dissolution test data 1.7.2 CPP 1.7.3 GMP data 1.7.4 DMF data 1.8 Contract documents (In case any process during manufacturing, QC test is outsourced) 1.9 Notarized TOC (Table of Contents) 1.10 Package insert(draft) 1.11 Other data	In English or Bahasa Malaysia: ACTD Part I: Administrative Data & Product Information Section A: Product Particulars Section B: Product Formula Section C: Particulars Of Packing Section D: Label (Mockup) For Immediate Container, Outer Carton And Proposed Package Insert Other admin doc: CPP, LOA, CA, GMP CE	I An RMP containing the Pharmacovigilance Plan shall be submitted by applicants, determining whether additional PV activities are necessary. (FDA Circular No. 2021-020, FDA Circular No. 2020-003)	Module 1 (or ACTD Part Ⅰ) documents e.g., Letter of authorizations Declaration on rejection, withdrawal and deferral Artwork of packaging material GMP certificate Patent declaration Reference country/ product appro: val and approved package insert, if applicable Registration status in other countries Confirmation of Reference Agency's Approval of Chemistry & Manufacturing Control (CMC) Aspects required for both GDAs and innovator brand's NDAs, if submitted under abridged route and for which approval in at least one of HSA's reference agencies not more than 5 years before the date of submission to HSA, plus completed Dossier Clarification Supplement.	NDA RTF checklist was revised on 18-Jun-2024 announced by TFDA. (https://www.fda.gov.tw/TC/siteListContent.aspx?sid=2984&id=46891)	E-Submission for all applications.	NDA submission is now carried out online entirely (including clinical and non-clinical dossier, BE/BA report, evaluation on following GMP of MFR dossier) via the DAV Public Service Portal: **https://dichvucong.dav.gov.vn/** and follows Administrative procedure No. 1.011205. Companies are expected to submit their dossiers digitally at https://dichvucong.moh.gov.vn/web/guest/dichvucong/-/dvc/thutuchanhchinh/3.html?_dichvucong_WAR_bytedvcportlet_redirectPage=https%3A%2F%2Fdichvucong.moh.gov.vn%2Fweb%2Fguest%2Fdichvucong%2F-%2Fdvc%2Fthutuchanhchinh%2F3.html%3F_dichvucong_WAR_bytedvcportlet_coQuanQuanLy%3D%26_dichvucong_WAR_bytedvcportlet_tenMaThuTuc%3Dgi%25E1%25BA%25A5y%2B%25C4%2591%25C4%2583ng%2Bk%25C3%25BD%26_dichvucong_WAR_bytedvcportlet_mucDo%3D0%26_dichvucong_WAR_bytedvcportlet_cur%3D1%26_dichvucong_WAR_bytedvcportlet_delta%3D10%26_dichvucong_WAR_bytedvcportlet_valueShowHide%3D%26_dichvucong_WAR_bytedvcportlet_hienThiTheoDangLuoi%3D&_dichvucong_WAR_bytedvcportlet_cur=1&_dichvucong_WAR_bytedvcportlet_tenMaThuTuc=giấy+đăng+ký&_dichvucong_WAR_bytedvcportlet_tthcId=1108213&_dichvucong_WAR_bytedvcportlet_mvcPath=%2Fhtml%2Fdvc%2Fportlet%2Fdichvucong%2Fxem_thutuc.jsp&_dichvucong_WAR_bytedvcportlet_delta=10&_dichvucong_WAR_bytedvcportlet_timKiem=true Required documents, regulated in Circular 08/2022 includes: - Part 1: Administrative documents - Part 2: Technical documents following Part 2 of ACTD or Part 3 of ICH-CTD - Part 3: Pre-Clinical documents following Part 3 ACTD or Part 4 ICH-CTD - Part 4: Clinical documents following Part 4 ACTD or Part 5 ICH-CTD

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NDA Approval review	Review organization (names of "review organi-zation", "decision organization", "advice committee" etc)	Review: CDE (Center for Drug Evaluation) Decision: NMPA (Notional Medical Products Administration) Inspection: CFDI of NMPA (Center for Food and Drug Inspection) Registration Testing NIFDC (National Institutes for Food and Drug Control) Drug Generic Name: ChPC (Chinese Pharmacopoeia Commission)	Review: Drug Office, DOH Approval: Pharmacy and Poisons Board	Technical review is conducted by CDSCO and Subject Matter Experts (SME) are invited by CDSCO for joint review of clinical and non-clinical data. Final decision is taken by CDSCO based on recommendations from Subject Expert Committees	BPOM regulation No. 15 year 2019 on Amendment to regulation of Head BPOM No. 24 year 2017 article 45 and article 49 1. Committee of Safety-Efficacy Evaluation with the task of evaluating the safety and efficacy aspect to be discussed in the periodic meeting of National Committee/ KOMNAS. 2. Committee of Quality Evaluation with the task of evaluating the quality aspect. 3. Committee of Product Information Labeling Evaluation with the task of evaluating in the aspects of Product Information and Labeling."	Review PMDA (Pharmaceutical and Medical Device Agency) Decision MHLW (Ministry of Health, Labor and Welfare) Advice CDFS (Council on Drug and Food Sanitation)	[Review] ・NIFDS ・Regional Office of MFDS [GMP inspection] ・MFDS Headquarter (for imported products, foreign manufacturing sites) ・Regional Office of MFDS (domestic, for manufacturing sites located in Korea) [Decision] ・MFDS Headquarter ・Regional Office of MFDS (Products of Notification, Generics) [Advise] ・Central Pharmaceutical Affairs Council	Review: National Pharmaceutical Regulatory Agency (NPRA) Advice: NPRA's Review Committee Decision: DCA (Drug Control Authority)	Review and Decision The Center for Drug Regulation and Research (CDRR) of the FDA Advice The FDA may hire external consultants for data requiring specific expertise (e.g. clinical and non-clinical data, abortifacient properties, etc)	HSA (Panel of internal and external reviewers.)	The review center is composed of TFDA and CDE. Drug Advisory Committee provides consultation during the review and further endorses the CDE review if there are special issues. Decision organization is TFDA.	Review Thai FDA, External Reviewer Decision Thai FDA Advice Drug Committee	Drug Administration of Vietnam (under the Ministry of Health); expert from Institutions, university in Hanoi, Ho Chi Minh city. The DAV assigned 4 universities (so far) as affiliated dossier review centres. Decision organization, Advice committee: Drug Committee with members include Ministry of Health, KOLs from Universities and Institutions.
	Number of reviewers	Around 700 in CDE, no exact numbers in sub centers of the Yangtze River Delta and the Greater Bay Area. CDE has removed the Real-time recruitment information on its website	Undisclosed	In 2025, the Central Drugs Standard Control Organization (CDSCO) is planning to expand its reach by opening new regional offices and testing laboratories to improve drug quality monitoring and accessibility. They are also streamlining internal processes, to speed up the review of drug and medical device applications. These changes aim to align CDSCO with global standards and improve efficiency in India's pharmaceutical regulation.	No information on amount of reviewer in regulation for each section committee.	All staff: 1056 (As of Jul.1,2025) Review Dept.: 641* Safety Dept.: 191* *: The figures for FY2025 have not been released, so they are from last year.	There is no official information	The Product & Cosmetic Evaluation Centre in NPRA has 130 officers currently. Other regulatory support are provided by the Regulatory Coordination & Strategic Planning Centre with 67 staff, and the Compliance & Quality Control Centre wit 249 staff.	CDRR has 51 reviewers	There is no official information	CDE is responsible for drug registration review and consultation service..As of December 31, 2023, the total number of personnel of the CDE was 333 persons, including non-reviewers. Among these manpower, 249 staff are responsible for drug & medical device review, including Clinical, Non-clinical, CMC, PK/PD, Phar,/Tox and statistical. Link to CDE 2023 Annual Report	Full assessment: A total of six reviewers: two for each part - Quality, Non-clinic, and Clinic. Abbreviated Assessment: Fewer than six reviewers, enabling a quicker review process	9 review centres, with 574 expert reviewers and 171 independent experts in multiple review committees (Legal; Quality & Specification; Pharmaceutical & stability; Pharmacology; Clinical).

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NDA Approval review	Review process/ flow	Working Procedures for Initiating Drug Registration Inspection and Testing (for Trial Implementation) was issued by CDE on Dec.20, 2021 and taken into effective since Jan. 1, 2022. Working Procedures for Initiating Drug Registration Inspection and Testing (for Trial Iming Procedure for Drug Registration Inspection (for Trial Implementation) and Working Procedure of Cohesion of Drug Registration Manufacturing On-site Inspection and Pre-marketing GMP Inspection (for Trial Implementation) were issued by CFDI on Dec.20, 2021 and taken into effective since Jan. 1, 2022. Additionally, CDE issued Working Procedures for Changes During the Review of Drug Registration Application (Trial) on Nov.11, 2022, including 1)Changes during the review of drug clinical trial application and supplementary application during clinical trials, 2) Changes during the review of drug marketing authorization application, 3) Changes during the review of post-marketing supplementary application and re-registration application for drugs manufactured overseas. CDE issued Management Practice for Suspension and Resumption of the Review Timing in the Evaluation Process of National Medical Products Administration (Trial) (Yaoshenye [2022] No.614) on Nov.16, 2022, applicable to the registration application of all types of drugs (including APIs) and the related application of pharmaceutical excipients and drug packaging materials, including the drug marketing authorization application, drug supplemental application, renew application of imported drugs, consistency evaluation application, etc. CDE issued Working Specification of the CDE for Accelerating the Evaluation of NDA of Innovative Medicines (Interim) on Mar.31 2023 to further promote innovation, effected from the issuance date. NMPA issued Working Procedure for Adding Pediatric Use Information into Package Inserts of Marketed Products (Interim) (NMPA 2023 No.68) on May. 31 2023 so as to improve the pediatric use information into package inserts of marketed products and to improve the safety level for pediatric drugs, effected from the issuance date. NIFDC has issued the Standard for Drug Registration Testing Procedures and Technical Requirements (2025 Revision) to improve testing efficiency. Key measures include expanding pre-registration testing to post-marketing supplementary applications, differentiated reduction of registration test sample quantities, and shortened testing cycles for priority review and clinically urgent orphan drugs.	Undisclosed	New Drug approval is a three steps process for imported products namely- NDA, Registration Certificate, and Import License. Parallel submission and review are acceptable for NDA and Registration Certificate	Pre-registration review document until complete documents --> Payment of pre-registration fees-->submit pre-registration --> Evaluation--> Approval Pre-Registration Registration review document --> Payment of registration fees --> Submit registration documents --> Clock start of registration review /Evaluation à Approved Registration Number Currently all registration processes are performed in e-reg (New Aero system). Master data registration is necessary to be completed for API, all excipients, API manufacturer, excipients manufacturer & drug product manufacturer prior apply in electronic registration system. According to BPOM regulation No. 15 Year 2019, Approvable letter was removed. Approvable letter would be issued only for drug that has not yet produced in commercial scale. Note: * Only NCE/ Biological Product (including biosimilar) New Additional Indication and Posology - Non-Clinical & Clinical were evaluated through Committee of Safety-Efficacy evaluation and National Committee then continue with Committee of Quality Evaluation, and Committee of Product Information. *Others (Generic & variation) were evaluated with Committee of Quality Evaluation, and Committee of Product Information.	See https://www.pmda.go.jp/english/review-services/reviews/0001.html	Refer at MFDS website 1) Chemical: www.mfds.go.kr/eng/wpge/m_17/de011008l001.do 2) Biologicals: www.mfds.go.kr/eng/wpge/m_22/de011012l001.do 3) Herbal Medicines: www.mfds.go.kr/eng/wpge/m_23/de011013l001.do	Disclosed. See DRGD Section B: Product Registration Process	A semi-electronic process is currently being used by FDA 1.Appointment, screening/pre-assessment (for completeness and compliance to format; not face-to-face) 2.Payment (online/bank transfer) 3.Queuing, Evaluation 4.Regulatory Decision 5.Releasing (FDA Circular No. 2020-026)	For therapeutic products Reference to GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE , TPB-GN-005-010 – TARGET PROCESSING TIMELINES. APPENDIX 5 TARGET PROCESSING TIMELINES appendix-5_target-processing-timeline.pdf (hsa.gov.sg) Screening: 50 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Verification: 60 working days For Class 2 CTGTP Screening: 50 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Reference: HSA	Fees and turnaround time for CTGTP	Link to New Drug Application Process RTF (refuse to file) notification will be issued on Day 42 when a new drug application (NDA) or biologics license application (BLA) is deemed incomplete by the TFDA, the agency can decide not to review the application since 20-Aug 2019. And updated RTF checklist (Refuse to File) for NCE and Biological products (including Biosimilar) on 18-Jun-2024. https://www.fda.gov.tw/TC/siteListContent.aspx?sid=2984&id=46891	Steps: (1) Submission (100% e-submission) with payment according to List No. 1 (2) Document screening (3) Payment according to List No. 2 (4) 1st round assessment • In necessary cases, the Medicines Regulation Division may invite the applicant to a Pre-review meeting to present the registration dossier before entering the technical assessment. (5) 2nd round assessment (if needed) (6) Committee, Subcommittee, Working group meeting (7) Decision (8) Licensure issuance (9) Submission of electronic labels (e-labelling) via email: drug-smarthelp@fda.moph.go.th (10) Payment to obtain the Product License (11) Preparation of Public Assessment Report (PAR) GMP Clearance for drug product in parallel is permitted only for urgent public health needs on a case-by-case basis. BE study report review for new generic drugs in parallel. Refer to Public Manual: Registration of Modern Drug Formulations for Humans and Animals, and Traditional Drugs for Animals (Electronic Submission) (Medicines) (cited 2025 DEC 12 media.php)	1. Upon receiving a dossier, Drug Administration of Vietnam (under Ministry of Health) will organize to evaluate. Different parts will be independently evaluated by different experts/expert groups. + DAV releases DL if dossier is not enough + If dossier is passed, it'll be present in Advice Committee meeting for granting MA. 2. Drug Committee/ Advisory Council to review and conclude in visa meeting to reject or approve 3. Official announcement by Ministry of Health

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
NDA Approval review	Review time	CTA/supplementary CTA: 60WDs (for applications that meet the requirements, the review complete within 30WDs). Resource: https://www.nmpa.gov.cn/zhuanti/zt2023/ypgzhlfzh/shypqxgg/ggzcwj/20250912092255131.html?type=pc&m= NDA: 200WDs Priority review: 130WDs Orphan drug with urgent clinical need: 70WDs Independent application for generics of domestic launched chemical AP: 200WDs Supplementary application for variation: 60WDs, supplementary application combined with several application items: 80WDs, and 200WDs for the case involved clinical data inspection and QC testing/inspection Drug generic name approval: 30WDs OTC eligibility review: 30WDs	NCE: 5-8 months Generic: 9-12 months	New drugs manufacture d in India: 8- 12 months New drugs imported to India: 12-18 months	Refer to BPOM regulation No. 23 Year 2025 Timeline of pre-registration 40 working days after completed documents for category 1,2,3. Timeline of generics for EUA: 5 working days Timeline of registration export-only drugs: 7 working days Timeline of renewal registration: 10 working days and 8 hour for pure renewal (unwritten regulation) Timeline for New Drug & Biological Product for EUA, notification variation, new indication/posology of drug and biological product for EUA: 20 working days Timeline of minor variation registration: 40 working days Timeline of first registration of new drug developed by Industry that perform investment in Indonesia: 50 working days Timeline of first registration of first generic drug that perform investment in Indonesia and variation registration of new drug and biological product related quality that has been approved in (at least) 1 reference country: 75 working days Timeline of registration 90 working days for a New Drug, Biological Product, major variation (new indication/ posology which has been approved in at least 1 (one) country with known good evaluationTimeline of registration 100 working days: a. New Drug & Biological Product that are indicated for the treatment of serious life-threatening human or infection disease b. New Drug & Biological Product are indicated for treatment of serious and rare diseases (Orphan drug), c. New drug, biological product, generic drug and branded generic drug for public health program d. New drug & Biological product by Pharmaceutical industry that perform investment in Indonesia e. New drug & Biological product which development by Pharmaceutical industry / research institution in Indonesia through at least 1 clinical trial in Indonesia f. New generic drug that has same formula, source of materials, drug specification, quality, packaging specification, production process, production facility as those the approved branded generic drug g. Registration of major variation with new indication/posology for the drug as referred to point a to e. h. Registration of major variation in respect of quality and product information. Timeline of registration 150 working days for New Registration of Generic and Branded Generic drug not covered by the evaluation procedure provided in registration 100 working days. Timeline of registration of 300 working days after completed documents for a New Drug, Biological Product, major variation (new indication /posology) not covered by the evaluation procedures provided in registration 100 and 90 working days. Additional: Timeline of renewal registration for 8 hour for pure renewal (unwritten regulation) is removed in the BPOM online System because of an national incident of acute kidney injury due to ethylene glycol and diethylene glycol substances.	Review time change (80 percentile value) Priority review: 8.9 months (FY2024) Standard review: 12.0 months (FY2024)	1. FP: 90 working days 2. DMF: 20 working days 3. Biologics: 115 working days (If there is no additional questions or request of additional documents from the MFDS)	See DRGD Section 10.3 Evaluation Timeline For Product Registration Eg: NCE/NBE: 245 working days; Hybrid: 210 working days; Generics: 210 working days, etc. Shorter review timelines are targeted for different accelerated pathways. Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023 [https://www.npra.gov.my/easyarticles/images/users/1051/Direktif--Guideline-FRP-Nov-2023.pdf] ● **FRP Abbreviated review: 90 working days** ● **FRP Verification review: 30 working days** DRGD APPENDIX 13: Designation-and-Registration-of-Orphan-Medicines Orphan drug: 120 working days	The updated Citizen's Charter 2023 provides a working timeline for new drug applications at 180 working days. With the new reliance scheme called "Facilitated Review Process" and "WHO Collaborative Review Procedure" in place, the timelines can now be as soon as 60 days. (FDA Circular No. 2022-004) https://www.fda.gov.ph/citizen-charter-center-for-drug-regulation-and-research-cdrr/	For therapeutic products Reference to GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE Aug 2022, TPB-GN-005-010 – TARGET PROCESSING TIMELINES. APPENDIX 5 TARGET PROCESSING TIMELINES appendix-5_target-processing-timeline.pdf (hsa.gov.sg) Screening: 50 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Verification: 60 working days For Class 2 CTGTP Screening: 50 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Reference: HSA	Fees and turnaround time for CTGTP	NCE NDA & BLA standard review: 360 days Priority review: 240 days Abbreviated review: 180 days/120 days For the non-NCE NDA with efficacy & safety clinical data, the review timeline in TFDA/CDE is 300 days. For the non-NCE NDA without efficacy & safety clinical data, the review timeline in TFDA/CDE is 200 days. Link to NDA Instructions	Product Category Timeline (working day) (Full assessment) (Abridged assessment) (WHO CRP/SRA CRP Reliance assessment[a]) new drug (NCE) 220 154 90 new biologics and biosimilar* 220 (230*) 154 90 vaccine 280 154 90 biologics (follow-on) 160 110 90 generics and new generics 135 115 90 Advanced Therapy Medicinal Products (ATMPs) are classified as new biologics. [a]Regulatory time starts after a valid application for registration according to the Procedure has been received and access to the confidential information has been granted (whichever is the later). Refer to Public Manual: Registration of Modern Drug Formulations for Humans and Animals, and Traditional Drugs for Animals (Electronic Submission) (Medicines) (cited 2025 DEC 12 media.php)	within 12 months under normal scheme within 09 months under Reliance

