Asia Partnership Conference of Pharmaceutical Associations (APAC)

Analysis Report

ver. 2017

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

APAC Regulations and Approvals Expert Working Group

April 5, 2017
Tokyo, Japan

Member Associations	
HKAPI	Hong Kong Association of the Pharmaceutical Industry
IPMG	International Pharmaceutical Manufacturers Group
IRPMA	International Research-Based Pharmaceutical Manufacturers Association
JPMA	Japan Pharmaceutical Manufacturers Association
KPMA	Korea Pharmaceutical Manufacturers Association
KRPIA	Korean Research-based Pharmaceutical Industry Association
OPPI	Organization of Pharmaceutical Producers of India
PhAMA	Pharmaceutical Association of Malaysia
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PReMA	Pharmaceutical Research & Manufacturers Association
RDPAC	China Association of Enterprise with Foreign Investment R&D-based Pharmaceutical Association Committee
SAPI	Singapore Association of Pharmaceutical Industries
PG	Pharma Group (Vietnam)

Abbreviation

Abbreviation	Description
A.O.	Administrative Order (Philippines)
ACTD	ASEAN Common Technical Document
ADR	Adverse Drug Reaction
AE	Adverse Event
AIDS	Acquired Immune Deficiency Syndrome
ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
ARs	Adverse Reactions
ASEAN	Association of South-East Asian Nations
B.E.	Buddha Era
BA	Bioavailability
BE	Bioequivalence
BLA	Biologics License Application
BP	British Pharmacopoeia
BPOM	Badan Pengawas Obat dan Makanan
BPOM	(Indonesian national agency of drug and food control)
BSE	Bridging study evaluation (Taiwan)
CDCR	Control of Drugs and Cosmetic Regulation (Malaysia)
CDE	Center for Drug Evaluation
CDFS	Council on Drug and Food Sanitation(Japan)
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
cGMP	current Good Manufacturing Practice
Ch.P.	Chinese Pharmacopoeia
CHGRAO	China Human Genetic Resources Administration Office
CIOMS-I	Suspect Adverse Reaction Report Form (CIOMS Form I)
CIRB	Centralised Institutional Review Board (Singapore)
c-IRB	Central IRB
CMC	Chemistry, Manufacturing and Control
CMO	Contract Manufacturing Organization
CoA/COA/CA	Certificate Of Analysis
CoI	Co-principal Investigator
CPO	Contract Pharmaceutical Organization.
CPP	Certificate of Pharmaceutical Product
CRC	Clinical Research Centre
CRF	Case Report Form
CRM	Clinical Research Materials Notification
CRMC	Clinical Research Management Committee
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
CTD	Common Technical Document
CTIL	Clinical Trial Import License （Malaysia）
CTN	Clinical Trial Notification
CTRI	Clinical Trials Registry- India
CTX	Clinical Trial Exemption
CV	Curriculum Vitae
DAV	The Drug Administration Department of Vietnam
DB	Double Blind
DCA	Drug Control Authority (Malaysia)
DCGI	Drugs Controller General India
DLP	Data Lock Point
DMF	Drug Master File
DMP	Data Management plan

Abbreviation	Description
DMR	Data Management Report
DOH	Department of Health
DP	Drug Product
DRGD	Drug Registration Guidance Document (Malaysia)
DS	Drug Substance
EC	Ethical/Ethics Committee
EMEA/EMA	European Medicines Agency
EP	European Pharmacopoeia
EPAR	European Public Assessment Report
EPW	Empowered Procurement Wing (India)
ERB/ERC	Ethical Review Board/ Committee (Philippines)
d	European Union
FDA	Food and Drug Administration (U.S.)
FDC	Fixed Dose Combination
FERCIT	Forum for Ethical Review Committees in Thailand
FIH	First in Human
FIM	First in Man
FSC	Free Sale Certificate
FtoF or F2F or FTF	Face to Face
FY	Fiscal Year
GCP	Good Clinical Practice
GDA	Generic Drug Application
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GS-1	Global Standard One
GSB	Global Safety Board
GTIN	Global Trade Item Number
HA	Health Authorities
HAS	Health Sciences in Singapore
HGR	Human Genetic Resources
HIV	Human Immunodeficiency Virus
HKD	Hong Kong dollar
HKOP	Hong Kong Office of President
HSA	Health Sciences Authority (Singapore)
IB	Investigator's Brochure
IBD	International Birthday
ICF	Informed Consent Form
ICH	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH E17	ICH E17 Guideline (Multi-Regional Clinical Trials)
ICH E5	ICH E (Efficacy) 5 Guideline (Ethnic Factors in the Acceptability of Foreign Clinical Data)
ICH E6	ICH E (Efficacy) 6 Guideline (Good Clinical Practice)
ICSR	Individual Case Safety Report (Philippines)
IDL	Import Drug Licence （China)
IDR	Indonesia Rupiah
IEC(EC)	Independent Ethics 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
IRB	Institutional Review Board
JP	Japanese Pharmacopoeia
KOL	Key Opinion Leader
KOMNAS	The Indonesian Human Rights National Commission (Komnas HAM)
KP	Korean Pharmacopoeia
KRW	Korea won
LOA	Letter of Authorization
LTOC	List of Table of Contents
MAH	Marketing Authorization Holder

Abbreviation	Description
MAV	Major variation application
MF	Master File (Japan)
MFDS	Ministry of Food & Drug Safety (Korea)
MHLW	Ministry of Health, Labour and Welfare (Japan)
MHRA	Medicines and Healthcare Products Regulatory Agency
MOH	Ministry of Health of the People's Republic of China
MOH or MoH	Ministry of Health (Malaysia) (Vietnam)
MOPH	Ministry of Public Health (Thailand)
MRCT	Multi-Regional Clinical Trials
MREC	Medical Research & Ethics Committee (Malaysia)
MTA	Material TransferAagreement
NADFC	National Agency for Drug and Food Control (Indonesia)
NBE	New Biological Entity
NCCR	National Committee for Clinical Research (Malaysia)
NCE	New Chemical Entity
NCO	New Combination
ND	New Delivery system
NDA	New Drug Application
NDAC	New Drug Advisory Committee (India)
NDOS	New Dosage form of Approved New Drug
NF	The National Formulary
NHFPC	National Health and Family Planning Commission (China)
NHG DSRB	National Healthcare Group Domain-Specific Review Board (Singapore)
NI	New Indication
NIBIO	National Institute of Biomedical Innovation (Japan)
NIFDC	National Institutes for Food and Drug Control (China)
NME	New Molecular Entity
NMRR	National Medical Research Register (Malaysia)
NPRA	National Pharmaceutical Regulatory Agency (Malaysia)
NR	New Route of administration
NRPB	National Research Program for Biopharmaceuticals (Taiwan)
NS	New Strength of Approved New Drug
NSAE	Non Serious Adverse Event
NT	New Taiwan dollar
ODD	Orphan Drug Designation (Taiwan)
OTC	Over-The-Counter
PAL	Pharmaceutical Affairs Law
PBRER	Periodic Benefit Risk Evaluation Report
PD	Pharmacodynamics
PFDA	Provincial Food and Drug Administration (China)
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
PI	Package Insert
PIC/S or PIC/s	Pharmaceutical Inspection Convention (PIC) / Pharmaceutical Inspection Co-operation Scheme (PICS)
PIL	Patient Information Leaflets
PK	Pharmacokinetics
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMF	Plant Master File
PMS	Post-Marketing Surveillance/Study
PNHRS	Philippine National Health Research System
PP	Philippine Pharmacopoeia
PRH	product registration holders (Malaysia)
PSD	Product Services Division (Philippines)
PSUR	Periodic Safety Update Report
QOS	Quality Overall Summary
R&D	Research and Development
r-DNA	recombinant DNA
REMS	Risk Evaluation and Mitigation Strategy
RFID	Radio Frequency Identifier
RM	ringgit
RMA	Risk Minimisation Activities
RMB	renminbi = CNY (CHINESE YUAN)

Abbreviation	Description
RMP	Risk Management Plan
RRC	Research Review Committee (Malaysia)
Rs	Rupee
RTF	Refuse-to-file (Taiwan)
S&E	Safety & Efficacy
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Advance Reaction
SAR	Statistical Analysis Report
SEC	Subject Expert Committee
SG-GCP	Singapore Guideline for Good Clinical Practice
SKU	Stock Keeping Unit
SMF	Site Master File
SMP	Safety Monitoring Program (Thailand)
SMPC/SmPC	summary product characteristics
SOH	Safety of Health (Vietnam)
SOP	Standard operating procedure
STM	Specification & Test Method
SUSAR	Suspected Unexpected Serious Adverse Reaction
TB	Tuberculosis
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration (Australia)
Thai-FDA	Thailand Food and Drug Administration
TOX	Toxicology
UP-PGH	University of the Philippines - Philippine General Hospital
US	United States
USP	United States Pharmacopoeia
WHO	World Health Organization

Survey Results
Data sheets from Each Economy
on the areas of IND, NDA, Clinical Trials and GMP Evaluation System

China	(RDPAC)
Hong Kong	(HKAPI)
India	(OPPI)
Indonesia	(IPMG)
Japan	(JPMA)
Korea	(KPMA)
Korea	(KRPIA)
Malaysia	(PhAMA)
Philippines	(PHAP)
Singapore	(SAPI)
Taiwan	(IRPMA)
Thailand	(PReMA)
Vietnam	(PG)

Item	Contents	Detail or Example	China RDPAC	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KPMA/KPPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA	Vietnam PG
IND/CTA	Requirements of the applicant	CRO is possible?	Companies or regulatory agency (CRO) or MAH (R&D institution or scientific researcher within the pilot areas) "Pilot Scheme of the Marketing Authorization Holder System" was issued by the State Council on Jun 6, 2016.	Basically, CRO and doctors who can follow standards of GCP.	Sponsor companies, CROs and doctors who can follow standards of GCP.	CRO , Companies and doctors who can follow standards of GCP.	GCP applies to clinical trials conducted by companies and investigators.	Yes. Company, CRO or doctor, who can follow standards of GCP, can be IND holder.	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.	As per A.O. 2014-0034, a license is required for a Contract Research Organization (CRO) and its sponsor, prior to the conduct of clincial trial. Sponsor companies, CROs and doctors who can follow standards of GCP.	Sponsor company should make the application.	CRO can be an applicant, just the company has to be registered as a pharmaceutical company in Taiwan.	Drug manufacturing/import license holder or government (applicant can be sponsor or CRO	Sponsor companies, CROs and doctors who can follow GCP standards CPO or CRO
	Clinical trial consultation system	System, Timing, Procedure	"Communication and Exchange of Drug R&D and Technical Evaluation Procedure (No.94 of 2016) was issued by CFDA on Jun 6, 2016. This procedure gives priority to communication and exchange during registration for innovative drugs, drugs with advanced preparation technologies and drugs in urgent clinical demand. 1) Types of meetings: Class I meeting: Meeting for major safety issues during the drug clinical trials, and major technical issues of breakthrough therapy drugs in R&D process; Class II meeting: in the critical stages of research and development of innovative drugs, ①Before PhI, ②After PhII/before phIII, ③Before NDA, ④Before approval for post-marketing risk control; Class III meeting : Other meetings than class I and class II meetings. 2) Timing of the meetings ; I class : within 30 days after submission, II class : within 60 days after submission, III class : within 75 days after submission 3) Meeting form: Face-to-face meeting, record the minutes, CDE video recording 4) other communication ways: Applicants could consult general technical issues with project management personnel in CDE via "Window for applicants", internet consulting platform, telephone, fax, email, mail etc.	No	Non-formal consultation is possible. Pre-screening of the application is done at DCGI office before accepting our application. 1. IND- For phase 1 trials of NCEs application is referred to IND committee scheduled to meet every quarter. For molecule discovered outside India FIM studies are not permitted. 2. Other IND application -The application is referred to Subject Expert Committee(SEC) for review. Post review, the Sponsor/CRO is invited to a face to face meeting with SEC where they need to present & defend the proposal.	The consultation with Head of evaluator is available on every Tuesday or consult by email and consultation with Assistant Director of registration is available on every Wednesday or by appointment .	Various Clinical trial consultations are provided on new drugs and biological products by PMDA. （e.g., pre-PhI/ Pre-PhIIa/Pre-PhIIb /End ofPhII study, Pre-application, Quality, Safety, etc）	There are official and unofficial consultation system in Korea. Official pre IND consultation can be held 40 days before expected consultation meeting and it should be requested in written form. Meeting minutes will be issued 10 days after the meeting by MFDS(Ministry of Food and Drug Safety). Pre-review system covers IND preparations. F2F meeting 14~24 days after primary review result.	A formal and structured consultation system is currently not in place but consultation may be requested on an informal basis.	For company-initiated local trial, the proposed clinical trial protocol is prepared by the medical department in consultation with a physician-specialist who becomes a co-author. The protocol is then submitted to the GSB and regional Safety Department & Regulatory Department for approval. The final approval comes from the FDA. For investigator-initiated trials, the proposed protocol is written by the authors subject to the approval of the medical dept of HI-Eisai. (see FDA Circular 2012-007)	No. But for first-in-human trials, HSA would prefer if company has a pre-submission consultation about 2 months before submission.	Regulation consultation service is available for all phases of product development. It is free of charge without legal binding. Sponsors can choose official letter correspondence face to face meeting - to conduct the consultation. The procedure for face to face meeting should be on-line submission first. Then the project manager of CDE will contact with the applicant for confirm the question which applicant raised and requesting more information. 2 to 4 weeks after the submission will be taken for meeting arrangement. Also the project manager will arrange the appropriate time and attendee list for the consultation meeting. In general, 1 hour for FTF meeting, and meeting minutes may be available 2 weeks after the meeting.	Can consult at FDA (Such as direct contact, telephone)	There is no official consultation in place however, sponsor can send letter to Ministry of Health, Administration of Science Technology and Training in order to request consultation.

