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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
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)
Cat.	Category
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
ChP	Chinese Pharmacopoeia
ChPC	Chinese Pharmacopoeia Commission
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
CoA/COA/CA	Certificate Of Analysis
Co-I	Co-Investigator
CoPP	Certificate of Pharmaceutical Product
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
CTA	Clinical Trial Authorization
CTA	Clinical Trial Approval
CTC	Clinical Trial Certificate
CTGTP	Cell, Tissue and Gene Therapy Products
CTD	Common Technical Document

Abbreviation	Description
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
CV	Curriculum Vitae
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
EC-MOPH	Ethics Committee - Ministry of Public Health
eCTD	Electronic Common Technical Document
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
FP	Final Product
FRP	Facilitated Regulatory Pathway
FSC	Free Sale Certificate
G	Generic
GACP	Good Agricultural and Collection Practices
GCP	Good Clinical Practice
GDA	GMP Desktop Assessment
GDA	Generic Drug Application
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)
Hep C	Hepatitis C
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)
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
IP	Investigational Product
IPMG	International Pharmaceutical Manufacturers Group (Indonesia)
IRB	Institutional Review Board
IRPMA	International Research-Based Pharmaceutical Manufacturers (Taiwan)
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
LoA	Letter of Authorization
LoQ	List of Questions
LPLV	Last Patient Last Visit
LTO	License to Operate
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)
MiV	Minor variation
MOH or MoH	Ministry of Health (Malaysia) (Vietnam)
MoHFW	Ministry of Health and Family Welfare (India)
MOPH	Ministry of Public Health (Thailand)
MOST	Ministry of Science and technology (China)
MRCT	Multi-Regional Clinical Trials
MREC	Medical Research & Ethics Committee (Malaysia)
MTA	Material Transfer Agreement

Abbreviation	Description
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
NeeS	Non-eCTD Electronic Submission (Thailand)
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
NUHS	National University Health System (Singapore)
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)
PhAMA	Pharmaceutical Association of Malaysia
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PhIRDA	China Pharmaceutical Innovation and Research Development Association
PhP	Philippine Peso
PHREB	Philippine Health Research Ethics Board
PI	Package Insert
PI	Principal Investigator
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
PReMA	Pharmaceutical Research and Manufacturers Association (Thailand)
PRH	Product Registration Holders (Malaysia)
PRISM	Pharmaceutical Regulatory Information System (Singapore)
PSAR	Pandemic Special Access Route (Singapore)
PSM	Pre-submission Meeting (Malaysia)

Abbreviation	Description
PSUR	Periodic Safety Update Report
PV	Process Validation
PvPI	Pharmacovigilance Program of India
QC	Quality Control
QOS	Quality Overall Summary
QP	Qualified Person
QR	Quick Response
R&D	Research and Development
RC	Registration Certificate
r-DNA	recombinant DNA
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
SMF	Site Master File
SMP	Safety Monitoring Program (Thailand)
SMPC/SmPC	Summary Product Characteristics
sNDA	supplemental New Drug Application
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authorities
SSR	Site Summary Report
SUSAR	Suspected Unexpected Serious Adverse Reaction
TCTC	Taiwan Clinical Trial Consortium
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration (Australia)
Thai-FDA	Thailand Food and Drug Administration
THB	Thai Baht
TP	Therapeutic Products
TPI	Taiwan Package Insert
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 2025

China	RDPAC/PhIRDA	Drug Review and Approval, Registration Related Regulation NMPA Notice on Implementing Electronic Application of Drug Registration（No.110 in 2022） https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20221130190751164.html CDE Notice on Requirements of Electronic Application of Drug Registration Applications https://www.cde.org.cn/main/news/viewInfoCommon/4b75cceb52914fbfe55f5214d93b804b CDE Notice on Working Specification of the CDE for Accelerating the Evaluation of NDA of Innovative Medicines（Interim） https://www.cde.org.cn/main/news/viewInfoCommon/ace377c025ad4f2bbf94790673b2646e CDE Notice on Guidelines on Acceptance and Review of Chemical Active Pharmaceutical Ingredients（Trial）（No.38 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/46bc16e98abddf4095de30e659fc4385 NMPA Notice on the Renewal Management of Chemical APIs and Other Related Matters（No.129 in 2023） https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20231013120255151.html Notice on Updating the Technical 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Development of New Drugs for Ovarian Cancer（Trial Version）（No.21 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/8bbb9c0d7eabbcb4e824525b2bc5c778 CDE Notice on Technical Guidelines on Clinical Research and Development of Antitumor Antibody-Drug Conjugates（No.25 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/24952a6fc17093a08aa81070a648c8c5 CDE Notice on Technical Guidelines for Registration of Drugs Based on Animal Rule（Trial）（No.26 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/7a5c1daf996a5b9f103426df70d2be7f CDE Notice on Technical Guideline for Clinical Trials of Drugs for Respiratory Syncytial Virus Infection（No.28 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/7836390b975d8b53d59eaf9b9e78bd41 CDE Notice on Technical Guidelines for Clinical Trial Design of Gene Therapy for Hemophilia（No.29 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/a0470fe8e6a9c38fb71e0b125d5f0762 CDE Notice on Technical Guideline on Clinical Trials of Active 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Guideline on the Quality Risk Management of the Co-line Production of Different Medicinal Products https://www.cfdi.org.cn/resource/news/15186.html On-Site Inspection Guidance of Preparations for Inhalation https://www.cfdi.org.cn/resource/news/15190.html NMPA Notice on Provision on MAH Implementation the Supervision and Management of Drug Quality Safety Subject Responsibility（No.126 in 2022） https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20221229195805180.html NMPA Notice on Amendment clauses of Administrative Measures for Drug Inspection（Trial Implementation） https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20230721091201181.html CDE Notice on Technical Guidelines for Quality Control Studies of Liposomal Drugs and Technical Guidelines for Non-clinical Pharmacokinetic Studies of Liposomal Drugs（No.54 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/e0ebfc0e2363f4cf4293c2acde947360 NMPA Notice on Strengthening the Supervision and Management of Contract Manufacturing by Marketing Authorization Holders（No.132 in 2023） https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20231023160426145.html NMPA Notice on Guidelines for On-site Inspection of Contract Manufacturing of Drug Marketing Authorization Holders https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20231024161543188.html Drug Distribution and Use Quality Regulation https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/fgs/art/2023/art_db526cfcd7204874b8b23297fa3b02dc.html NMPA Notice on Measures for Administration for Good Laboratory Practice of Non-Clinical Studies of Drugs（No.15 in 2023） https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20230119160441145.html Human Generic Sources（HGR） Decree No. 21 of the Ministry of Science and Technology Rules for the Implementation of Regulations on Management of Human Genetic Resources https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/bmgz/202306/t20230601_186416.html Annual Report 2022 Annual Drug Evaluation Report https://www.cde.org.cn/main/news/viewInfoCommon/849b5a642142fc00738aff200077db11 Annual Report on the Progress of Clinical Trials for New Drug Registration in China（2022） https://www.cde.org.cn/main/news/viewInfoCommon/46260e34bfe67292bfae1de8863d20fe CFDI Annual Drug Inspection Report of 2022 https://www.cfdi.org.cn/resource/news/15638.html ICH Q13 CDE Notice on Technical Guidelines for Continuous Manufacturing for Oral Solid Dosage Form of Chemical Drugs（Trial）（No.19 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/fcd2eeca1882b5782411bf00fe21e123 Policies for Drug Package Insert CDE Notice on Guidelines for Writing Pharmaceutical Information in Package Inserts and Labels of Chemical Drugs（Interim）（No.20 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/defca6a1f3ba33d0bad6f309e5a0b816 NMPA Notice on Work Plan for the Pilot Reform of Age-appropriate and Barrier-free Package Inserts（No.142 in 2023） https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20231031153424162.html CDE Notice on Guidelines for the Preparation of Package Inserts（Simplified Version）and Package Inserts（Large-character Version）and Format Requirements for Electronic Package Inserts（Complete Version）（No.56 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/fbe67f9737e40e062cf5770727d81d71 NMPA Notice on Working Procedure for Adding Pediatric Use Information into Package Inserts of Marketed Products（Interim）（No.68 in 2023） https://www.nmpa.gov.cn/yaopin/ypggtg/2023053142548157.html Other Important Regulations CDE Notice on Common Pharmaceutical Issues and Relevant Technical Requirements in the Pre-Phase III Meeting of Innovative Chemical Drugs（Trial）（No.23 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/28a6683aa4cf9401b806ccdf8b8a4afc NMPA Notice on Implementation of the Provisions for GLP Certification（No.81 in 2023） https://www.nmpa.gov.cn/yaopin/ypggtg/20230621092337177.html NMPA Notice on Measures for Administration of the Drug Standards（No.86 in 2023） https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20230705191500136.html CDE Notice on Working Standards for the Submission and Review of Drug Clinical Trial Protocols（No.51 in 2023） https://www.cde.org.cn/main/news/viewInfoCommon/6edaf1a68f4565b60e9f540a26adb15d NMPA Notice on Issuing the "Supervision and Inspection Measures for Drug Clinical Trial Institutions（Trial）"（No.56 in 2023） https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20231103175749117.html CFDI Notice on Key Points and Judgment Principles of the Supervision and Inspection of the Drug Clinical Trial Institutions（Trial Implementation）（No.9 in 2023） https://www.cfdi.org.cn/resource/news/15690.html