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NDA Approval review	Priority review system	In new DRR (SAMR No.27), there are 4 accelerate pathways, including Breakthrough, Conditional Approval, Priority Review and Special Approval. To accelerate the entry of overseas new drugs urgently needed in clinical practice to China, first batch of "List of Overseas New Drugs Urgently Needed in Clinical Practice" was issued by NMPA&NHC in Nov. 2018. The list has been updated for three batches until 31st Dec,2020. The application of drugs in the list can be submitted directly in accordance with the Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs. the National Medical Products Administration (NMPA) Seeks Public Comments on the Announcement of the NMPA Regarding Further Optimization of the Review and Approval Process for Clinically Urgent Drugs Already Marketed Overseas https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjyp/20240625142147136.html On January 7, 2026, the National Medical Products Administration issued the "Announcement on Further Optimizing the Review and Approval of Urgently Needed Clinical Drugs Already Marketed Overseas (No. 3 of 2026)" https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20260107152912184.html In order to prevent drug shortages, "Key Monitoring List of National Clinical Essential and Shortage Drugs" was issued by NHC in Dec 2020. The application of drugs in the list can be included in the Priority Review pathway. https://www.nhc.gov.cn/wjw/c100175/202012/e7e9f8c9bba04ceba807799dd93da1d2.shtml	Usually no; except the following situations, 1. official request from Hospital Authority upon urgent situation. Special pathway ("1+ mechanism") will be expedited for new drugs, piloting priority evaluation and approval of innovative drugs recommended by the Hospital Authority for treatment of severe or rare diseases. 2. there is a local unmet medical need of the product for communicable diseases or matters of public health importance (e.g. vaccine of recent epidemic outbreak)	CDSCO has issued the circular on 09 Dec 2024 and requested to all state drug controller in reference to monitor the compliances regarding the timeline of the approval of all rare disease drugs and devices which should be processed within 90 days from the date of receiving. The circular also mention that concerned division at CDSCO office also to monito and proactively keep a watch on GCT and local CT for rare disease and process such files expeditiously.	Reliance system with 90 working days Refer to BPOM regulation No.-23 Year 2025 and Q&A of Reliance Mechanisms (2020). Refer to BPOM regulation No. 27 Year 2020 on 2nd amendment to Regulation of Head BPOM No. 24 Year 2017 and No. 13 Year 2021 on 3rd amendment to Regulation of Head BPOM No. 24 Year 2017 (Emergency Use Authorization) and 5th amendment to Regulation of Head BPOM No. 23 Year 2025	A priority review system exists. The following items apply. (1) Orphan drugs. However, those designated early are not applicable. (2) SAKIGAKE designation drugs (3) Early conditional approval drugs (4) Early access for Specific-use drugs (5) Drugs for serious diseases that are clearly superior in efficacy and safety compared to existing drugs and treatment methods	Yes Targeted area for the expedited review is as below. 1) Drugs used to treat or to prevent from life-threatening or serious diseases (including orphan drug, development stage orphan drug) that there is no existing treatment or aims to improve significantly in efficacy or safety than existing treatment options. 2) Drugs for prevention or treatment against the prevalence of biological terrorism or infectious diseases that may cause serious risks to public health 3) New drug developed by an innovation pharmaceutical company (a company designated by the Government)	Yes Priority Review Conditions, Product categories and Timelines as given in the APPENDIX-12-Priority-Review.pdf (npra.gov.my). There is also Facilitated Registration Pathway (FRP) [https://www.npra.gov.my/easyarticles/images/users/1051/Direktif--Guideline-FRP-Nov-2023.pdf]	Currently, the FDA prioritizes the following types of applications: 1.Products to be manufactured exclusively for export 2.New drug products considered to be a major therapeutic advancement 3.First five products of newly-licensed establishments 4.Products for government projects 5.Imported pre-qualified vaccines. Applicant must make a request for priority review, to be approved by FDA. When granted, application is put ahead of the queue; no explicit mention of reduction in processing timelines. In 2020, the FDA issues two Administrative Orders providing for alternative registration procedures. AO 2020-0044 adopts the Collaborative Procedure for WHO pre-qualified products, while AO 2020-0045 provides for the facilitated registration pathways such as the abridged reviews and verification reviews. Guidelines for implementing AO2020-0045 were issued in June 2022. (FDA Circular No. 2022-004) Guidelines for implementing AO2020-0044 were issued in October 2022. (FDA Circular No. 2022-009)	Priority review system or pathway is only applicable to product submitted via Abridged Evaluation (with 1 reference country approval); and meets the pre-defined criteria in the guide (unmet medical need, etc.). Grant of priority review is on case-by-case basis, at discretion of the Agency during Screening. Applicant will be notified at the point of acceptance of application, if request is granted.	Yes To improve the new drug accessibility to public and accelerate the new drug review and efficiently utilize the review resource, TFDA announced or amended the several designations for sponsor utilization since Nov 2019 which include: 1.Designation Request of Medications for Pediatric Population or the Minority Patients with Serious Diseases 2. Abbreviated review designation 3.Priority review designation 4.Accelerated Approval 5.Breakthrough Designation Reference: Link to NDA Instructions https://www.fda.gov.tw/TC/siteListContent.aspx?sid=2984&id=32228 (no change comparing current regulation)	Yes Expedited review (4 categories: Emergency Use Authorization: 30 working days, Accelerated review, Fast track review, and Priority review: 90 working days) Abbreviated assessment (2 categories: Abridged assessment and WHO CRP Reliance assessment) Refer to Notification of the Food and Drug Administration Re: Consideration Guideline for Modern Drug Registration Submitted Electronically B.E. 2568 (cited 2025 DEC 12 media.php)	Vietnam introduced reliance review pathway for NDA in 2024 via the Pharma Law revision (Pharma Law 44/2024/QH15, Art. 56) and came into effect under Circular 12/2025/TT-BYT. Category of review pathways for NDA and timeline (Article 45, Circular 12/2025/TT-BYT): - Normal pathway – 12 months - Reliance pathway – 9 months - Accelerated evaluation pathway – 6 months (Circular 12/2025/TT-BYT,): applied for new drugs; brand-name drugs; orphan drugs; vaccines; the first domestically manufactured generic drugs; the first domestically manufactured biosimilars; high tech drugs; drugs that have undergone clinical trial in Vietnam; drugs manufactured from herbal materials that satisfy Good Agricultural and Collection Practices for Herbal Materials; drugs and medicinal materials manufactured as a result of accepted national, ministerial or provincial science and technology missions; drugs satisfying requirements for national defense and security, incident and disaster recovery, disease prevention and control.

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NDA Approval review	Orphan drug system	First "List of Rare Diseases" was issued by NHC/MOST/ MIIT/NMPA/NATCM on May of 2018, including 121 rare diseases. The second batch of the list was issued by NHC/MOST/MIIT/NMPA/ NATCM/General Logistics Dept. of Central Military Commission on Sep.18 2023, including 86 rare diseases. In principle, the interval is not less than 2 years. There is no specific orphan drug review pathway but priority review pathway or special pathway. - Priority review pathway: Please refer to previous article "Priority review system" in new DRR. - Review time limit: 70WDs for the orphan drugs in urgent clinical needs that have been marketed overseas Additionally, CDE issued 2 guidelines regarding orphan drug review, CDE Notice on Technical Guidelines for Clinical Drug Development for Rare Diseases (No.71 in 2021) and CDE Notice on Statistical Guidelines for Clinical Research on Rare Disease Drugs (Trial) (No.33 in 2022). CDE also issued Notification on publication of "Pilot Program for Patient-Centered Rare Disease Drug Development (" Care Program ") (PAB/ELD Notification No. 2024 500).	Drugs with orphan drug designation in reference countries may register via special NCE pathway (1+ mechanism) if it meets the additional requirements. Please refer "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity" section 4 for special pathway ("1+ mechanism"). https://www.ppbhk.org.hk/eng/files/Guidance_on_Reg_of_Pharm_Prod_Containing_New_Chem_or_Bio_Entity_en.pdf?v=8xag5	Orphan Drug has been defined in Rule 2(x) of the NDCT Rules, 2019 as "a drug intended to treat a condition which affects not more than five lakh persons in India" No procedure or process outlined in NDCT Rules for Orphan Drug designatio n of a New Drug.	Orphan Drug system with 100 working days Refer to BPOM regulation No.15 Year 2019 Annex	Yes An orphan drug system exists. Designation criteria Number of patients - Less than 50,000 in Japan. Segregation of diseases was allowed based on appropriate medical and pharmaceutical grounds. Medical need -There are no appropriate alternative drugs or treatment methods. -The efficacy and safety are expected to be outstanding and significantly greater than those of the existing drugs. Possibility of development -There is a system and plan that allows domestic development. Specifically, an overview of the clinical trials that are scheduled to be conducted prior to fling for approval must be clear. In addition, at least the non-clinical studies necessary to conduct the first human clinical study must have been largely completed. Incentives (1) Subsidy payment (2) Guidance and consultation on research and development activities (MHLW, PMDA, NIBIO). PMDA provides a priority consultation system. (3) Preferential tax treatment (4) Priority review˙ (5) Extension of re-examination period *: For the time being, priority review will be available only if the previous orphan designation criteria are met. The reexamination period for orphan and pediatric drugs will be extended by up to 12 years, except for drugs that received early designation..	Yes. The orphan drug system exists. Designation criteria : -Prevalence is less than 20,000 in Korea -Drugs to treat diseases for which appropriate therapy and drugs have not been developed or have been significantly improved in terms of safety and/or efficacy, compared to existing alternative drugs - The validity of the development plan (including the clinical trial protocol) as an orphan drug in Korea is recognized. Also there is a designation system of "orphan drug on the development stage" for products that are in clinical phase in Korea (or products that are in non-clinical phase where have the possibility enter to clinical trials)	Yes The Malaysian Orphan Medicines Guideline was issued in December 2020. APPENDIX-13-Designation-and-Registration-of-Orphan-Medicines.pdf (npra.gov.my)	The Philippines has an Orphan Drug Law, where FDA shall: •Prioritize the registration of orphan drugs •Facilitate the issuance of Compassionate Special Permit for the restricted use of orphan drugs We are yet to see the implementation of this law, but the new guidelines have formally recognized "Orphan Drugs" as a product type. (Administrative Order No. 2024-0013)	No orphan drug designation available	Yes 23-Sep-2015 Orphan Drug Designation procedure was issued by TFDA, all ODD should submit technical documents according to application form and need to provide Orphan Drug safety efficacy tracking protocol execute after approval with periodical report to TFDA for review until NDA approval. Also provide Orphan Drug NDA registration schedule to TFDA.	Even though there is an orphan drug regulation in Thailand, the intention of this regulation is to address drugs needed for rare and serious diseases, which have low usage, no alternatives, and face nationwide shortages. The drug can be proposed by healthcare professionals, pharmaceutical companies, or patient advocacy groups. These proposals are then considered for enlisting by Thai FDA Subcommittee on Orphan Drugs. Refer to Notification of the Food and Drug Administration Re: Orphan Drug List B.E. 2568 (cited 2025 DEC 12 media.php)	Yes The Ministry of Health issued Circular 26/2019/TT-BYT on Orphan drug list (currently under revision), with following criteria: 1. A drug is considered to be included in the orphan drug list for prevention, diagnosis and treatment of a rare disease when it meets any of the following requirements: a) The drug is for prevention, diagnosis and treatment of a rare disease as stipulated by Minister of Health; b) The drug is indicated and classified as an orphan drug by one of the reference regulatory authorities. 2. A drug is considered to be included in the list of drugs not readily available is one for which in the Vietnam market there are no readily available other drugs that can substitute it, or one with documents proving significant quality, safety and efficacy benefits over other substitutable drugs in the local and international markets and falls under any of the following cases: a) A drug for prevention, diagnosis and treatment of diseases with low prevalence rate in a population at any point in time not exceeding 0.05% of the population and which is any of the following: a genetic, congenital, cancer, autoimmune, communicable, tropical infectious, or any other disease as decided by Minister of Health upon advice by the Professional Board formed by Minister of Health; b) Any vaccine, drug for diagnosis or prevention with estimated usage not exceeding 8,000 cases every year in Vietnam; c) A radioactive drug; a marker; d) A drug for which business activities do not generate sufficient profit to cover investment and marketing of the same in Vietnam market.
	approval matters	The format of drug approval numbers for drugs manufactured domestically is: Guo Yao Zhun Zi H (Z, S) + 4-digit year number + 4-digit serial number. The format of drug approval numbers for drugs manufactured in China Hong Kong, Macau and Taiwan is: Guo Yao Zhun Zi H (Z, S) C + 4-digit year number + 4-digit serial number. The format of drug approval numbers for drugs manufactured overseas is: Guo Yao Zhun Zi H (Z, S) J + 4-digit year number + 4-digit serial number. - In each case, H represents a chemical drug, Z represents a traditional Chinese medicine, and S represents a biological product. - Drug approval numbers shall not change following post-marketing variations. - Traditional Chinese medicines shall be subject to its provisions if any. Mandatory requirements since Dec.1 2020.	Current Certificate of Drug/ product registration form, the following information is described. ・Company name/ address ・Name of Drug/product ・Expiry date of the certificate ・Registration requirements and conditions	Data as required under Table 1 & Table 2 of the Second Schedule of NDCT Rules 2019	Refer to BPOM regulation No 24 year 2017 article 27, 28 & 29 : All submitted information in the electronic registration system are binding and subject to approval by the authority. Those are followings: 1.Information as master data 2.Administrative Documents 3.Quality Documents 4.Non-Clinical Documents 5.Clinical Documents 6.Product Information & Labelling	・Non-proprietary Name ・Brand name ・Ingredients and Contents or Nature ・Manufacturing Method ・Dosage and Administration ・Indications ・Storage Methods and Expiration Date ・Specifications and Test Method ・Name of the Manufacturing Site used to Manufacture the Product, Address, License/ Accreditation Category, etc.	1. Product name 2. Classification number and classification (prescription drug or OTC) 3. Composition of the Drug Product 4. Appearance 5. Manufacturing method Would be written as "According to 3.2.S.2, 3.2.S.3 and 3.2.P.2, 3.2.P.3, 3.2.P.4, 3.2.P.7 of CTD," or for non-CTD application document, Name and address of API manufacturing site should also be written in the manufacturing method table.) 6. Therapeutic Indications 7. Administration/dosage 8. Cautions for use 9. Packaging unit 10. Storage conditions and expiration date 11. Specification and test method 12. Manufacturing site 13. Conditions for Approval	All registration particulars. (Re: DRGD)	Brand Name Labels Priority Review FDA GMP Clearance	・Non-proprietary Name ・Brand name ・Ingredients and Contents or Nature ・Manufacturing Method ・Dosage and Administration ・Indications ・Storage Methods and Expiration Date ・Specifications and Test Method ・Name of the Manufacturing Site used to Manufacture the Product, Address, License/ Accreditation Category ・Forensic status of drug	TFDA will issue approval letter with draft Taiwan Package Insert (TPI) after completion of NDA review. TFDA will issue notification letter after TPI is finalized within 15-30 days after approval letter is issued. Applicants can prepare printed TPI and packaging material samples to collect the drug license after receiving License Collection Notification within 3 months. Drug product can be manufactured/imported after License collected.	Any changes require variation submission and approval is required.	MA covers the following information, ・Brand name ・Active substance and strengths/ concentration ・Dosage form ・Package size ・Quality Specification ・Shelf-life * MA Number, Decision Number, issuance date, validity of MA ・Name & address of MAH ・Name & address of manufacturer ・Name & address of assembler, if any

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NDA Approval review	Other information concerning approval review	NMPA issued Announcement on Issuing Electronic Drug Registration Certificates ([2022] No. 83) on Oct.9, 2022, indicated that NMPA will issue electronic drug registration certificates from Nov.1, 2022. The scope of issuance includes the certificates of drug clinical trials, drug marketing authorization, drug renewal, drug supplementary application, protection of traditional Chinese medicines, imported medicinal herbs, chemical APIs, etc. and the certificates of Good Laboratory Practice approved or issued by the National Medical Products Administration (NMPA) from Nov 1, 2022. Electronic drug registration certificates shall have the same legal effect as paper registration certificates.	If an applicant fails to reply and provide the outstanding information within 60 days in response to the deficiency letter, the application under screening will be automatically refused for filing. For applications with Special Pathway ("1+ mechanism"), pre-NDA meeting can be requested at least SIX weeks prior to the proposed meeting dates. Please refer to below link for details: https://www.drugoffice.gov.hk/eps/do/en/doc/onePlus_Pre-NDA_Meeting_Guidance_en.pdf Application with Special Pathway ("1+ mechanism") may opt for using electronic product information (ePI) to replace a physical packaging insert served to provide product information intended only for healthcare professionals. In any circumstances, a patient information leaflet to be supplied to patients as required must be in physical form to be provided with the container or package of product. "Stop-clock" mechanism for special pathway ("1+ mechanism") is applied. For details, please refer to the link below: https://www.drugoffice.gov.hk/eps/do/en/doc/stop_clock_en.pdf	For vaccines CDL Kasauli is also engaged for CMC review	NCE should provide API Drug Master File or Internal Monograph as required in Part II Quality of Drug Substance & GMP Certificate of API's manufacturer. Approval of SMF should also be considered to get approval of registration number	-	-	There are four types of evaluation procedures **1. Full evaluation (standard pathway)** **2. Full Evaluation (Conditional Registration)** **3. Evaluation via Facilitated Regulatory Pathway (FRP) (Lampiran A - Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023)** **4. Abridged review** Special reviews include Conditional Registration for Pharmaceutical Products During Disaster, Priority Review and Orphan Drug pathways (as mentioned above)	There is a separate review team and processing timelines for New Drug Applications of Biological products.	Inclusion of Pandemic Special Access Route (PSAR) for supply of emergency Therapeutic Products to facilitate early access to critical novel vaccines, medicines and medical devices during a pandemic, such as the current COVID-19 pandemic. (https://www.hsa.gov.sg/hsa-psar	The application of new therapeutic, new combination, new administration, generic, biosimilar, new/change indication and follow first applicant to add/change indication need to of the addition of a new indication need to complete the Regulations for the Patent Linkage of Drugs Anne x II Declaration form of the status of pharmaceutical patents. The announcement was announced on 14-Jan.-2020.	Reference country required: US, EU, UK, Switzerland, Japan, Canada, Australia Pre-review meetings are usually implemented for WHO CRP Reliance assessment Abbreviated assessment (Abridged assessment and WHO CRP Reliance assessment): An additional clarification on 1. Cases where documents differ from those submitted to the Reference SRA and WHO; and 2. Preparation of an additional context consideration table. Refer to Public Manual: Registration of Modern Drug Formulations for Humans and Animals, and Traditional Drugs for Animals (Electronic Submission) (Medicines) (cited 2025 DEC 12 media.php)	-
NDA Pre-approval inspection	GCP inspection	Not mandatory in principle, in practice, pre-NDA GCP inspection is still applied for majority of NDAs. After the centralized acceptance since Dec.1st 2017, CDE entrust CFDI to conduct GCP on-site inspection during NDA review per CDE review needs. It is applicable for both domestic drug and import drug.	GCP site inspection conducted by DH may start from Q4 2026,	DCGI/CDSCO or State FDAs may conduct GCP on- site inspection. DCGI will issue instructions to the CDSCO officers/ Inspectors to conduct the inspection identifying the clinical trial site/ facilities to be inspected. CDSCO issued GCP Inspection Checklist in Feb 2018	GCP inspection for local clinical study in Indonesia. GCP inspection for import product is not required.	The GCP on-site inspection is executed by PMDA for 2 or 4 medical institutions and applicants. The reliability inspection is conducted both in-person and remotely.	Yes. For all of the NDA that has clinical trials(Bioequivalence test included, usually domestic clinical trials).	Yes for local clinical studies. Details given in the. Malaysian Guideline For Good Clinical Practice (GCP) Inspection	GCP inspection for local clinical studies (if ever conducted) is not routinely done but may be done by FDA The FDA shall conduct inspections to ensure that the rights, safety, and well-being of study subjects have been protected, to ensure the integrity of the scientific data collected, and to assess adherence to GCP Principles and other applicable FDA regulations. (AO 2020-0010)	CT in Singapore Pre-marketing approval application inspections are usually done announced and apply to completed clinical trials. Criteria during GCP Inspections: (i) Protocol (ii) Applicable clinical trial and clinical research material regulations* (iii) ICH E6 (R2) Good Clinical Practice Guidelines (ICH E6 GCP) (iv) Applicable Sponsor / Contract Research Organization (CRO) / Site Standard Operating Procedures (SOPs) for clinical trials (CLINICAL TRIALS GUIDANCE GUIDANCE ON GCP COMPLIANCE INSPECTION FRAMEWORK GN-IOCTB-11 Rev. No. 003)hsa_gn-ioctb-11_gcp_inspection.pdf （JAN 2026）	TFDA announced about GCP inspection process on 28-May-2020 and the implementation date is 1-July-2021 https://www.uqs.com.tw/tw/p/962/announcement--strengthening-the-plan-to-strengthen-the-link-between-gcp-verification-of-drug-clinical-trials-and-registration-and-review-of-new-drug-inspection "The process has been updated on Jan. 5, 2024. Refer to the announcement No. 1121414566 dated January 5, 2024.	If required. For new domestic manufacturing categories, new biological products, or foreign sites requiring GMDP/GCP inspection—including bioequivalence studies—officers will request an inspection application with supporting documents, conduct the inspection, and issue results for registration consideration. Refer to Public Manual: Registration of Modern Drug Formulations for Humans and Animals, and Traditional Drugs for Animals (Electronic Submission) (Medicines) (cited 2025 DEC 12 media.php).	N/A. Applicable for local clinical trials only. When local clinical trial is conducted, GCP inspection is carried out. (Article 8. Circular 50/2025/TT-BYT)