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IND/CTA	Flow of clinical trial notification, IND application and IRB permission	Flowchart	Clinical trial can be initiated after IND approval, IRB permission, human generic resource approval (MOST). In China, clinical trial application is required. IND approval letter should be submitted for IRB permission. IND approval letter and IRB permission letter should be submitted for human generic resource approval. For BE study, notification system is applied from Dec.01,2015 and for other studies, CTA system is applied	Approval by DOH is required. IRB approval is also required.	Clinical trial on new drug shall be initiated after authorization by CDSCO (NOC:No Objection Certificate from DCGI) and approval of respective EC. In case of parallel applications, CDCSO will grant conditional approval and note that the trial should start after Ethics approval.	Flow Chart of Clinical Trial Notification See Annex 1, Flow Chart of Post Marketing Clinical Trial See Annex 2.	A clinical trial is conducted based on notification, not on application. Contracts with clinical sites should be signed after 30 days from the clinical trial notification (14 days from the second trial onwards).	There is no clinical trial notification system, and only IND approval is available. Clinical trial should be conducted within 2 years after IND approval. (See the flow chart at Annex 3)	A Clinical Trial Import Licence (CTIL) authorising the licensee to import a product for purposes of clinical trials is required. The sponsor/ investigator shall not start the clinical trial until the ethics committee/ Institutional Review Board has issued a favourable opinion and approved by the Drug Control Authority (DCA). All the clinical trials that require CTIL/ CTX (Clinical Trial Exemption) must be registered with NMRR (National Medical Research Register). NPRA will only accept favourable opinion/ approval issued by EC that is registered with the DCA.	We now have a central ethical review board in the FDA. This board reviews the protocol. Once approved, the CT may proceed. Centers where the clinical trial is to be conducted is notified. Please see FDA Circular 2012-007 (p. 6 &8)	Under the Health Products Act and its subsidiary legislation, the Health Products (Clinical Trials) Regulations, and require either Clinical Trial Authorisation (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 authorisation (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 authorisation (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. (See Annex 4)	Some IRBs need to sign the contract before get approval letter.	Same. Except the Guideline on Application for Drug Import permit into Thailand for Clinical Trial was updated since 9 Sep 2016 (to become effective on 1 Oct 2016)	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 SOH and People's Committee before submit to HA), we can continue submission to health authority (HA). The CT can be initiated after getting HA, in this case the Ministry of Health, approval. Import License (IL) in only obtained after having HA approval.
	Time required for clinical trial notification, IND application and IRB permission obtainment	Official timeline: (working days) Timeline based on actual experience	Based on RDPAC timeline survey results in 2016, IND review and approval usually takes 10-18 months, IDL-CTA needs 16-24 months. Waiting time for CTAs were significantly shortened after September 2015 under the effect of reform policy. Applicant should start clinical trial study within 3 years after getting IND approval. If overdue, permission will be invalid.	4 months	IND review: 6-8 months EC review: 2-4 months	Timeline for evaluation is 20 working days for protocol & amendment of clinical trial after NADFC stated the protocol & amendment complete	The rule of "after 30 days from the first clinical trial notification" for drugs containing new active ingredients, new ethical combination drugs and drugs with a new administrative route. The clinical trial can be started after 14 days from clinical trial notification for the second trial onwards (for the same product).	IND application official timeline based on the results of the consultation: 30 working days Timeline based on actual experience: Given 1 time query by MFDS during their IND review period, it takes 2-3 months. According to sites, IRB review will be held every 2 weeks to every 2 months depending on the sites. Totally, for initial 3 months, we can get IND approval & IRB approval in parallel.	Official Timeline for CTIL/CTX: 45 working days for phase I trial, clinical trial involves biological/ biotechnological, cell therapy product and gene therapy product as well as herbal product. For Others: 30 working days The IRB/IEC should review a proposed clinical trial within a reasonable time. Ethics approval: complete submission without queries can be approved within 4 to 8 weeks. (Re Edition 6.1 Malaysian Guideline for Application of CTIL & CTX, NPRA)	No specific timelines for trial notification. (Basically not more than 60 days from submission)	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 and tissue products Clinical Trial Notification (CTN): 5 working days. Clinical Research Materials Notification (CRM): Immediate	The time for (CTA-Clinical Trial application) will be within 30 days. General IND application procedure will review protocol in detail by CDE and may request to revise protocol based on their review result. The approved time may take around 30 working days. If the protocol is simultaneous submission in A10 countries with same protocol number, fast track review is available so that the overall review time can be reduced as short as 14 days. IRB permission time depends. The approval time may take around 3-4 months in average.	Trial product import license official timeline: Chemical - 20 WD Biological - 60 WD IRB : (each study site or EC of MOPH) - institute EC 2-3 months/ EC-MOPH 6 months	Time required for clinical trial notification: 1 month; Hospital IRB: 1.5-3 months; IND application and MOH IRB permission obtainment: 2-3 months

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IND/CTA application materials	Application form	Requirements and language	Yes : application form (in Chinese) "New Document Submission Requirements based on New Registration Classification of Chemical Drugs (No.80 of 2016)" was issued by CFDA on May 4, 2016.	Application form for Certificate for Clinical Trial	Yes (Form 44, in English)	There is a checklist requirement	Yes: Clinical trial notification form (in Japanese)	Submission system were changed to the internet-based system.	Application form for CTIL/CTX (Clinical Trial Import Licence/ Clinical Trial Exemption). In English or Bahasa Malaysia	Yes, in English. Please see FDA Circular 2012-007	Application for Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate to HAS. IRB has no form.	Application form is needed and it can be in English. But the format is in Chinese.	Local form (in Thai)	Yes, in Vietnamese
	A statement regarding the reason why the sponsoring of the proposed clinical trial is scientifically justified	Requirements and language	Yes (in Chinese)	No	Yes (in English) and vernacular language	Yes	Yes (in Japanese)	Yes (in Korean)	No	Please see FDA Circular 2012-007 (p.4)	No	Yes, the official letter to indicate the sponsoring of proposed clinical trial is needed.	Cover letter (have template in Thai)	No
	Protocol	Requirements and language	Yes (in Chinese)	Yes, in English	Yes (in English)	Yes	Yes (in Japanese)	Yes (in Korean)and all data	Yes, in English or Bahasa Malaysia Malaysian Guideline for Application of CTIL & CTX, Edition 6.1 September 2015) and all data must be in English or Bahasa Malaysia	Yes, in English	Yes, in English	Required. Both Chinese or English version are acceptable.	See detail in guideline, can be in Thai or English	Protocol is mandatory in VNM and ENG. MOH EC members refer to ENG version to verify information.
	IB	Requirements and language	Yes (in Chinese)	Yes, in English For Ph IV trials, HK registered pack insert can be used.	Yes(in English)	Yes,(in Indonesian or English)	Yes (in Japanese)	Yes (English acceptable)	Yes, in English or Bahasa Malaysia. For content and format of the IB, reference is made to section 7, current version of Malaysian Guideline for GCP.	Yes, in English	Yes, in English	Required. Both Chinese or English version are acceptable.	See detail in guideline (for unregistered drug in Thailand)	In English and Vietnamese. It is also accepted for submission of English and summary in Vietnamese
	CRF (sample)	Requirements and language	MRCT: Yes (in Chinese) Import product: No	Yes, in English	Yes (in English)	Yes, (in Indonesian or English)	No, if the description of CRF is to be read by PC.	Yes (English acceptable)	Yes, in English or Bahasa Malaysia	Yes, in English	Yes, in English	Required. Both Chinese or English version are acceptable.	No requirement	ENG mandatory; VNM optional
	Informed consent	Requirements and language	MRCT: Yes (in Chinese) Import product: No	Yes, in English or Chinese	Yes- ENGLISH to be submitted to DCGI. ICF in local regional languages has to be submitted to Ethics committee for EC approval. (in a language that is non-technical and understandable by the study subject.)	Yes, (in Indonesian or English)	Yes (in Japanese)	Yes (in Korean)	Requirements as in 1. Malaysian Guideline for Good Clinical Practice, section 4.8 Informed Consent of Trial Subjects: 2. Malaysian Guideline for Application of CTIL and CTX, section 4.4.12 Informed consent form (Initial version only): The informed consent form (ICF) provided can be in either English or Bahasa Malaysia.	Yes, in English	Yes, in English	ICF checklist is required upon ICF amendment, and the comparison table is also required.	Yes, in Thai	Yes, in Vietnamese and English (both are mandatory)
	Investigator's CV	Requirements and language	No	CV of PI	Yes (in English)	Yes, (in Indonesian or English)	No	No	The GCP certificate and CV for investigator/ PI of each trial site should be provided. The GCP course should be recognised/ approved by National Committee for Clinical Research (NCCR), Ministry of Health Malaysia. The requirement is in accordance to the current version of Malaysian Guidelines for GCP. in English or Bahasa Malaysia	Yes, in English PI of abroad in case of global trial statement of PI	CV of PI, in English	Required for both PI and Co-I. Both Chinese or English version are acceptable.	No requirement	Yes, in Vietnamese or English