Indonesia	IPMG	▪ BPOM issued some new regulations, such as BPOM Regulation No. 15 Year 2023 regarding Fourth Amendment to BPOM Regulation No. 24 Year 2017 (enacted on Jul 21, 2023), Head of BPOM Regulation No. 456 Year 2023 concerning the List of Medicines and Food whose Importation is Restricted into Indonesian Territory (enacted on Nov 3, 2023), BPOM Regulation No. 28 Year 2023 concerning Amendments to BPOM Regulation No. 27 Year 2022 concerning Control of Importation of Drugs and Food into Indonesian Territory (enacted on Nov 3, 2023), BPOM Regulation No. 26 Year 2023 concerning Supervision of the Use of Drugs and Vaccines for Corona Virus Disease 2019 (COVID-19) After the End of Handling the Corona Virus Disease 2019 (COVID-19) Pandemic in Indonesian Territory (enacted on Oct 6, 2023), BPOM Regulation No. 24 Year 2023 concerning Safety and Quality Requirements for Health Supplements (enacted on Sep 18, 2023), Head of BPOM Regulation No. 284 Year 2023 concerning Phases of Implementation of Drug Management Reporting using 2D Barcode Authentication Methods by Distribution Facilities and Pharmaceutical Service Facilities (enacted on Aug 7, 2023), BPOM Regulation No. 14 Year 2023 concerning Amendments to BPOM Regulation No. 2 Year 2022 concerning Reporting on Activities of the Pharmaceutical Industry and Pharmaceutical Wholesalers (enacted on Jul 20, 2023), Circular Letter of the Head of BPOM No. 5 Year 2023 concerning Qualifications of Medicinal Ingredient Suppliers (enacted on May 29, 2023), Head of BPOM Regulation No. 148 Year 2023 concerning Guidelines for Good Drug Regulatory Guideline (enacted on May 11, 2023), BPOM Regulation No. 1 Year 2023 concerning Certification Guidelines for Vaccine Batch/Lot Release (enacted on Jan 10, 2023).Guidelines for Assessing the Safety and/or Quality of Medicines and Medicinal Substances against Nitrosamine Contamination (enacted on Jan 10, 2023), ▪ Ministry of Health issued some regulations, such as Decree of ministry of health HK.01.07/menkes/1903/2023 about application of Indonesian pharmacopoeia sixth edition and supplement I of IDP sixth edition (enacted on Oct, 2023). Ministry of Health issued some regulations, such as Decree of ministry of health HK.01.07/menkes/1904/2023 about supplement II of IDP sixth edition (enacted on Oct, 2023). ▪ President of the Republic of Indonesia issued Law Number 17 of 2023 concerning Health (enacted on Aug 8, 2023). ▪ Several draft regulations also being discussed, such as Draft BPOM Regulation concerning Amendments to BPOM Regulation No. 34 Year 2018 concerning Guidelines for Good Manufacturing Practice.
Japan	JPMA	Based on the results of the MHLW's drug regulatory review meeting held in 2023 to eliminate drug lag and drug loss, a basic concept of Japanese data for rare disease drugs when overseas data is available, and a notification of partial revision of the conditional approval system, were issued.
Korea	KPBMA/KRPIA	According to the amendment of the Pharmaceutical Affairs Act, starting from February 2025, the integrated RMP will be implemented replacing the Re-Evaluation system.
Malaysia	PhAMA	**Developments in the regulatory landscape in Malaysia for 2024** include the following: **Publication of assessment reports for additional indication(s):** In addition to publishing the Technical Evaluation Summary Report (TESR) for new products applications for New Drug Entities (NCEs) and Biologics, the NPRA also published the TESR for additional indication applications from June 2024.The added initiative to publish the additional indication applications reports are in line with the WHO Global Benchmarking Tool (GBT) indicators as well as to enhance transparency. **CPP Requirements**: an update of the DRGD's Appendix 29 'Certificate' was published in the July 2024 DRGD revision to allow flexibilities for situations where the CPP is not available. The revisions included additional sections for 'Alternative documents in lieu of CPP to support registration applications for imported products', and 'submission of a CPP for product not registered in any other country' (which opens up the possibility for wave 1 products to be considered). https://www.npra.gov.my/index.php/en/drug-registration-guidance-documents-drgd-e-book.html **Priority Review:** Amendments on Priority Review (Appendix 12) in the July 2024 DRGD revision included a lowering of the minimum requirement of 10% of subjects in Malaysian clinical studies to a minimum of 5% in this eligibility condition for Priorirty Review, however these should be global, multicentre trials, i.e. Priority review may be granted for new product application (in the category of New Drug Products, Biologics and Generics) which fulfils the listed conditions: 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) **Reliance Pilot for New/Additional Indications:** NPRA rolled out a pilot study on Reliance for New/Additional Indications from 01 August 2024 for a one-year period. The Pilot applies to both Full Evaluation and Verification pathways. https://npra.gov.my/index.php/en/component/content/article/453-english/announcement-main/announcement-2024/1527643-announcement-to-product-registration-holders-prhs-revision-of-categories-and-criteria-for-new-additional-indication-application-a-pilot-study.html?Itemid=1391 **Pilot Project for Post-Approval Changes (Variation) Using Reliance**: NPRA initiated a Pilot on PAC Reliance to assess the effectiveness of utilizing reliance approach for post-approval changes, aiming to reduce timelines and improve efficiency. After the pilot program ends on 1 June 2025, NPRA will conduct a review for its inclusion in the DRGD. https://www.npra.gov.my/index.php/en/component/content/article/225-english/1527676-announcement-to-product-registration-holders-prhs-pilot-project-for-post-approval-changes-variation-using-reliance.html?Itemid=1391 **QUEST 5 Development:** NPRA is developing an improved online submission platform to replace QUEST 3+ in line with current policy and technology changes, and has noted industry's needs including parallel submissions for Additional Indications and Variations (Post-approval Changes), and also for multi-site registrations on a single licence. NPRA is looking into incorporating these in their current Quest 5 development. For now, the regulatory process implemented at NPRA is not 100% end-to-end where there is 30% still implemented manually. QUEST 5 will be developed using cloud computing technology that aims to implement 100% end-to-end work processes. This project will be implemented with 2 releases where release 1 is expected to go live in early 2027 and release 2 in early 2028. **Site-Specific Stability (SSS) Data Requirements:** Following several engagements with industry, SSS Requirements will be revised by NPRA and the DRGD will be updated for Appendix 3 (New Drug Products), Appendix 4 (Biologics), Appendix 5 (Generics), and Appendix 11 (API). This is expected to be published in the DRGD Jan 2025 revision. **Track & Trace Implementation plans**: The MOH has shared that they are targeting to conduct a pilot project from 2025 to 2028. The PTTS (Pharmaceutical Track & Trace System) implementation timelines are currently expected after 2028. **Patent Linkage**: Following Malaysia's ratification into the CPTPP on 30th September 2022 and its entry into force on 29th November 2022, the National Pharmaceutical Regulatory Agency (NPRA) has embarked on implementing Article 18.53, which mandates patent linkage within 4.5 years until May 2027. NPRA is diligently exploring optimal mechanisms that balance the interests of innovators and generic manufacturers without undue burden. Concurrently, efforts are underway to establish a legal framework for patent linkage. NPRA has actively engaged with innovators and local generic manufacturers to solicit insights and ideas from them. This proactive approach underscores NPRA's commitment to fostering collaboration and ensuring a smooth implementation process. NPRA introduced **reliance toolkits** such as FRP reliance checklist and FAQ to enhance effectiveness of reliance implementation in Malaysia. The FRP Reliance Checklist was issued on 19 Feb 2024: Direktif Berkenaan Pengemaskinian dan Pelaksanaan Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023 The FRP Reliance FAQ was posted on 25 June 2024): https://www.npra.gov.my/easyarticles/images/users/1051/FAQs-for-FRP_NPRA25062024.pdf NPRA issued a directive to amend Appendix 19 of DRGD specifically to Animal Source Declaration Labelling requirement on 13 August 2024 : https://www.npra.gov.my/index.php/en/directive-general/1527645-pengemaskinian-drug-registration-guidance-document-drgd-berkaitan-keperluan-deklarasi-bahan-bersumberkan-haiwan-pada-label-produk.html. Following PhAMA-NPRA Dialogue and industry advocacy, NPRA issued an FAQ that clarified certain exemption provisions on 13 Dec 2024: https://www.npra.gov.my/index.php/en/component/content/article/225-english/1527682-frequently-asked-questions-faqs-appendix-19-general-labelling-requirement-for-products-containing-animal-derived-materials.html?Itemid=1391
Philippines	PHAP	The Philippine FDA released 3 new policies that aim to reform the drug regulatory framework. These new guidelines-the licensing of drug establishments, registration of drug products, and schedule of fees and charges-were released in Q4 2024. While the licensing and new schedule of fees are already implemented, the drug registration guidelines are awaiting implementing circulars to be fully implemented. We are yet to see the impact of these new policies, which aim to incorporate many international best practices-including multiple sites in a single MA, do and tell, elabeling, among others.