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NDA Approval review	GMP inspection	The CDE shall decide whether or not to carry out drug registration development site inspection based on the risks, the innovativeness of the drug, and the previous inspection results of drug research institution. Where the CDE decides to initiate drug registration development site inspection, the CFDI shall be notified to organize and implement inspection during the review period, and the applicant shall be informed at the same time. The CFDI shall complete on-site inspection within the prescribed timelines and present related materials including inspection results and inspection conclusions to the CDE for comprehensive review. The CDE shall decide whether or not to carry out drug registration manufacturing site inspection based on the product under registration application, the process, facilities, previous inspection results and the risks Conduct during 40 WDs after acceptance and 40 WDs before complete the review. Priority review: Conduct during 25 WDs after acceptance and 25 WDs before complete the review. In order to clarify the principle, procedure, timeline and requirement for implementation of drug registration inspection, to specify the cohesion of drug registration manufacturing on-site inspection and pre-approval GMP inspection, CFDI issued Working Procedure for Drug Registration Inspection (for Trial Implementation) and Working Procedure of Cohesion of Drug Registration Manufacturing On-site Inspection and Pre-marketing GMP Inspection (for Trial Implementation) and Key Points and Determination Principle of Drug Registration Inspection (Pharmacology and Toxicology Study, Drug Clinical Trials, Pharmaceutical Development and Manufacturing Site) (for Trial Implementation) on Dec.20, 2021 and taken into effective since Jan. 1, 2022. Working Procedures for Initiating Drug Registration Inspection and Testing (for Trial Implementation) was issued by CDE on Dec.20, 2021 and taken into effective since Jan. 1, 2022.	For manufacturer with PIC/S GMP: Document inspection only, CPP/GMP certificate from source country accepted. For manufacturer without PIC/S GMP: DH would conduct PIC/S inspection to the facilities before its product would be considered for registration in HK.	The guidance for risk-based site inspection of drug manufacturing site issued by CDSCO office. Guidance document for risk based inspection.pdf	BPOM Regulation No. 7 Year 2019: For imported product: Based on evaluation of Site Master File, if necessary, desk inspection and GMP inspection site will be request by BPOM. GMP Inspection Report from PIC/S country will be evaluated and can be considered for waiving on inspection	GMP compliance inspections are mandatory requirements prior to seeking marketing approval. Application for GMP compliance inspections for all manufacturing sites listed in the application for marketing approval must be submitted to the GMP compliance inspection authority (PMDA or respective Prefectures) by each manufacturing site	Yes. For sites that has no MFDS inspection history. For sites of which there is MFDS inspection history, waiver period for on-site inspection is given. (5 years for non-sterile products, 3 years for sterile products). Also for non-sterile products, on-site inspection is replaced to desk-top assessment if the manufacturing site is located in the territory of PIC/s Participating Authority and has submitted an appropriate inspection report of the competent PIC/s Participating Authority.	On-site inspection (both local and oversea) required unless exempted (e.g., inspected by a PIC/S participating authority or located in an ASEAN member country which have been inspected by the local HA). (Details given in Guidance Document Foreign GMP Inspection, 9th Edition https://www.npra.gov.my/easyarticles/images/users/1133/2023%20Mar/Guidance-Document---Foreign-GMP-Inspection_9th-Edition.pdf	Before submitting an NDA for imported products, applicants must first secure a foreign GMP certificate from FDA for each manufacturer involved in the final product. This is obtained either through desktop review (if PIC/S-GMP certified), or through on-site inspection (for non-PIC/S) For locally manufactured products, the GMP certificate is issued through actual inspection.	Documentary evidence must be provided to certify that the manufacturer(s) complies with current applicable GMP standards. Applicants must submit appropriate proof of GMP compliance for all manufacturing sites including, but not limited to, drug substance manufacturers, bulk product manufacturers, primary packagers and secondary packagers. Ref: https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/guidance-on-therapeutic-product-registration-in-singapore.pdf?sfvrsn=cd174383_52 If the drug product is manufactured by a new overseas drug product manufacturing site not previously registered with HSA before 1st April 2004, a GMP Conformity Assessment will be conducted by HSA. Thus, when applicable, applicants must also submit the application form to request for GMP Evidence Evaluation or for an Overseas GMP Audit with the required documents as stipulated in the Guidance Notes on GMP Conformity Assessment of an Overseas Manufacturer.	TFDA website for PMF for reference: https://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=417	Require GMP clearance for all manufacturing flow in P3 except Quality testing site. Site inspection might be required in case submitted document is insufficient.	- Normally, GMP certificate from source country is accepted. But according to Decree 163, (Article 95, clause 1), Inspection can be conducted in cases of: a) It is suspected that the application for marketing authorization provided by the manufacturer are altered; or the information and data provided are inaccurate b) Drugs manufactured by the manufacturer are concluded to violate at the first-degree by the Ministry of Health c) Ministry of Health concludes that there is insufficient evidence to prove that the manufacturer meets the GMP requirements; d) GMP principles and standards of the exporting country do not align with GMP principles and standards issued and recognized by the Minister of Health of Vietnam; đ) Manufacturers applying for the first-time marketing authorization in Vietnam not belong to case of mutual recognition and acknowledgement of results of inspection and audit by drug regulatory authorities, or manufacturers that have been inspected and certified to comply with GMP by SRA or a drug regulatory authority recognized by the Ministry of Health based on the classification of WHO - Mutual recognition, acceptance of inspection, outcomes from pharmaceutical regulatory authorities with regard GMP compliance shall be applicable to: a) Manufacturers of countries on the MOH-issued list of countries with which Vietnam has international mutual recognition treaty regarding GMP inspection outcomes, SRA countries, except for the cases stipulated in points a and b (above). b) Manufacturers of countries whose drug regulatory authorities are SRAs or recognized by the Ministry of Health based on classification of WHO and inspection of GMP compliance for such manufacturer is conducted by these agencies, except for cases specified in points a and b (above)
	Other inspections	The revised China GLP (draft) was issued for public comments on Nov.21st 2018. China PV Inspection Guidelines was issued on Apr 15th 2022 to guide drug regulatory authorities to carry out pharmacovigilance inspection in a scientific and standardized manner. There are 100 inspection items listed in the guidelines to evaluate MAH compliance and implementation of the requirements for establishing pharmacovigilance system. NMPA can conduct an unannounced inspection for drugs and medical devices. The unannounced inspection refers to the supervision and inspection conducted in the process of research, development, manufacture, distribution and use of drugs and medical devices by the regulatory authority without advance notice. Measures for Administration for Good Laboratory Practice of Non-Clinical Studies of Drugs was published in January 2023 and effective on July 1, 2023. Source: https://www.gov.cn/zhengce/zhengceku/2023-01/20/content_5738186.htm	GLP inspection and PV inspection are not required.	GLP audit shall be the part of GMP audit.	In the GMP inspection site, the Laboratory is inspected by NADFC. The Laboratory inspected following GLP requirements.	"Paper-based compliance inspections" are executed by PMDA to confirm whether the data attached to the NDA application accurately reflects the results of clinical trials, and other studies, and whether those were conducted in accordance with GCP, GLP and reliability standards. GLP site inspections will be conducted as necessary.	Laboratory should get the GLP certification. GLP inspection will be conducted by MFDS if necessary and valid GLP certification may be issued.	Laboratory should get the GLP certification if applicable, and GLP inspection will be conducted if necessary. Detailed information and condition regarding procedures under which test facilities inspections and study audits are performed can be found in the NPRA GLP Compliance Programme Manual. (https://www.npra.gov.my/easyarticles/images/users/1062/GLP/NPRA-GLP-Compliance-Programme-Manual-Version-5-March-2023.pdf)	Regular On-site inspection is conducted for all local establishments. On-site inspections of foreign manufacturers are tentatively restricted by COVID-19. (FDA Circular2020-020)	PV inspection is not required. GLP inspection is under the care of other government agency. · https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pdf · https://www.sac-accreditation.gov.sg/services/accreditation-services/glp-compliance-monitoring/	Business undertakings engaged in wholesaling, importing and exporting pharmaceuticals (including raw material), shall meet the standard of Western Pharmaceuticals Good Distribution Practice (GDP) Regulations, and shall obtain the western pharmaceuticals distribution license upon the inspection and approval from the central competent health authority. Raw material pharmaceuticals need to comply with GDP Management scope before 31-Dec.-2022. TFDA website for GDP for reference: https://www.fda.gov.tw/TC/siteListContent.aspx?sid=4071&id=40430 https://www.fda.gov.tw/TC//siteContent.aspx?sid=332 https://www.fda.gov.tw/TC/site.aspx?sid=4070&r=610624134	No requirement for GLP inspection	-

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Clinical trials	Necessary procedures to start clinical trials	IRB approval isn't mandatorily required by CDE before IND submission but should before starting the clinical trial. IND permission/IRB approval => HGRAC approval => start clinical trial	a. IRB approval b. Approval from Drug Office, Department of Health for clinical trial certificate (CTC) application	Clinical trial on new drug shall be initiated after approval by CDSCO and respective Institutional EC or an Independent EC. Application to CDSCO and EC can be made in parallel. Trials should also be registered with CTRI (Clinical Trial Registry of India; Indian Registry) before screening patients	After receiving Clinical Trial Approval Letter from BPOM, the Clinical Study can be started. Refer to BPOM Regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval and BPOM regulation No 24 Year 2025 for 1st CTA under IND Approval Process	Need to submit Clinical Trail Notification (CTN) to PMDA. Contracts with clinical sites should be signed after 30 days from the date of CTN submission in case of 1st CTN, and 14 days in case of 2nd or later trial.	To start clinical trials in South Korea, you must develop a protocol in compliance with Good Clinical Practice (GCP), secure Institutional Review Board (IRB) approval, and obtain regulatory approval from the Ministry of Food and Drug Safety (MFDS) by submitting an Investigational New Drug (IND) application with necessary pre-clinical data, Investigator's Brochure, and GMP documentation. Additionally, agreements with trial sites must be established, investigators trained, and participants recruited with proper informed consent. Throughout the trial, compliance with monitoring, reporting, and data management requirements is essential, concluding with a final report submitted to the MFDS.	Submission to NPRA and Research Review Committee (RRC) / Medical Research Ethics Committee (MREC) can be done in parallel. 1. Clinical Trial Import License (CTIL)/ Clinical Trial Exemption (CTX) application to NPRA2. Application to the relevant RRC/ MREC 2. Application to the relevant RRC/MREC After receiving the approval for each of these processes, the clinical trial can be started.	1.Secure a License to Operate (LTO) for CRO and/or Sponsor 2.Secure Clinical Trial Approval and Import License (from FDA) 3.In parallel secure IRB/ EC from institution (Administrative Order No. 2020-0010)	Reference to: Clinical Trials Guidance Determination of whether a Clinical Trial requires Clinical Trial Authorization (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC) https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-01_cta_ctn_ctc.pdf?sfvrsn=8a42c4b6_4 Clinical Trials Guidance Regulatory Requirements for New Applications and Subsequent Submissions https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl.pdf?sfvrsn=38b22922_6 For CTGTP: Chemistry, Manufacturing and Controls Requirements for Cell, Tissue or Gene Therapy Products for Clinical Trials and Product Registration (Appendix 8) appendix-8-chemistry-manufacturing-and-controls-requirements-for-cell-tissue-or-gene-therapy-product-for-clinical-trials-and-product-registration.pdf (hsa.gov.sg)	1. Compile a full dossier including protocol, CMC, non-clinical data, IB, etc. 2. Submit the application via TFDA's online platform with all required documents and fees. 3. Ensure IRB approval for the trial protocol and ICF. 4. Ensure investigators are trained and certified for GCP / ethics. 5. If required, obtain an import permit for investigational product. 6. Once both TFDA and IRB approvals are obtained — you can initiate the trial. 7. Clinical Trial contract signed with the sites.	Clinical trials not mandatory required for drug registration at Thai FDA	Procedures for registering a clinical trial 1. The owner of the drug for clinical trial shall submit an application for permission for clinical trial to the Administration of Science Technology and Training, the Ministry of Health, whether directly or by post. 2. The Administration of Science Technology and Training, the Ministry of Health shall verify legality of the application within 05 working days from the receipt of the application. If the application is not satisfactory, the applicant shall be instructed in writing to complete the application until it is satisfactory. 3. The applicant shall cooperate with the Administration of Science Technology and Training, the Ministry of Health in completing the application within 60 days from the date on which it is instructed in writing. After the aforementioned deadline, the application will be rejected. 4. Within 05 working days from the receipt of the satisfactory application, the Director of the Administration of Science Technology and Training, the Ministry of Health shall grant a written approval for clinical trial according to the Form No. 13 in the Appendix III hereof. If the application is rejected, it is required to respond and provide explanation in writing.
	Required data/ documents/ brochures to start clinical trials Are there any local requirements of specific data other than ICH-M3 or S6, for initiation of clinical trials?	No All the toxicity data is included in the IB.	No specific local requirements	Data required as per Second Schedule of NDCT Rules, 2019	Clinical Trial Documents consist of: UK-1 Form, Protocol, Investigator's Brochure, Informed Consent, Documents of trial drugs, Summary Protocol of Batch Production (for Vaccine and biological products). Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval	No Generally necessary data and or documents are followed as per ICH requirements. In some instances, additional reproductive toxicity tests are requested prior to clinical trials.	No In South Korea, the requirements for initiating clinical trials generally align with ICH guidelines, including ICH-M3 (Nonclinical Safety Studies) and ICH-S6 (Biotechnological Products).	Yes CTIL/CTX Application: The necessary data / documents are covered in the latest edition of the Malaysian Guideline for Application of CTIL and CTX. Regulatory submissions are made in parallel with IRB submissions. IRB/IEC Application: Details of documents required for submission are available, e.g., for The Medical Research and Ethics Committee (MREC), the relevant information is a vailable under the User Manual/Documents section in NMRR website (https://www.nmrr.gov.my). https://nmrr.gov.my/documents?type=user-manual	FDA follows ICH Safety and Efficacy Guidelines, ICH GCP (Administrative Order No. 2020-0010)	The sponsor should submit the supporting documents (listed in Table 1) to HSA for CTA, CTN and CTC applications. Reference to Clinical Trials Guidance Regulatory Requirements for New Applications and Subsequent Submissions GN-IOCTB-04 Rev. No. 004, 28 Apr 2021	Yes the standard global-style data set (non-clinical data, CMC, IB, protocol, ICF, etc.) remains the core requirement under Taiwan's regulatory framework. On top of that, local requirements emphasise appropriate documentation in Chinese (or Chinese-language synopsis), validated translations of any patient-facing materials (e.g. PRO questionnaires), and submission via TFDA's platform (ExPRESS).	Not applicable	An application for permission for clinical trial consists of: a) An application form b) Documents containing information about the drug (general information about the drug for clinical trial: name, ingredients, indications, physical and chemical properties, dosage form and other relevant information); pre-clinical trial documents; documents about the clinical trial in previous phases), prepared in Vietnamese or English language and accompanied by a summary made in Vietnamese language.

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Clinical trials	Required data/ documents/ brochures to start clinical trials Are there any local requirements of documents/ brochures outside IND/ CTA dossier?	Yes -CRF & ICF -Contract with site -IRB approval -Human genetic resource approval -Some sites require insurance certificate for the clinical trial -IMP Certificate of Analysis (Some sites require GMP certificate), and PI's CV are required.	No specific local requirements	Data required as per Second Schedule of NDCT Rules, 2019	Informed Consent to the patient Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval	Yes Explanatory materials and consent form used for obtaining informed consent	Yes Investigational products must be manufactured, handled, and stored in compliance with applicable Good Manufacturing Practice (GMP) standards. Additionally, an insurance certificate is required prior to the initiation of clinical trials.	Yes The Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption covers all the main requirements including Informed Consent Form. https://npra.gov.my/easyarticles/images/users/1140/Malaysian-Guideline-for-Application-of-CTIL-and-CTX-8th-Ed-Final.pdf Other key guidelines for conducting clinical trials in Malaysia are: ● **Malaysian Guideline for Good Clinical Practice** ● **Malaysian Guideline for Safety Reporting of Investigational Products** ● **Guidelines for Good Clinical Practice (GCP) Inspection** ● **Malaysian Guideline for Bioequivalence Inspection** ● **Malaysia Guideline for Phase 1 Unit Inspection and Accreditation Programme**	•Application Form •IP and ancillary supplies info •Import license application •Clinical Trial Protocol •GCP Certificate and CV of Primary Investigators for each trial site •Informed Consent Form •Investigator's Brochure •Pharmaceutical Data •Labeling Materials (Administrative Order No. 2020-0010)	Yes ・Informed Consent Form ・Investigator's Brochure ・Principal Investigator's CV ・List of overseas sites (if applicable) ・GMP certificates ・COA for study batches of investigational product ・CMC documents, if requested by HSA. Reference: GN-IOCTB-04 Rev. No. 004 REGULATORY REQUIREMENTS FOR NEW APPLICATIONS AND SUBSEQUENT SUBMISSIONS Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl.pdf?sfvrsn=38b22922_6	Yes **IRB/IEC submission package**, including: •Study protocol •Informed Consent Form (ICF) •Investigator's Brochure (IB) •Recruitment materials (if applicable) •Investigator's CV and valid GCP training certificate •Site-specific forms (e.g., feasibility form, COI form, PI declaration) **Clinical Trial Agreements (CTAs)** between sponsor/CRO and the investigational sites. **Clinical trial insurance certificate** covering subject injury, meeting TFDA requirements. **Import permits**, if applicable: **•Drug Import Permit for Clinical Trial Materials (CTM)** issued by TFDA, required for importing investigational products (IP), comparators, or placebo. **•Medical Device Import Permit** (for investigational or ancillary devices used in the study). **•Biological sample import/export permits**, if biological samples will be shipped across borders. **Local laboratory certifications** or normal reference ranges, if required by the study or IRB. **Site SOP-related documents or data protection/privacy documents**, as requested by individual IRBs.	Material Transfer Agreement (MTA) is a legal contract that governs the transfer of tangible research materials between a provider and a recipient. It defines the rights, obligations, and restrictions associated with the use of the transferred material. Rather than requiring both the provider and recipient to sign the MTA, many institutions accept an agreement between a local sponsor and the institution itself. However, this depends on the content of the transfer and requires review and approval by the institution's legal department.	Yes a) An application form b) Documents containing information about the drug for clinical trial: - Drug trial documents: composition, manufacturing process, quality standard and drug test report (in the case of a modern drug, herbal drug or traditional drug, it is required to have a drug test report of the state-owned drug-testing facility that complies with GLP or provider of drug/medicinal ingredient testing services that complies with GLP within its scope of operation or of the manufacture that complies with GMP; in the case of a vaccine, it is required to have a quality test report of the National Institute for Control of Vaccine and Biologics or Certification of analysis in the case of a batch of vaccines and biologics); - Documents about pre-clinical trial of the drug that needs to be tested: reports on pharmacological effects, toxicity, safety, proposed dose, administration route and directions for use; - Documents about the clinical trial in previous phases (if the trial facility applies for permission for clinical trial in the next phases and the drug is not exempt from clinical trial in previous phases). c) Legal documents about the drug for clinical trial: - A copy of the written approval for registration of the clinical trial granted by the Administration of Science Technology and Training, the Ministry of Health. - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the application form for permission for phase 4 clinical trial submitted by the competent pharmacy authority if the drug is requested to undergo phase 4 clinical trial; - Package insert of the drug licensed for free sale if the drug is requested to undergo phase 4 clinical trial; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the trial facility's certificate of eligibility for pharmacy business; - A confirmation of participation provided by the trial centers if a multicenter trial is conducted in Vietnam; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the written approval for participation in the trial granted by the People's Committee of the province or central-affiliated city if a field trial is conducted; - A clinical trial agreement between the organization/individual that has the drug for clinical trial and the provider of clinical trial services; between the organization/individual that has the drug for clinical trial and the trial assistance organization (if any). d) A clinical trial outline and its description: - A description of the clinical trial outline (Form No. 08 in the Appendix III hereof); - A Case Report Form (CRF); dd) Principal investigator's academic résumé and copy of the certificate of completion of GCP training course which is issued by the Ministry of Health or GCP training institution; e) Participant information sheet and volunteer letter (Form No. 09 in the Appendix III hereof); g) A record on scientific and ethical assessment prepared by the internal Biomedical Ethics Committee; h) Label of the drug prescribed in the Circular 01/2018/TT-BYT, dated January 18, 2018 of the Minister of Health, amended by Circular 23/2023/TT-BYT and supplemented by Circular 12/2025/TT-BYT

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Clinical trials	Required data/ documents/ brochures to start clinical trials Document Language and acceptability of English documents	In Chinese	Documents in English. Patient information and patients consent form in both English and Chinese or in Chinese only.	Submission to CDSCO (Indian RA) in English only Patient Information Sheets, and ICF needs to be translated in vernacular languages for submission to Institutional/ independent ECs.	Indonesian or English	In principle, all documents must be in Japanese language.	The summary of the Korean (extract of the mail contents) and the original text (in English) should be submitted. The MFDS can require protocol and consent form translated in Korean in case when they need it.	Documents in English or Bahasa Melayu.	English. For those intended for study subjects, English and/ or Filipino language	English	**Protocol** •*Language:* English is acceptable; no Chinese translation required. **Investigator's Brochure (IB)** •*Language:* English is acceptable. **Informed Consent Form (ICF)** •*Language:* Chinese is required for subjects. •English version may be submitted as a reference. **Investigator's CV and GCP Training Certificate** •*Language:* English or Chinese is acceptable. **Ethics/IRB submission documents** (including application forms and site-specific documents) •*Language:* Usually required in Chinese; some IRBs may accept bilingual or English attachments for scientific content. **IND/CTA application documents** (if applicable) •*Language:* Key scientific documents (protocol, IB, IMPD/ CMC) may be in English. •Administrative forms must follow TFDA Chinese formats. **Clinical trial insurance certificate** •*Language:* English or Chinese is acceptable; some IRBs prefer Chinese or bilingual versions. **Contracts (CTAs) and agreements** •*Language:* Typically Chinese or bilingual (Chinese–English) per institutional preference. **Import permits for investigational products and/or medical devices** •*Language:* Chinese official format required.	Thai and/or English	Vietnamese or English language
	Acceptability of overseas clinical data, and requirements of additional local clinical studies for domestic NDA application when foreign data is to be used. Are there any conditional requirements to accept foreign data, for example proof of the similarity in PK/PD?	To support NDA approval in China, data obtained from clinical studies are required to demonstrate sufficient efficacy and safety in Chinese population. In principle, foreign clinical trial data is acceptable as a source of supportive documents, may not be utilized as the direct evidence to obtain NDA approval in China. Exceptional considerations may be allowed for life threatening situation where no available therapies existed etc., Pre-NDA consultation is preferable to obtain CDE's opinion with below technical justifications: - Overseas clinical trial data should meet ICH GCP and support the evaluation of efficacy and safety of target indications. - No ethnic sensitivity factors that influence the efficacy and safety based on PK/PD study.	Not necessary for conventional NDA pathway, no requirement to prove similarity in PK/ PD Local clinical data would be needed for 1+ NDA pathway. Asian data may be accepted for 1+ pathway if the drug has been shown in accordance with ICH E5 to be ethnically insensitive and extrinsic factors are generally similar to those in Hong Kong.	Vide Order dated August 7, 2024, the office of the Drugs Controller General of India (DCGI) notified the names of countries under the Rule 101 of New Drugs and Clinical Trial Rules, 2019 (NDCT) related to new drug approval. The notification states as follows: — The list of countries will apply for both imports as well as manufacture in India. — The countries notified are – USA, UK, Japan, Australia, Canada and EU. — Further, the list will be relied upon for grant of local CT waivers only for following categories of new drugs: ▪ Orphan Drugs for rare diseases ▪ Gene and cellular therapy products ▪ New drugs used in pandemic situation ▪ New drugs used for special defence purpose New Drugs having significant therapeutic advance over the current standard care	Acceptable, if the clinical data following GCP and the result based on evaluation of safety and efficacy is good.	Yes Acceptable if the similarity in PK/PD is indicated.	Yes Foreign clinical data are acceptable if the similarity in PK/PD is indicated.	No	Yes Acceptable if the similarity in PK/PD is indicated.	Yes	Yes The following drug items are subject to a bridging study assessment: 1. New chemical entities (NCE); or 2. Genetically engineered drugs, vaccines, plasma derivatives of new molecular entities, and allergen extracts of new molecular entities Foreign clinical data *can* support an NDA application in Taiwan — but for new chemical entities or novel biologics, regulators generally require a formal bridging study evaluation. If the bridging study is required (or TFDA deems it necessary), local clinical or PK/ PD data may need to be generated to ensure the foreign data are applicable to the local population.	Yes	Yes, if: The clinical trials on drugs, the clinical data included in clinical documents must be in line with guidelines of ICH, Vietnam Ministry of Health or other organizations recognized by Vietnam (including guidelines of international organizations of which Vietnam is a member, guidelines of the reference regulatory authorities). If clinical trials are conducted before above-mentioned regulations on drug development become available, the data from such trials shall be acceptable for the purpose of dossier evaluation. Clinical data (except vaccine) shall cover information adequate for the analysis, the explanation of Asian ethnic factors on the safety and efficacy of the drug to allow extrapolation of the clinical data on Asian population according to the guidelines stipulated above or there must be data of bridging studies according to ICH-E5 for the extrapolation of clinical data on Asian population