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IND/CTA application materials	Non-clinical summary	Requirements and language	Yes (in Chinese) Chemical drugs: Summary chart of non-clinical study information + overview of non-clinical study data	No	Yes (in English)	Yes, (in Indonesian or English)	No Non-clinical information is included in IB	Yes (in Korean)	Investigator's brochure in English or Bahasa Malaysia	Yes, in English	No	No separate document is required. Referred to IB.	including in IB	Not applicable (often included in IB) If provided, Vietnamese/English
	Non-clinical report	Requirements and language	Yes (in Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (English acceptable)	Investigator's brochure in English or Bahasa Malaysia	Yes, in English	No	No separate document is required. Referred to IB.	including in IB	Not applicable (often included in IB) If provided, Vietnamese/ English
	Clinical summary	Requirements and language	Yes (in Chinese) Chemical drugs: Summary chart of clinical study information + overview of clinical study data	No	Yes (in English)	Yes, (in Indonesian or English)	No Clinical information is included in IB	Yes (in Korean)	No	Yes, in English	No	No separate document is required. Referred to IB.	including in IB	NA If provided, Vietnamese/ English Clinical summary is often included in Protocol and IB.
	Clinical report	Requirements and language	Yes (in Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (English acceptable)	Published clinical data in English or Bahasa Malaysia	Yes, in English	No (for HSA, every 6 monthly, status report of the trial to be submitted; for IRB usually annually)	Not required.	including in IB	NA. it is often included in IB
	CMC summary	Requirements and language	Yes (in Chinese) Chemical drugs: Cat. 1: summary chart of CMC information for IND application Cat. 2 and Cat. 5.1: summary chart in CTD format of CMC information	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (in Korean)	Yes	Yes, in English	No	IMPD should be provided to TFDA once it updates. TFDA provided the checklist.	See detail in guideline (for NCE)	Yes (IMPD, CoA, SmPC, label…) English/Vietnam
	CMC report	Requirements and language	Yes (in Chinese)	No	Yes (in English)	Yes, (in Indonesian or English)	No	Yes (English acceptable)	Yes	Yes, in English	No	Not required.	See detail in guideline (for NCE)	Same as CMC summary
	GMP certificate of the investigational drug	Necessary or Unnecessary	For IND of IMCT, GMP certificate is not required. But a statement that investigational products are formulated in accordance with GMP should be submitted; For CTA of import drug , CPP with GMP statement is required; For CTA of domestic drug, hard copy of GMP certificate of manufacturing plant is required.	Yes	YES	Yes, (in Indonesian or English)	No	Necessary	Yes, necessary.	Yes, in English COA of investigational drug,	No (HSA application, to provide GMP certificate of the Drug Product site of Investigation drug, during CTC application)	GMP certificate of the investigational drug is NOT mandatory.	Necessary	Necessary
	Sample of the investigational drug (for IND review)	Requirements and language	For IND application (IMCT/Chemicals), sample of the investigational drug is not needed to provide. For CTA application, sample of the investigational drug is needed for QC test and specification review.	Yes, proposed label and COA also.	Samples of reference standards and finished product (equivalent of 50 clinical doses or more, if requested by the Authority), with testing Protocol/s, full impurity profile and release specifications. DCGI normaly asks the applicant to submit the samples of the drug product along with reference standard to the government laboratory (Central Drug Testing Laboratory or Indian Pharmacopoeial commission Laboratory). The Applicant needs to submit the samples in the quantity sufficient for three fold analysis.	Product Information of investigational drug, CoA of investigational drug, Summary Batch protocol (Three consecutive batch)→ only for Vaccine, Lot release only special for vaccine.	No	No	No, COA only.	Yes (Laboratory testing may be requested)	No	Not required.	No requirement	No. Minimal required is label mockup. Dossier still can be submitted without pictures.

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NDA	Acceptance of CTD format	CTD or ACTD or Others ?	According to "New Document Submission Requirements based on New Registration Classification of Chemical Drugs (No.80 of 2016)", full CTD + Chinese Module 1 + China unique requirements (such as SAP, SAR, DMP, DMR etc.) are acceptable.	Not specified. CTD can be accepted.	ICH-CTD is acceptable. However, it is not indicated in document issued by HA.	ACTD format.	CTD format.	CTD format is required for NCE (New Chemical Entity), IMD(Incrementally Modified Drug) and generic drugs requiring BE(Bioequivalence) test data.	All applications are made in ASEAN CTD format.	Application data for new drugs have to be handled by the ASEAN CTD format. There is flexibility on the use of ICH dossier as per FDA Adoption of ACTD.	ACTD or ICH-CTD	All new drug applications including generic application should be submitted in ICH CTD format after 1-July-2014.	Effective from 1 Jan 2016 (with 6 months grace period), the application for NCE and New Biologics/Vaccine for human use have to be in eCTD format. For other classification, the document has to be in ACTD. The ICH-CTD may be acceptable with mapping to ACTD.	ACTD and ICH-CTD format, or CTD for NCE For NCE: ACTD or ICH-CTD is accepted. For the rest: only ACTD is accepted.
	Category of NDA	ex. NCE, Generic, Supplemental,	New registration categories for chemical drugs are issued on Mar.04,2016. 1.Innovative drugs not marketed in and outside China. Drug substances and their preparations containing new compounds with definite structure and pharmacological actions and possessing clinical value. 2.Improved new drugs not marketed in and outside China 2.1 Drug substances and their preparations containing optical isomers with known active ingredients made through such methods as resolution or synthesis, or esterification of known active ingredients, or saltification of known active ingredients (including salts containing hydrogen bond or coordinate bond), or the alteration of the acid radicals, basic groups or metal elements, or the formation of other non-covalent bond derivatives (complex, chelate or clathrate) and possessing significant clinical advantages ii. Preparations of new dosage forms containing known active ingredients (including new administration systems), new formulation and manufacturing processes, new routes of administration and possessing significant clinical advantages. 2.2 Preparations of new dosage forms containing known active ingredients (including new administration systems), new formulation and manufacturing processes, new routes of administration and possessing significant clinical advantages. 2.3 New compound preparations containing known active ingredients and possessing significant clinical advantages. 2.4 Preparations of new indications containing known active ingredients 3.Drugs generic to original drugs marketed overseas yet not marketed in China 4.Drugs generic to original drugs marketed in China 5.Applications of drugs marketed overseas for marketing in China 5.1 Applications of original drugs marketed overseas (including drug substances and their preparations) for marketing in China 5.2 Applications of non-original drugs marketed overseas (including drug substances and their preparations) for marketing in China	Two categories: 1. New Chemical Entity (NCE); 2. Generic (i.e. drug substance already registered at Department of Health (DOH))	New Drug: 1) New Chemical Entity (NCE), 2) New indications, dosage, dosage form and route of administration 3) Fixed Dose Combination (FDC) (See 122E of the Drugs and Cosmetics Rule) Note: all vaccines and Recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority	A. New Registration consist of : a. Category 1: New Drug and Biological Product registration including Biosimilar Product. b. Category 2: copy drug / generic product. c. Category 3: Registration of other dosage form. B. Registration of drug variation, consist of : a. Category 4: Major variation registration (VaMa) b. Category 5 : Minor variation registration that needs an approval (VaMi-B) c Category 6.: Minor variation registration with notification (VaMa-A) C. Renewal a. Category 7: Renewal	Regulatory filing for ethical drugs is required in the CTD format. As for generic drugs this requirement will be as a basic rule, beginning on March 1, 2017. The new requirement will exclude biologics, radiopharmaceuticals, recombinant products, cell therapy products, specified biological products (such as blood products), and in-vitro diagnostics.	<Chemical> (1) New Drug 1) New chemical structure (NCE) 2) Combination drug including NCE (2) Data requiring drug (Drug for supplementary data submission) 1) Drug with new salt or isomer, etc. 2) Drug with a new indication 3) New dosage drug - Increase/Decrease amount of API - New combination drug 4) Drug with a new adminstration route 5) Drug with a new dosage and administration 6) Enzyme, yeast, microorganism derivated drug with new origins 7) Drug with a new formulation(same route of administration) <Biologics> (1) Drug containing new molecular entities 1) DNA recombinant durg and Cell culture drug 2) Biologics - Vaccine, antitoxins - Blood products - Biologics other than above (therapeutic antigens, botilinium products, ect). (2) Data requiring drug(Drug for supplementary data submission) 1) Biologics : strains and manufacturing methods are different from authorized biologics 2) Recombinant DNA products: hosts, vectors, or methods to obtain DNA is different from authorized biologics 3) Cell culture derived products: same cell line, but different cell culture or purification methods from authorized biologics 4) Cell culture derived product: cell line is different from authorized biologics 5) When final bulk is the same, but the site for manufacture is different 6) New dosage forms with the same route of administration 7) Biosimilar product(recombinat DNA) 8) Total plasma and component preparations 9) Others not separately classified	Drug Registration Guidance Document (DRGD) Section A, 1.2 Categories Of Product : 1) New Drug Products a) New Chemical Entity (NCE)/ Radiopharmaceutical Substance b) New Combination Product c) Supplemental Product 2) Biologics 3) Generics 4) Health Supplements 5) Natural Products	(1) Drugs containing new active ingredients (2) New ethical combination drugs (3) Drugs with a new administration route (4) Drugs with a new indication (5) New dosage form drugs (6) New dosage drugs (7) Follow-on biologics (8) Drugs supplied in an additional dosage form (9) Similar ethical combination drugs (10) Other drugs	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 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 strenths of the generic chemical product.	New Drug I : (1) New chemical entity (2) New indication (3) New combination (4) New administration route New Drug 2 (1) New dosage form (2) New usage dose (3) New unit dose	1) Chemical drugs 1.1) New Drugs (NCE, NI, NCO, ND, NR, NDOS, NS) 1.2) New Generic (NG) 1.3) Generic (G) 2) Biological Products *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. First time registration NDA (First time application) includes: NCE, line extension (new strength, new dosage form), generic 2. Re-registration 3. Renewal registration 4. Registration of change, supplementation

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NDA	Requirement of CPP	Timing of submission. ex. at NDA, before approval Number of required CPP. Source country. ex. Manufacturing/exporting country, Marketing country (FSC)	According to "New Document Submission Requirements based on New Registration Classification of Chemical Drugs (No.80 of 2016)", for new Cat. 1 and 2 import chemical drug, the oral informal consulting result is that CPP is not requested, but it's not recorded in a written form. for new Cat.5.1 CPP should be submitted at the submission of CTA and NDA. Both CPP granted by manufacturing country or marketing country are acceptable.	To be submitted at the time of application No. of CPP required: NCE: 2 ICH countries Generic: 1 (source country only)	CPP or Free sale certificate (FSC) issued by country of origin is required at NDA. The CPP and FSC should be notarised and apostilled or legalised by Indian embassy of the country of origin.	Copy CPP is submitted during pre-registration. The original CPP should be present at the submission of NDA. CPP only required for imported product. The product with one CPP will be evaluated within 300 working days. The product with three CPP + two Assessment Report from Other Health Authority (one CPP from manufacturing country , two CPPs from EU, US, AUS, UK) will be evaluated within 150 working days (See Annex 5)	Not required	Imported new drugs: CPP submission is mandatory (Issuance date of CPP should be less than 2 years based on the submission date) Others except imported new drugs: Exemption of CPP submission(if there is any GMP certificate issued by the MFDS) Drugs listed in the pharmacopeia of the US, Japan, UK, Germany, France, Italia and Canada: CPP can be replaced by specific documents both signed by a person in charge of drug manufacturer and authenticated by competent authority. Timing : Before approval Number : One original document or legalized (apostilled) copy Source : Manufacturing country/Marketing country (For the manufacturing country, the GMP certificate can replace the CPP.)	Category 1 & 2: CPP required at time of application; Category 3: CPP required at time of application but not required for locally produced generics; CPP from the competent authority in the country of origin; or GMP Certification/ Manufacturing License for the manufacturer from the relevant competent authority, together with CPP from the country of the product owner; or CPP from country of release, if CPP from the country of the product owner is not available)	Timing of submission is at NDA. Number of required CPP is 1 from Source country e.g. ex. Manufacturing/ exporting country, Marketing country (CPP or FSC/GMP) or any reference country	Submission of CPP is not compulsory and depends on type of submission. In case a bridge of NDA product, proof of approval by any drug regulatory agency is required.	CPP(s) are required before NDA approval. 2 CPPs from 10 advanced countries are required for NCE/BLA approval if no clinical studies in Taiwan. At the time of filing, NCE/BLA can be submitted without CPP. When approaching approval time, if Taiwan participates two global clinical trials (Ph1+Ph3 or Ph2+ Ph3) with designate numbers of Taiwan subjects enrolled, (Clinical development in Taiwan in earlier) then CPP can be waived. NCE/BLA can be approved with one CPP in one of 10 advanced countries but also need one clinical trial in Taiwan (Ph1 or Ph2 or Ph3) with designate number *of* Taiwan subjects enrolled into the study. 1 EMA CPP accounts for approvals in 5 advanced countries. Product has to be launched in source country or 10 advanced countries.	CPP is required at the timing of submission. 1 CPP from manufacturing country (with marketed status). The product detail has to be supplemented to the CPP i.e. manufacturing sites for all steps to be supplied for Thailand i.e. DP manufacturer, primary and secondary packager and batch releaser. The full composition is also needed to be presented on the CPP.	Provide upon submission 1 CPP from manufacturing or reference countries (ICH, Australia) for each dossier Switzerland is accepted as belongs to ICH
	Approval can be obtained by utilizing foreign clinical trial data.	Requirement of bridging data/report and global clinical trial data/report. Necessity of PK study in local population.	Global / MRCT clinical data for chemical drugs are acceptable, but Chinese P3 and PK data is indispensable. There are also Chinese samples size requirements at the same time. For biologicals, global / MRCT clinical data is acceptable. For imported pediatric drugs in clinical needs and already marketed in the United States, the European Union and neighboring regions of China, relevant clinical trial data completed overseas may be used for the drug registration applications in China.(from CFDA opinion on implementing priority review and approval to resolve the backlog of drug registration applications on Feb 26, 2016.)	The overseas clinical trial data is acceptable. Bridging data are not required.	Clinical data in Indian population is required except few life saving therapeutic categories which is at the discretion of the regulatory agency. However now a days, DCGI has become very strict and insists for local clinical trial data for every new drug.	Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guideline. Local regulatory trials is required for TB program and drug for family planning program /	The overseas clinical trial data is accepted in accordance with ICH E5. The drugs approved by using a bridging strategy or global clinical trial data have increased. But Japanese PK data is indispensable. Discussion of ICH E17 is ongoing.	Only for New Drugs, bridging data is needed additionally. (See figures at Annex 6)	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 regulatory trials are not required.	The overseas clinical trial data is accepted.	Overseas clinical trial data is acceptable	BSE is also mandatory for BLA such as gene-engineering drugs, vaccines, new molecular of plasma preparations and allergenic preparations NDA.	Not required	Global clinical trial data/report. Since the new Pharma Law takes effect (1 Jan 2017), Vietnam is drafting legislations guiding clinical trials requirements for registration, including criteria for local clinical trial exemption.