Singapore | SAPI

1. Guidance Therapeutic Products Guidance updates with effect from 1 Aug 2024
i. New tool for estimating key evaluation milestones for NDA, GDA and MAV-1 full and abridged applications
To improve transparency and predictability in regulatory processes, industry can expect to receive the first evaluation Input Request (IR) for NDA, GDA and MAV-1 product applications at the following timepoints:

Type of Applications	Evaluation Route	No. of working days
NDA / MAV-1	Full	160
NDA/ MAV-1	Abridged	120
GDA	Abridged	150

Note: excluding any stop-clock time between acceptance and issuance of first evaluation Input Request.
Industry can also use the webtool to estimate the key application milestone timelines for NDA, GDA and MAV-1 applications.
ii. New cloud-based platform for submission of application dossier and DMF "EasiShare"
Companies now have a new option of submitting their dossiers via a cloud-based file exchange software (EasiShare) in addition to the existing submission modes via electronic media (CDs/DVDs) or PRISM.
iii. Guidelines on post-approval changes that do not require notification to HSA
A list of post-approval changes which do not require notification to HSA has been published in Section 4 of Appendix 13_Guideline on MIV Applications for Chemical Therapeutic Products and Appendix 14_Guideline on MIV Applications for Biological Therapeutic Products to provide transparency on such changes. Some changes previously categorized as MIV-2 Do-and-Tell (D&T) now fall under this category. For example, notification of product labelling changes related to machine readable codes (e.g. QR code) for e-labelling is no longer required.
Other changes to the current variation checklists include deletion of checklist for renewal of CEP due to CEP 2.0 implementation in September 2023, consolidation of product labelling D&T changes related to product registrant, as well as editorial updates.
iv. Implementation of the Health Products (Therapeutic Products) (Amendment) Regulations 2024
Following the public consultation on the proposed amendments to regulation 23 of the Health Products (Therapeutic Products) Regulations 2016 ["TPR"] for the implementation of restraining patents held from 1 March to 12 April 2024, HSA has published a summary of responses to the feedback received on HSA website, including information detailing the scope of patents and the patent declaration process under the revised regulation 23 to provide the necessary clarity.
The Health Products (Therapeutic Products) (Amendment) Regulations 2024 has been published on the Government Gazette and will come into effect on 1 August 2024. Accordingly, the patent declaration forms specified under regulations 23(2) and 23(5) of the TPR, and regulation 23(8)(b)(iii) of the Amendment Regulations have been updated and published on the HSA website, and should be used with effect from 1 August 2024.
v. Introduction of Swissmedic as HSA's reference agency
Swissmedic will be added as one of HSA's reference agencies, along with EMA, FDA, Health Canada, MHRA and TGA.
The guidance documents have been updated accordingly with above information.
vi. Revision of Appendix 7: Points to consider for Singapore Labelling of the Guidance on Therapeutic Product Registration in Singapore
Appendix is updated to include the following change which will take effect from 28 Mar 24
i) Removal of mandatory requirement for manufacturing date to be reflected on the outer carton/inner label.
ii) Flexibility for either the manufacturer, product owner or registrant's name and address to be included on the outer carton/ inner label.
iii) Removal of mandatory requirement for precautionary statement on interchangeability of biosimilar products in the PI.
iv) Minor editorial updates.
2. Status update on implementation of GMP requirements for chemical DS manufacturers with effect from 1 Oct 2024
The requirement for Evidence of Good Manufacturing Practice (GMP) Compliance for manufacturers of chemical drug substance (DS) will be fully implemented on **1 October 2024.** This follows a one-year transition period which commenced in September 2023 for companies to comply with the requirement. Accordingly, NDAs, GDAs, and MIV-1 applications (for addition of new chemical DS manufacturers) submitted on or after 1 October 2024 must be accompanied by the required GMP Compliance Evidence for DS manufacturers.
3. Other updates for Therapeutic Products
i) Status update on eCTD implementation
eCTD (electronic common technical document) is the standard structured format for the electronic transfer of regulatory information related to therapeutic products from industry to health authorities. eCTD submissions minimize the need for using storage media such as CD/DVD ROMs for dossier submissions. It also allows better product life cycle management for both industry and HSA.
HSA will adopt a phased approach for eCTD implementation for therapeutic product submissions based on ICH eCTD specification 3.2.2.
HSA has released **the SG-HSA eCTD specification package (v 1.0) on 25 Sept 2024.** This is an updated version of the eCTD package v 0.9 incorporating changes based on feedback received during the industry consultation exercise held in May-June 2023.

ii) Streamlining of RMP requirements for biosimilar applications
As of April 2024, the submission of RMP documents, including the Singapore-Specific Annex (SSA), is no longer mandatory for biosimilar (NDA-2) applications, unless requested by HSA. The submission of RMP documents is still required for NDA-1 applications.
Applicants are also reminded to use the updated SSA form as part of the RMP documentary requirements for NDA-1 applications. Appendices 16/16A of the Guidance on Therapeutic Product Registration are no longer applicable.

4. Online Self-help Cell, Tissue and Gene Therapy Product (CTGTP) Classification tool
HSA has launched a new CTGTP Classification Tool on the HSA website in March 2024. This self-help tool assists stakeholders in determining if their product is a Class 1 or 2 CTGTP or a non-CTGTP.

5. Launch of Singapore Health Product Access and Regulatory E-system (SHARE)
In January 2024, HSA has launched the Singapore Health Product Access and Regulatory E-System (SHARE), a one-stop digital portal for Cell, Tissue and Gene Therapy Products (CTGTP) Dealer's Notice and Class 1 CTGTP Notification. This new portal is part of HSA ongoing efforts to streamline regulatory processes to achieve efficient transactions and enable closer collaboration among regulators, businesses, industry partners and the public, facilitating access to safe health products in Singapore. With the introduction of SHARE, applicants can now submit, check and update new dealer's notices and product notifications all in one system, resulting in enhanced process efficiency, regulation and compliance. SHARE will be progressively rolled out to other product types and eventually replace the Pharmaceutical Regulatory Information System (PRISM). SHARE is rolled out to Class 2 CTGTP Registration in October 2024.
6.Launch of pilot programme to extend electronic labelling to pharmacy only (P) and General Sale List (GSL) therapeutic products (TP)
E-labelling is currently implemented for prescription only medicines (POM) in Singapore. Based on positive feedback received from the industry, HSA is initiating a pilot programme to assess the feasibility of extending e-labelling to non-prescription TPs (P or GSL). As part of a calibrated approach in consultation with industry stakeholders, HSA will launch a pilot exercise with effect from 1 April 2024. Companies are encouraged to participate in the pilot for products that satisfy the eligibility criteria.
7.Project Orbis Webpage on HSA website
Project Orbis is an initiative of the US Food and Drug Administration (FDA) Oncology Center of Excellence. It provides a framework for the collaborative review of oncology products among international regulatory partners. Online resources on Project Orbis are now available on HSA website.
8. Clarification on criteria for expedited review of pending MIV applications
To streamline the review process and minimize indiscriminate requests, HSA has introduced an online request form to guide applicants on the eligibility criteria for expedited review of pending MIV applications.
To make an expedited review request, the request must meet one of the following criteria:
i) There is no equivalent or alternative therapeutic option to the product in the Singapore market.
ii) The product is urgently required for supply under the National Procurement by ALPS.
iii) The requested change is mandatory and forms a crucial part of the National Procurement by ALPS.
Any expedited review requests should be accompanied by appropriate justifications, including the reasons for any delays in making the MIV submission. Outcome will be provided within 5 working days.
9. HSA and Korea MFDS signed Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) for Medicinal Products on 26 Feb 2024
The MRA will enable the mutual recognition of GMP certificates and inspection outcomes of medicine manufacturers in Singapore and South Korea.
10. New Risk Management Plan (RMP) Webpage on HSA website from 01 Apr 2024
The new webpage has been developed with the aim of providing industry stakeholders with a one-stop portal containing information on RMP requirements for TPs and CTGTPs during product registration and post-registration. The information on the webpage has been incorporated into the RMP requirements under Sections 6 to 8 of the Guidance for Industry on Post-marketing Vigilance Requirements for Therapeutic Products and Cell, Tissue and Gene Therapy Products.
11. Formalisation of HSA Innovation Office in November 2024
The HSA Innovation Office, which was initiated as a pilot programme since 2018, has now been formally established. HSA has published a new guidance on the 'Submission of Innovation Office Requests', along with related forms designed to streamline interactions with HSA.