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Clinical trials	Acceptability of overseas clinical data, and requirements of additional local clinical studies for domestic NDA application when foreign data is to be used. Please comment whether there are any requirements of local clinical study data for NDA application and local clinical study is necessary or not, especially for necessity of PK / healthy subject data and/or patient data in the country.	To support NDA approval in China, data obtained from clinical studies are required to demonstrate sufficient efficacy and safety in Chinese population. Involvement of China into global MRCT or local clinical studies is being considered and adopted as preferable approach. Chinese PK data is required by CDE to support China NDA/BLA. If conditional approval is agreed by CDE, limited Chinese data can be used to support NDA/BLA and post-marketing commitment is required.	Not necessary for conventional NDA pathway For 1+NDA pathway, no requirement is specified for the local clinical data	NDCT Rules (Rule 101) update - The Drugs Controller General of India (DCGI) has recently taken a significant decision under which the Central The Central Licensing Authority (CLA) has specified six countries under the Rule 101 of the NDCT Rules 2019, for considering local clinical trial waiver during the approval process of five categories of new drugs. The names of the countries specified through an order now include US, United Kingdom, Japan, Australia, Canada and European Union. The notification of the countries is expected to help faster decisions on the waiver of the requirement of local clinical trials, with consistency and predictability. New drugs from these countries, including orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situation, new drugs used for special defense purpose, and new drugs having significant therapeutic advance over the current standard care, will be considered for clinical trial waiver. =Ref: CDSCO le no. DC-DT—15011 (11)/85/2024 dated 07.08.2024; cdsco. gov.in/ opencms/ opencms/ system/ modules/CDSCO. WEB/elements/ download-file_ division.jsp?num_ id=MTE1ODI= Local clinical trial may not be required, if, in addition to the above, there is no probability or evidence, on the basis of existing knowledge, of difference in Indian population of the enzymes or gene involved in the metabolism of the new drug or any factor affecting Pk and PD, safety and efficacy of the new drug. Ref: Rule 75(7)(iii) of the NDCT Rules 2019	Generally, Indonesian patient's data requested which indicates similarity in drug response (i.e. Efficacy and safety) with foreign data for drug which is used for family planning programme and other drugs based on request from Authorized body, for example public health programme for TB, etc	In case the MRCT progresses in overseas, in general, the additional phase 1 studies in Japanese people to join the MRCT are not necessary if the safety and tolerability can be explained and the safety is clinically acceptable and manageable. In addition, if overseas validation data is available, there are cases in which Japanese data at the NDA is not required for rare disease drugs.	Foreign data is acceptable. In principle, similarity in PK/PD between Korean and foreign data should be indicated. If the appropriate bridging data doesn't exist, bridging study is requested by MFDS for bridging data in Korean.	Not necessary	Local clinical trials for NDA approval of imported products are not mandatory.	Not necessary	NCE has to submit a Bridging Study Evaluation package before or simultaneously with NDA. If BSE is successfully waived and at least 2 of 10 R countries have approved (2 CPP), foreign data package can be accepted and there is no need to perform domestic study. If a bridging study is required, local PK or clinical data is required. •**Foreign clinical data can support an NDA**, but TFDA evaluates whether those data are sufficient and relevant to the Taiwanese population. •**Bridging Study Evaluation (BSE)** is the formal mechanism: for many NCEs/novel biologics, a BSE must be submitted before or together with the NDA to determine whether foreign data can be accepted as-is or whether bridging (local) data are needed. CDE+1 •**If a BSE is waived**, TFDA may accept the foreign package without additional local trials — one common pathway is when the product already has approvals and review reports from major agencies (e.g., US FDA, EMA, PMDA) and other criteria are met. TFDA guidance and MOHW summaries note that approvals/assessment by major regulators (and a positive BSE waiver) can allow reliance on foreign data. •**Conditional requirements when foreign data are used:** TFDA specifically assesses racial/ethnic differences in PK/PD, safety, and efficacy. If differences are suspected or cannot be excluded, TFDA may require **local PK, PD, or clinical bridging studies** to confirm appropriate dosing, safety, or efficacy in the Taiwanese population. •**Practical "2-CPP / reference country" pathway:** For NCEs, TFDA has historically allowed reliance on foreign approvals (and may accept foreign data without local studies) if certain conditions are met — e.g., approvals and review reports from major authorities (US/EMA/PMDA) and favorable bridging assessment — but applicants should confirm the current TFDA interpretation for each molecule •**If bridging studies are required**, TFDA expects appropriate data (examples: single/multi-dose PK in local subjects, PD markers, or clinical safety/efficacy data) — the exact scope depends on the regulator's BSE outcome and the specific product. CDE+1 **Bottom line:** foreign clinical data are acceptable in principle, but TFDA will decide case-by-case via a Bridging Study Evaluation. If the BSE is waived (often when robust foreign approvals/reports exist), domestic clinical studies may not be necessary; if not waived, local PK/PD or clinical bridging data will be required. CDE+1 If you want, I can draft the single-sentence response formatted for an application checklist (yes/no + brief explanation) or pull the exact TFDA guidance document(s) you should cite in a submission.	Not necessary	Not necessary if: If clinical trials are conducted before above-mentioned regulations on drug development become available, the data from such trials shall be acceptable for the purpose of dossier evaluation. Clinical data (except vaccine) shall cover information adequate for the analysis, the explanation of Asian ethnic factors on the safety and efficacy of the drug to allow extrapolation of the clinical data on Asian population according to the guidelines stipulated above or there must be data of bridging studies according to ICH-E5 for the extrapolation of clinical data on Asian population

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Clinical trials	Acceptability of overseas clinical data, and requirements of additional local clinical studies for domestic NDA application when foreign data is to be used. When requirement of the local subject data exists, please specify the required number (or rate) of local subjects in the pivotal clinical studies for NDA approval	No requirements for specific number or rate of local subjects in a MRCT. The applied principle is the data generated from clinical studies are required to demonstrate sufficient efficacy and safety in Chinese population. The total subjects' number depends on the trial design and the needs of statistics, of which Chinese subject number should meet the consistency evaluation with overall population in drug response.	Number of local subjects required is not specified.	Based on the recent industry experience, no. of local subject in the clinical trial may varies due to the disease prevalence and burden in the country. Sometimes, it may require a statistically significant sample size.	Local clinical trial is needed for new drugs for family planning programme, TB drugs, and others drug based on request from Authorized body.	Data from overseas clinical data or non-Japanese subjects are acceptable, but typically Japanese data are required to be included in the local NDA application package, with notifications issued on how much Japanese data is required for each phase. With the notification in December 2021, the limit on the required number of patients (1 year, 100 cases) was lifted for long-term administration data of Japanese in chronic diseases.	Not specified. Authority often requests statistically meaningful number of patients to be included even in the local study.	N/A	There is no required number of local subjects in clinical trials for NDA approval. For local Phase IV Clinical trials, 3000 patients, unless justified. (Administrative Order No. 2006-0021, Bureau Circular No. 5 s. 1997)	N/A. But in the HSA CTC application, applicant has to declare expected number of subjects to be enrolled from each site.	It is requested to show the consistency in drug response between Asia population and Caucasians in multi-national clinical trials. For this purpose, at least 15-20% of all subjects is hopefully to be Asian population. As for NDA approval, it was divided to two situations. Non-CPP: Early clinical development in Taiwan, Ph 1+ Ph 3 or Ph 2+ Ph 3. Taiwan patient No. for Ph1 study: ≧10, for Ph 2 study: ≧20, for Ph3 study:≧80. One-CPP: One of Ph 1, Ph2 or Ph3 study in Taiwan. Taiwan patient No. for Ph1 study:≧10, for Ph 2 study: ≧20 or 10%, for Ph3 study:≧80 or 10%, or Multinational Ph3 study for US FDA and EMA registration purpose: total sample size ≧200 then Taiwan No.≧30 or 5%, total sample size ＜200 then Taiwan No.≧10. Two or more CPP: Clinical trials in Taiwan is not mandatory. However, there might be requested local study if the consistency in drug response between Asia population and Caucasians could not be shown. •**Foreign clinical data are acceptable in principle**, but TFDA evaluates whether those data are applicable to the Taiwanese (East-Asian) population via a **Bridging Study Evaluation (BSE)** (based on ICH E5 concepts). TFDA expects applicants to show ethnic comparability (PK/PD, safety, efficacy) or provide bridging data if differences are possible. 行政院食品藥物管理署 +1 •**When to submit a BSE:** for many new chemical entities (NCEs) / novel biologics, a BSE should be submitted **before or concurrently with** the NDA to determine whether foreign data can be accepted as-is or whether local bridging data are needed. If TFDA **waives** the BSE (based on science and regulatory reliance), the foreign package can be accepted without local studies. CDE+1 •**Expectation for multi-regional trials:** TFDA and guidance documents recommend demonstrating consistency of drug response across ethnic groups. A practical target often cited is **~15–20% Asian subjects** in the overall MRCT population to help show comparability, although the exact requirement is case-by-case. APAC Asia+1 •**When local subject data are required — practical thresholds used in review (case examples / TFDA practice):** ◦ **Non-CPP pathway (no CPP from a reference country):** local early clinical development (e.g., Ph1+Ph3 or Ph2+Ph3). Typical Taiwan subject targets cited: **Ph1 ≥ 10; Ph2 ≥ 20; Ph3 ≥ 80.** APAC Asia ◦ **One-CPP pathway (one clinical development piece performed in Taiwan):** if one phase is run locally, commonly applied thresholds: **Ph1 ≥ 10; Ph2 ≥ 20 or ≥ 10% of total; Ph3 ≥ 80 or ≥ 10% of total**. For multinational Ph3 intended for US/EMA registration: if **total ≥ 200**, Taiwan subjects **≥ 30 or ≥ 5%**; if **total < 200**, Taiwan subjects **≥ 10**. APAC Asia+1 ◦ **Two (or more) CPPs / multiple reference approvals:** local clinical trials are generally **not mandatory**; however, TFDA may still request local data if ethnic sensitivity cannot be excluded by the available foreign data. 行政院食品藥物管理署 +1 •**What counts as "local data" when required:** TFDA may request **local PK (single-/multi-dose) studies, PD biomarkers, safety/efficacy data, or a local pivotal cohort** — scope depends on the BSE outcome and the product's sensitivity to ethnic factors. 行政院食品藥物管理署 **Bottom line:** foreign data can support an NDA in Taiwan, but TFDA reviews ethnic comparability through the BSE process. If the BSE is waived (or sufficient foreign approvals/CPPs exist and comparability is demonstrated), **domestic clinical studies may not be required**. If TFDA cannot be satisfied about ethnic similarity, **local PK/PD or clinical bridging data (with the practical subject thresholds above)** will be requested	Not necessary	N/A

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Clinical trials	Environment for conducting clinical trials Practical number of clinical centers or sites in the country. Please comment if there is any license system for clinical study site.	Drug clinical trials shall be conducted in properly filed clinical trial institutions with needed conditions. Vaccine clinical trials shall be carried out or organized by tertiary medical institutions or disease prevention and control institutions above the provincial level that meet the requirements prescribed by the NMPA and the National Health Commission.	Two university hospitals and five major government hospitals Other government hospitals and private hospitals can also be also involved. No license system for clinical study sites; however, the clinical study sites are usually university or government hospitals.	Based on the no. of trials and site approved by the CDSCO office in last year the no. is exceeded to more than 1500.	- Number of CRU is 27 sites. Source: https://iasmed.org/clinical-trial/	Clinical trial can be initiated in many study sites. No license system for clinical study site.	All investigational sites must be certified by MFDS, there are 208 sites(Nov. 2025).	In 2023, Malaysia achieved a record of 259 clinical trial sites. https://clinicalresearch.my/wp-content/uploads/2024/04/29-Apr-Website_CRM_AR2023.pdf Site participation depends on ethics approval and investigator qualifications, not a formal site license.	Clinical trial can be initiated in a study site that is Philippine Health Research Ethics Board (PHREB)-accredited (ethics committee exists)	There are 13 public hospitals and 16 private hospitals which can conduct clinical trials.	All medical centers or teaching hospitals and specialized hospitals are qualified to conduct clinical trials in Taiwan. It's around 142 centers/teaching hospitals https://www.taiwanclinicaltrials.tw/tw/spotlight/health_overview/medical_institution Taiwan has a robust clinical trial environment, with approximately 23 **qualified medical centers, 118 teaching hospitals, and 1 specialized hospital (Psychiatrc hospital)** able to conduct trials. There is **no separate license system for clinical trial sites**; instead, institutions must comply with **Good Clinical Practice (GCP)** standards and obtain **TFDA approval for each trial protocol.** **Key Points** •Qualified institutions**:** All medical centers, teaching hospitals, and specialized hospitals in Taiwan are eligible to conduct clinical trials. •Scale of sites**:** Around 120 centers/hospitals are practically available for trial activities. •No site-specific license**:** Taiwan does not require a special license for a hospital or center to be designated as a clinical trial site. •Regulatory oversight**:** Each clinical trial must be reviewed and approved by the **Taiwan Food and Drug Administration (TFDA)**, with compliance to GCP and ethics committee (IRB/cIRB) requirements. •Transparency**:** Approved trials are listed on the TFDA's Clinical Trial Information System, ensuring public access to trial details and oversight This means Taiwan's system emphasizes **institutional qualification and protocol-level approval**, rather than licensing individual sites. The environment is well-structured, internationally recognized, and designed to support high-quality, GCP-compliant clinical research.	No data available in public sources.	Practicable no. of clinical study sites not specified; No license system for clinical study sites; however, the clinical study sites are usually university or State hospitals.
	Environment for conducting clinical trials Installation of IRB system for clinical trials. Is there National IRB?	No	No National IRB but there is Central IRB for government hospitals.	Independent Ethical Committee (IEC) Institutional Ethics Committee No National IRB or Central EC For reviewing proposals of regulated clinical trials, all ECs needs to be registered at CDSCO (Indian Regulatory Authority) EC registration need to be renewed once every five year	- Ethical review in clinical trials involves local Institutional Review Boards (IRBs) / Independent Ethics Committees (IECs) which operate under a coordinated system managed by the Indonesia Clinical Research Center (INA-CRC). Source: 1. https://ina-crc.kemkes.go.id/en 2. https://ina-respond.net/2025/06/19/regulatory-ethics-mta-submission/#:~:text=In%20accordance%20with%20the%20MoH,Clinical%20Trial%20Approval%20from%20BPOM.	No. Institutional IRB.	IRB should be established at each investigational site. A central IRB (joint IRB) is also available.	No But a Central Ethics Committee, called the Medical Research and Ethics Committee (MREC), reviews and approves all clinical trials to be conducted at all MOH hospitals as well as institutions without a Local Ethics Committee.	Ethics committee of a clinical trial site should be accredited by PHREB.	Singapore has 3 clusters of public hospitals. 1 cluster is under NHG DSRB (National Healthcare Group Domain-Specific Review Board), NUHS Group and the SingHealth CIRB (Centralised Institutional Review Board). For private hospitals, they have their own IRB/EC	C-IRB (jointed IRB review) system led by the TFDA has been adopted since 2013. Systems to reduce review periods and to prevent the duplication of inquiries and inconsistencies between IRBs have been adopted. Deliberations are carried out in turn by the 7 major facilities. After c-IRB, the sponsor can receive an abbreviated review by each IRB using the results of the c-IRB. Taiwan has established a **centralized IRB review system (c-IRB)**, coordinated by the **TFDA since 2013**, to streamline clinical trial oversight. This system is not a single "national IRB," but rather a **joint review mechanism** involving **seven major medical centers** that deliberate in turn. **Key Points** •**c-IRB system:** Introduced in 2013 under TFDA leadership to harmonize IRB reviews. •**Efficiency measures:** Designed to **reduce review periods**, avoid **duplicated inquiries**, and prevent **inconsistencies** across IRBs. •**Joint deliberation:** Reviews are conducted sequentially by **seven major facilities**. •**Abbreviated local review:** Once c-IRB approval is obtained, sponsors can receive **shortened reviews** from individual IRBs using the c-IRB results. •**Outcome:** The system improves consistency, accelerates trial initiation, and strengthens regulatory oversight without requiring a single national IRB. This means Taiwan's IRB environment is **collaborative and centralized in function**, ensuring both efficiency and quality in clinical trial governance.	No national IRB Most sites accept submission via central IRB (CREC). After the approval of CREC, the approval of LREC is needed as well.	Yes There are EC both at the Site and on the health authority level