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NDA	Application fees	Fees necessary for applying for approval as for NME drug with full data (Category (1))	・Registration fee for category 1 and 2: NDA: 432,000 RMB (local drug) 593,900RMB (import drug) Registration fee for category 5: NDA: 502,000RMB (import drug) Authorities comment: Application fee gap between the import drug and local drag are due to the difference in the inspection cost.	Application fee: HKD 1100 License fee: HKD 1370 Renewal fee (every 5 years): HKD 575	Structure remains the same, but draft proposal to increase the same by 3 to 4 times has been proposed. Application fees: NDA: INR 50000 (include MAA fee) Import License: Rs 1000 and at the rate of Rs.100/- for additional drug. Registration Certificate (for import drug): 1500USD for one manufacturing site or its equivalent in Indian currency and 1000USD for one drug or its equivalent in Indian currency. An additional fee at the rate of one thousand US dollars for each additional drug. Duplicate Registration certificate: three hundred US dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost. Inspection Fee: The applicant shall be liable for the payment of a fee of five thousand US dollars for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority Test License:The fee of import licences for test and analysis of a drug has been kept Rs. 100 for a single drug and at the rate of Rs. 50/- for each additional drug	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: copy product 7.5 MIDR, copy product with BA/BE data: 12.5 MIDR Category 3 : other product: 7.5 MIDR Category 4: VaMa : 2 MIDR for each dosage form/packaging Category 5: VaMa-B : 2 MIDR for each dosage form/packaging. Category 6: VaMi-A : 1 MIDR for each dosage form/packaging. Category 7: renewal : 5 MIDR For pre-inspection GMP document: 7.5 MIDR. For GMP site inspection: three inspector three day = 90 MIDR	Application fees of drugs containing new active ingredients To Government : 533,800 yen To PMDA for review : 23,788,100 yen for paper-based compliance inspection : 6,747,000yen for GCP inspection : domestic 2,801,000 yen, overseas 3,098,000 yen +Travel expense for GMP inspection : domestic 760,900 yen, overseas 960,200 yen +Travel expense	Application fee was increased on 30th, November, 2016(Based on mail application. For electronic application, 10% discount) <STM review + S&E review + GMP review> (1) New drugs (including biologics): KRW 6,828,150 (2) Orphan drugs : KRW 3,755,850(Fee can be discounted to KRW 1,877,920 when clinical study report is attached after conducting clinical trial according to the Pharmaceutical Affairs Act) (3) Others: KRW 2,218,650 * There can be discount when review is excluded Cf. Generics(BE, CMC, GMP review included) : KRW 1,707,300 For GMP/GCP inspection(around 7,500,000KRW/person (overseas)) : This one is the travel expense for inspectors, so if GMP inspection would be waived, no more fee is needed.	Fees are required and details are given in the DRGD Appendix 1: Fees. These are according to product categories, number of active ingredients, types of applications etc.	NCE: 900 USD Initial Registration: 340 USD (1USD= 45 PhP) * above rates are current; however these may change pending implementation of proposed new revised fees.	Registering a product – NDA & GDA a) Screening (Payable upon submission) (i)Abridged/Verification Dossier (NDA & GDA) $550 (ii) Full Dossier (NDA)* $2,750 b) Evaluation (Payable upon acceptance) (i) NDA Abridged Dossier (Chemical Drugs & Biologics) -NDA-1 & NDA-2 $11,000 - NDA-3 $5,500 (ii) NDA Verification Dossier (Chemical Drugs & Biologics) - NDA-1 & NDA-2 $16,500 - NDA-3 $5,500 (iii) NDA Full Dossier* $82,500 (iv) GDA Abridged Dossier - GDA-1 $3,850 - GDA-2 $2,200 (v) GDA Verification Dossier - GDA-1 $10,000 - GDA-2 $5,000 (vi) GDA Verification Dossier (CECA Scheme) - GDA-1 $10,000 - GDA-2 $5,000	NDA: Application fees (the charge fee is amended on May 13, 2015, "Fee-Charging Standards for the Registration of Western Medicines and Medical Devices") 1. Product registration of a new drug which is of new active pharmaceutical ingredient(s), including new biological drugs / genetical engineering drugs: NT800,000. 2. Product registration of a new drug which is of new combination or new administration route: NT300,000. 3. Product registration of a new drug which is of a new dosage form, new strength with new indication, new dose unit, or controlled release dosage form, new strength of the same therapeutic compound(s) and the same administration route: NT150,000. GMP Inspections for Western Medicines: 1. GMP Inspections for domestic pharmaceutical manufacturers which is new establishment, relocation, expansion, resumption of operations, or addition of a new active pharmaceutical ingredient, dosage form, process operation, medicinal product: NT120,000; Additional fee of NT20,000 will be charged whenever there is an additional dosage form, biological drug, or active pharmaceutical ingredient. 2. GMP Inspections for foreign pharmaceutical manufacturers 1. Review of a Plant Master File (PMF) of an foreign pharmaceutical manufacturer: NT120,000; Additional fee of NT20,000 will be charged whenever there is an additional dosage form, biological drug, or active pharmaceutical ingredient. New foreign manufacturing site overseas on-site inspection: NT700,000 or above.	As per current Drug Act, only 2,000 Thai Baht is paid for approved product registration license. However, Thai FDA with support from the government are under working to implement the fee for application and technical evaluation fee, expecting to be effective in 1Q-2Q 2017.	NDA: 250 USD
	Other requirements		It's mandatory to follow 3submissions-3approvals regulation in drug applications using IMCT data .		Application for Import License is required after marketing approval and Registration Certificate	Specific country requirement on product labeling on product package, example: generic name, retail price, symbol of prescription drug, the name of importer. Site Master File is requested for non registered oversea factories at submission. Inspection may be conducted against overseas factories if necessary		For the NDA of a New Drug, i) Safety & Efficacy ii) Quality (including Specification and Test Method) iii) GMP iv) DMF reiviws are mandatory For new drugs and orphan drugs, Risk Management Plan is mandatory		Reference Standard Sample (at least 300 mg) subject to FDA advise	For GDA, the reference product must be the registered product with Singapore HSA	N/A		Sample, Plant master file, Labeling, Package Insert, COA for Drug Substance and Drug Product, Trademark… Registration certificate for trademark in Vietnam is required if there is ® symbol on labeling