Taiwan	IRPMA	No major updates are provided. However, there are some updates on the pages: 6, 7, 8, 9, 12, 13, 14, 14, 16, 20, 21, 22, 23, 25, 26, 28, 30, 31, 33, 34, 35, 36, 37, 38, 40, and 41 which are highlighted in yellow for your convenience.
Thailand	PReMA	The Thai FDA is continuously advancing digital transformation and regulatory reforms with several key developments below. E-Submission is implemented for all submissions. • **Risk Management Plan (RMP)**: 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). • **Biosimilar:** The well-characterized Biosimilar requirements are aligned with the Replacement of Annex 2 of WHO Technical Report Series, No. 977. Notification of Biosimilar Guideline B.E. 2567 dated 7 Aug 2024.(cited 2025 FEB 3 media.php) • **GMP Clearance Renewal**: The extension of GMP Certificate validity can be processed through variation pathway whilst waiting for the new GMP certificate for renewal submission. Notification of Criteria, Method, and Condition for Requesting, Issuing and Renewing GMP Clearance Letter for Oversea Manufacturers – 3rd edition, dated 6 Aug 2024.(cited 2025 FEB 3 media.php) • **Patient Information Leaflet (PIL) User Testing**: Two specific drug categories i.e. household remedies and non-dangerous & non-specially controlled drugs are required for PIL User Testing. Guideline for e-submission registration (2nd edition), dated 16 Aug 2024.. (cited 2025 FEB 3 media.php) • **Low-risk drugs**: The ingredient-based evaluation was introduced for low-risk drugs, instead of product-based evaluation. Guideline for Low-risk drugs registration, dated 17 Oct 2024. (cited 2025 FEB 3 media.php) • **ATMPs**: The conditional approval was introduced to facilitate registration. Guideline for Conditional Approval of ATMPs, dated 24 Oct 2024. (cited 2025 FEB 3 media.php) • **E-tracking system**: Launched on 2 Jan 2025 for real-time tracking of application status and predicting approval timelines. (cited 2025 FEB 3 www.fda.moph.go.th.docx) • **GDP inspection**: In 2025, for importers, there are two approaches, i.e. Desktop inspection and On-site inspection, both based on the risk level of the site. (cited 2025 FEB 3 media.php). Clinical Trial Authorization: e-submission is implemented for all applications. More flexible GMP requirements. 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) Overall Thai FDA is enhancing its potential and opportunities for business growth by promoting economic health products for sustainable development and increasing effectiveness, positioning itself to be recognized globally. (cited 2025 FEB 3 https://www.fda.moph.go.th/news/2102567)
Vietnam	PG	2024 saw significant changes to the legislative framework governing the pharmaceutical sector in Vietnam, notably the Law amending, supplementing several articles of the Pharmaceutical Law 2016 (revised Pharma Law). Overall, the revision is positive and is expected to address critical shortcomings of the current Law, at the same time introducing some good practices being implemented in other countries. From the view points of the innovative industry, key improvements include: the introduction of Regulatory Reliance aiming to shorten the timeline for registration of medicines approved by stringent regulatory authorities, Recognition mechanism, simplification of Marketing Authorization Renewal procedure to avoid supply disruption, incentives for sector development activities including local manufacturing and clinical trials, reduction of administrative procedures such as removed the requirement for drug information approval, companies' responsibility for authenticity and legality of documents provided to authorities. Currently, the Vietnamese government is speeding up the preparation for guidance regulations, which includes the overhaul of the Decree guiding the implementation of the Pharma Law and the Registration Circular.

Item	Contents	China RDPAC/PhIRDA	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KPBMA/KRPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA	Vietnam PG
IND/CTA	Requirements to be the IND/CTA applicant	Sponsor (Companies) or regulatory agency(CRO) or institute.	CRO or doctors who can follow standards of GCP.	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-8th-Ed-Final.pdf (#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 clinical trial. (Administrative Order No. 2020-0017)	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 sponsor's delegation in Taiwan. CRO can be an applicant if the company also has been registered as a pharmaceutical company in Taiwan.	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	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).	No	Yes, the New Drugs and Clinical Trials Rules, 2019 (NDCT Rules) 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, 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-IND/CTA consultations are offered by IND/CTA applicants throughout medical product development phases of chemical and biological products. The primary review opinions will be returned or face-to-face meeting instead of the review opinion can be will be held within 20 days after pre-IND consultation requests. The IND/CTA applicants can also request the face-to-face meeting. The final review opinions will be returned within 30 working days after application by MFDS if there isn't any argument.	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	Clinical Trial Authorization official timeline (Initial) Study category A (low risk): Full Assessment Review: 15 WD Study Category B (medium risk): Full Assessment Review: 25 WD; Reliance - Assessment Report from SRA: 15 WD; Complicated application (FIH, NCE, NBE, ATMP): 40 WD Study Category C (high risk): Full Assessment Review: 40 WD; Reliance - Assessment Report from SRA: 25 WD; Complicated application (FIH, NCE, NBE, ATMP): 70 WD Note: Plus 10 WD for IND internal process (cited 2025 FEB 3 media.php) Clinical Trial Authorization official timeline (Amendment) General application: 25 WD Complicate application (FIH, NCE, NBE, ATMP): 44 WD Note: Plus 6 WD for IND internal process (cited 2025 FEB 3 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.	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.	Parallel submission to Department of Health 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/Ind ependent 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.	Refer to BPOM regulation No. 8 Year 2024 about Procedure of Clinical Trial Approval	A clinical trial is conducted base 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-8th-Ed-Final.pdf [§ 5.1 and S5.2]. Note: The process flow also includes First-In-Human Clinical Trials (S5.2).	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.	Drug manufacturing/import license holder or government (applicant can be sponsor or CRO)	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 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	120 calendar days.	CT- of a ND or IND review- 90 days (as per New Drugs & Clinical Trial Rules, 2019) CT of a ND or IND as part of discovery, research ad manufacture in India – 30 days or else seemed approval. (as per New Drugs & Clinical Trial Rules, 2019) EC review – 14 to 60 days (depending on the Institutional EC meetings timelines, industry experience)	Timeline for evaluation is 20 working days for protocol & amendment of clinical trial after NADFC stated the protocol & amendment complete	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, clinical trials involving biological/biotechnological products, CGTPs as well as herbal products with therapeutic claim. For FIH clinical trials, this timeline includes the review time taken by external Panel of Expert(s). 30 working days: For Products other than mentioned above **Fast Track: 22 working days for clinical trials involving biological/biotechnological products, CGTP products, and herbal products with therapeutic claim.14 working days: For Products other than mentioned above. Malaysian-Guideline-for-Application-of-CTIL-and-CTX-8th-Ed-Final.pdf [§ 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/ 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. Phase I expansion cohort is available to apply for accelerated approval process. Link to IND Review Time and Process	Yes Can consult at FDA (Such as direct contact, telephone, official letter)	**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)	Application form for Certificate for Clinical Trial.	Yes, Application form is in English language and is called Form CT-04	Yes There is a checklist requirement Refer to BPOM regulation No.8 Year 2024 about Procedure of Clinical Trial Approval, annex I	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 The official format of application is in Chinese. The applicant can write in English.	Yes Local form (in Thai) Form is changed from NorYorMor1 to Sor Yor1	Yes, in Vietnamese or in English (Article 6, Circular 08/2022/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.	Yes Cover letter (have template in Thai)	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 requested.	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 ICF should be in Chinese and there is a template for CIRB. TFDA announced on 3-Nov-2018 that TFDA authorizes 35 IRBs for ICF amendment review and approval of drug clinical trial from 2018/11/6 to 2020/12/31.A new list of TFDA authorized IRB is released on 14 Nov, 2024. There are 41 IRBs and the period is from 01 Jan 2025 to 31 Dec. 2028. Thus, the ICF amendment is no need to submit TFDA for approval for these 41 IRBs. (https://www.fda.gov.tw/TC/newsContent.aspx?cid=3&id=30810)	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 PI and Co-I, either the Chinese or English version is acceptable. TFDA regulated necessary training hours needed for GCP and ethical then qualified to conduct clinical trial.	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	No	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 required documents is provided from "nedrug web 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 Biologicals or Certification of analysis in the case of a batch of vaccines and biologicals); - 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

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IND/CTA application materials	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 No separate document is required. Referred to IB.	No including in IB	No Not applicable (often included in IB) If provided, Vietnamese/English
	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 No separate document is required. Referred to 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 No separate document is required. Referred to IB.	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 data, or conduct clinical trial in other countries or the products has been marketed, the applicant should provide the whole clinical trial data, 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	Yes Either Chinese or English version are acceptable.	No including in IB	No NA. it is often included in IB

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IND/CTA application materials	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. appendix-8-chemistry-manufacturing-and-controls-requirements-for-cell-tissue-or-gene-therapy-product-for-clinical-trials-and-product-registration.pdf (hsa.gov.sg)	No However, CMC data is required either in English or Chinese.	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	Yes CMC data is required either in English or Chinese.	Yes See detail in guideline (for NCE)	Same as CMC summary
	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	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	GMP certificate of the investigational drug is NOT mandatory.	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
IND/CTA application materials	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 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 Sample NOT required.	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.	Required The applicant should honestly and completely fill out the application form, including the company name, code, address, telephone number, drug company license number, the person in charge of the business, the pharmacist in charge of the management or manufacturing, and the pharmacist's address, and license number.	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, (Administrative Order No. 2013-0021, FDA Circular No. 2020-026)	ACTD or ICH-CTD	All new drug applications including generic application should be submitted in ICH CTD format after 1-July-2014.	Effective from 15 Feb 2023, all applications must be in eCTD or NeeS format.	ACTD and ICH-CTD format