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Clinical trials	Environment for conducting clinical trials How is the actual subject enrollment situation? Are there any supportive system for patient enroll-ment, such as clinical trial network?	There is intensely competitive between different clinical trials for subject enrollment. Some regional clinical trial networks are established spontaneously by researchers.	The government's policy is to recommend the implementation of clinical trials regardless of the phases from the perspective of industrial development. There are 2 major clinical research centers under the umbrellas of 2 large medical universities, and they are participating in more than 1,000 multinational clinical trials.. The Phase 1 Clinical Trial Centre of CUHK and the Phase 1 Clinical Trial Centre of HKU started operations in December 2013 and the 1st quarter of 2014, respectively. Greater Bay Area International Clinical Trial Institute (GBAICTI) was opened in November 2024 and will establish the GBA Clinical Trial Collaboration Platform. A total of 31 clinical specialties or areas (located in four hospitals) have been accredited by the National Medical Products Administration (NMPA) to conduct clinical trials for applying drug registration with the NMPA	Regulatory environment very conducive for clinical trials Single step review process by Regulators New rules are clear and streamlined Over 20 Subject Expert Committees support the CDSCO Approval timelines is < 90 days Responsibility of ECs strengthened Safety reporting and compensation regulations are very clear Subject enrollment is relatively faster given the population size of the country	Unknown	It is generally said that "the number of the patients enrolled per institute still remains low" and "the cost of clinical trial cost is high", however it's not always clear cut. It depends on the specific situation. The environment of clinical trial is improving gradually. In addition, industries, regulator and academia have various discussion to prepare more efficient environment for clinical trials.	It depends on the situations of target diseases or investigational sites. In general, the subjects are recruited in good manner.	Subject enrollment in Malaysia is generally steady but challenging, with recruitment rates varying by therapeutic area. To support patient enrollment, Malaysia has established systems such as the National Medical Research Register (NMRR), Clinical Research Malaysia (CRM) services, and specialized patient recruitment companies that assist investigators and sponsors. The Network of Ethical Review Committees in Malaysia (NERCIM) was established to harmonize ethics review among all IRBs/IECs in Malaysia.	Clinical trials in the country must be conducted following ICH GCP guidelines.	HSA has set up an Innovation Office in April 2018 to provide a conducive regulatory environment that supports the development of the biomedical sector, by providing scientific and regulatory advice for early stage clinical development of innovative therapeutic products intended for product registration in Singapore. A guidance titled: CLINICAL TRIALS GUIDANCE SUBMISSION OF INNOVATION OFFICE REQUESTS is available to guide sponsors on the procedure to seek scientific and regulatory advice. Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/gn-ioctb-17_001_io_requests.pdf?sfvrsn=a88a0c10_4	Previously, Taiwan's subject enrollment were supported by a network TCTC. Now there is supported by a new subject enrollment **network of 32 Taiwan Clinical Trial** **Consortiums (TACTA) will establish on December 8, 2025**, which provide infrastructure and collaboration for patient recruitment. However, **actual enrollment varies significantly by principal investigator and site capacity**, and there is relatively **limited referral activity between study sites and non-study sites**. **Key Points** •**32 TACTA:** Established to strengthen patient enrollment and trial execution across therapeutic areas. •**Enrollment variation:** Subject recruitment depends on each **PI's experience, site resources, and disease area focus**. •**Referral limitations:** There are **fewer cross-referrals** between study and non-study sites, which can constrain broader patient access. •**Supportive system:** The TCTC network provides a **structured platform for collaboration**, but patient enrollment efficiency still relies heavily on site-level practices. This means Taiwan has a **formal supportive system through TCTCs**, but enrollment outcomes remain **site-dependent** and could benefit from stronger inter-site referral mechanisms. Additinally, two other medical centers outside the 32 TACTA network also conduct clinical trials.	In most cases, participation in multinational clinical trials are from Phase 3. Inter-facility clinical trial network has been established	Participations in multinational clinical trials are possible. Local regulations are referring to the guidelines of ICH, WHO, Vietnam Ministry of Health or other organizations recognized by Vietnam. Vietnam does not have a clinical trial network. (Source: Article 18 Circular 50/2025/TT-BYT)
	Environment for conducting clinical trials Prevalence of GCP in clinical centers	Registrational clinical studies must be conducted by GCP qualified clinical institutions.	Yes Hong Kong participated in over 1000 global clinical trials since 1996, all requiring ICH GCP compliance.	GCP, GLP and GMP is mandatory for all clinical trials. However, there is a need for upgrading GMP	GCP is observed in all clinical studies	GCP is observed in all clinical sites.	GCP is mandatory. Regulatory authority often conduct an inspection of site to verify compliance to GCP	GCP is observed in all clinical study sites. (GCP is required 100% clinical site in Malaysia). Authority conducts site inspections to verify compliance to GCP.	GCP is observed in all clinical sites. Part of the licensing requirements for CROs and Sponsors is compliance to GCP. This is verified during inspection. Likewise, inspection of sites during clinical trials is conducted to verify compliance to GCP.	GCP is observed in all clinical studies	GCP implementation in all clinical trials is mandatory since 1997. TFDA has officially become the Regulatory Member of ICH in June, 2018. Subject enrollment in Taiwan varies by site and investigator capacity, but the regulatory environment ensures strong compliance standards. **Good Clinical Practice (GCP) implementation has been mandatory for all clinical trials since 1997**, and Taiwan's regulatory framework was further strengthened when the **TFDA became a Regulatory Member of the International Council for Harmonisation (ICH) in 2018**. **Key Points** •**Enrollment situation:** Recruitment levels differ across sites, depending on investigator expertise, site resources, and therapeutic focus. •**Mandatory GCP:** All clinical trials in Taiwan must adhere to GCP requirements, in place since 1997. •**ICH membership:** TFDA's role as an ICH Regulatory Member since 2018 reinforces international alignment and credibility. **In summary:** Taiwan's clinical trial environment combines **variable enrollment outcomes** with **uniform, internationally recognized GCP standards**, ensuring both patient safety and global regulatory consistency.	GCP is required in all clinical studies Refer to Ministerial Notification Re: Rules, Procedures, and Conditions for Clinical research to Support the Submission of Pharmaceutical Product Registration B.E. 2566 (cited 2025 DEC 12)	Regulated entities of GCP principles 1 Every trial facility shall conduct the clinical trial according to the approved clinical trial outline and GCP guidelines. 2. An assessment team shall inspect the site and classify GCP compliance (from level 1 to 3) of the local trial facility. MOH shall publish on its portal the GCP-certified trial facilities. (Source: Article 7, 8 & 9; Circular 50/2025/TT-BYT)
	Environment for conducting clinical trials Number of investigators who will conduct or participate in the clinical studies.	The number of Chinese doctors is large and countless. In 2024, the clinical trial was registered in the drug clinical trial registration and information publicity platform. The total number of tests reached 4900 (calculated as CTR), an increase of 13.9% compared with 2023. Among them, the number of new drug clinical trials (registered with acceptance number) was 2539, compared with 2023, 9.3% annual increase. Annual Report on the Progress of Clinical Trials for New Drug Registration in China (2024) https://www.cde.org.cn/main/news/viewInfoCommon/d0bc4836cfc4cb7c9ecf29ddaa7be6ea	Yes Large number of investigators. For CUHK and HKU, there are over 50 and over 80 investigators respectively. According to HKU Clinical Trials Registry, currently there are over 2,990 clinical studies registered.	Large pool of trained Investigators and treatment-naïve patients in diverse therapeutic areas.	No data for the number of investigators. Investigator must have GCP training before the trial and understand the protocol comprehensively in order to conduct the trial in accordance to GCP.	Large number of physicians in Japan	Uncountable, lots of investigators in Korea. Mandatory educational system exists in Korea.	Since the introduction of the first edition of the Malaysian GCP in 1999 until 2018, more than 12,000 healthcare professionals and researchers have been GCP-trained and certified. https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/MalaysianGuidelineforGoodClinicalPractice.pdf	Applicants are required to submit the CV of Primary Investigators for each trial site	No information	No data for the number of investigators. The physician who is working on a qualified clinical site would be able to conduct/participate in the clinical studies. However, all investigators should meet TFDA's qualification, including required GCP & Ethical training etc. There is **no official published data on the total number of investigators** conducting clinical trials in Taiwan. In practice, any **physician working at a qualified clinical site** (medical center, teaching hospital, or specialized hospital) may serve as an investigator. Importantly, all investigators must meet the **Taiwan Food and Drug Administration (TFDA) qualification requirements**, which include completion of **mandatory Good Clinical Practice (GCP) and ethical training**. **Key Points** •**No official count:** The exact number of investigators is not available. •**Eligibility:** Physicians at qualified clinical trial sites are able to conduct or participate in studies. •**TFDA requirements:** All investigators must fulfill TFDA's qualification standards. •**Mandatory training:** GCP and ethical training are required for investigator participation. **In summary:** While the precise number of investigators is not tracked, Taiwan ensures that all participating physicians are **qualified through standardized GCP and ethics training**, maintaining consistency and compliance across clinical trial sites.	No information (Beware of USFDA blacklist)	All investigators must possess appropriate qualifications, training, and experience. All investigators involved in the trial must have had formal training in good clinical practices (GCPs), and submit proof that a GCPs course has been completed. Principal investigator's academic résumé and copy of the certificate of completion of GCP training course which is issued by the Ministry of Health or GCP training institution shall be submitted in the application for permission for clinical trial. (Source: Article 18.5 of Circular 50/2025/TT-BYT)

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Clinical trials	Investigational drug Condition of customs procedure.	The management of drugs for clinical trials shall conform to the relevant requirements of the GCP. As IND approval system changed to implied permission system, clinical trial notice letter is issued by CDE instead of CTA approval letter, which can be used for Customs procedures and clearance.	Application of Import License based on the approved CTC.	The application should be made through NSWS portal in Form CT-16 with applicable fee.	Sponsor request to import unregistered product was to BPOM. Approval letter for Importation from BPOM is used for release product in the customs.	-	After receiving IND approval from the Ministry of Food and Drug Safety, a standard customs clearance report should be completed and approved by the Korea Pharmaceutical Traders Association.	Clinical trial import license and proper clearance required.	For the importation of each investigational drug product and ancillary materials, an import license is required. This is issued together with the clinical trial approval valid for three years, and can be used repeatedly within the validity. (Administrative Order No. 2020-0010)	Reference to CLINICAL TRIALS GUIDANCE CLINICAL RESEARCH MATERIALS https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-03_crm.pdf?sfvrsn=f3734c83_6	The import permit is issued by TFDA and Customs will allow investigational product import into Taiwan within the quantity on the import permit. For investigational drugs in Taiwan, the **import permit is issued by the TFDA**, and **Customs clearance is granted strictly within the quantity specified on the permit**. This system ensures regulatory oversight and controlled entry of investigational products. **Key Points** •**Import permit:** TFDA issues the official permit for investigational drug importation. •**Customs clearance:** Customs authorities allow entry only for the quantities approved on the permit. •**Controlled process:** The procedure ensures compliance with regulatory standards and prevents unauthorized importation. **In summary:** Taiwan maintains a **permit-based customs procedure** for investigational drugs, with TFDA approval as the prerequisite for Customs clearance, ensuring strict regulatory control over trial product imports.	Condition of customs procedure - import license, CoA, Air waybill, invoice, License Per Invoice, National Single Window	MOH's DAV is responsible for authorizing the import and export of drugs in Vietnam. According to these sources, IPs for use in clinical trials are categorized as finished drugs without registration numbers. Once the MOH approves the clinical trial dossier, an import permit application must be submitted to the MOH's DAV for approval of the IP in the quantity specified in the clinical protocol. The import permit is valid for one (1) year. (Source: Article 94.1 of Pharmaceutical Law No.105)
	Investigational drug Requirements of Investigational drug labeling and its language.	Yes (in Chinese) Requirements include: 1) Indicate "only used for clinical trial". 2) For investigational drugs used in IMCT, sponsor name, trial number, kit number, dosage and administration, only used for clinical trial, dosage form, administration way, strength, batch number, storage condition, expiry date etc. need to be indicated in the label.	IP name: Strength, dosage, storage condition, manufacturer - English or English and Chinese	Ref: NDCT Rules, 2019, CHAPTER VIII (66) Manner of labelling	In Indonesia language for clinical trial in Indonesia. In Clinical trial Multicenter / country English language is acceptable.	Yes Investigational drug label written by Japanese is needed	Yes. An investigational drug label written in Korean is required.	Yes The labelling requirements should be in accordance with Malaysian Guideline for Application of CTIL & CTX, Appendix E (Labelling Requirements). Language in Bahasa Melayu or English.	YES In English. Note that importation of investigational drug products requires an import permit.	Reference to CLINICAL TRIALS GUIDANCE LABELLING OF INVESTIGATIONAL AND AUXILIARY PRODUCTS IN CLINICAL TRIALS GN-IOCTB-07 Rev. No. 005 (2 JAN 2026) hsa_gn-ioctb-07_labelling_ip_ap.pdf	Yes Label has to be prepared in traditional Chinese under PIC/S GMP regulation. In Taiwan, **investigational drug labeling must comply with PIC/S GMP requirements**. Labels are required to be prepared in **traditional Chinese**, ensuring clarity for local regulatory review and patient safety. This requirement applies uniformly to all investigational products used in clinical trials. **Key Points** •**Mandatory language:** Labels must be in **traditional Chinese**. •**Regulatory basis:** Governed under **PIC/S GMP standards**, ensuring international alignment. •**Scope:** Applies to all investigational drugs imported or manufactured for clinical trial use in Taiwan. •**Purpose:** Ensures consistency, regulatory compliance, and clear communication for trial participants and oversight bodies. **In summary:** Taiwan enforces a **strict labeling requirement in traditional Chinese under PIC/S GMP**, reinforcing both **regulatory compliance** and **patient safety** in clinical trials.	Yes Require product name or random number/subject no., dosage, amount, manufacturer, expiry date and the content of 'this product is used for clinical trial only in Thai. Comprehensive list. (1) Non-proprietary name or drug code including strengths of active substance(s) (2) Study number and/or study title (3) Batch number (4) Subject number/kit number and visit number (if applicable) (5) In case of self-administration drug, e.g. home medication, etc., Thai or English instruction on how to use drug, which is understandable by subjects, should be provided (6) Name, address and telephone number of the sponsor (7) Expiry date or retest date. (8) Storage condition (9) Indicate the sentence "for trial use only" in Thai (10) Indicate the phrase "keep out of reach of children" in Thai for take-home drugs *The auxiliary label that utilizes locally (by institution/investigational sites) does not need to be submitted for approval by Thai FDA as well.*	Yes IP must be clearly labeled with the wording: "Products used for clinical trials. Use for other purposes is prohibited." A sample IP with the label in the smallest packed unit must also be included in the clinical trial dossier. Label of the drug shall be according to clause 2 Article 88 of Pharma Law, clause 4 Article 11 of Circular 01/2018/TT-BYT amended by Circular 23/2023/TT-BYT and Circular 12/2025/TT-BYT. (Source: Article 18.8. Circular 50/2025/TT-BYT)

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Clinical trials	Investigational drug Acceptability of the use of domestically unapproved drug as comparator.	Domestically unapproved drug can NOT be used as comparator in Clinical trials, unless a CTA for the unapproved drug is submitted, or CDE is endorsed via consultation meeting.	Not specified.	Approvals are granted case to case basis, mostly approved comparator is preferred	We can't use domestically unapproved drug as comparator. Comparator can be imported using special access scheme (SAS) path	Yes	It is possible to use if the unapproved drug is the international standard drug. It is recommended to consult with the MFDS in advance.	Yes Details given in Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption.	YES The guideline does not define restrictions on the comparator drugs. For instance, the issued List of Comparator/ Reference Drug Products for BA/BE studies include unregistered drugs.	The unapproved drug can be used as a comparator as long as its protocol and CTC/CTA/CTN have been approved. CLINICAL TRIALS GUIDANCE CLINICAL RESEARCH MATERIALS GN-IOCTB-03 Rev. No. 002 hsa_gn-ioctb-03_ crm_1mar2021.pdf	Yes It is possible to use as IMP Under current Taiwan regulations, it remains **acceptable to use a domestically unapproved drug as a comparator** in clinical trials. Such a product can be designated as an **Investigational Medicinal Product (IMP)**, provided the trial protocol is submitted to and approved by the **Taiwan Food and Drug Administration (TFDA)**, with full compliance to **Good Clinical Practice (GCP)** and ethical review requirements. **Key Points** •**Acceptability:** Domestically unapproved drugs may be used as comparators in clinical studies. •**IMP designation:** These drugs are treated as **Investigational Medicinal Products (IMP)** under TFDA oversight. •**Regulatory review:** Use requires **protocol approval by TFDA** and adherence to GCP standards. •**Ethical compliance:** All comparator use must undergo **IRB/c-IRB review** to ensure patient safety and ethical conduct. **In summary:** Taiwan continues to permit the use of **unapproved drugs as comparators under IMP designation**, with strict regulatory and ethical safeguards ensuring trial integrity and patient protection. Would you like me to refine this into a **step-by-step compliance pathway** (protocol submission → TFDA approval → IRB review → trial conduct) for executive briefing purposes? Sources: Taiwan FDA – Regulations for Good Clinical Practice Taiwan Clinical Trials Regulatory Structure	No Not accept.	Yes For use as reference standards/ comparator drug in bioequivalence studies; if it is a new drug, it shall be used exclusively for the study according to the already approved protocol under clause 1 Article 100 of Pharmaceutical law. (Source: Article 58.1.c of Decree 163)
	Availability of the support from multi-national CRO	Yes	Yes (domestic and multi-national companies).	Health Ministry has notified Rules to register CROs under NDCT Rules, 2019 – The amended rules came into effect from April 1, 2025. A new chapter VA has been inserted in the NDCT Rules 2019 on CROs, it stipulates that no CRO shall conduct any clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug in human subjects without registration granted by the Central Licencing Authority (CLA) under these rules.	Multi-national CRO is available in Indonesia	Yes Multi-regional CRO is available in Japan	Yes Multi-national CRO is available and local CROs are also available to support the clinical trials.	Yes International CROs include IQVIA, Novotech. PAREXEL, Icon, PPD LLC, Questra, etc.	YES Multi-national CROs are present in the country.	Yes Available	Yes As of 2025, Taiwan hosts **around 20–25 Contract Research Organizations (CROs)**, with a mix of **multi-national CROs** (such as Parexel, ICON, Novotech, QPS Taiwan, Worldwide Clinical Trials) and **local/regional CROs**. The majority of largescale clinical trial support is provided by global CROs, while local CROs remain fewer and smaller in scale. **Detailed Context** •**Overall number:** Current listings show **approximately 20–25 CROs** active in Taiwan. •**Global presence:** Major international CROs like **Parexel, ICON, Novotech, and QPS Taiwan** operate locally, offering fullservice trial management and regulatory support. •**Local CROs:** Taiwan also has smaller domestic CROs (e.g., Level Biotechnology, ScinoPharm), but their scale and service scope are more limited compared to global firms. •**Regulatory environment:** CRO activities are overseen by the **Center for Drug Evaluation (CDE)** and the **Taiwan Food and Drug Administration (TFDA)**, ensuring compliance with GCP and international standards. •**Industry trend:** Taiwan's CRO sector is stable, with global CROs dominating complex, multinational trials, while local CROs focus on niche or regional projects. **In summary:** Taiwan in 2025 has **20–25 CROs**, with global CROs playing the leading role in supporting clinical trials, while local CROs remain fewer but contribute to specialized or regional studies.	Yes There are many international CRO in Thailand	Yes
	Export of biological sample derived from subjects	According to the regulation, if export biological samples, getting the permission from IRB, HGRAC's approval is required as per based on "Human Genetic Resource Interim Management Measures" In practice, need to have sufficient rationale to get HGRAC's approval to export biological sample.	It is possible to export biological samples.	Allowed	There are restrictions on the export of biological samples from subjects (Ministry of Health Regulation No, 85 Year 2020). Application for the export of biological samples must be made to the Ministry of Health. Please refer to MoH for MTA procedure: Layanan MTA (Material Transfer Agreement) - Badan Kebijakan Pembangunan Kesehatan	BKPK Kemenkes	Yes It is possible to export biological samples if they are included in the signed informed consent document.	Yes It is possible to export biological samples.	Yes It is possible to export biological samples.	YES It is possible to export biological samples.	Yes It is possible to export biological samples if the importing country's conditions are met. Meeting the conditions of the importing country is the responsibility of the applicant. An export license is not required from HSA for shipping of biological samples for testing overseas. Clinical Trials Guidance Regulatory Requirements for New Applications and Subsequent Submissions GN-IOCTB-04 Rev. No. 004, 28 Apr 2021 hsa_gn-ioctb-04_ new_and_ subsequent_ appl_28apr2021.pdf Additional considerations: HBRA guidance must be filled as necessary, especially if biological samples for future research are involved. Source: MOH | Human Biomedical Research Act.	Yes It is possible (okay) to export biological samples and required to apply for export permit Under current Taiwan regulations (2025), it is still **permissible to export biological samples derived from clinical trial subjects**, provided that an **export permit is obtained from the TFDA**. The process remains tightly controlled to ensure compliance with ethical and regulatory standards. **Key Points** •**Export allowed:** Biological samples may be exported for research or trial purposes. •**Permit required:** An **export permit issued by TFDA** is mandatory before shipment. •**Regulatory oversight:** Export activities are subject to TFDA review to safeguard subject rights and data integrity. •**Controlled process:** Customs clearance is granted only within the scope of the approved permit. **In summary:** Taiwan continues to allow the **export of biological samples with TFDA authorization**, ensuring strict regulatory control and ethical compliance in clinical research.	Yes It is possible to export MTA may be required by IRB.	Yes It is possible to export.

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Clinical trials	Adverse reaction reporting during clinical trial	Expedited Reporting of ICSR adopt to ICH E2A, E2B(R3) -SUSAR occurred during the clinical trial in China and outside of China should be reported to CDE. -For fatal or life-threatening SUSAR, sponsor needs to report to CDE within 7 days after initial receiving SUSAR; for non-fatal or life-threatening SUSAR, sponsor can report to CDE within 15 days after initial receiving SUSAR. -If Chinese translation can't be prepared well, sponsor can submit the English report to CDE firstly, then Chinese report can be submitted in the next 15 days. During the clinical trial, the electronic transmission met hod of the drug vigilance sy stem gateway was updated to the same E2B (R3) elect ronic transmission system with the post-marketing en vironment. The system beg an trial operation at 17:00 on November 6, 2023 and supports receiving reports of suspicious and unexpect ed serious adverse reactio ns. The trial operation perio d is one year (until Novemb er 5, 2024) (https://www.cd e.org.cn/main/news/viewInf oCommon/40ef95178d594 1b2f7b82389b29d54cd) DSUR adopt to ICH E2F (with the addition of China-specific regional appendices requirement) - DSUR should be annually submitted within two months after the anniversary of DIBD. - DSUR should be accompanied by 5 regional appendices which are listed in "Management Guidance of Development Safety Update Report (Trial)" issued on July 1st 2020 -DSUR should be submitted to CDE on an ongoing basis after the domestic clinical trial is approved, until the last marketing authorization application for the drug has been submitted in China or until no further development in China is required. Other potential serious safety risk information - Other potential serious sa fety risk information during clinical trials should prompt ly be communicated with C DE and submitted to CDE within 15days after determi ned by the applicant. (http s://www.cde.org.cn/main/n ews/viewInfoCommon/dde a289e856a539aa70121ae 04ec38ac)	Serious and unexpected adverse events - Fatal/life threatening: no later than 7 calendar days; submit report in 8 additional calendar days - Others: 15 calendar days NSAE and serious expected adverse events: - Brief summary at the end of trial	Reference: NDCT; Third Schedule; 3. Responsibility (2) Investigator (ii) Investigator shall report all serious adverse events to the Central Licensing Authority, the sponsor or his representative, whosoever had obtained permission from the Central Licensing Authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty-four hours of their occurrence.	Additional information: Sponsor should report serious adverse event in clinical trial which have life threatening within 7 working days start from the first time known the event, and following 8 working days to complete the report.	Cases of death by unknown, adverse events have to be reported to PMDA within 7 days. Cases of death by known adverse event and unknown serious adverse event have to be reported within 15 days.	Serious and unexpected adverse events - Fatal/life threatening: no later than 7 calendar days after first knowledge by the sponsor that a case qualifies, followed by as complete a report as possible within 8 additional calendar days - Others: no later than 15 calendar days	Death or possibly leading to death SAEs within 7 days, other SAEs within 15 days.	Serious and unexpected adverse events - Fatal/life threatening: no later than 7 calendar days; complete report within 8 additional calendar days - Others: no later than 15 calendar days For expected ADRs, reporting is part of the annual progress report. (Administrative Order No. 2020-0010)	For fatal or life-threatening USADRs, local sponsors must submit the initial report as soon as possible and no later than 7 calendar days, with the next follow-up report within 8 calendar days of the initial report. Subsequent follow-up reports should be submitted in a timely manner as they become available. For other USADRs, local sponsors must submit the initial report as soon as possible and no later than 15 calendar days. Subsequent follow-up reports are to be submitted in a timely manner as they become available. Guidance: CLINICAL TRIALS GUIDANCE EXPEDITED SAFETY REPORTING REQUIREMENTS FOR CLINICAL TRIALS https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-10_safety_reporting.pdf?sfvrsn=6687bb4f_6	As of 2025, Taiwan's requirements for **adverse reaction reporting during clinical trials** remain consistent with international standards and unchanged from prior years. **Suspected Unexpected Serious Adverse Reactions (SUSARs)** must be reported to the **TFDA** within **7 days for fatal or lifethreatening cases**, and within **15 days for other serious cases**. The submission of **Development Safety Update Reports (DSURs)** is still **not mandatory**, per TFDA's official letter No. 1100003843 (April 6, 2021). The **IRPMA PV Task Force** has confirmed that current safety reporting practices continue without modification. **Key Points** •**SUSAR reporting:** ◦ **7 days** → death or lifethreatening cases ◦ **15 days** → other serious cases •**Alignment:** Same as international ICH E2A/ E2D guidelines. •**DSUR:** Not required; TFDA confirmed in 2021 letter, still valid in 2025. •**Consensus:** IRPMA PV Task Force agreed no changes to reporting requirements. **In summary:** Taiwan's adverse reaction reporting framework in 2025 remains **stable, internationally aligned, and unchanged**, ensuring consistent safety oversight in clinical trials.	To FDA: - Only Local SUSAR, death or life-threatening related to study product within 7 days, other local SUSAR within 15 days (from sponsor awareness) - Annual safety report - End of study safety report To site IRB/EC: - Death or life-threatening within 7 days, other SAE within 15 days (FERCIT) Line listing submission every 6 months	Acc. to Article 18, Appendix I Good Clinical Practice of Circular 50/2025/TT-BYT CRO, and other relevant organization, person have responsibility to report AEs/ SAEs: a) AE/SAE occurred in VN territory: - For death or life-threatening SAE: urgently reported within 7 working days when having SAE information. - Other SAE: within 15 working days when having SAE information. - Information of ongoing SAE to be continuously reported in additional reports until the study participant recovers or stabilizes. b) AE/SAE occurred outside VN territory (VN is one of countries in multi-national CT): All SAEs occurring at study sites outside VN that resulted in the withdrawal of study participants or amendments to the study protocol should be reported to Administration of Science Technology and Training-MOH, National Ethics Committee, National ADR Center and drug information in a periodic safety report. - Timeline of report: no more than 6 months since the last reporting cycle.