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NDA application materials	CMC summary	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes, in English	Yes (in Indonesian or English as in part II Quality)	Yes (in Japanese in s M2 in CTD)	Yes (M2 in CTD, Korean)	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	Yes,ACTD Part II in English	Yes (in English)	Yes (In English as M2 in CTD) For the new drug application, TFDA requires to include the API information in detail. API DMF is required.	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 3 batches from API manufacturer and DP manufacturer) and Excipients (at least 1 batch from Excipients' manufacturer and DP manufacturer).	QOS of DS, DP Vietnamese or English
	CMC report/body of data	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes (English is acceptable as M3 in CTD)	Yes (in Indonesian or English as in part II Quality)	Yes (English is acceptable as M3 in CTD)	Yes (M3 in CTD, English is acceptable, but spec.and test methods for DP and DS with non-pharmacopeial spec. should be prepared in Korean in Application package.)	Yes - in full (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) For the new drug application, TFDA requires to include the API information in detail.	In addition to ACTD on Quality Part II (or ICH CTD Module 3), the Certificate of Analysis for Finished product (3 batches), API (for 3 batches from API manufacturer and DP manufacturer) and Excipients (at least 1 batch from Excipients manufacturers and DP manufacturer).	Vietnamese or English - 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).
	Non-clinical summary	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes, in English	Yes (in Indonesian or English as in part III Non Clinical Data)	Yes (in Japanese as M2 in CTD)	Yes (M2 in CTD, Korean)	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)	ACTD on Non-Clinic Part III or ICH CTD Module 2	Vietnamese or English 1. Non-clinical written summary 2. Non-clinical tabulated summaries
	Non-clinical report	Requirements and language	Yes (Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	for NCE only (document in English)	Yes (English is acceptable as M4 in CTD)	Yes (in Indonesian or English as in part III Non Clinical Data)	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)	ACTD on Non-Clinic Part III or ICH CTD Module 4	Vietnamese or English 1. Pharmacology 1.1 Primary Pharmacodynamics 1.2 Secondary Pharmacodynamics 1.3 Safety Pharmacology 1.4 Pharmacodynamic 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	Requirements and language	Yes (Chinese)	for NCE only (document in English)	Yes, in English	Yes (in Indonesian or English as in part IV Clinical Data)	Yes (in Japanese as M2 in CTD)	Yes (M2 in CTD, Korean)	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)	ACTD on Clinic Part IV or ICH CTD Module 2	Vietnamese or English 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 2. Summary of clinical pharmacology study 3. Summary of clinical efficacy 4. Summary of clinical safety 5. Synopses of Individual Studies
	Clinical report	Requirements and language	Yes (Chinese) Usually synopsis or abstract of each report in Chinese is required, attached with source report.	for NCE 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	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)	ACTD on Clinic Part IV or ICH CTD Module 5	Vietnamese or English 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 Pharmacodynamic (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	Requirements and language	Application form Summary part of application dossiers: (1) Name of the drug (2) Certified Documents, including CPP etc. (3) Objectives and basis for development (4) Self-evaluation report (5) Information about the holder of the drug marketing approval (6) Information about the reference listed drug (7) packaging insert and its reasons, and latest references (8) artwork and labeling	Needs to be in English. General requirement for product registration: 1. Authorization letter from manufacturer – to authorize HKOP register, import and market the product 2. Manufacturer license – original 3. CPP- original 4. Information on the manufacturing facilities and practices of the manufacturer & GMP Certificate which meets PIC/S GMP standards 5. Registration sample – color photos/scanned image to show the product and sales pack/container appearance. 6. Proposed sales pack – color prototype 7. Proposed pack insert - prototype - The following document(s) to support the proposed indication(s), dosage, route of administration and other contents of the package insert (if any): a. a copy of reputable reference b. documentary evidence showing that the package insert has been approved by one of the listed countries 8. Master formula (Batch formula not accepted) - Non-proprietary names of ingredients, colour Index number or E-number for all colourants used should be provided 9. Finished product specifications 10. Method of analysis 11. COA of a representative batch 12. Stability data 13. Bioequivalence data for anti-epileptic 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. 14. Safety documents for ingredients with animal origins Additional requirements for NCE registration 1. 2 ICH country approvals 2. expert evaluation reports on the safety, efficacy and quality of the product. CV of experts who draft the report. 3. EU-RMP and/or US-REMS, if applicable. Information on whether any risk management plan activities and mitigation strategies will be implemented in HK. 4. clinical and scientific documentation substantiating the safety and efficacy of the product.	AS described in Schedule Y of the Drugs and Cosmetics Rules 1945 1.1 Comprehensive table of contents (Modules 1 to 5) 1.2 Administrative information 1.2.1 Application in Form 44 and Treasury Challan (fee) 1.2.2 Legal and statutory documents 1.2.3 Coordinates related to the application 1.2.4 General information on drug product 1.2.5 Summary protocol of batch production and control 1.2.6 List of countries where MA or import permission for the said drug product is pending and the date of pendency. 1.2.7 List of countries where the drug product has been licensed and summary of approval conditions. 1.2.8 List of countries where the drug product is patented 1.2.9 Domestic price of the drug followed in the countries of origin in INR 1.2.10 A brief profile of the manufacturer's research activity 1.2.11 A brief profile of the manufacturer's business activity in domestic as well as global market. 1.2.12 Information about the expert(s)/ Information regarding involvement of experts, if any 1.2.13 Environmental risk assessment 1.2.14 Samples of drug product	See regulation No.HK.03.1.23.10.11.08481from BPOM regarding the Criteria and Procedure of Drug Registration	CTD Part I (Module 1) in Japanese 1.1 Table of Contents 1.2 Approval application (copy) 1.3 Various certificates 1.4 Information on patent matters 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 the same 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 poisonous 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 Signature of the person in charge of preparation of CTD, His/Her information(career) 1.4 Certificate of translator 1.5 Information on the use of the applied drug in foreign countries 1.6 Information on comparison with other similar products available in the Korean market and properties of the applied drug 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 A contract(In case any process during manufacturing, QC test would be outsourced) 1.9 LTOC 1.10 Package insert(draft) 1.11 Other data	In English or Bahasa Malaysia: ACTD Part I :Administrative Data And 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	The following documents as ACTD part I (FDA Circular 2013-019) Sec.A Introduction Sec.B Table of Contents Sec.C Administration data and Product Information 1 Application Form 2 LOA 3. Certificates For import product, a. License of pharmaceutical industry b.CPP c. SMF 4. Labeling 5. Product information 5.1 Package Insert 5.2 SmPC 5.3 PIL	Module 1 (or ACTD Part Ⅰ) documents e.g, Letter of authorizations Declaration Artwork of packaging material GMP certificate Patent declaration Reference country/product approval and approved package insert, if applicable	CTD Module 1 (Taiwan Specific) CTD format was announced in July 2012 and became mandatory for NCE products since Nov. 01, 2012. New Drugs other than NCE, as well as generic products also need to be submitted in CTD format starting from July 01, 2014. 1 Administrative Information and Prescribing Information 1.1 Table of Contents of the Submission Including Module 1 1.2 Application Fee Receipt 1.3 Official Letter and Document 1.4 Application Form (original copy and duplicate copy) 1.5 Affidavit 1.6 Form for Sticking Label and Package Insert TFDA requires to include the material and name of excipient in Prescribing Information. 1.7 Certificate/License 1.8 Letter of Authorization 1.9 CPP of Source Country 1.10 Formulation Basis 1.11 Certificate of PIC/S GMP/cGMP 1.12 CPP 1.13 Bridging Study Evaluation 1.14 Status of Clinical Study Taiwan involved 1.15 Status of Bioavailability (BA)/ Bioequivalence (BE) Study Taiwan involved TFDA partially updated the Guidance of Bioavailability (BA) and Bioequivalence (BE) Test on March 6th, 2015. 1.16 Contract Manufacturing 1.17 Applications of Contract Analysis 1.18 Radiation Dosage Study Report 1.19 Risk Evaluation and Mitigation Strategy (REMS) 1.20 Other Documents or Reports	e-Submission for NCE and new biologics / Vaccine for human use.	CoPP, GMP, Label mockup, Manufacturing profile(a brief format of Plant Master File, following DAV template) Vietnamese or English

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NDA Approval review	Review organization	Review organization, Decision organization, Advice committee	Review CDE (Center for Drug Evaluation) Decision CFDA (China Food & Drug Administration) Inspection Regional Drug Administration / Center for Food and Drug Inspection of CFDA	Review: Drug Office, DOH Approval: Pharmacy and Poisons Board	CDCSO/DCGI (Drug Control General of India) Twelve New Drug Advisory Committees (NDAC) were newly constituted to examine the applications for permissions for clinical trials and approvals for new drugs.	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. National Committee on Drug Evaluation with the task of discussing formulating, giving consideration and decision of the results of drug evaluation through a periodic forum meeting. 3. Committee of Quality Evaluation with the task of evaluating the quality aspect. 4. 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, Labour and Welfare) Advice CDFS (Council on Drug and Food Sanitation)	MFDS and NiFDS(National Institute of Food and Drug Safety Evaluation) Advice : Central Pharmaceutical Affairs Council	National Pharmaceutical Regulatory Agency (NPRA): Receive and review applications; NPRA's Review Committee will finalise and propose it to the Drug Control Authority (DCA) for approval/rejection. DCA: decide on registrations & licenses, and new/revised regulatory requirements	Philippines FDA Department of Health Food and Drug Administration	HSA (Panel of internal and external reviewers.)	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.	Thai FDA	Review organization: Drug Administration of Vietnam (under the Ministry of Health); expert from Institutions national wide. Decision organization, Advice committee: Drug Committee with members include Ministry of Health, KOLs from Universities and Institutions.
		Number of reviewers ex. Clinical, Non-clinical, CMC, Chemical/Biological	<As of Aug 2016> All staffs : 284+101 Traditional Chinese drug : 14 CMC : 56 Biologics : 21 Non-clinical : 27 Clinical : 41 Biostatistics and clinical pharmacology : 11 Clerical work : 107 Temporary from local FDAs:101 <As of Oct 2016> All staffs: 455 <2020 personnel plan> CDE : 1600 in total	Undisclosed	CDSCO total manpower 327 (as of 2009). No detailed information.		All staffs : 862 Review Dept. : 554 Safety Dept. : 140 (As of Sep. 1, 2016) Pharmacology : 384 Medical doctors and Dentists : 42 Engineering : 44 Veterinarian and Toxicity : 25 Biostatistics : 13 Science and agriculture, etc. : 63 Clerical work : 101 (As of April 1, 2012)	MFDS Chemical Administration - Drug policy: 28 - Drug management: 16 GMP: 21 Clinical Trial Management: 17 Narcotics: 16 Bio Administration(Bio policy): 18 Bio GMP: 15 Traditional medicine: 9 Patent Management: 8 Safety Evaluation: 16 NiFDS Drug Review Management: 37 Pharmaceutical Standardization: 15 Cardiovascular and Neurology products: 15 Oncology and Antimicrobial products: 13 Gastroenterology and Metabolism products: 12 Bioequivalence Evaludation: 20 Biologics: 21 Recombinant Products: 11 Cell & Gene Therapy: 13 Herbal medicines: 10 and Regional KFDAs	Total NPRA staff: ~500 Centre for Product Registration: ~120	All staffs : 400 FDA employees		Division of Medicinal Products under TFDA, which is responsible for all drug products, has around 100 active staff including administrative, drug safety and regulation build-up. Among the manpower, about 40-50 staff belongs to new drug, generic drug and clinical trial reviewing force.	See Attached sheet-Number of reviewers (Annex 7) i.e. 2 external reviewers for each section of Clinical, Non-clinical and CMC.	5 Groups, with 3 experts/reviewers in each Group (Administration, quality control, pharmaceutical, pharmacology, clinical)

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NDA Approval review	Review process	Append the flow of the review of applications for new drug with the attached paper.	CFDA accepts the NDA application documents and transfer these documents to CDE in 30 work days, then CDE reviews and evaluates it in 150 working days after the application enter reviewing plan ,finally, CFDA approves it in 30 work days. CDE review process for IND/NDA is attached for reference. From 2014, CFDA started requesting additional clinical trial waiver application for import drugs after completion of MRCT and before NDA.	Undisclosed	DCGI accept the application in Form 44 and then it is forwarded to NDAC for expert review.	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 → Approvable Letter → submit data Commercial Product (copy importation/other data, CoA, Mock up product, sample) → evaluation → Approved Registration Number See Annex 8 Note : * Only NCE/Biological Product 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 Annex 9	See figures at Annex 10	See Annex 11 (Re DRGD 8. FLOW OF REGISTRATION PROCESS)	Please see Flowchart_PSD _ revised_Aug 2007 Submit to Center for Drug Regulation and Reseach (CDRR)	(See Annex 12)	New NDA milestones were announced on 26-Oct and for NDA submit to TFDA after 1-Jan-2017 will be applied for new review process with Refuse-to-file (RTF) mechanism after 60 days from filing and only one-time comments from TFDA. Annex 20	Review process, see public manual of each NDA Annex 13	1. Upon receiving dossier submission, Drug Administration of Vietnam (under Ministry of Health) will review and conclude 2. Drug Committee to review. Different parts will be independently evaluated by different experts. 3. Official announcement by Ministry of Health
	Review time	The standard period of time from acceptance of applications to the approval of new drugs.	Official timeline of CTA / NDA of import drug from submission to approval: 145 working days. Based on RDPAC timeline survey results in 2016, IDL-NDA approval time was prolonged due to the clinical trial data inspection and the benchmark was not recommended. After publication of the Opinions of the State Council（Aug 2015 No. 44 ）, review speed is rapidly up, especially for CTA applications with registration category 3.1 and BE application for generic drugs. In addition, CFDA issued the formal opinion on implementing priority review and approval to resolve the backlog of drug registration applications on Feb26, 2016. Within the application scope, the new drug NDA can benefit to speed up review.	NCE: 7-10 months Generic: 9-12 months	About 12-15 months for marketing approval and registration certificate. About 3 months for Import License.	Timeline of pre-registration 40 working days after completed documents for category 1,2,3,4,5.Timeline of registration 100 working days after completed documents for : a. New Drug & Biological Product that are indicated for the treatment of serious life-threatening human disease , or classify as Orphan drug, or classify for public health program, or new drug which development by Pharmaceutical industry / research institution in Indonesia b. New registration of generic essential copy drug. c. New registration of copy drug with standard electronically information (Stinel). d.Major variation . Timeline of registration 150 working days after completed documents for a New Drug , Biological Product , major variation with : 3 (three) CPP from countries with known good evaluation, system or approved in the country that has applied harmonized evaluation system (EU , EPAR, EMEA). b. New Registration of Copy Product without Stinel. Time line of registration of 300 working days after completed documents:1 CPP from original country. Timeline Renewal product without variation : 10 working days Timeline Export Product : 7 working days (See Annex 14, Annex 15)	Review time of FY 2015 (60 percentile for Priority review, 70 percentile for Standard review) Priority review products : 8.7 months Standard review products : 11.3 months	Practically around 12 months are needed for NDA	See DRGD Section 8.4.4 Timeline For Product Registration Eg: NCE/NBE: 245 Working days; Generics: 210 working days, etc	Review time of FY 2012 (Median) Priority review products : 9 months Standard review products : 15 months New lead time: 18 months	Reference to GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE NOVEMBER 2016 – TARGET PROCESSING TIMELINES. APPENDIX 5 TARGET PROCESSING TIMELINES Screening: 25 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Verification: 60 working days	NCE NDA & BLA standard review: 360 days Priority review: 240 days Streamlined review: 180 days For the non-NCE NDA with efficacy & safety clinical data, the review timeline in TFDA/CDE will extend from 200 days to 300 days. Attached with new milestone figure.	The committed approval timeline is announced as per Licensing Facilitation Act B.E. 2558 which is effective from 21 Jul 2015. Timeframe for approval, New Drug (NCE) - 280 working days New Biological products – 320 working days Vaccine - 350 working days Generic and New Generic - 155 working days.	24-30 months