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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) - New Drugs and Clinical Trial 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 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 Decree 54/2017 and Decree 155/2018, Circular 08/2022/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. Biologicals (Biological Reference 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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NDA	Requirement of CPP	Yes For new Cat. 1 and 2 import chemical drug and innovative therapeutic biological product (not marketed in China and overseas), CPP is not requested in the whole process of NDA, but CPP is needed to supplemented during review when oversea approved. For new Cat.5.1 (chemical drugs) and 3.1 (biologicals), CPP should be submitted at the submission of CTA and NDA. Both CPP granted by manufacturing country or marketing country are acceptable. 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 120 WD (reliance) and 300 WD. For Path 120 WD (reliance), BPOM refer to reference countries : EU, US, Australia, Canada, UK& Japan. 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	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 08/2022/TT-BYT) 4. 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 must bear the signature, name of the signer, issue date and the seal of the CPP issuing authority; If the CPP does not bear the certifying seal of issuing country's competent authority, the registrant shall provide supporting documents proving that as a rule in the issuing country a seal is not required on CPP. d) With regard to **imported new pharmaceuticals, vaccines, biologics, other than probiotics:** A CPP issued by the manufacturing country's competent authority certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. If the CPP-issuing competent authority of the manufacturing country is among the authorities on the list stipulated in clause 9 Article 2 of this Circular, submission of just 01 CPP shall suffice. If the CPP-issuing competent authority of the manufacturing country is not on the list stipulated in clause 9 Article 2 of this Circular, additional official papers issued by a regulatory authority of the countries on the list stipulated in clause 9 Article 2 of this Circular certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. The official paper should cover at a minimum the following information: drug name, drug substance, strength or concentration of drug substance, dosage form, name and address of manufacturer or supporting documents proving that that the drug is of the WHO list of prequalified medicines. đ) With regard to drugs that are the subject of application for **brand name drug, or reference biologic designation:** A (01) CPP issued by the manufacturing country's competent authority certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. If the CPP-issuing competent authority of the manufacturing country is among the authorities on the list stipulated in clause 9 Article 2 of this Circular, submission of just 01 CPP shall suffice. If the CPP-issuing competent authority of the manufacturing country is not on the list stipulated in clause 9 Article 2 of this Circular, additional official papers issued by a regulatory authority of the countries on the list stipulated in clause 9 Article 2 of this Circular certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. The official paper should cover at a minimum the following information: drug name, drug substance, strength or concentration of drug substance, dosage form, name and address of manufacturer. e) With regard to **imported drugs, vaccines, biologics for which a CPP meeting the requirements of point c, d of this clause cannot be provided**, the Minister of Health shall review the case

								(GMP) certificate from the relevant competent authorities are required as alternative documents. <u>For product not registered in any other country</u>: 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]					based on the advices from the 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. g) 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. **<u>Reference regulatory authority</u>** (Art. 2 Circular 08/2022/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 - 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 New Drugs and Clinical Trials Rules (NDCTR), 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 file 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 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 (international organizations to which Vietnam is a member, regulatory authorities specified in Clause 9 Article 2 of this Circular), except for the case specified in Clause 3 of this Article. If clinical trials are conducted before the above-mentioned regulations on drug development become available, the data from such trials shall be acceptable for the purpose of dossier evaluation. Art. 13, Circular 08/2022/TT-BYT
	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.	

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<tr><th>RDPAC/PhIRDA</th><th>HKAPI</th><th>OPPI</th><th>IPMG</th><th>JPMA</th><th>KPBMA/KRPIA</th><th>PhAMA</th><th>PHAP</th><th>SAPI</th><th>IRPMA</th><th>PReMA</th><th>PG</th></tr>
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<td>NDA</td>
<td>Application fees</td>
<td>New standard for drug registration fee was published by NMPA, refer to link for details.
https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20200630211101986.html</td>
<td>Application fee: HKD 1100
License fee: HKD 1370
Renewal fee (every 5 years): HKD 575</td>
<td>As per Sixth Schedule of New Drugs and Clinical Trial Rules, 2019 (FEE PAYABLE FOR LICENCE, PERMISSION AND REGISTRATION CERTIFICATE)</td>
<td>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)</td>
<td>The application fee was revised on Sep 1, 2020.
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</td>
<td>Application fee are defined in the Annex 1 of the “Regulation of Fees for Approval of Medical Products”</td>
<td>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.</td>
<td>In the recently released new FDA schedule of fees and charge, here are the new fees, depending on the product type:

<table>
<tr><th>Product Type</th><th>Fees per year</th></tr>
<tr><td>New Chemical Entity/ Biological/ Vaccine</td><td>43,000.00</td></tr>
<tr><td>Generic Drug Rx</td><td>18,000.00</td></tr>
<tr><td>Non-Pre-scription Drug / Household Remedy</td><td>17,000.00</td></tr>
<tr><td>Medical Gas</td><td>9,000.00</td></tr>
<tr><td>Traditional Medicine</td><td>14,500.00</td></tr>
<tr><td>Herbal Medicine</td><td>17,000.00</td></tr>
</table>

(Administrative Order No. 2024-0016 (https://app.doh.gov.ph:1024/Rest/GetFile?id=813327))</td>
<td>For therapeutic products
Registering a product – NDA & GDA
a) Screening (Payable upon submission)
(i) Abridged/ Verification evaluation route (NDA & GDA) $610
(ii) Full evaluation route (NDA) $ 3060
b) Evaluation (Payable upon acceptance)
(i) NDA Abridged evaluation route
- NDA-1 & NDA-2 $11,600
- NDA-3 $ 6030
(ii) NDA Verification evaluation route
- NDA-1 & NDA-2 $17,100
- NDA-3 $ 6,030
(iii) NDA-1,2,and 3: Full evaluation route $83,100
(iv) GDA Abridged evaluation route
- GDA-1 $4,280
- GDA-2 $2,450
(v) GDA Verification evaluation route
- GDA-1 $10,600
- GDA-2 $5,500
(vi) GDA Verification evaluation route (CECA Scheme)
- GDA-1 $10,600
- GDA-2 $5,500
C) Annual retention fee (per registered product)
- NDA & GDA $330

HSA website:
https://www.hsa.gov.sg/therapeutic-products/fees

For Class 2 CTGTP Full route application for NDA-1/2/3:
- Screening: $2,900
- Evaluation fees: $82,700

Abridged route application:
- Screening: $570
- Evaluation fees for NDA-1/2: $13,700
- Evaluation fees for NDA-3: $5,700

Annual retention fees per registered product: $310

HSA website:
https://www.hsa.gov.sg/ctgtp/fees-and-turnaround-time</td>
<td>“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</td>
<td>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 as designated by the Minister of Public Health.
(cited 2025 FEB 3 media.php)</td>
<td>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</td>
</tr>
</table>

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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)		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 schedule- 1. 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 lab test by DMSC will be required 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 (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 Biologicals (NICVB); Registration certificate for trademark in Vietnam is required if there is ® symbol on labeling *: Evaluation on good manufacturing practice (GMP) compliance of MFR (Decree 54/2017/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) 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, c, the manufacturer can provide Self-declaration as Form 10/TT 08/2022 GMP Principles and Standards for production of pharmaceuticals have been applied by administration of country or other international organization. (Circular 08/2022/TT-BYT, 29/2020/TT-BYT)

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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 3-ICH-CTD. - 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

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NDA application materials	Non-clinical summary	Yes (in Chinese)	For NCE/Biosimilar/ATP only (document in English).	As per recent circular, 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 New Drugs and Clinical Trials 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 4-ICH-CTD.