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Clinical trials	GCP site inspection	Yes Clinical trial inspection was conducted based on the review needs.	GCP site inspection conducted by DH may start from Q4 2026	Licensing authority conduct the GCP site inspection on risk-based approach.	BPOM will do GCP site inspection during clinical trial	Yes After NDA and Package Insert Revision Consultation application, PMDA inspects the applicant and 2-4 medical institutions based on GCP.	Yes, by MFDS	Yes	Yes The authority inspects the applicant and medical institutions based on GCP.	Yes Will be conducted by the HSA Clinical Trial Branch, on locally conducted clinical trials.	Yes TFDA requests GCP on site inspection for TW NDA registration purpose studies after CSR is submitted. However, effective from July 2021, for NME, the timing of GCP inspection will be trigger by NDA submission, Other than NME, the timing is still be trigger by CSR submission as the current practice. Effective from July 2024, the timing of GCP inspection will be triggered by NDA submission for NME, new indication and dosing change. Other than that, the timing is still be triggered by CSR submission as the current practice. Overseas GCP inspection may be triggered per the need of case review. On 5-Jan-2024 TFDA announced the GCP inspection amendment indicated that the Sponsors, the CRO, and the data management will include in the GCP inspection items. (https://www.fda.gov.tw/tc/newsContent.aspx?cid=3&id=30328) As of 2025, Taiwan's **TFDA GCP site inspection requirements** remain aligned with the phased updates introduced in recent years. For **New Molecular Entities (NMEs), new indications, and dosing changes**, the **timing of inspection is triggered by NDA submission** (effective July 2024). For other studies, inspections are still triggered after **CSR submission**. Additionally, **overseas GCP inspections** may be initiated when deemed necessary for case review. **Key Points** **•Inspection timing:** ◦ **NME, new indication, dosing change → NDA submission triggers inspection** (since July 2024). ◦ **Other studies → CSR submission triggers inspection** (current practice). **•Scope expansion:** Since January 5, 2024, TFDA's GCP inspection amendments include **Sponsors, CROs, and data management units** in inspection items. **•Overseas inspections:** May be conducted if required for case review. **•Regulatory intent:** Strengthens oversight, ensures data integrity, and aligns Taiwan's practices with international standards. **In summary:** Taiwan's GCP inspection framework in 2025 applies **NDA-triggered inspections for NMEs, new indications, and dosing changes**, while maintaining **CSR-triggered inspections for other studies**, with expanded scope to include **Sponsors, CROs, and data management**.	Yes	Yes (Article 8, Circular 50/2025/TT-BYT) GCP inspection is limited to domestic clinical site only.

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Manufac-turing	Acceptance test for Import drug	Specifications and test methods are set according to Chinese Pharmacopeia and product own specification	Based on the approved particulars.	Imported drug commercial shipment are get tested as per the in-house specification acceptance criteria or if the drug is in Pharmacopeia then the acceptance criteria get referred to respective pharmacopeial specification.	Specification and test methods are following Indonesian Pharmacopeia VI, USP/NF, BP, EP, JP.	Specifications and test methods are to be set according to JP.	Specification and test methods are usually set in accordance with official compendium or registered in-house specifications.	Both compendial and non-compendial specifications are accepted.	Specifications and test methods are set according to pharmacopeia, or by companies supported with appropriate validation documents (Administrative Order 2013-0021, Administrative Order No. 2024-0013)	To be tested according to approved specifications & test methods	There is no need to have acceptance tests in Taiwan except for vaccines, toxins, and plasma produced products. TFDA will provide certification seal after TFDA QC acceptance test. TFDA will issue product releasing certificates and provide a serial sealing label on the individual products. Need to provide sample of NCE, new compound medicine, and first API to TFDA for future inspection prior to be on the market, except radiopharmaceutical drugs, cell-based preparation and bio products needed to be tested.	Both compendial and non-compendial method are acceptable	Yes With regard to vaccines, antibody containing sera, blood derivatives and plasma from human: The registrant must collect samples for quality control testing at the National institute for control of vaccines and biologics. The registrant must submit certificate of analysis, specifications and test method certified by the National Institute for Control of Vaccines and Biologics (NICVB) or state drug testing facilities in charge of testing, evaluating and monitoring vaccines and medical biological as assigned by MoH as part of the registration dossier
	Pharmacopeia	All import drugs and domestic drugs should follow Chinese Pharmacopeia. ChP2025 came into effect on October 1,2025. https://www.gov.cn/zhengce/zhengceku/202503/content_7015673.htm	BP, USP, EP and JP. Pharmacopeia of People's Republic of China, International Pharmacopoeia, or in-house specification for NCE is also accepted by DOH.	If a DP/DS is official in the Indian Pharmacopeia (IP) than must conform to IP if not official in IP than BP/USP/EU Pharmacopeia standards are to be followed	Standard Pharmacopeia: Indonesian Pharmacopeia VI Other accepted Pharmacopeia: USP/NF, BP, EP, JP	JP (Japanese Pharmacopeia)	Standard: KP Accepted: JP, Ph. Eur (EP), USP (NF), BP, Deutsches Arzneibuch, Pharmacipee Francaise	The main pharmacopeia references are BP and USP. Others are JP and EP	The FDA recognizes USP-NF, official Homeopathic, Pharmacopoeia of the United States, Philippine Pharmacopoeia, official Philippine National Drug Formulary (PNDF), BP, EP, JP, Indian Pharmacopoeia, and any national compendium or any supplement to any of them (Republic Act No. 9711)	Pharmacopeias accepted by HSA are Ph. Eur., USP, BP, and JP	USP/NF, EP, JP, BP and ChP. are all acceptable.	Standard Pharmacopoeia: USP 39/ NF 34 and supplements, BP 2016 volume 1-5, the fifth edition of IP and supplements, the eighth edition of EP and supplements plus updated revision, JP 17th edition*, and Thai-pharmacopoeia II volume I part 1 and supplements. In addition, the updated version of standard pharmacopoeia as announced is accepted. * Effective in February 2020	Standard: Vietnam Pharmacopoeia Reference (USP/NF, JP, EP, BP, IP) Pharmaceutical business establishments and drug preparing facilities can apply Vietnam's pharmacopeia or one of the following reference pharmacopeias: European, British, United States, International, and Japanese; (Source: Article 4 Circular 30/2025/TT-BYT)
	GMP system What is current GMP require-ments?	- Chinese GMP 2010 version (MOH order 79) - According to revised China DAL, there will be no GMP certificating and relevant requirements will be included in the qualification of drug manufacturing license. - NMPA released an appendix of GMP for IMP on May 27 2022.(source: https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20220527182006196.html)	PIC/S has been adopted for local manufacturer and overseas manufacturer.	The Union Health Ministry notified the revised Schedule M norms for good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products, with provisions for annual Product Quality Review (PQR), Quality Risk Management (QRM), Pharmaceutical Quality System (PQM) and others in order to bring the pharma and biopharmaceutical quality standards in the country on par with the international standards. Ref: G.S.R. 922(E).28.12.2023 The revised GMP will be fully effective from December 31, 2025. cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA4MTU=	Indonesian GMP, PIC/S GMP & WHO GMP requirements	Japan has been a member of PIC/S GMP since July 2014.	PIC/S GMP requirements	PIC/S	PIC/S GMP is the standard used (Administrative Order No. 2012-0008)	PIC/S GMP requirements	TFDA announced on Jan. 2020 that the APIs for exportation only should be mandated to fulfill GMP requirements from Jan. 2022. Amendments of PIC/S GMP application forms and checking list for foreign manufacturing sites were announced on May 24th, 2024 to accommodate the updates of PIC/S GMP standard. Please refer to TFDA website https://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=417&chk=9e77d38c-4b40-4e38-839f-d035268b9653&param=pn%3d1%26sid%3d301 PIC/S GMP Annex1 was revised on Jun 14th, 2023. https://www.fda.gov.tw/TC/lawContent.aspx?cid=68&scid=180&id=3488	Thai FDA is PIC/s country member effective from 1 Aug 2016.	**Current GMP requirements (**Art. 3 in Circular 28/2025/TT-BYT**)** 3a. Manufacturers follow WHO-GMP, PICs-GMP or EU GMP standards & other GMP principles and standards equivalent to EU-GMP principles and standards promulgated by regulatory authorities of SRA countries. - Other GMP standards that have been assessed and recognized to be conformable with standards issued or announced by the Minister of Health. 3b. For manufacturers of excipients: - In addition to the GMP principles above, manufacturers of excipients are entitled to apply other GMP principles of International Pharmaceutical Excipients Council (IPEC), the Certification Scheme for Pharmaceutical Excipients (EXCiPACT), American National Standards Institute (ANSI), United States Pharmacopeia (USP) or other principles for manufacture of excipients applied by regulatory authorities of countries or other international organizations related to excipients used to manufacture pharmaceutical products, cosmetics and foods. 4. Document updating GMP principles and standards: a) If WHO makes any revision to GMP principles (hereinafter referred to as "updated documents") above, within 03 months from the date on which updated documents are published on WHO's web portal; the DAV or Administration of Traditional Medicine and Pharmacy shall, according to the assigned field of management, publish contents of the updated documents for retrieval, updating and application by relevant entities; translate such documents and publish Vietnamese translations (for reference) on the web portal of the MoH and the website of the DAV or Administration of Traditional Medicine and Pharmacy; b) If the Pharmaceutical Inspection Co-operation System (PIC/S) or the European Union has the updated documents specified above which have not been published on the web portal of the MoH and the website of the DAV, manufacturers applying such documents shall send English versions to the DAV. Within 10 days from the date of receipt, the DAV shall publish English versions on the web portal of MoH and DAV for retrieval, updating and application by relevant entities. (Source: Article 94, Decree 163)

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Manufac-turing	GMP system Please describe GMP evaluation process by the authorities.	According to new DRR, - The CDE shall decide whether or not to carry out drug registration development site inspection based on the risks, the innovativeness of the drug, and the previous inspection results of drug research institution. - The CDE shall decide whether or not to carry out drug registration manufacturing site inspection based on the product under registration application, the process, facilities, previous inspection results and the risks. - The principles, procedures, timelines and requirements for initiating drug registration inspection shall be formulated and published by the CDE; the principles, procedures, timelines and requirements of implementing drug registration inspection shall be formulated and published by the CFDI. In order to clarify the principle, procedure, timeline and requirement for implementation of drug registration inspection, to specify the cohesion of drug registration manufacturing on-site inspection and pre-approval GMP inspection, CFDI issued Working Procedure for Drug Registration Inspection (for Trial Implementation) and Working Procedure of Cohesion of Drug Registration Manufacturing On-site Inspection and Pre-marketing GMP Inspection (for Trial Implementation) and Key Points and Determination Principle of Drug Registration Inspection (Pharmacology and Toxicology Study, Drug Clinical Trials, Pharmaceutical Development and Manufacturing Site) (for Trial Implementation) on Dec.20, 2021 and taken into effective since Jan. 1, 2022	For overseas manufacturer, inspection is usually not required if the manufacturer complies with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP standards. For local manufacturer or manufacturer without PIC/S GMP certification, an inspection by pharmacist inspector will be conducted at the company's premises within 2 weeks from the submission of a new application. The application will be considered by the committee. If approved, a license valid for 1 year will be granted.	CDSCO issued the Guidance document for Risk based inspection of drug manufacturing sites-related, in order to streamline and uniformity in execution and action to be taken based on Risk based Inspections of drug manufacturing sites. cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEzNjY=	Additional information BPOM Regulation No. 7 Year 2019 on the assessment on GMP compliance of imported drug manufacturing facilities. This regulation is planned to change in 2026. The manufacturer involved in DP manufacturing (for chemical) and DP and DS manufacturing (for biological) in NDA or transfer site submission should provide SITE MASTER FILE (SMF), Inspection Report, and CAPA status/plan (for major finding) for GMP evaluation. After evaluation of SMF, BPOM will approve to continue registration process of NDA or request a desktop inspection or request site inspection. Before inspection, the manufacturer should provide Pre-inspection document for preparation of the site inspection. After inspection, BPOM will issue approved or reject to continue registration NDA. The inspection report from other Authorized Health Authority can be consider for Waive of Inspection to the Manufacturer. BPOM do not disclose total amount of inspection in a year. Referring to the BPOM Regulation No. 7 Year 2019 article 13: Point 2 mentioned amounts of BPOM inspector at least 2 person and maximum 4 person each section Point 3. Mention that inspection conducted maximum 3 days for non-sterile products and 4 days for sterile products.	GMP compliance is a pre-requisite for obtaining Product Marketing Approval in Japan (see Pre-approval inspection, GMP). GMP inspection of a licensed manufacturer is performed every five years either as an on-site inspection or by inspecting the documents.	Pre-approval GMP assessments basically are conducted by desk-top assessment by reviewing the GMP documents that are listed in the regulation. If necessary, on-site inspection will be conducted under following conditions: 1) Manufacturing site that has no history of inspection conducted by MFDS or where waived inspection period has passed 2) Sites with any significant reason for conducting inspection during desk-to assessment (e.g. Manufacturing sites with critical GMP non-compliances, significant changes in facilities compared to the previous inspection, necessity of inspection during the approval and review process, and request of an applicant on on-site inspection) After the GMP inspection, the domestic manufacture is given GMP certificate according to the dosage forms that MFDS have found to be GMP compliant. The GMP certificate is generally valid for 3 years. Upon renewal, the validity is extended for another 3 years if an on-site inspection is conducted. If the inspection is waived due to reasons such as natural disasters, infectious disease outbreaks, or no significant facility changes, the extension is limited to 2 years, and an on-site inspection is required at the next renewal. For foreign manufacturers, we also conduct post-approval GMP inspection based on risk-based plans.	Manufacturers are subject to GMP conformity assessments through acceptable GMP evidence or GMP inspection. GMP certification are accepted from PIC/S or ASEAN MRA countries.	GMP clearance for foreign manufacturers is obtained either through desktop review (if PIC/S-GMP certified manufacturer), or through on-site inspection (for non-PIC/S) For locally manufactured products, GMP certificate is issued through actual inspection. (Administrative Order No. 2013-0022)	Domestic manufacturers in Singapore are subjected to licensing and periodic GMP audits by HSA. All new overseas manufacturers will be subjected to a GMP Conformity Assessment by HSA. Refer to: GMP CONFORMITY ASSESSMENT OF AN OVERSEAS MANUFACTURER, https://www.hsa.gov.sg/docs/default-source/hprg-ald/guide-mga-020.pdf?sfvrsn=5b43e0b4_7	Measures for the Management of Changes in Foreign Manufacturers of Imported Pharmaceuticals (Version 3) was announced on Nov. 16th, 2022. The major changes include newly added requirements (i.e. (1). Notify the change for any in-factory major change for the imported products within 90 days after notified by the manufacturing site and before the product importation to Taiwan) (2). Apply for PIC/S GMP registration for the expansion- involved change The Notice of paper periodic review for foreign manufacturing sites was announced on Jul 5th 2024. Please refer to TFDA website. https://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=7454	GMP accreditation was replaced by GMP clearance. On-site inspection is required if document verification is insufficient. Require GMP clearance for all manufacturing flow in P3 except Quality testing site. Site inspection might be required in case submitted document is insufficient. GMP Clearance for drug products in parallel is permitted only for urgent public health needs on a case-by-case basis.	**GMP evaluation process** (Art. 7 of Circular 28/2025/TT-BYT) Documents used during the inspection of GMP compliance comprise documents about WHO - GMP principles or GMP principles specified in points a and b clause 1 and clause 2 Article 3 of this Circular equivalent to the manufacturer's manufacturing operations. Steps including: 1.Manufacturer presents summary of organization, personnel and activities applying for GMP 2.Evaluation team conducts GMP assessment at the production facility. In cases where an registrant performs one or several stages of the production process, the evaluation content shall cover only the requirements corresponding to one or several production stages performed by the registrant; 3.Evaluation team meeting with manufacturer to inform about any pending items 4.Evaluation team prepare and sign the evaluation form, to also be signed by manufacturer 5.Complete the Evaluation Report.
	GMP system Please describe frequency/ number of on-site inspections to domestic/ overseas manufacturers by the authorities.	Since Nov. 2019, CFDI newly established a column on its website to notice the list of drug registration applications received from CDE, to which CDE required research on-site inspections and manufacturing on-site inspections https://www.cfdi.org.cn/cfdi/index?module=A001&nty=A24 This column has been integrated to Drug Inspection Column, Medical Device Inspection Column, and the Cosmetics Inspection Column, to facilitate clearer classification and more convenient reference. from 2023. (https://www.cfdi.org.cn/cfdi/index?module=A001&m1=10&m2=&nty=A27) https://www.cfdi.org.cn/cfdi/resource/news/15118.html	Since the manufacture license valid for only 1 year, inspection will be made at least on annual basis for the concerned manufacturers.	Annually for domestic manufacturers by State FDA and in some cases joint inspection by State and CDSCO. For overseas manufacturers, CDSCO has provision to inspect the sites on case to case basis	No published information	In FY2024, there were 126 GMP inspections (25 in Japan and 101 overseas) were conducted on-site.	[Frequency] routine inspection: every 3 years, but could be changed based on risk-based plans. [Number of on-site inspections] There is no official information.	Number of GMP Inspections in 2023 was 432 https://www.npra.gov.my/index.php/en/informationen/annual-reports/npra-annual-reports.html# https://www.npra.gov.my/index.php/en/informationen/annual-reports/npra-annual-reports.html?task=convert.getpdf&id=51&filename=ANNUAL%20REPORT%20NPRA%20LATEST%20EDIT%2010_10_2024_4PM.pdf	For local manufacturers, inspection is required prior to opening, with follow-up inspection within the validity of the issued license (three years). For foreign manufacturers, inspection prior to product registration is mandatory for non-PIC/S certified manufacturers. Follow-up inspection may be conducted but is not mandatory for renewal of GMP certificate. (Administrative Order No. 2013-0022 and FDA Circular No. 2014-016)	No official data	The overseas GMP site inspection was re-activated in 2023 after the COVID-19 pandemic period. TFDA can conduct 30 oversea inspections each year. Please refer to TFDA website https://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=418&chk=2d4f1912-6ea2-494c-94eb-ea47f235ae38&param=pn%3d1%26sid%3d301#6	Depending on risk assessment and management (frequency can be 1 or 2 or 3 years)	GMP periodic inspection every 3 years (not including ad-hoc inspections by MoH, DOH) (Source: Article 9, Circular 28/2025/TT-BYT)