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NDA NDA Approval review	Priority review system	Presence of priority review system, Content of system, Subject drug for priority review ex. unmet medical needs, for serious life-threatening disease	Special review procedure exists, which is appropriate for following applications of new drugs: 1) Active ingredients extracted from plants, animals or minerals, etc. and their preparations not yet marketed in China, and newly discovered Chinese crude drugs and their preparations; 2) Chemical drug substance and their preparations and biological products not yet approved for marketing in China or abroad; 3) New drugs for the treatment of diseases such as AIDS, malignant tumors and rare diseases, etc. with significant clinical advantages; and 4) New drugs for the treatment of diseases, for which effective therapeutic method is not available. For those drugs specified in items 1) & 2), the applicant of drug registration (hereinafter “the Applicant”) may apply for the special examination and approval when submitting the application for clinical trials of the new drugs. For those drugs specified in items 3) & 4), the Applicant may apply for the special examination and approval only when submitting the production applications. Priority review and approval procedure is issued on Feb.26,2016. Scope of priority review and approval 1. Drug with significant clinical value satisfying following conditions: 1).Innovative medicines not yet launched in domestic and overseas market 2).Innovative new drugs with manufacturing site transferred to China 3).Drugs with advanced formulation technologies, or innovative therapies, or sufficient clinical advantage 4). Clinical trial application for drugs whose originator patent will be expired within 3 years; marketing application for drugs whose originator patent will be expired within 1 year. 5). New drug CTA that applicant simultaneously filed the same application and got permitted to conduct clinical trial in EU or US; New drug NDA manufactured the product in China, which is undergoing simultaneous filing in EU or US and passed GMP/GCP inspection by EMA/FDA (products manufactured with same production line) 6).Traditional Chinese Medicine with clear clinical therapeutic purpose in prevention and treatment for major diseases. 7).New drug listed in the National Major Science and Technology Projects and National Key R&D Plan 2.For below diseases prevention and treatment and can show significant clinical advantage 1)AIDS; 2)TB;3)Hepatitis;4)Rare disease;5)Malignant tumor;6)Pediatric drug;7)Diseases with high incidence or unique in elderly people 3.thers 1). Post approval manufacturing process change of a generic drug with the aim to meet generic drug quality consistency compared with reference products 2).For ANDAs which had been listed in CFDA GCP self-inspection Notice (CFDA notice No. 117 in 2015), if the applicant withdraw the application and then complete research to show quality and efficacy consistency compared with reference product, the later ANDA submission will be eligible for priority review. 3).Urgent unmet medical needs and drugs in shortage. The List should be provided by NHFPC and Ministry of Industry and Information Technology. The list should also be reviewed by CDE and related agencies/ experts invited by CDE. The priority review and approval is applicable for both IND,CTA and NDA applications. The purpose of this document is to resolve the application backlog issue.	usually no; except official request from Hospital Authority upon urgent situation	There is no formal priority review system. Depends on therapeutic area and unmet requirement.	There is no priority system. The review following the timeline of registration (100 or 150 or 300 working days)	The priority review system exists. Orphan drugs receive priority review automatically. New drugs not designated as orphan drugs which target other serious diseases and which are apparently expected to contribute to the improvement of quality of healthcare may be designated as "non-orphan priority review products" based on overall evaluation of the seriousness of the target disease and medical usefulness of the drugs. Designation is made based on the opinions of external experts if an application is submitted with an application for marketing approval.	The priority review system exists in regulation but a specific guidance is under preparation. 1) Drugs which target for life-threatening or serious diseases such as AIDS, cancers etc. 2) Drugs of which is deemed necessary because treatment is not possible with existing therapies due to resistance or other reasons 3) Other drugs such as anti-cancer agents, orphan drug, DNA chip etc : recognized by MFDS minister for patients or industrial development 4) Orphan drugs for unmet medical needs	There is no formal priority review system in place. Priority review status will be provided on case to case basis, based on the applicant's justification. Timeline for Priority Review: 6-9 months	The priority review system exists. For serious diseases and life-threatening conditions and which are apparently expected to contribute to the improvement of quality of healthcare based on overall evaluation of the seriousness of the target disease and medical usefulness of the drugs. Consideration is made based on the opinions of external experts if an application is submitted with an application for marketing approval. Please refer to FDA Circular on Facilitation of Evaluation.	No separate priority review system or pathway. Only if product is 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.	Priority review designation should be applied and get approval before NDA submission. If your NDA would like to apply as PR process s, granted TFDA agreement before NDA is mandatory. Streamlined review process: For the product which approval by two of three regions from USFDA, EMA and MHLW/PMDA, assessment reports should be provided, and BSE should be waived upon NDA submission.	Priority Review: for product in need e.g. anti-HIV, anti-cancer or product in need as per endorsed from Thai FDA. Abridged Evaluation: effective from 1 Oct 2015 by referring to the approval & evaluation from one of the reference agencies i.e. US FDA, EMA (Centralized system), MHRA, Swiss Medic, TGA, Health Canada, PMDA. The full assessment report including all response to LoQ are required for Thai FDA consideration whether the application can be reviewed under this route.	The Drug Administration of Vietnam and the Department of Medical Device and Construction (as regards in-vitro diagnostic biologicals) will consider priority review for: a. Drugs for special treatments specified in the list of orphan drugs issued by the Ministry of Health; b. Drugs for treatments in emergencies, natural disasters, epidemics; c. Local drugs manufactured on modern GMP production lines, within no more than 18 months as from the date of issuing the GMP certificate. d) Vaccines pre-qualified by the WHO. The abovementioned authorities will consider issuing registration numbers or release written replies before the standard timeline, based on the request of the relevant applicants.

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	Orphan drug system	Presence of orphan drug system, Criteria for designation, Incentive, etc.	No orphan drug designation system.	No	The orphan drug system does not exists.	Drugs for rare disease will be evaluated within 100 working days. No regulation establishing.	The orphan drug system exists. Designation criteria Number of patients Less than 50,000 in Japan Medical need There are no appropriate alternative drugs or treatment methods. The efficacy and safety are expected to be outstandingly greater than those of existing drugs. Possibility of development There is a theoretical ground for using the drug for the target desease and the development plan is acceptable. Incentives (1) Subsidy payment(The total budget for financial year 2010 was 650 million yen.) (2) Guidance and consultation on research and development activities (HMLW, PMDA, NIBIO). PMDA provides a priority consultation system. (3) Preferential tax treatment (4) Priority review (5) Extension of re-examination period The re-examination period for the drugs will be extended up to 10 years.	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 - Products which do not meet the criteria above can be designated as an orphan drug if it is acknowledged that the limited supply of product would cause any serious harm to the concerned population or the MFDS minister recognizes it. Also there is a developed phase orphan drug in Korea.	Details given in DRGD 5.1.4 Registration Of Orphan Product. For all categories of products namely new chemical entities/new drugs, biologics and generics (including Non-Scheduled Poison product): i. Application for registration that being submitted to National Pharmaceutical Regulatory Agency (NPRA) will only be accepted/ considered after the products have been designated as orphan products. ii. Application for registration must be submitted via online system and with appropriate processing fee. iii. Upon receipt of complete application, the application will be processed within ninety (90) working days.	The orphan drug system does not exists but we have a DOH A.O. 4 s. 1992 for Compassionate Special Permit for life-saving drugs. This is the closest that we can get in as far guidelines for orphan drugs are concerned.	For a product with a proposed indication that has been designated as an Orphan Drug by at least one reference drug regulatory agency or a product that has been approved by at least one reference drug regulatory agency via an accelerated/fast-track approval, approval under exceptional circumstances or equivalent approval process, the applicant should consult HSA on the eligibility of such a product through the verification route prior to its submission	2015.9.23 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 there is an orphan drug regulation in Thailand but the intention of this regulation is for the drug in need for rare & serious disease, low usage with no alternatives and face a problem of shortage nationwide. The drug has to be proposed by prescriber's association and be considered for enlisting in the list considered by Thai FDA Subcommittee. The regulatory requirement for generic drug is applied for orphan drug registration.	Yes. According to new Pharma Law (effective 1 Jan 2017), the Ministry of Health will issue criteria and list of orphan drugs. This will be in the form of a Circular, being drafted by the MOH and expected to be issued in the next few months.
NDA Approval review	approval matters	You may append the approval matters with the attached paper.	Approval number ・Marketing License Holder and its address ・Manufacturer and its address ・Non-proprietary Name ・Brand name in Chinese if applicable ・Active ingredients and Contents or Nature ・Dosage form ・Dosage strength ・Packaging size ・Shelf life ・Specification & test methods ・labeling and artwork ・packaging insert		・Generic Name ・Brand name ・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	Before Marketing Authorization , applicant receive Approvable Letter. In the Approvable Letter, it mentions some data to be submit (PI & packaging for commercial production, copy importation for import product only, if necessary NFADC will do on site inspection for local product before issued Marketing Authorization. The Duration between Approvable letter and Marketing Authorization Letter is two years. NAFDC will evaluate the data(with timeline 20 workdays) as requested before issued Marketing Authorization. The Marketing Holder will attached with Registration Form, Approved Package Insert, Approved Patient Information Leaflet	・Non-proprietary Name ・Brand name ・Ingredents 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/Accredetation Category, etc.	・Non-proprietary Name ・Brand name ・Ingredents and composition ・Appearance ・Manufacturing process ・Dosage and Administration ・Indications , Precautions for use ・Storage Conditions and Shelf-life ・Specifications and Test Methods ・Name and address of Manufacturing Site for DP and DS ・Proudct category: License/Accredetation, New Drug/ Orphan drug, etc., Therapeutic area, etc. ・Approval condition, if applicable.	Upon registration of a product by the Authority, the product registration holder shall be notified by the Authority and a product registration number (i.e. MAL number) shall be assigned to the registered product via the system. . Registration status of a product shall be valid for five (5) years or such period as specified in the Authority database (Re DRGD 8.5 Regulatory Outcome)					
	Other information concerning approval review			N/A		NCE should provide API Drug Master File or Internal Monograph as required in Part II Quality of Drug Substance or CEP of API with attachment & GMP Certificate of API's manufacturer . Approval of SMF should also be considered to get approval of registration number.			As stipulated under the CDCR 1984, Regulation 11(1), the Authority may, at any time reject, as well as cancel or suspend the registration of any product if there are deficiencies in safety, quality or efficacy of the product or failure to comply with conditions of registration.			Biosimilar registration guidance with monograph was updated in 12-Jun-2015.		