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NDA application materials	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 3 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 biologicals Online submission via the MOH Public service portal The non-clinical trials shall be prepared in conformance with the guidelines of ACTD - Part III or Module 4-ICH-CTD. Vietnamese or English Letter 72/QLD-DK/2018 and ACTD guidelines on Non-Clinical data mention that Non-clinical summary is enough. Non-clinical report is only required when VN authority wants to double check the summary. In that case, 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 4 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 new chemical drugs, vaccines, and biologicals The clinical trials shall be prepared in conformance with the guidelines of ACTD - Part IV or Module 5-ICH-CTD. The clinical document shall be prepared in conformance with Letter 72/QLD-DK/2018 by both hard-copy and soft-copy.
	Clinical report	Yes (in Chinese) According to newly issued Guidelines for Acceptance and Review of Chemical Drug Registration (For Trial Implementation) (2020 No.10) and Guidelines for Acceptance and Review of Biological Products Registration (2020 No.11), 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 4 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 new chemical drugs, vaccines, and biologicals The no-clinical trials shall be prepared in conformance with the guidelines of ACTD - Part IV or Module 5-ICH-CTD. Vietnamese or English Letter 72/QLD-DK/2018 and ACTD guidelines on Clinical data mention that for hard copy list of clinical trails is enough. Clinical report is only required when VN authority wants to double check the summary. In that case, the content of Clinical report includes: 1 Reports of Biopharmaceutic Studies 2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials 3 Reports of Human Pharmacokinetic (PK) Studies 4 Reports of Human Pharmacodynamics (PD) Studies 5 Reports of Clinical Efficacy and Safety Studies 6 Reports of Post-marketing Experience 7 Case Reports Forms and Individual Patient Listing

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NDA application materials	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.	All documents in English. **General requirements:** 1. An authorization letter from the overseas manufacturer for the applicant; 2. Soft copy of the business registration certificate; 3. Soft copy and certified true copy of the manufacturer's license; 4. Methods, standards and conditions of the manufacture of the pharmaceutical product, manufacturing and quality control facilities, technical personnel, etc.; 5. Soft copy and certified true copy of GMP certificate which meets PIC/S GMP standards; 6. Soft copy and original or certified true copy of CPP from the country of origin; 7. One set of prototype sales pack for each pack size, complying with the labelling requirements; 8. Color photos or scanned image of product including any inner container/ packaging and image of unit dose form; 9. Master formula (Batch formula not accepted) - Non-proprietary names of ingredients, colour Index number or E-number for all colourants used should be provided; 10. Finished product specifications; 11. Method of analysis; 12. COA of a representative batch; 13. Stability data; 14. Bioequivalence data for anti-epileptic drugs and critical dose drugs (The BE studies should be conducted in accordance with World Health Organization guidance on the "Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability" or other international guideline); 15. Safety documents for ingredients with animal origins **For Generic:** Reputable reference and/or approved pack insert in reference country to support proposed indication, dosage, RoA an other contents of pack insert **For NCE or biological entity** 1. Soft copy and original or certified true copies of CPP from 2 or more (conventional pathway) or 1 (special pathway – 1+ mechanism) of the reference countries; 2. ICH CTD Mod 2, 3 and 5; 3. Expert evaluation reports on the safety, efficacy and quality of the product. CV of the expert and the expert's signature on the corresponding reports are required;	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 approval 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=trueRequired 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 -

			4. RMP and or REMS from reference countries. Information on whether any of the risk management plan activities and mitigation strategies will be implemented in HK; 5. Proposed package insert of the product. Where the package insert is in the form of a patient information leaflet, a prescribing information leaflet for healthcare professionals for use in HK should also be submitted; 6. Risk assessment report of elemental impurities in accordance with ICH Q3D; 7. Information on pre-registration importation of product and local clinical trial information (if applicable) 8. Comparison of indications, dosage, warnings & precautions, contraindications or side effects in reference countries; 9. Worldwide registration status; 10. Any other countries/ regions where the product was refused / suspended / revoked **Additional requirements for NCE or biological entity with Special Pathway (1+ mechanism)**_ 1. The product is approved with ODD, BTD, priority review designation or equivalent in reference country; 2. There are local clinical data or clinical data generated from Chinese and/ or Asian population (the drug has been shown in accordance with ICH E5 to be ethnically insensitive and extrinsic factors in these region(s) are generally similar to those in Hong Kong) related to proposed indication and posology; 3. Assessment report by local expert on product safety and efficacy, review of global and local epidemiology of disease, Int'l and local tx paradigms 4. Evaluation report by expert on local clinical data related to proposed indication and posology 5. Assessment report, post-authorization requirement and licensing condition in reference country 6. PSUR, summary safety reports, or equivalent 7. Post-registration development plan About Biosimilar guideline, please refer "Guidance Notes for Registration of Biosimilar Products" (Aug 2021) About ATP guideline, please refer "Guidance on Application of Certificate of Drug/Product Registration – Advanced Therapy Products" (23 Feb 2023)										

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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. Real-time recruitment information could be referred to from CDE website (https://www.cde.org.cn/main/fullsearch/fullsearchpage).	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: 1066 Review Dept.: 641 Safety Dept.: 191 (As of May.1,2024)	There is no official information	The Product & Cosmetic Evaluation Centre in NPRA has 128 officers currently. Other regulatory support are provided by the Regulatory Coordination & Strategic Planning Centre with 64 staff, and the Compliance & Quality Control Centre wit 232 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.	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)		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 (5) 2nd round assessment (if needed) (6) Committee, Subcommittee, Working group meeting (if needed) (7) Decision (8) Licensure issuance GMP Clearance for drug product in parallel. BE study report review for new generic drugs in parallel. (cited 2025 Feb 3 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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NDA Approval review	Review time	- CTA/supplementary CTA: 60WDs - 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. 15 Year 2019, Timeline of pre-registration 40 working days after completed documents for category 1,2,3. 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 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 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 120 working days for a New Drug, Biological Product, major variation	Review time change (80 percentile value) Priority review: 9.0 months (As of Mar. 2023) Standard review: 12.0months (As of Mar. 2023)	1. FP: 90 working days 2. DMF: 120 working days(if inspection is required) / 90 working days (if inspection is not required) 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 , 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*) new drug (NCE) 220 154 90 new biologics and biosimi-lar* 220 (230*) 154 90 vaccine 280 154 90 biologics (fol-low-on) 160 110 90 generics and new generics 135 115 90 *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). (cited 2025 Feb 3 media.php)	within 12 months under normal scheme

					(new indication/ posology which has been approved in at least 1 (one) country with known good evaluation 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 120 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.								

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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 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. (source: http://www.nhc.gov.cn/yaozs/s7653/202012/f30aad8ec4ba48a9afa2e559f4d20e7c.shtml)	Usually no; except the following situations, 1. official request from Hospital Authority upon urgent situation. 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 120 working days Refer to BPOM regulation No. 15 Year 2019 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)	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 advance 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 (3 categories: Accelerated review, Fast track review, Priority review) Abbreviated assessment (2 categories: Abridged assessment and CRP Reliance assessment)	Vietnam introduced reliance review pathway for NDA in 2024 via the Pharma Law revision. (Pharma Law 44/2024/QH15, Art. 56). Further guidance for this pathway is being developed at the Circular level. Category of review pathways for NDA and timeline: - Normal pathway – 12 months (Pharma Law 44/2024/QH15, Art. 56) - Reliance pathway – 9 months (Pharma Law 44/2024/QH15, Art. 56) - Accelerated evaluation pathway – 6 months (Circular 08/2022/TT-BYT, Art. 33) - Abbreviated evaluation pathway – 6 months (Circular 08/2022/TT-BYT, Art. 33)

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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	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 re-examination period for the drugs will be extended up to 10 years. However, those designated early are not applicable.	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.	Yes The Ministry of Health already issued Circular 26/2019/TT-BYT on Orphan drug list, 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.

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NDA Approval review	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	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 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
	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. 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.	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 meeting is usually implemented for WHO CRP Reliance assessment	-

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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.	Not required	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_13sep2022.pdf	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.	No requirement	N/A. Applicable for local clinical trials only. When local clinical trial is conducted, GCP inspection is carried out. (Article 10. Circular 29/2018/TT-BYT)

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NDA Pre-approval inspection	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 product, 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 54, (Article 96, clause 3), Inspection can be conducted in cases of: a) MFR has registration dossiers of drug product, drug substance which is modified, or suspected of untrue information, data. b) MFR has drug product which is concluded as level 1 of quality violation by MOH. c) MFR has submitted a dossier of requesting manufacture condition evaluation, but the dossier is concluded as not matching requirement of GMP by MOH. - 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, ICH countries and Australia, except for the cases stipulated in clause 3 (above). b) Manufacturers belonging to ICH member countries, Australia and that are inspected and assessed as in conformity with Good manufacturing practice by US Food and Drug Administration, USFDA, European Union member countries, European Medicines Agency (EMA), Australia (Therapeutic Goods Administration, TGA), Japan (Pharmaceuticals and Medical Devices Agency, PMDA) or Canada (Health Canada), except for the cases stipulated under clause 3 of this Article (above).

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NDA Pre-approval inspection	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	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.TFDA approval and Import permit of IMP 2.IRB approval (IND in TFDA and IRB can be submitted parallel) 3.CTA signed with site 4.1st payment done to medical institution 5.IMP shipment to site (Import permits are needed if any lab kits and devices required)	Clinical trials that will be submitted for drug registration require approval from 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.