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Manufac-turing	DMF system Please describe DMF system (or plan for introduction). Is DMF mandatory or optional?	Manufacturers of chemical APIs, excipients and primary packaging materials and containers shall register product information and research data on the registry platform. When a drug product applicant submits the drug registration application, the chemical APIs, excipients and primary packaging materials and containers having been registered can be directly selected; where chemical APIs, excipients and primary packaging materials and containers having not been registered are selected, related study data shall be submitted together with the drug registration application.	Not specified.	No DMF system exists. (Note: CMC part of application dossier is called DMF, but it does not mean DMF system as in other countries.) API DMF as per ICH CTD is also acceptable.	DMF (open & closed part) of API are needed as mandatory for generic and NCE API, and new DS manufacturing site.	The submission of Master File (MF) is optional. Drug substance, Intermediate, New excipient, Packaging material etc. are components of the MF.	DMF system is mandatory for the following drugs: - drug substance of a new drug product - drug substances announced by the MFDS - drug substances derived from human placenta - drug substances for injection [Excludes] - orphan drugs - Biologics, Advanced biopharmaceutical drugs - radiopharmaceuticals - export-only drugs - pharmacologically inactive ingredients (excipients, additives, etc.) - Ingredients that fall under the drug shortage prevention drugs classification, and drug substances aimed at providing nutrients (e.g. glucose, amino acids, fatty acids, vitamins, minerals, etc.)	A DMF is required for API registration and may be replaced by a CEP or full details of Part II S ACTD.	With the adoption of the ASEAN CTD, maintenance of DMF is mandatory but not required for submission.	DMF is optional, if a Drug Master File is submitted, then a separate declaration letter issued by the applicant must also be provided to state that the DMF submitted to HSA is identical to that submitted to the chosen reference drug regulatory agency. GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE APPENDIX 11 GUIDELINE ON DRUG MASTER FILE (DMF) https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/appendix-11_guideline-on-drug-master-fileb0e2d1d9ed9349b4b3f8012545bf9712.pdf	Drug substance DMF is mandatory for NDA approval. DMF dossier can be reviewed during NDA review process or applied as a separated application. DMF is required for replacing or alternative sites of drug substance. Please refer to TFDA website for DMF RTF https://www.fda.gov.tw/TC/siteListContent.aspx?sid=3001&id=37420	DMF is optional.	N/A
	DMF system Annual or periodical update reporting required?	Yes NMPA is establishing the system of annual report. According to new DRR, (1) Minor changes in drug manufacturing process; (2) Other changes subject to reporting as specified by the NMPA shall be included by MAH in annual report. Besides, NMPA issued Annual Report Administration Regulation and Template . https://www.nmpa.gov.cn/yaopin/ypfgwj/ypfggzwj/20220412172455115.html	Not specified.	N/A	No. Update will be as one requirement on certain registration variation (eg. MA Transfer, etc)	ICH Q12 was issued in Oct, 2021	Yes DMF change management is divided into major changes and minor changes according to the level of change compared with the previously registered DMF. In case of major changes, documents shall be reviewed after the change registration, and minor changes are processed as change report (annual report).	No (Changes are to be submitted as post-approval variation applications.)	Maintenance/updating of DMF is mandatory but not required for submission.	Yes DMF holders and applicants are responsible for maintaining and updating the DMF. When a DMF has been updated, the table of summary of changes and the DMF Submission Form must be provided together with the updated sections of the DMF. If there are changes to the DMF that will result in a post-approval variation to the drug product, product registrants must file a post-approval variation (see GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE; Chapter F Post-Approval Process). GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE APPENDIX 11 GUIDELINE ON DRUG MASTER FILE (DMF) https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/appendix-11_guideline-on-drug-master-fileb0e2d1d9ed9349b4b3f8012545bf9712.pdf	There is no annual update reporting in Taiwan. However, DMF approval is valid for 5 years and combined with NDA drug license. Once the change including major or minor change, it should be filed to TFDA, the detail post-approval major/ minor change classification, please refer to appendix 12 of “Drug Review and Registration Guidance.”	No Not required	No N/A for imported products.

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Manufac-turing	Contents of packaging label and language	The required contents are described in CFDA order 24, Regulation on Drug Insert Sheet and Label. According to Announcement of the NMPA on Relevant Matters for Implementation of the Drug Registration Regulation (No. 46 of 2020), MAH should update the Package Insert and label in accordance with new DRR Article 123 since Dec. 1st. NMPA initiate the pilot for age-appropriate of package insert, issued Work Plan for the Pilot Reform of Age-appropriate and Barrier-free Package Inserts on Oct.31 2023. CDE issued Guidelines for the Preparation of Package Inserts (Simplified Version) and Package Inserts (Large-character Version), and Format Requirements for Electronic Package Inserts (Complete Version) on Nov.24 2023 The contents should be written in Chinese. CDE issued Guidelines for the Writing of Pharmaceutical Information on Instructions and Labels of Chemical Drugs (Trial) on Mar. 21 2023. Source: https://www.cde.org.cn/main/news/viewInfoCommon/f181ed96619e3bef4ce8154bb66d91bb CDE issued General Formats and Drafting Guidelines for Instructions for Chemical and Biological Products on May.23 2022. Source: https://www.cde.org.cn/main/news/viewInfoCommon/defca6a1f3ba33d0bad6f309e5a0b816 Notice of the Center for Drug Evaluation of the National Medical Products Administration on the Release of the Technical Guidance Principles for the Preparation of Biosimilar Product Labels (No. 12 of 2025) https://www.cde.org.cn/main/news/viewInfoCommon/02c265536d59d0ec97d81a23627afa37 Notice of the Center for Drug Evaluation of the National Medical Products Administration on Issuing the "Guidelines for Writing Information on Medication Use in Elderly Populations in Drug Instructions (Trial)" (No. 43 of 2025) https://www.cde.org.cn/main/news/viewInfoCommon/ba056d1147d71784407288123b07a414	English or English and Chinese, requirements described in Guidelines on the Labeling of Pharmaceutical Products.	The manners of labelling of new drugs for the purpose of clinical trial, BA/BE Study are described in rule 66 & 73 of Chapters VIII and IX respectively of the NDCT Rules 2019. Package Insert and packaging labels should be written in English. The labeling requirements for primary and secondary and all labels are outlined in Rules 96 and 97 of Drugs Rules 1945	Annex II BPOM Drug Registration Guideline No 23 Year 2025 on minimum information that must be stated in the product information and packaging materials	According to the enforcement of the revised PMD Act in August 2021, the package inserts have been digitized, and the provision of information on paper included in the products has been abolished in principle.	The contents of each labeling type are described according to the following regulations. (1) Container • Article 56 of the "Pharmaceutical Affairs Act" • Article 69 of the "Regulation on Safety of Medicines, etc." (2) Carton (outer package) • Article 57 of the "Pharmaceutical Affairs Act" • Article 69 of the "Regulation on Safety of Medicines, etc." (3) Package leaflet • Article 58 of the Pharmaceutical Affairs Act" • Article 70 of the "Regulation on Safety of Medicines, etc."	Details given in the DRGD. The labeling for pharmaceutical products are in English or Bahasa Melayu. Some labelling statements are mandatory in Bahasa Melayu. Some country specific requirements include declaration of ingredient derived from animal origin (active and excipient) including starting materials and gelatine (e,g., porcine, bovine), name and content of alcohol, where present and Controlled Medicine.	The required contents are described in Guidelines on the Labelling of Pharmaceutical Products. The contents should be written in English and/or Filipino. (Administrative Order No. 2016-0008) In the new labeling guidelines, there is a provision to recognize electronic labels, but this is yet to be implemented. (Administrative Order No. 2024-0013)	The product labels, PI and/or PIL must be in English. If non-English text is included in the labelling, applicants must provide an official statement to declare that the non-English text is complete, accurate and unbiased information and is consistent with the English text. Information provided in the labels should be consistent with the information submitted in the application dossier. Any discrepancies should be highlighted and brought to HSA's attention. Ref: GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE APPENDIX 7 Points to Consider for Singapore Labelling, ~~https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/tpb-gn-021-000_appendix-7a-guidance-on-electronic-labelling-for-therapeutic-products.pdf?sfvrsn=1f3ad3d0_5~~ Registrants of Therapeutic Products (TP) who have a secure online system may distribute the HSA-approved PI and/or PIL in the form of an e-PI/PIL. The e-PI/PIL may be distributed with or without physical printed copies contained in the products. Ref: APPENDIX 7A GUIDANCE ON ELECTRONIC LABELLING FOR THERAPEUTIC PRODUCTS, https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/tpb-gn-021-000_appendix-7a-guidance-on-electronic-labelling-for-therapeutic-products.pdf?sfvrsn=1f3ad3d0_5	The requirement is described in Article 20 of "Regulations for Registration of Medicinal Products." The contents of outer box should be both in English and Chinese. Chinese packaging insert is mandatory while English PI is optional. Any local redressing activities need CMO registration to the drug license and showed CMO information in the package insert Please refer to Article 20 in this link: Regulations for Registration of Medicinal Products	Follow ASEAN labeling requirements Thai language required for - category of drug - expiration date - special warning Patient Information leaflet (PIL) in Thai. SmPC in English. New drug applications must apply e-labelling. Thai PIL in Thai FDA template must be physically included unless fall within the paperless scope while English HCP leaflet in SmPC format can be paperless. Legacy products only require e-labelling upon renewal. Paperless e-Labelling is voluntary and restricted to: • Injectable dosage forms. • Products for medical facilities that are not sold in pharmacies. • Exclusions: Self-administered injectables, human/animal vaccines, and injectables for food-producing animals. PIL User Testing is mandatory for "Household Remedies", "Non-Dangerous and Non-Specially Controlled Drugs" and "Drugs that have been reclassified from Dangerous/Specially Controlled status to Non-Dangerous and Non-Specially Controlled Drugs or Household Remedies status". Refer to Thai FDA Notification Re: Guidelines for the Evaluation of Modern Medicine Registration Submitted via Electronic Methods B.E. 2568 (cited 2025 DEC 12 media.php) and Medicines Regulation Division Notification Re: Guideline for Medicinal Leaflet Development, dated 20 Jan 2025 (cited 2025 DEC 12 media.php). Implementation of Reference SmPC/PIL is mandatory for renewals of product certificate under the RMP framework. All published documents are available via the official Medicines Regulation Division website under the dedicated Ref. PIL / Ref. SmPC section. This database serves as the central repository for reference PIL and SmPC required for renewals of product certificate. Refer to Thai FDA website https://drug.fda.moph.go.th/drug-information/category/medicine-for-people-and-professional (cited 2025 DEC 12).	Vietnamese. The currently valid Circular on Labelling no. 01/2018/TT-BYT, amended by Circular 23/2023/TT-BYT & Circular 12/2025/TT-BYT: Outer package labels (Article 7) For drugs, drug raw materials: 1.1 The outer packaging label of a drug must show the following contents: a) Drug name; b) Dosage form; c) Composition, strength, weight or concentration of pharmaceutical substances, medicinal materials in the drug formulation; d) Packaging size; đ) Indications, method of administration, contraindications; e) Number of certificates of marketing authorization or the number of import license (if applicable); g) Batch number, manufacturing date, expiry date, DP's specification, storage conditions; h) Warnings and precautions; i) Name, address of DP's manufacturer; k) Name, address of importer (in the case of imported drugs); l) Origin of the drug. 2. The outer packaging label of a drug raw material (including medicinal materials, traditional medicinal semi-finished medicinal materials, semi-finished drugs) must show the following contents: a) Name of the drug raw material; b) Weight or volume of the drug raw material in the smallest package unit; c) Quality specification of the drug raw material; d) Number of certificates of marketing authorization or number of import license (if applicable); đ) Batch number, manufacturing date, expiry date, storage conditions of the drug raw material; e) Name, address of manufacturer; g) Name, address of importer (in the case of imported drug raw materials); h) Origin of the drug raw material. 3. Labels of controlled drug raw materials (including semi-finished drugs): Apart from the contents stipulated under clause 2 of this Article, raw materials being pharmaceuticals, medicinal material or semi-finished drugs containing pharmaceutical substances, medicinal materials belonging to the List of narcotic, psychotropic substances, drug precursors, hazardous drug raw materials, hazardous medicinal materials, radioactive drug raw materials, must have outer packaging printed with the wording "Narcotic raw materials", "Psychotropic raw materials", "Drug precursor raw materials", " Hazardous raw materials", "Hazardous medicinal materials", "Radioactive materials" respectively. The wording "Narcotic raw materials", "Psychotropic raw materials", "Drug precursor raw materials", " Hazardous raw materials", "Hazardous medicinal materials", "Radioactive materials" must be printed in Bold in a textbox and on the label's facesheet bearing the name of the drug raw materials. 4. Where the contents stipulated in clause 1 of this Article cannot be fitted into the outer packaging label, the contents stipulated in point đ clause 1 of this Article may be summarily presented as follows: indications, contraindications and other information: see enclosed package insert. Secondary packaging labels (Article 8) 1. The secondary packaging label must show at a minimum the following contents: a) Name of the drug; b) Batch number; c) Expiry date. 2. In cases where the secondary packaging is made of a transparent material that allows for information on the primary packaging label to be seen through, such secondary packaging does not have to be printed with the contents stipulated in clause 1 of this Article. Primary packaging labels of drugs, drug raw materials (Article 9) 1. Labels of drug primary packaging must show all the following mandatory contents: a) Drug name; b) The quantitative composition, strength, concentration or volume of pharmaceutical substances, medicinal materials in the drug formulation; c) Batch number; d) Expiry date; đ) Name of manufacturer. 2. Labels of primary packaging of drug raw materials With regard to drug raw materials that have an outer packaging showing all the contents stipulated in clause 2 and clause 3 Article, unless they are removed from the outer packaging for retailing, labelling on the drug primary packaging shall not be required. 3. With regard to drugs, drug raw materials having no outer packaging, the contents stipulated for outer packaging labels under Article 7 of this Circular must be printed in full on the primary packaging. Format of supplementary labeling (Article 10) 1. Supplementary labels must show all the mandatory contents in Vietnamese language that are not yet available or still missing from the original label in accordance with the provisions of Article 7 of this Circular. 2. Where the size of supplementary labels is too small to fit all the mandatory contents stipulated under clause 1 of this Article, some of such contents shall be presented as follows: a) Indications, method of administration, contraindications and other information: see enclosed package insert; b) Cross reference of manufacturing date, expiry date, batch number that are presented on the original label; c) Number of certificates of marketing registration or number of import license: may be left blank but number of certificates of marketing registration or import license (if applicable) must be filled in before placing the drug on the market.

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Manufac-turing	Bar code on packaging materials	NMPA published Announcement of the National Medical Products Administration on the Building of the Information Traceability System for Key Products (No. 111, 2020), MAH shall implement the main responsibility of drug quality management in the whole process, establish an information traceability system, and collect the traceability information throughout the process. By December 31, 2020, the traceability of key products such as the selected products in volume-based procurement, narcotic drugs, psychotropic drugs, and blood products should be basically achieved. In Drug Distribution and Use Quality Regulation issued by NMPA which effected on Jan.1 2024, indicated that MAH and the distributors should establish and implement the drug traceability system. Additionally, NMPA published Identification Specification of Drug Traceability Code and Display Specification for Consumer Query Results of Drug traceability (No.50, 2022) on Jun.23, 2022.	Not required for product registration.	The Health Ministry has notified draft Drugs (Amendment) Rules 2025 proposing to add Table 2 containing – 1) All Vaccines; 2) All Antimicrobials; 3) All Narcotic and Psychotropic drugs listed under the Narcotic and Psychotropic drugs Act, 1985; and 4) All Anticancer drugs in the existing Schedule H2 of the Drugs Rules, 1945 Schedule H2 requires printing or affixation of Bar Code or QR Code on the drug's primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data as specified under the DR. Ref: MoH GSR 757(E) dated October 16, 2025	New Regulation BPOM Regulation No. 22 Year 2022 regarding 2D Barcode, enacted on Oct 5, 2022. Authentication must be implemented no later than 4 years after the first electronic MA certificate is issued. Identification must be implemented no later than 12 months after the electronic MA certificate is issued since this regulation is enacted. There are grace period for authentication until Dec 7, 2027 (prescription drug including biological product, narcotics, psychotropic) and Dec 7, 2025.(Drugs included in the class of over-the-counter drugs and Limited over-the-counter drugs, herbal medicine, quasi drug, health supplement, cosmetic food) There are grace period for identification until Dec 7, 2023. The grace period for both primary and secondary packaging. The regulation for drug, food, herbal medicine, cosmetic & health supplement.	Yes Bar Code display including information such as expiration date, serial number or serial number and product code.	Yes. Barcode or electronic tag (RFID tag) should be indicated on every drugs(manufactured or imported.)(excludes medical gas, API that are manufactured only for the purpose of manufacturing its own drug product, medicinal herbs, medicine for clinical trials)	No. Bar code is optional.	Bar code on packaging materials	No No regulatory requirement on bar code. It is an internal company logistics requirement.	OTC products should be printed QR code in the outer box by Dec 31st 2019. The announcement of "The principle of e-labeling of drug package insert" was issued on 26th Sep 2023. https://www.fda.gov.tw/TC/siteListContent.aspx?sid=9354&id=45855	No No regulatory requirement for Bar code But some hospitals require barcode	The label of the drug's, the drug's raw material outer packaging must be printed with a bar code or a QR (quick response) code or a Data Matrix Code (DMC): but the road map to implement this requirement has not been issued. Point h clause 1 Article 55 of Circular 12/2025/TT-BYT: Formulate regulations on use of barcodes, QR codes, DataMatrix codes or other printed codes, as prescribed by relevant laws, on secondary package labels of drugs/medicinal materials of manufacturer to serve management, identification and tracing of origin of the drugs and medicinal materials placed on the market, and the roadmap for implementation thereof according to regulations adopted by the Minister of Health; In Circular 23/2023, the MOH also mandated a roadmap for e-labeling and serialization. The current draft Decree guiding the Law on Product and Goods Quality (including e-labelling) also outline clearer definition of e-labelling and assign responsibilities to relevant ministries (hereby the Ministry of Health).
Others		NMPA conducted the pilot program for segmented manufacturing of biological products in some specified drug varieties, the pilot will be closed by Dec.31 2026. https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20241022112249149.html											
Post approval	Renewal system of approved license	Renewal is required every 5 years, and should be submitted by MAH no less than 6 months before expiration date of approval license.	Renewal required every 5 years.	Renewal system has been implemented for the followings. 1) Import license (Every 3 years. Renewal application should be made 3 months before the expiry of the existing license.) 2) Registration certificate (Every 3 years. Renewal application should be made 9 months before the expiry of the existing license.) 3) Manufacturing license – perpetual subject to payment of retention fee every 5 years. The license will be expired if the renewal applications not made within six months of its expiry) Marketing Authorization is one time issue, no renewal required.	Renewal required every 5 years	Not renewal, but a re-examination system is adopted. Drug monitoring is required for 8 years for NCE drug, 4-6 years for new indication/ administration route, 10 years or orphan drug, and up to 12 years for drugs for orphan diseases and pediatric drugs.	Yes. Renewal should be applied to the MFDS, and the related documents must be submitted every five years (or every ten years for orphan drugs) in accordance with the "Regulation on the Renewal of Drug Products."	Renewal required every 5 years. Renewal needs to be submitted 6 months prior to registration expiry. A conditional registration is valid for two years. Thereafter, the conditional registration may be renewed 2 times. For products approved via Conditional Registration During Disaster pathway, the conditional registration is valid for 1 year and can be renewed up to maximum of 2 times.	Renewal required every 6 or 12 years, at the applicant's choice. (Administrative Order No. 2024-0013 and 2024-0016)	Reference to "RETENTION OF THERAPEUTIC PRODUCT ON THE PRODUCT REGISTER TPB-GN-002-002". guidance-for-retention-of-therapeutic-product-on-the-product-register.pdf (hsa.gov.sg) All registered therapeutic products will remain on the Register, unless: a) The registration is suspended or cancelled by HSA, or b) The registration is cancelled upon application by the registrant, or c) The registrant has failed to make a payment for an annual retention fee within 60 calendar days after the retention fee due date	Renewal required for approved license every 5 years. On-line renewal procedure (e-submission) is mandatory from 1st Jul 2020. According to the amendment of "Regulations for Registration of Medicinal Products" announced on 14th Sep 2021, the post-approval letter of the specifications and testing methods based on the latest edition of pharmacopoeia or the manufacturer's specifications should be provided. If the specifications are not changed, the assessment statement should be provided.	Company license: There are 3 kinds of license in Thailand which are Manufacturing license, Import license and Sale license (wholesale or retail), all of which require annual renewal. Based on new Thai Drug Act 2019, the certificate of drug formula registration shall be valid for seven years from the date it was issued. Product license will be automatically withdrawn if there is no production/ importation every 2 consecutive years. The drug classified as narcotics and psychotropics shall subject to renewal every 5 years. It is necessary to ensure GDP validity for company license renewal. In 2025, for importers, there are two approaches, i.e. Desktop inspection and On-site inspection, both based on risk level of the site. (cited 2025 FEB 3 media.php)	(Art. 12 Circular 12/2025/TT-BYT) 1. The validity period of a marketing authorization is 05 years from the issuance date or renewal date, except for the cases specified in clause 2 of this Article. 2. The validity period of a marketing authorization of the following drugs subject to extended monitoring of safety and efficacy is 03 years from the issuance date or renewal date: a) New chemical drugs, vaccines and biologics (except probiotic) which are granted the marketing authorization in Vietnam for the first time; b) Drugs having the same drug substance(s), concentration, strength or dosage form as those of a new drug which has not been granted a 05-year marketing authorization; c) Any of the drugs specified in point a or b of this clause which is not actually placed on the market during the validity period of its marketing authorization; d) A drug which is mentioned in neither of points a, b and c of this clause but is subject to an extended monitoring of safety and efficacy as advised by the Advisory Council; 3. When a marketing authorization of drug or medicinal material expires after DAV has received an application for renewal thereof, it may be used until an official approval for renewal is granted or DAV issues a notification that the application for renewal is rejected or the marketing authorization is suspended in case the drug or medicinal material is found potentially unsafe for users or legal documents in the application are suspected of being forged. 4. Each approved MA shall be granted a marketing authorization with a unique marketing authorization number whose structure is specified in Appendix V enclosed herewith. 5. An application for renewal of the marketing authorization of a drug or medicinal material must be submitted before its expiration date. An application for renewal of the marketing authorization which is submitted after its expiration date shall be refused by DAV. In this case, the applicant is required to submit an application for issuance of a new marketing authorization. With the issuance of Pharma Law no 44/2024/QH15 and Circular 12/2025/TT-BYT, when a marketing authorization of drug or drug raw materials expires after the DAV already receives an application for renewal thereof, it can be used until it is officially renewed or DAV issues a written notification that the application is rejected or the marketing authorization is suspended in case the drug or drug materials are found at risk of being unsafe for users or legal documents are suspected of being forged.