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NDA Pre-approval inspection	GCP inspection		CFDA has conducted the inspection of drug clinical trial data for all NDA/sNDA submitted for manufacturing or import. If not pass the CFDA inspection of drug clinical trial data, the product will not be approved for marketing by CFDA.	Not required	DCGI 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 'GUIDANCE ON CLINICAL TRIAL INSPECTION' in Nov. 2010.	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 to 2 or 4 medical institutions and applicants.	GCP on-site inspection to sites, company and CROs according to MFDS's plan (Pre-approval inspection for pivotal studies in Korea, Regular inspection).	The Guideline for GCP Inspection is intended to provide comprehensive information on National Pharmaceutical Regulatory Agency (NPRA) inspection programme and covers inspections at the clinical trial sites, clinical laboratories, computer systems, sponsors and/or contract research organisations (CRO), bioequivalence studies and independent ethics committee/ institutional review boards. This guideline is also intended to serve as a guide to the sponsors/CROs, local investigators and others on NPRA inspection procedures. Requirements as given in GUIDELINES FOR GOOD CLINICAL PRACTICE (GCP) INSPECTION	The GCP on-site inspection is executed by FDA to medical institutions and applicants. Frequency not clear.	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)Medicines (Clinical Trials) Regulations (iii)SG-GCP, adapted from ICH E6 on GCP (iv)SOPs for conducting clinical trials	The GCP on-site inspection is executed by TFDA around 4-6 weeks after CSR submitted to TFDA in selected medical institutions (depends on the number of involved site)	No requirement	N/A. Applicable for local clinical trials only. When local clinical trial is conducted, GCP inspection is carried out.
	GMP inspection	ex. On-site inspection, Document inspection, CPP/GMP certificate from source country accepted	GMP overseas inspections are conducted for some import drugs selected by CFDA during the CDE technical review of drug registration application or after IDL approval.	Document inspection only, CPP/GMP certificate from source country accepted	GMP inspection of Indian mfg. units will be arranged before granting the manufacturing license and periodic review of the mfg. unit The Licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority of India may inspect the manufacturing premises of mfg. units outside India on need basis	For imported product : Based on evaluation of Site Master File, if necessary GMP inspection site will be request by NAFDC. GMP Inspection Report from PIC/S country will be evaluate and can be consider for Waive on Inspection	Since the amendment of the Pharmaceutical Law (PAL) in April 2005, GMP compliance inspections have become a requirement that must be met for marketing approval. Application for GMP compliance inspections for all manufacturing sites listed in the applications for marketing approval must be submitted to the GMP compliance inspection authority (PMDA or prefectures) by each manufacturing site	GMP inspection can be done for manufacturing sites of drug product and drug substance. Basically MFDS conduct on-site inspection (from 2009). For chemical products, some waiver period for on-site inspection would be allowed (5 years for non-sterile products, 3 year for sterile products). Even in case of on-site inspection waiver, GMP documents should be submitted.	On-site inspection required unless exempted. (NOTE: NPRA will perform GMP Inspections on facilities in non-PIC/S countries. This is effective for New Registrations from 1 July 2016, and for Existing Products upon renewal starting 1 January 2017. Inspection exemption for renewals of sites in non-PIC/s countries may be granted if supported by GMP certification from the listed reference and/or PIC/S countries.)	Since 1989, GMP compliance inspections have become a requirement that must be met for marketing approval. For foreign manufacturer, CPP and GMP certificate is being required	Documentary evidence must be provided to certify that the manufacturer(s) complies with current applicable GMP standards. Applicants must submit a GMP certificate issued by a drug regulatory agency for all drug product manufacturing sites including, but not limited to, bulk product manufacturers, primary packagers and secondary packagers. 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	Foreign manufacturer has to be registered before NDA approval. The registration can be done by either PMF (paper review) or on-site inspection under PIC/S GMP standard. If multiple manufacturing sites are involved in different manufacturing process of the product (e.g., semi-product, bulk un-labeled, final packaging...), each of the sites has to be registered.	The on-site GMP inspection of new overseas manufacturer may be required if needed at the process of GMP Accreditation.	N/A. GMP certificate from source country accepted
	Other inspections	ex. GLP requirement and evaluation	Since from Jul 22, 2015, all NDA applications should complete clinical trial data inspection before completing comprehensive evaluation in CDE before transiting to CFDA for final approval.	Not required	N/A	In the GMP inspection site , the Laboratory is inspected by NAFDC . The Laboratory inspected following GLP requirements.	"Paper-based compliance inspections" is executed by PMDA to confirm whether data attached to NDA applications accurately reflect the results of clinical trials and other studies, and whether those are made in accordance with GCP, GLP and reliability standards.	Laboratory should get the GLP certification and GLP inspection will be conducted by MFDS	NPRA also conducts other inspections including for GLP, GCP, GDP, BE centres.	Paper-based compliance inspections is executed by FDA to confirm whether good distribution practice is being implemented.	Non-clinical studies providing toxicology information to support clinical trials should be conducted in compliance with GLP.	GDP will be implemented after 2019, thus TFDA asks to submit GDP applications allocating the submission schedule like: 1st tier: Distributors by 31-Jul- 2016 2nd tier: MAH with cold-chain products by 31-Aug- 2016 3rd tier: MAH with control drugs by 30-Sep-2016. 4th tier: Other MAHs should submit by 31-Dec-2017.	No requirement for GLP inspection	N/A

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Clinical trials	Necessary procedures to start clinical trials	The actual procedures to start clinical trials, for example, IND/CTA => import of investigational drugs => IRB etc.,	IND/CTA => import of investigational drugs and IRB (EC) review => Clinical Trial Management Committee review and approval of Office for Human Genetic Resource Administration (OHGRA) => start of clinical trial. clinical trial should be started within 3 years after obtaining CTA. (Additional approval process by clinical research management committee (CRMC) after IND approval was announced (国卫医发 (2014) No.80)) Actually clinical trial management committee is not established in many clinical sites. Ministry of Technology and Science intends to raise the legal position of HGR regulation. All clinical trials with the involvement of foreign investment are required the submission and approval of HGR.	a. IRB approval b. if study medication is required to be imported, then Application of clinical trial certificate (CTC) at Drug Office, Department of Health is required	Clinical trial on new drug shall be initiated after authorization by CDSCO and approval of respective EC. In case of parallel applications, CDCSO will grant conditional approval and note that the trial should start after Ethics approval. Trials should also be registered with CTRI (Indian Registry) before screening patients	After receiving Clinical Trial Approval Letter from NAFDC, the Clinical Study can be started.	Notice of claimed investigational new drug exemption to PMDA. Contracts with clinical sites should be signed after 30 days from the clinical trial notification (14 days from the second trial onwards).	Regulatory approval: Obtain IND Approval and IRB approval in parallel. IND approval will be taken 30 days, however it will take about 2-3 months normally including additional data submission Import approval: After above regulatory approval, obtain import approval on clinical study supply, if necessary, in order to initiate the clinical trials.	Application to The Research Review Committee (RRC) & The Medical Research Ethics Committee (MREC) required. Also, application to the National Pharmaceutical Regulatory Agency (NPRA) for clinical trial import license (CTIL) is necessary. Parallel submission is possible. (Re: Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption Edition 6.1)	Clinical Trial Protocol approval is required. Please see FDA Circular 2012-007 (flowchart).	Reference to: Guidance on Determination of Whether a Clinical Trial Requires a Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC), 1 Nov 2016 Guidance on Regulatory Requirements for New Applications and Subsequent Submissions, 1 Nov 2016	IND approval by TFDA＋ Import permit of IMP → IND approval by IRB (IND in TFDA and IRB can be parallel) → CTA approval by medical institution → Payment pay to medical institution completely →Site initiation visit. Since final ICF is approved by TFDA, it is needed to submit ICF approved by IRB.(Notification:1011410615)	Submission to EC and FDA can be done in parallel 1. We have to submit the EC approval letter within 15 days after the approval letter of last site is available 2. When we submit the EC approval letter, if there is any change to documents we submit earlier (i.e. submit SIIC v.1 in IL package but EC approval shows SIIC v.2), we need to submit the revised documents (SIIC v.2) together with EC approval letter. 3. We can start the trial when we receive both EC approval and IL. 4. IL will be valid for 4 years from the date of TFDA's signature on NYM. If product importation period is more than 4 years, we need to apply for new IL but can refer to document in previous package.	Clinical trial should be submitted to Site level first. After receiving IRB/Ethics Committee approval at site level, we can continue submission to health authority (HA). Import License (IL) is only obtained after having HA approval. The CT can be initiated after getting HA approval.
	Necessary data/ documents/ brochures to start clinical trials	Necessary Tox data for initiation of clinical trials (specify local requirement other than ICH-M3 or S6)	Protocol & IB. Usually TOX data aren't required for initiation of clinical trial because all data have been reviewed by authorities. Because site/IRB always follows CTA.	Please refer to the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test)	List of necessary Tox data is shown in APPENDIX III of Schedule Y, the Drug and Cosmetics Rules 1945.	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).	Generally necessary data and or documents are followed ICH requirement. Sometimes additional reproductive toxicity tastings are requested before clinical trials.	In May 2011, it was amended and inserted into the Enforcement Regulation of Pharmaceutical Affairs Act and, in March 2013, it was transferred to Regulation on Safety of Pharmaceutical Drugs Etc: Korean Good Clinical Practice (KGCP) of Medicinal Products, Specifications for Clinical Trial Control of Pharmaceutical Drugs	Application to The Research Review Committee (RRC) & The Medical Research Ethics Committee (MREC) required. Also, application to the National Pharmaceutical Regulatory Agency (NPRA) for clinical trial import license (CTIL) is necessary. Parallel submission is possible. (Re: Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption Edition 6.1)	Generally follow ASEAN requirement. Please see FDA Circular 2012-007	The sponsor should submit the supporting documents (listed in Table 2) to HSA for CTA, CTN and CTC applications. (See Annex 16)	Investigator brochure is required for clinical trial approval.	ICH E6	IB submission is required.

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Clinical trials	Necessary data/ documents/ brochures to start clinical trials	Are there any necessary documents/ brochures outside IND/CTA dossier	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.	Please refer to the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test)	As per Schedule Y Registration of clinical trial is mandatory in the ICMR Clinical Trial Registry prior to initiation of the trial.	Informed Consent to the patient	Explanatory materials and consent form used for obtaining informed consent	Sample CRF(Case Report Form) GMP warranty letter or certificate, Insurance certificate	Submission of Investigator Brochure is required.	Documents needed to get patients' consent. Please see FDA Circular 2012-007. Patient informed consent form is already part of the CTA dossier. Suggest answer should be: clinical trial agreements/contracts	Original declaration document of the principal investigator and sponsor has to be submitted	No extra document requires outside IND/CTA dossier. Only for biosample needs to send out to oversea, the statement from central lab is needed.	Material Transfer Agreement	- Informed Consent - IRB approval - Agreement template - PI CV -IMP related documents - Insurance
		Document Language (acceptability of English document)	In Chinese.	preferably English and patients consent form in English and Chinese/Chinese only	English ICF: neccecary to translated into local language on site	Indonesian or English	In principal all documents have to be described in Japanese	Protocol and consent form should be translated into Korean. However English IB is acceptable to MFDS. Also phase I except FIH can be submitted in English	Re: Malaysian Guideline for Application of CTIL & CTX Edition 6.1:- 4.6.2 Language: Application form must be filled in English or Bahasa Melayu. All data must be in English or Bahasa Melayu and must be legible. In cases where supportive documents is not originally in English or Bahasa Melayu, a copy of the document in its original language, accompanied by authenticated translation in English or Bahasa Melayu shall be submitted. The ICF has to be in English, Bahasa Malaysia, Mandarin and Tamil (where required).	English For study documents to be used by healthcare professionals - English. For patient materials - English, plus any language applicable to the locale, eg Cebuano, Hiligaynon, HAS	English	Protocol synopsis should be in Chinese.	Thai and/or English	Vietnamese
	Requirement of domestic clinical data for NDA application, if there is foreign data	Necessary or Not-necessary -Necessity in PK / healthy sbj. -Necessity in patient data	Usually Chinese patient's data including DB study and PK study are needed, which indicates similarity in drug response (i.e. efficacy and safety) with foreign data.	Not necessary	Necessary waiver for clinical trial in Indian population for approval of new drugs, which have already approed outside India can be considered only in cases of national emergency, extreme urgency, and epidemic and for orphan drugs for rare diseases and drugs indicated for conditions/diseases for which there is no therapy (Office order dated 03.07.2014)	Generally, Indonesian patient's data requested which indicates similarity in drug response (i.e. Efficacy and safety) with foreign data for drug which used for family planning programme and other drugs based on request from Authorized body , for example public health programme for TB , etc	In principal PK in healthy Japanese sbj and P2b data in Japanese patients are requested.	Foreign data is acceptable. But bridging data in Korean should be generated.	Not necessary	Local clinical trial is optional; PSUR submission will be required as part of Post-Marketing Surveillance. Comment: For NDA, there is no requirement in the Philippines,	Not necessary	NCE has to submit Bridging Study Evaluation package before or simultaneously with NDA. If BSE successfully waived and at least 2 of 10R countries has approved (2 CPP), foreign data package can be accepted and no need to perform domestic study. If a bridging study is required, local PK or clinical data is required.	Not-necessary	Not necessary for certain cases. Regulation on criteria for domestic/local clinical trials requirements being drafted by Ministry of Health, expected to be issued in the next few months.
	Acceptance of foreign clinical data for NDA	Is there any conditional requirements, for example similarity in PK/PD?	No, just for reference. (Even if the similarity in PK/PD is indicated we can't rely only on foreign data to China NDA)	Yes (for NCE products) Not required for generic products	Foreign Clinical data can be a supportive document, however Indian data (PhaseIII) is must.	Acceptable if the clinical data following GCP and the result based on evaluation of safety and efficacy is good.	Acceptable if the similarity in PK/PD is indicated.	Acceptable; in case of similarity on S&E or PK/PD.	Yes	Acceptable if the similarity in PK/PD is indicated.	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. Regulation on conditional requirements and criteria for domestic/local clinical trials requirements being drafted by Ministry of Health, expected to be issued in the next few months.