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Clinical trials	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.	For additional requirements per individual scenarios, please refer to Appendix I of the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/ Medicinal Test version Jan 2024), p.11-14.	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 available 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 Investigator Brochure is required for clinical trial approval.	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.	For additional requirements per individual scenarios, please refer to Appendix I of the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/ Medicinal Test version Jan 2024), p.11-14.	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	Yes •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 For bio-sample needed to send out overseas, the statement from the central lab and the export permit are required. For the case authorized to CRO, the authorization letter from the sponsor is required.	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 Biologicals or Certification of analysis in the case of a batch of vaccines and biologicals); - 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.
	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	Only protocol synopsis and documents to subjects should be in Chinese.	Thai and/or English	Vietnamese or English language

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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. 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 preferrable 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	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 New Drugs and Clinical Trials Rules (NDCTR), 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 file 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=	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	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 for biologics similar to reference biologics and vaccines similar to the vaccines already licensed for marketing in Vietnam) 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 sbj. 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 preferrable 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.	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 New Drugs and Clinical Trials Rules (NDCTR), 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 file 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=	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.	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 for biologics similar to reference biologics and vaccines similar to the vaccines already licensed for marketing in Vietnam) 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.	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.	Not necessary	N/A
	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.	It is around 50 clinical centers.	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 210 sites(Dec. 2024).	The number of clinical research have increased by over 80% since 2016, with now almost 260 centres in Malaysia having had conducted clinical research. (CRM Annual Report 2023) https://clinicalresearch.my/wp-content/uploads/2024/04/29-Apr-Website_CRM_AR2023.pdf	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 120 centers/ teaching hospitals https://www.taiwanclinicaltrials.tw/tw/spotlight/health_overview/medical_institution	36 clinical sites (12 sites under MoPH, 18 sites under universities, and 6 sites under others) with 25 Thai FDA-recognized IRB/IEC.	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.

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Clinical trials	Environment for conducting clinical trials Installation of IRB system for clinical trials. Is there National IRB?	When the drug clinical trial application is approved, the sponsor shall formulate the corresponding drug clinical trial protocol and have it reviewed and approved by the ethics committee before carrying out the subsequent phase of clinical trial, and submit the corresponding protocol and supporting dossiers on the website of the CDE.	Yes. Central IRB in 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	There is National IRB system	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.	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
	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.	Clinical Research Malaysia supports clinical research 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	There are 23 TCTC. (https://www.taiwanclinicaltrials.tw/tw/ctc) The enrollment per site varied by PI and site. There are less referrals among the study and non-study sites	In most cases, participations 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 (Source: Article 19 Circular 29/2018/TT-BYT)

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Clinical trials	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.	GCP is required in all clinical studies	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. DAV shall inspect the site and classify GCP compliance of the local trial facility. MOH shall publish on its portal the GCP-certified trial facilities (Source: Article 7& 11; Circular 29/2018/TT-BYT)
	Environment for conducting clinical trials Number of investigators who will conduct or participate in the clinical studies.	Uncountable number of physicians in China. Additionally, in 2019, the number of drug clinical trials in China exceeded 1,600, a more than 20-fold increase from less than a decade ago. The number of clinical trial sites in China has also increased steadily over recent years, growing from less than 400 in 2015 to more than 1,000 in 2020, mirroring to some extent the increased number of clinical trials Sponsors are also inevitably attracted to leading clinical trial sites when choosing a site, with little willingness to consider other sites. Annual Report on Clinical Trial Progress of New Drug Registration in China (2023) https://www.cde.org.cn/main/news/viewInfoCommon/d25e2879906bd2d3ae6c929aece41e34	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.	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.	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 19.2.dd. of Circular 29/2018/TT-BYT)
	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 by 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.	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)

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Clinical trials	Investigational drug Requirements of Investigational drug labeling and its lan-guage.	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 product requires an import permit.	Reference to CLINICAL TRIALS GUIDANCE LABELLING OF INVESTIGATIONAL AND AUXILIARY PRODUCTS IN CLINICAL TRIALS GN-IOCTB-07 Rev. No. 004, 1 Mar 2021. https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-07_labelling_ip_ap.pdf?sfvrsn=f5f61777_6	Yes Label has to be prepared in traditional Chinese under PIC/S GMP regulation.	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 the Labelling Circular 01/2018/ TT-BYT (Source: Article 19.2.h. Circular 29/2018/TT-BYT)
	Investigational drug Acceptability of the use of domestically unapproved drug as compar-ator.	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	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 73.1.b of Decree 54)

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Clinical trials	Availability of the support from multi-national CRO	Yes	Yes (domestic and multi-national companies).	Health ministry notifies Rules to register CROs under NDCTR, 2019 – The amended rules will come into force from April 1, 2025. Adding a new chapter VA to the NDCTR on CROs, it stipulates that no clinical research organisation 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 There are around 20 CRO in Taiwan (https://www1.cde.org.tw/ct_taiwan/search_display_cro.php) There are less local CROs in Taiwan.	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.	Yes It is possible to export biological samples if it is 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 fulfilled as necessary, especially if biological samples for future research are involved. Source: MOH I Human Biomedical Research Act.	Yes It is possible (okay) to export biological samples and required to apply for export permit	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 method of the drug vigilance system gateway was updated to the same E2B (R3) electronic transmission system with the post-marketing environment. The system began trial operation at 17:00 on November 6, 2023 and supports receiving reports of suspicious and unexpected serious adverse reactions. The trial operation period is one year (until November 5, 2024) (https://www.cde.org.cn/main/news/viewInfoCommon/40ef95178d5941b2f7b82389b29d54cd) 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 safety risk information during clinical trials should promptly be communicated with CDE and submitted to CDE within 15days after determined by the applicant. (https://www.cde.org.cn/main/news/viewInfoCommon/ddea289e856a539aa70121ae04ec38ac)	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 Rules, 2019; Third Schedule; 3. Responsibility (2) Investigator (ii) Investigator shall report all serious adverse events to the Central Licencing Authority, the sponsor or his representative, whosoever had obtained permission from the Central Licencing 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	SUSAR: report to Authority within 7 days for death and life threatening cases, within 15 days for other cause. It is same as international rule. DSUR is not mandatory according to the official letter No. 1100003843 dated Apr 6th, 2021. It indicated the requirement remains the same as current practice. Meanwhile, IRPMA PV Task force team reached consensus: According to this, there is no change and we will keep the same safety reporting for 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 Decision 62/QD-K2DT/ 2017: 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. - In case of additional information on medical happening of SAE, or happening of patients with SAE, or change of relationship between SAE and investigational product: within 15 working days since the day having additional information. b) AE/SAE occurred outside VN territory (VN is one of countries in multi-national CT): All SAEs which makes trial protocol change, or make trial pause in one country member should be reported to Administration of Science Technology and Training- MOH, EC of MOH, National center of ADR and drug information as CIOMS form or appendix 1 of the Decision 62. - Timeline of report: not more than 15 working days since the day having decision on trial protocol change, or trial pause.

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Clinical trials	GCP site inspection	Yes Clinical trial inspection was conducted based on the review needs.	GCP site inspection is not conducted by DH, but maybe conducted by overseas health authorities.	Licensing authority conduct the GCP site inspection on risk-based approach.	BPOM will do GCP site inspection during clinical trial	Yes After NDA, 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)	Yes	Yes (Article 10, C#29/2018/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, 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 Test certificate, test standard and method, certified by the National institute for control of vaccines and biologics as part of the registration dossier
	Pharmacopeia	All import drugs and domestic drugs should follow Chinese Pharmacopeia. ChP2020 will be effect since Dec.30, 2020 ChP2025 will be effective in 2025. https://www.nmpa.gov.cn/yaowen/ypjgyw/hyyx/zhhyx/zhhyx20241127164851184.html	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 Pharmacop eia (IP) than must conform to IP if not official in IP than BP/USP/EU Pharmacop eia standards are to be followed	Standard Pharmacopeia: Indonesian Pharmacopeia 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 11/2018/TT-BYT)

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Manufac-turing	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 has 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 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 35/2018 revised by Circular 12/2022) 3. Manufacturers follow WHO-GMP, PICs-GMP or EU GMP standards & other GMP principles and standards equivalent to EU-GMP principles and standards promulgated by pharmaceutical management agencies of SRA countries. 4. Document updating GMP principles and standards: a) In case the World Health Organization amends and supplements the principles and standards of Good Manufacturing Practice for drugs and drug raw materials (hereinafter referred to as updated documents) specified at Points a and b; Clause 1 of this Article, within 3 months from the date on which the updated documents are published on the Web Portal of the World Health Organization; The Drug Administration of Vietnam or the Administration of Traditional Medicine and Pharmacy according to their assigned management capacity, organize translations and publish the revised and supplemented content on the website of the Ministry of Health for relevant parties to search, update and execute; b) In the case of the Pharmaceutical Inspection Cooperation System (PIC/S) or the European Union has updated documents specified at Points c and d, Clause 1 of this Article, and those documents have not been posted on the Portal of the Ministry of Health and the website of the Drug Administration of Vietnam, the manufacturer of drugs and medicinal ingredients that implements the application is responsible for translating and certifying the translation in accordance with the law on notarization and certification to submit it to the Drug Administration of Vietnam. Within 10 days from the date of receipt of the notarized and certified translation sent by the manufacturer of the drug or medicinal ingredient, the Drug Administration of Vietnam shall review, amend, and post it on the Portal of the Ministry of Health and the website of the Drug Administration of Vietnam. For foreign manufacturers having drugs registered for marketing in Vietnam: must submit GMP certificate from country of origin. Mutual recognition, acceptance of inspection, audit 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, ICH countries and Australia. b) Manufacturers belonging to ICH member countries, Australia and that are inspected and assessed as in conformity with GMP by USFDA, EMA, Australia TGA, Japan PMDA or Canada. (Source: Article 96, Decree 54) Art. 97 (Decree 88/2023) amending Decree 54/2017) c) If GMP principles and standards do not fall under any of the principles and standards promulgated or declared by the Minister of Health in accordance with Point a Clause 1 of this Article, authorization advisory council shall evaluate conformity of principles, standards of exporting countries relative to principles, standards of the Minister of Health. Once conformity assessment results are produced, the Minister of Health shall issue decision recognizing conformity of GMP principles, standards of exporting countries in order to assess manufacturing facilities.