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Post approval	Post marketing surveillance or safety monitoring program	Yes MAHs shall proactively carry out post-marketing studies to further verify the safety, efficacy and quality controllability of drugs and enhance ongoing management of marketed drugs. Where the drug approval license and its attachments require the MAH to carry out related post-marketing studies, the MAH shall complete the studies within the prescribed timeline and submit a supplementary application, notification or report as required. After a drug is marketed after approval, the MAH shall continue to carry out the drug safety and efficacy studies, timely file notification or submit supplementary applications for revision of the package inserts according to the relevant data, and constantly update and improve the package inserts and labels. The drug regulatory authorities may require the MAH to revise the package inserts and labels according to the adverse drug reaction monitoring and post-marketing review results. Additionally, NMPA revised and issued the Provisions on the Administration of Drug Recalls on Oct. 26, effective on Nov 1, 2022. NMPA issued Administrative Provisions on Annual Reports for Drugs on Apr.12, 2022. The cut-off date for filling the 2021 annual report information is Aug 31, 2022; from next year onwards, the annual report information of the previous year shall be filled in before Apr 30 the next year.	For NCE, ATP and biosimilar. PSUR has to be submitted every 6-monthly for the first 2 years of product registration approval, and annually in the following 3 years. For special pathway (“1+ mechanism”), PSUR has to be submitted every 6-monthly	PSUR submission is mandatory for a period of four years. For new drug, every 6 months for the first 2 years, and annually for another 2 years. May be extended by the authority in the interest of public health. (Reference: Fifth Schedule of NDCT 2019) PSURs due for a period must be submitted within 30 calendar days of the last reporting period	BPOM Regulation No. 15 Year 2022 regarding Pharmacovigilance Implementation Article 5-12 and Article 14.. This regulation is planned to change in 2026. PSUR/PBRER submission is required for marketed drug with new safety issue and need to monitor the safety aspect based on the assessment, new drug, biological product including biosimilar, certain generic drug and changes in drug that can increase a safety risk. PSUR/PBRER need to be submitted every 6 months for the initial 2 years, and every year for 3 years later. There is an obligation to report all Adverse Events (unexpected/expected, serious/ non-serious) in Indonesia and literature report from Indonesia and international to BPOM. There is signal management process and reporting.	Yes According to the ICH E2C(R2) guidelines, PSUR has been changed to PBRER. PBRER submission is mandatory every 6 months in the first two years and annually after two years. Use-result survey data should be included in the submission.	Yes. According to Annex 4-3 of the “Regulation on the Safety of the Medicinal Products, etc”. , it is mandatory for the MAH to conduct Post marketing surveillance program and report to the MFDS regularly.	Yes PSUR/PBRER is mandatory for NME: every 6 months in the first 2 years, and annually for the subsequent 3 years. Other safety monitoring programs may be requested if deemed necessary	An RMP containing the Pharmacovigilance Plan shall be submitted by applicants, determining whether additional PV activities are necessary. (FDA Circular No. 2021-020, FDA Circular No. 2020-003)	Reference to: GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS AND CELL, TISSUE AND GENE THERAPY PRODUCTS, 1 Mar 2021 guidance-for-industry_post-marketing-vigilance-requirements-for-therapeutic-products-and-ctgtp_v5_07-oct-2024.pdf ~~guidance-for-industry--post-marketing-vigilance-requirements-for-therapeutic-products-and-cell-tissue-and-gene-therapy-products_v3_01mar2021.pdf (hsa.gov.sg)~~ This guidance addresses the types of documents to be submitted at the point of application for product registration, and during the post-marketing phase of the therapeutic products and CTGTP (e.g. during variation application review or when new significant safety issues are identified). The requirements and timelines for reporting safety information related to therapeutic products and CTGTP are also included. The topics covered in this guidance include the following: ▪ Records of adverse events (AE); ▪ Serious AE reporting; ▪ Risk management plans (RMP); ▪ Periodic benefit-risk evaluation reports (PBRER); ▪ Updates on actions taken by other regulatory authority or company in response to safety issues.	Yes Pharmacovigilance period is the first 5 years for new drugs. PSUR should be submitted every 6 months in the first 2 years and annually for the rest 3 years. PSUR/PBRER submission period can be adjusted based on global international birthday (IBD) and its data lock point (DLP) within 3 months upon receipt of drug license.	Yes Active pharmacovigilance for early approval drugs for example clinical phase II registration. SMP is no longer implemented and replaced by RMP for safety monitoring throughout product life cycle. The transition from SMP to RMP. Refer to Medicines Regulation Division’s Notification Re: Practice Manual for the Transition from the Safety Monitoring Program (SMP) to the Risk Management Plan (RMP) System. (cited 2025 DEC 12 media.php) Pharmacovigilance is integrated into the extended scope of Good Distribution Practice (GDP). Note: Good Pharmacovigilance Practices (GVP) have not yet been fully implemented. Refer to Ministerial Notification Re: Criteria, Methods, and Conditions for the Distribution of Modern Medicines B.E. 2568 (cited 2025 DEC 12 media.php).	(Art. 10, Circular 12/2025/TT-BYT) 1. Each applicant shall submit the following reports to serve the monitoring of safety and efficacy of the drug during its marketing: a) Periodic report, for new drugs, vaccines and biologics (except probiotic) following Form 2A/TT b) Ad-hoc reports on all adverse events occurring in Vietnam related to drugs (adverse drug reactions, drug-related errors, suspected counterfeit drugs, drugs not meeting quality standards, and drugs lacking or failing to achieve treatment efficacy) following Form 2B/TT 2. Reporting time: a) For periodic reports as prescribed in point a clause 1: After obtaining a marketing authorization, the applicant shall submit reports on a periodical basis of every 06 months within the first 02 years; from the third year to the fifth year, the applicant shall submit reports on an annual basis; b) For ad-hoc reports on all adverse events occurring in Vietnam as prescribed in point b clause 1: The applicant shall submit reports within the time limit prescribed in the National Pharmacovigilance Guidelines issued by MoH. 3. Submission methods, recipients: Submission methods and recipients of reports shall comply with the National Pharmacovigilance Guidelines issued by MoH. 4. Handling and assessment of reports, and provision of information for state regulatory authorities and Specialized Councils of MoH to serve management of marketing authorization-related tasks: Comply with the National Pharmacovigilance Guidelines issued by MoH

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Renewal system of approved license	Risk Manage-ment Plan (RMP)	-Adopt to ICH E2E for the NDA submitted after Feb. 12th 2020 and the NDA approved after May. 12th 2020. -For the initial NDA or BLA of oncology drug in China, RMP should be submitted to CDE together with NDA/BLA. When NDA/BLA approved, MAH should strictly implement the pharmacovigilance plan and risk minimization measures specified in the RMP. -RMP is required the periodical review and updates, which initial review will be 2 years after drug launching. When 5-year renewal of license, MAH also needs to report the implementation status of RMP. CDE has issued Editing Guideline on Clinical Risk Management Plan (Trial Implementation) on Jan.6, 2022, effective since the issuance day.	Required for NCE, ATP and biosimilar registrations.	Risk Management Plan to be part of the Periodic Safety Update Report (PSUR), wherein the license holder will provide the brief details of safety concern and necessary action taken by him to mitigate these safety concerns. Separate RMP is not asked for.	BPOM Regulation No. 15 Year 2022 regarding Pharmacovigilance Implementation Article 4, 13 and Annex II. RMP submission is required for new drug, biological product including biosimilar, certain generic drug and changes in drug that can increase a safety risk. As part of registration dossier (Administrative Document). RMP could be in Bahasa or English. RMP format could refer to global RMP.	RMP document is mandated for NDA as CTD M1.11.	RMP submission is required for new drugs, orphan drugs, and advanced biopharmaceuticals (e.g., cell, gene, and tissue-engineered therapies), as well as certain prescription drugs such as those with (1) different active substances or composition ratios, (2) different routes of administration, or (3) clearly different therapeutic indications compared to already-approved products. The MFDS may also request an RMP for other products when safety concerns arise after marketing. The detailed items to be included in RMP is specified in the Annex 6-2 of the "Regulation for Approval, Notification and Review for Drugs ", Annex 9-2 of the "Regulation of Approval and Review of Biologics" and Annex 5 of the "Regulation of Approval and Review of Advanced Biopharmaceutical drugs"	Yes. RMP document is required for New Drug Products/ Biologics, and in certain cases, new indications. A new RMP or an update, as applicable, may need to be submitted at any time during a product's life-cycle. (Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders 1st Edition August 2021)	RMP is required for submission of NDAs. There's no local format of RMP, but FDA recommends compliance to EU format. FDA requires the creation of a Philippine-specific RMP, detailing specific RMP activities for the Philippines. FDA also requires an RMP for the establishment. Manufacturers are required to submit this as part of LTO applications; other establishments need not to submit this but are part of inspection requirements. (FDA Circular No. 2018-013, FDA Circular No. 2020-003, Administrative Order No. 2020-0017)	RMP requirements explained in GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS AND CELL, TISSUE AND GENE THERAPY PRODUCTS, An RMP must be submitted for all New Drug Applications type 1 (NDA-1) for therapeutic products or CTGTP. This requirement will also apply to products with a long history in the international market. Companies may propose to implement only routine PV activities and RMA if the product has been shown to have an acceptable and well-established safety profile. For other application types, including NDA-2/3, variation applications or generic drug application (GDA), an RMP is to be submitted only upon HSA's request during application review. Companies must continue to comply with the routine PV activities and RMA, regardless of RMP submission to HSA. Ref: guidance-for-industry_post-marketing-vigilance-requirements-for-therapeutic-products-and-ctgtp_v5_07-oct-2024.pdf	The necessity of local RMP will be decided by TFDA during the NDA review. RMP protocol will be discussed and finalized between TFDA and NDA applicants.	RMP is required as a part of dossier submission for renewal of product certificate (cited 2025 FEB 3 media.php) and also required as a part of dossier submission for all registration applications with replacing Safety Monitoring Program (SMP). (cited 2025 FEB 3 media.php).	RMP is required to submit in the application for new chemical drugs, vaccines and biologics (except probiotic) – Form 03/TT (Article 31 Circular 12/2025/TT-BYT)
	Adverse drug reaction (ADR) reporting after marketing	ICSR reporting adopt to ICH E2D PSUR/PBRER adopt to ICH E2C PV annual report has been incorporated into MAH annual report for Drugs/Vaccines, only a few provincial ADR monitoring centers request separate PV annual report. (https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20220412172455115.html)	All drugs except ATP: Local Serious adverse drug reactions have to be reported as soon as possible and not later than 15 calendar days from date of first receipt ATP: Local serious or unexpected ADR have to be reported asap and no later than 15 calendar days from the date of first receipt For special pathway ("1+ mechanism"), Local Serious or unexpected adverse drug reactions have to be reported as soon as possible and not later than 15 calendar days from date of first receipt	Reference: Fifth Schedule – Post Market Assessment (NDCT Rules, 2019) Serious unexpected adverse reactions: must be reported to the licensing authority (DCGI) within 15 calendar days of initial receipt of the information by the applicant. Serious and Non- serious adverse reactions need to be report to PvPI (Pharmacovigilance program of India) within 15 days and 30 calendar days respectively. Other: to be reported in PSUR	BPOM Regulation No. 15 Year 2022 regarding Pharmacovigilance Implementation Article 5, 6, 10. Reporting is mandated for AE/ADR observed in post-marketing products. 1. Spontaneous serious unexpected in Indonesia, no later than 15 calendar days. 2. Spontaneous non-serious unexpected in Indonesia, report every 6 months. 3. Spontaneous serious expected in Indonesia, no later than 15 calendar days. 4. Serious from Indonesia and international literature, no later than 15 calendar days. 5. Non serious unexpected from Indonesia and international literature, report every 6 months.	Reporting is mandated for ADR observed in the post-marketing products including PMS. Reporting period of Serious ADR is within 15 days (or 30 days for expected ADR).	Reporting is mandated for ADR observed in post-marketing products including PMS. SAE: within 15 days from reported day NSAE: within the first month after every quarter	Reporting is mandated for ADR observed for marketed products. PRHs are required to monitor and report any product safety issues that arise locally or internationally to the NPRA. The timeline for ADR reporting differs by reporter category. (Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders 1st Edition August 2021)	ADR reporting is mandatory. (FDA Circular No. 2020-003)	ADR requirements explained in GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS AND CELL, TISSUE AND GENE THERAPY PRODUCTS, Upon becoming aware of any serious AE, the company must report the event to the Vigilance and Compliance Branch as soon as possible and no later than 15 calendar days. The initial report of a serious AE should contain as much detail as available but should not be delayed for the sake of gathering more information. The clock for reporting starts as soon as any personnel in the company, including sales representatives, are made aware of the serious AE. If there is uncertainty about whether the serious AE is reportable, the company should still submit a report within 15 calendar days Ref: https://www.hsa.gov.sg/docs/default-source/hprg-vcb/guidance-document/guidance-for-industry_post-marketing-vigilance-requirements-for-therapeutic-products-and-ctgtp_v5_07-oct-2024.pdf?sfvrsn=48deb30c_4	Reporting is mandated for SADR observed in the post-marketing products. For medical care institutions and pharmacies: 1.Severe ADR cases cause death or life-threatening, the timeline of reporting and forwarding to license holders is 7 days. If the case information is not sufficiently provided, it shall be fully provided within 15 days. 2.other SADRs except of death and life-threatening, the timeline is 15 days For license holders, the report in accordance with regulations shall be submitted within 15 days once knowing the SADRs.	Thai FDA announcement on Stipulation of Certification of Registration Application Condition for Adverse Events Reporting of Medicines including Vaccines (dated 5 Feb 2016) 1. The Marketing Authorization Holder to follow up the drug safety and report adverse drug reaction and other drug related problems, including Adverse Events Following Immunization (AEFI) to the Thai FDA, strictly following the drug safety guidelines stipulated by the Thai FDA. 2. The Marketing Authorization Holder to report to the Thai FDA the information and decision condition of the Marketing Authorization Authority in case New Safety Issue is encountered.	The registrant shall periodically report on the surveillance and assessment of safety [and] effectiveness of the drugs it registered in accordance with the provision of Article 10 of Circular 12/2025/TT-BYT using Form 2A/TT (for new drugs, vaccines and biologics – except probiotics). In addition, Circular 12/2025/TT-BYT also mandates safety and efficacy reporting for all medicines upon the registants' request for renewal, using Form 2C/TT, which requires comprehensive details on usage and circulation of the drugs. Ad-hoc reports on all adverse events occurring in Vietnam related to drugs (adverse drug reactions, drug-related errors, suspected counterfeit drugs, drugs not meeting quality standards, and drugs lacking or failing to achieve treatment efficacy) following Form 2B/TT. The applicant shall submit reports within the time limit prescribed in the National Pharmacovigilance Guidelines issued by MOH.

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Renewal system of approved license	Variation guideline	For post-marketing changes to drugs, classified management shall be practiced depending on their risks to and the extent of their influence on the safety, efficacy and quality controllability of the drugs. Post-marketing changes are classified into changes subject to approval, notification and reporting. NMPA issued Provisions for Drug Post-approval Change (Trial Implementation) (No.8 2021) on Jan.13, 2021, Technical Guideline on Studies of Post-marketing CMC Changes to Chemical Drugs (For Trial Implementation) (No.15 2021) on Feb.10, follow by a series of supportive guidelines on variation. CDE issued the Management of Post-Approval Chemistry, Manufacturing, and Controls Changes for Chemical Drugs (Trial) (No. 46, 2025) https://www.cde.org.cn/main/news/viewInfoCommon/0889d723de12de0bb82f616ef34376e3	Special pathway ("1+ mechanism") apply to the change of indications, dosage and route of administration, effective on 29 Nov 2025. Please refer to the Guidance Notes on Change of Registered Particulars of a Registered Pharmaceutical Product/Substance, issued by the Drug Office, Department of Health of Hong Kong. https://www.ppbhk.org.hk/eng/doc/guidelines_forms/copGuide_en.pdf?v=pxy96f	CDSCO has released the Guidance For Industry (Biologicals) - Submission of Clinical Trial Application for Evaluating Safety and Efficacy (Doc. No. CT/032024 Version – 1.2); Requirements for Permission of New Drugs Approval (Doc. No. MA/032024 Version – 1.2); Preparation of the Quality Information for Drug Submission for New Drug Approval: Biotechnological/ Biological Products (Doc. No. QI/032024 Version – 1.2) Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy (Biologicals); Document No. - CT/032024 Version –1.2 Guidance-for-IndusrtBiologicals.pdf	BPOM Regulation No. 15 Year 2023: 1.Major Variation 2.Minor Variation 3.Minor Notification Do and Tell For Biological and Vaccine, follow WHO Guideline.	Yes Partial change application should be submitted for approval of changes. For minor changes, the notification system can be applied. Scope and handling of these changes are stipulated in the PMD Act and several notices.	Yes.(Regulation) "Equivalence Standards for Drugs"	Yes Malaysian Variation Guideline for Pharmaceutical Products, 2nd Edition (July 2022) Malaysian Variation Guideline for Biologics [MVGB_final_post_DCA_with_editorial_changes.pdf]	Requirements and process is similar to ASEAN Variation Guidelines, with additional country-specific changes and requirements. However, there are plans to establish Philippine-specific variation guidelines. (FDA Circular No. 2014-008, FDA Circular No. 2014-008-A, FDA Circular No. 2016-017)	Yes. Reference to GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE TPB-GN-005-012 ; Chapter F Post-Approval Process https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/guidance-on-therapeutic-product-registration-in-singapore.pdf?sfvrsn=cd174383_52 Reference to GUIDANCE ON CELL, TISSUE AND GENE THERAPY PRODUCTS REGISTRATION IN SINGAPORE GN-ATPB-001 - Chapter D Post-Approval Process https://www.hsa.gov.sg/docs/default-source/hprg-atpb/guidance-documents/guideline-on-cell-tissue-and-gene-therapy-products-registration-in-singapore.pdf	In Taiwan, not all information in Modules 3 is automatically treated as approval conditions requiring regulatory action. Regulatory action is required only for the items specified in the Variation Guideline and related regulatory provisions. •The Pharmaceutical Affairs Act and the Regulations for Registration of Medicinal Products provide the legal framework. •The Variation Guideline, updated with the amendment of the Regulations on September 28, 2021, and further clarified through the "Post-approval Changes in Oral Solid Dosage Form Drug Products" amendment announced on December 11, 2023, defines which changes in Module 3 require prior approval, notification, or can be handled without regulatory submission. •TFDA's approach is risk-based: only specific quality-related changes (e.g., manufacturing site, formulation, critical excipients, specifications, stability protocols) are considered approval conditions. Other routine updates in Module 3 that do not affect product quality, safety, or efficacy may not trigger regulatory action. •Since July 1, 2020, all post-approval variations must be submitted electronically via the Express e-submission system, ensuring consistency and traceability. In summary: Only the items listed in the Variation Guideline are treated as approval conditions requiring regulatory action. Module 3 as a whole is not automatically subject to approval requirements.	Yes As per ASEAN Variation Guideline (AVG) and non-AVG WHO guideline for vaccines EU guideline for biologics	The ASEAN Variation Guideline is adopted with few country-specific requirements.
	Post marketing clinical trial as approval requirement	Yes In the case of "conditional-approval", post-marketing clinical trials are usually required. For study for new indication, IND is required.	Not required.	It shall be based on the condition(s) mentioned in New Drug approval letter. Generally, all drugs approved for first time in India are requested to conduct post marketing surveillance/ a phase 4 trial (as recommended by the Subject Expert committee and DCGI)	No conditional approval in Indonesia. We need to submit completed report for NDA submission	Yes The Authority may request post- marketing clinical trials as an approval requirement if further assessment of efficacy and/or safety is deemed appropriate by the Authority. These requested trial plans are included as a part of the Risk Management Plan (RMP).	No requirement	No. Post marketing clinical trial is not a standard approval requirement currently. May be needed for Conditional Registration.	An RMP containing the Pharmacovigilance Plan shall be submitted by applicants, determining whether additional PV activities are necessary. (FDA Circular No. 2021-020, FDA Circular No. 2020-003)	Post-marketing clinical trial may be mandated by HSA as registration requirement, if HSA deem necessary.	No Post-marketing clinical trials are not a blanket approval requirement in Taiwan. They are required only when TFDA species them as part of the approval conditions, based on product risk, data gaps, or conditional approval circumstances.	Yes Active pharmacovigilance for early approval drugs for example clinical phase II registration. SMP is no longer implemented and replaced by RMP for safety monitoring throughout product life cycle.	No But Phase 4 can be requested by Advisory Council on issuance of marketing registration certificate for Drugs that have been licensed for marketing but still require further safety [and] efficacy assessment

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