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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. 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 expiration date of the GMP certificate is usually 3 years, but the date could be shortened based on risk-based plans. 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-mqa-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 required if document verification 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 evaluation process** (Art. 7 of Circular 35 revised by Circular 12/2022/TT-BYT) 1. Documents used in assessing the satisfaction of GMP principles and standards: The WHO - GMP principles and standards documents or the GMP principles and standards documents specified in Clauses 2, 3, 4, 5 and 6 Article 4 of this Circular correspond to the production activities of the manufacturer. 2.Manufacturing establishment presents summary of organization, personnel and activities applying for GMP 3.Evaluation team conducts GMP assessment at the production facility. In cases where an establishment 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 establishment; 4.Evaluation team meeting with manufacturing establishment to inform about any pending items 5.Evaluation team prepare and sign the evaluation form, to also be signed by manufacturing establishment 6.Complete the Evaluation Report.

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Manufac-turing	GMP system Please describe frequency/ number of on-site inspec-tions to domestic/ overseas manufacturers by the authori-ties.	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	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 publish information	In FY2023, there were 199 GMP inspections (47 in Japan and 152 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	Depend 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 35/2018/TT-BYT)
	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

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Manufac-turing	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/xxgk/zhqyj/zhqyjyp/20201210134834171.html?type=pc&m=&GXMEUwefOdZn=1607940264520	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	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 respectivel y of the NDCT, 2019. Package Insert and packaging labels should be written in English. The labeling requireme nts for primary and secondary and all labels are outlined in Rules 96 and 97 of Drugs Rules 1945	Annex X and XI, Drug Registration Guideline No. 24 Year 2017 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 in Thai. SmPC in English.	Vietnamese. The currently valid Circular on Labelling no. 01/2018/TT-BYT issued by the Ministry of Health which is going through the revision process: 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.	DTAB recommends inclusion of QR Codes for anti-cancer drugs - In an effort to fight counterfeiting of costly cancer medicines which put the lives of patients at risk, the DTAB, the body that advises the Central and state governments on technical matters related to drugs in the country, has recommended implementing track and trace mechanism on all oncology products through Quick Response (QR) and Bar Code.	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 requirement (GPIN) is voluntary. However, there is an initiative from the government to start pursuing track and trace, starting with barcoding. (FDA Circular No. 2016-011)	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. (Clause 13 b) Article 22, and Clause 1 l), Article 48, Circular 08/2022/TT-BYT)In Circular 23/2023, the MOH also mandated a roadmap for e-labeling and serialization.

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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 and 10 years or orphan drug.	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 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. 8 Circular 08/2022/TT-BYT) 1. The validity period of certificate of marketing registration of drugs, drug raw materials, is 05 (five) years from issue date or renewal date, except for the categories stipulated in clause 2 of this Article. 2. The validity period of certificate of marketing registration of the following drugs is 03 (three) years from issue date for certain drugs: New drugs, vaccines for the first time issued with certificate of registration for marketing in Vietnam; Drugs having the same drug substance, concentration, strength, dosage form with those of a new drug for which a 5 (five) year-validity certificate of marketing registration has not been issued; Drugs for which ongoing monitoring for safety [and] effectiveness is recommended by the Council; Drugs of the categories stipulated in point a, b and c of this clause but at the point of dossier submission for certificate renewal the report on the drug safety, effectiveness is not yet available as the drugs have not been marketed or such report is already available but in the Council's opinion, the volume of the drugs being consumed, the number of patients the drugs were used on, the usage duration are still limited according to the opinion of the Council or the recommendation of the medical facility on the need to continue monitoring safety and effectiveness Before the revision of the Pharma Law no. 44/2024/QH15, Marketing authorization's validity must cease upon its expiry day (either after 5 years or 3 years). With the issuance of Pharma Law no 44/2024/QH15 and Circular 55/2024/TT-BYT, when a marketing authorization of drug or drug raw materials expires after the Drug Administration of Vietnam (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 raw material is 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.	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. 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-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.	(Art.5, Circular 08/2022/TT-BYT) 1. Pharmaceutical business establishments, medical service establishments shall monitor, supervise, collect, synthetize, evaluate information and send reports to the competent authority of cases of adverse reactions following vaccination, drug adverse reactions in accordance with the provisions of Article 77, Article 78 of Pharmaceutical law, national guidance on pharmacovigilance issued by Ministry of Health and applicable regulations. 2. The registrant shall report on the surveillance and assessment of safety [and] effectiveness of the drugs it registered in accordance with the provision of clause 2 Article 8 of this Circular using Form 2A/TT (for drugs) or Form 2B/TT (for vaccines): a) To DI&ADR National Centre every 6 months throughout the marketing registration's validity period; b) To Drug Administration upon the submission of application for renewal of marketing registration certificate; 3) Drug-consuming medical service establishments shall report on the consumption of the drugs stipulated in clause 2 Article 8 of this Circular using Form 2C/TT issued with this Circular every 6 months throughout the marketing registration's validity period and send the report to DI&ADR National Centre. 4) The DI&ADR National Central shall be responsible to synthesize, evaluate and send the reports to Drug Administration every 6 months.

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Post approval	Risk Management 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 is mandatory for new drugs, stem cell therapeutics, orphan drugs, Advanced biopharmaceutical drugs, drugs for which the Minister of the MFDS deems it necessary to submit risk management plans due to occurrence of serious side effects following marketing (e.g. valproic acid, isotretinoin, alitretinoin-contained drugs, etc.) and drugs that are designated for PMS. 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" * The Re-Evaluation system, which has been in effect since 1995, is a system that re-evaluates the safety and efficacy of new drugs and drugs determined by the minister of MFDS by investigating adverse event that did not appear in the approval process. However, as this system overlaps with the Risk Management Plan (RMP) introduced in 2015, issues such as duplicate data submissions have arisen. According to the amendment of the Pharmaceutical Affairs Act, starting from February 2025, the integrated RMP will be implemented replacing the Re-Evaluation system. Additionally, the drug data protection system, which was previously linked to the Re-Evaluation system, will be maintained in a separate provision in the Pharmaceutical Affairs Act.	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 only to submit in the application for vaccine registration. Otherwise not a mandatory requirement. (Art. 23, Circular 08/2022/TT-BYT). Vietnam MOH is planning to require RMP for chemical drugs and biologics (except probiotics) in the near future via the Registration Circular revision.

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Post approval	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/202204121 72455115.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	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. 4. 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 clause 2 Article 8 of Circular 08/2022/TT-BYT* using Form 2A/TT (for drugs) or Form 2B/TT (for vaccines). In addition, the newly issued Circular 55/2024/TT-BYT also mandates safety and efficacy reporting for all medicines upon the registants' request for renewal, using Form 2D/TT, which requires comprehensive details on usage and circulation of the drugs. * a) New drugs, vaccines granted circulation registration for the first time, reference biological products, similar biological products granted circulation registration for the first time in Vietnam; b) Drugs with the same active ingredient, concentration, content, and dosage form as new drugs that have not been granted circulation registration for a period of 05 (five) years; c) Cases that continue to monitor safety and effectiveness according to the advice of the Council; d) Drugs falling under the cases specified in Points a, b and c of this Clause but at the time of submitting the application for extension of the circulation registration certificate, there is no safety and effectiveness report because it has not been circulated or there is a safety and effectiveness report but the quantity of drugs used, the number of patients, and the duration of use are still limited according to the opinion of the Council or there is a recommendation from the medical examination and treatment facility on the need to continue monitoring safety and effectiveness.

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Post approval	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.	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.	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	Yes In Pharmaceutical Affairs Act and “Regulations for Registration of Medicinal Products”, there are some regulations taken as guideline. In addition, with the amendment of the “Regulations for Registration of Medicinal Products” announced on 28th Sep 2021, variation guideline was been updated. (https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030057) The amendment of “Post-approval Changes in Oral Solid Dosage Form Drug Products” was announced on 11th Dec 2023, the attachment table has been updated. https://www.fda.gov.tw/TC/siteListContent.aspx?sid=9354&id=45815 For the e-submission system (EXPRESS) online application for “drug product registration process, license renewal, withdrawal and the post-market administration variation are mandatory to submit by the system from 1st Jul 2020 and related detail announced by TFDA is on the following website: https://e-sub.fda.gov.tw/dohclient/Login.aspx	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.	Yes	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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