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Clinical trials	Required number (or rate) of local subjects in pivotal clinical studies for NDA approval	Please explain for both local and multinational clinical trials, if necessary. *ex.* totally around 100 *ex.* 1/5 of all subjects in multi-national studies	At least 20-30 for Ph-1, 100 for Ph-2, 300 for Ph-3 in treatment group for local trial (for category 1 of chemical drug). For registration purpose, 100 pairs of Chinese patients in pivotal studies is requested whatever local studies or MRCT. Meanwhile, it is requested to show similarity in drug response and safety profile between Chinese and foreign patients in MRCT. China MRCT guideline was published by CFDA on Jan 30 and effective on Mar 1, 2015	Not specified	P-I: 1-2 centers. At least 2 patients. P-II: 3-4 centers. At least 10-12 patients at each dose level. P-III: a. The drug already approved/marketed in other countries: at least 100 patients distributed over 3-4 centres. b. The drug is a new drug substance discovered in India and not marketed in any other country: at least 500 patients distributed over 10-15 centres. (According to draft guideline on Clinical trials and New Drug Approval 2011 - 2012) However Now a days DCGI asks for 200 patients or more for Phase III studies for the drug approved/marketed in other countries depending on the prevalence of disease and therapeutics area. (According to draft guideline on Biosimilars : Annex 17) There is a provision to consider 100 patients for Phase III and 200 patients for Phase IV trials or a combination of 300 patients for both Phase III + Phase IV trials combined.	Local clinical trial is needed for new drugs for family planning programme, TB drugs, and others drug based on request from Authorized body.	It is requested to show the consistency in drug response between Japanese and foreign patients in multi-regional clinical trials. For this purpose, at least 15-20% of all subjects is hopefully to be Japanese.	No definite requirement. For both local and multinational clinical trials, statistically meaningful number of subject is needed.	N/A	There is no required number of local subjects in clinical trials for NDA approval. For PMS studies, it is suggested (but not required) that there should be 3,000 subjects. Comment: PhIV/PMS is still required but number of patients will be set by the type of the drug and the disease set by FDA (FDA Circular 2013-003)	N/A. But in the HSA CTC application, applicant has to declare expected number of subjects to be enrolled from each site.	it is request 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 situation. 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: total sample size ≧200 then Taiwan No.≧30 or 5%, total sample size ＜ 200 thenTaiwan No.≧10.	Not-necessary	N/A Given the current legislative developments in Vietnam (new Pharma Law takes effect from 1st Jan 2017, guiding legislations are being drafted and not yet issued), old regulations such as Circular 03/2012/TT-BYT will continue to take effect as long as it does not contradict with the new Pharma Law.
	Practicable number of clinical centers or sites in the country	# of sites with facility of clinical trials Is there any license system for clinical study site?	Involved clinical center or site should get a license of CFDA. More than 300 sites/hospitals are qualified by CFDA. -Every qualified site need to be re-qualified every 3 years.	Practicable no. of clinical study sites not specified; No license system for clinical study sites; however, the clinical study sites are usually university or government hospitals.	More than 1000 sites	It around 50 clinical centre .	Clinical trial can be initiated in many study sites. No license system for clinical study sites.	Certified sites by MFDS: 171 sites(Nov. 2014)	The CRC has a network comprising of 33 centres in MoH hospitals, collaborations with 5 Private hospitals' and affiliations with 3 University hospitals, plus access to 120 other MoH hospitals.	Clinical trial can be initiated in many study sites. Protocols should be evaluated by IRB/EC. Comment: A clinical study site should have an ethics committee that is accredited or is ongoing accreditation procedures by PHREB.	There are 13 public hospitals and 16 private hospitals which can conduct clinical trials.	Need to be confirmed https://www.cims.tw/ch/taiwan_irbs	17 officially recognized sites (IRB/EC site) No (Beware of USFDA blacklist)	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.
	IRB system for clinical trials	Installation of IRB/EC in sites Is there National IRB?	NHFPC issued "Ethics Review Method of Human-Involved Biomedical Study" on Oct 21, 2016 and will take into effect from Dec.1, 2016. National Ethnic Committee, provincial and above the country level ethnic committee will be established.	Yes. An IRB for each cluster of hospitals	Independent Ethical Committee (IEC) & Institutional Ethics Committee No National IRB	There are National IRB system.	Institutional IRB.	There is not the national IRB but the Institutional IRB	Institutional and national IRB (MREC) available depending on sites. There are 13 IRBs/IECs in Malaysia registered with the NPRA. These include the Ministry of Health Medical Research and Ethics Committee (MOH MREC), the Penang Ethics Committee and ethics committees from universities and private hospitals. Clinical trials conducted at these sites have to be approved by the respective IRB/IEC.	Institutional IRB/Ethic Committee. The general guidelines on CT may be referenced from the "National ethical Guidelines for Health Research 2011 edition. Another reference is FDA Circular 2012-007 that recognize ERB/ERC for purposes of conducting CT of Investigational Medicinal Products and it also validates the agreement between the FDA and PNHRS or Philippine National Health Research System which includes the establishment of a clinical trial registry. Comment: Sites with its own EC should be accredited by PHREB or are currently undergoing accreditation process this year. For sites that do not have its own EC, the institutional ethics review board of UP-PGH can oversee and perform EC duties for that site.	Singapore has 2 clusters of public hospitals. 1 cluster is under NHG DSRB (National Healthcare Group Domain-Specific Review Board) and the other cluster is under SingHealth CIRB (Centralised Institutional Review Board). For private hospitals, they have their own IRB/EC	C-IRB is composed of 33 hospital IRBs. Some other sites may also take fast track for c-IRB approved trials. J-IRB covers 78 hospitals. (this information is collected from C-IRB website) NRPB-IRB is composed of 20 hospital IRBs. Every medical center has its own IRB. There is different requirement between different IRB.	Available Yes, National IRB or Central IRB.	Yes. There are EC at both Site and health authority level

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Clinical trials	Prevalence of GCP in clinical centers		GCP is observed in all clinical sites.	Yes	Yes. GCP is observed in all clinical sites.	GCP is observed in all clinical studies	GCP is observed in all clinical sites.	GCP is observed in all clinical sites. Same as Japan	GCP is observed in all clinical studies. (Local recognized GCP certificate is compulsory for all investigators.)	Yes, GCP is observed in all clinical sites. ICH Guidelines, GCP E6 Comment: Mandatory for the Investigators and the site staff who are directly involved in the ccnduct of the clinical trial.	GCP is observed in all clinical studies	GCP implementation in all clinical trials is mandatory since 1997.	A must	Yes
	Investigators	ex. about 50 physicians have been trained in US/EC	Uncountable number of physicians in China.	Yes	Large pool of trained Investigators in diverse therapy areas	Investigator must have GCP training before the trial and understand the protocol comprehensively in order to conduct the trial in accordance to GCP. No requirement investigator have been trained in US/EC	Uncountable number of physicians in Japan	Uncountable	The CRC has access to more than 550 clinical investigators.	Uncountable number of physicians. In addition to CVs, IRBs require that investigators undergo GCP training and this should be renewed or refreshed every 2 years.	No info	TFDA regulated necessary training hours needed for GCP and ethical then qualified to conduct clinical trial. No actual number of investigator to get GCP training.	No information (Beware of USFDA blacklist)	N/A
	Investigational drug	Condition of customs procedure	Tax and custom clearance. If imported investigational drugs to be used, CTA is necessary for Customs procedures and clearance.	Application of Import License based on the approved CTC	Permission to import of investigational product shall be obtained by applying for a test license. The application should be made in Form 12.	Sponsor request to import unregistered product was to NAFDC. Approval letter for Importation from NAFDC is used for release product in the customs.		After the IND approval. Import permit should be gotten from Korea Pharmaceutical Traders Association in advance.	Clinical trial import license and proper clearance required.	Yes	Reference to Guidance on Clinical Research Materials, 1 Nov 2016	It needs to get import permit that issue from TFDA, then 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	Application of Import License based on the approved CTC
		Investigational drug labeling (requirements and language)	Chinese label is needed. According to China GCP (2003 version), "only used for clinical trial" should be indicated in the label of investigational drug. In China IMCT guideline, the following information should be included in the label of investigational drug: 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.	IP name; Strength, dosage, storage condition; manufacturer - English or English and Chinese	• "For Clinical Studies only" • Name or a code number of the study • Name and contact numbers of the investigator • Name of the institution • Subject's identification code	In Indonesia language for clinical trial in Indonesia. In Clinical trial Multicenter / country English language is acceptable.	Japanese label is needed	1. "For clinical trial only" 2. The name of investigational drugs or identification marking (in case of blind design, both study drug and comparator should be indicated in the IP label), if necessary, formulation, administration route, quantity, assay of active ingredient or potency can be included in the label. 3. The lot number or code number 4. Name, address and telephone number of business/person who received the IND approval 5. The expiry period 6. The storage condition 7. "Keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects. 8. Reference code(clinical trial can be identified) 9. Subject identification number, treatment number, visit number	Refer to CTIL guideline. English acceptable.	Yes, in English Comment: Import license is required for each shipment of Investigational Drug. The government body responsible for issuing this is the Phil FDA,	Reference to Guidance on Labelling of Therapeutic Products and Medicinal Products Used in Clinical Trials, I Nov 2016. PIs see page 11. (See Annex 18)	Label has to be prepard in traditional Chinese under PIC/S GMP regulation.	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.	Required in Vietnamese. "For clinical trial only".

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Clinical trials	Availability of multi-national CRO	*ex*. local branch, many local CROs	Multi-national CRO is available in China, such as Quintiles, ICON, Covance, ICN, PPD, PRA, RPS etc	Yes (domestic and multi-national companies)	Multi-national CROs like Quintiles, Parexel, PPD, ICON etc are available	Multi-national CRO is available in Indonesian	Multi-regional CRO is available in Japan	There are many multi-national CROs branch. Many local CROs.	8 International CROs And 4 locally incorporated CROs	Multi-national CRO is available in Philippines	Available	Multi-national CRO is available in Taiwan	There are many international CRO in Thailand.	Yes
	Adverse reaction reporting during clinical trial	*ex*. SAE: report to Authority within 7 days etc.,	SAE: it is requested to report to the relevant authority in 24 hours after knowing the event.	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	NewGazette GSR889(E) was published on 12 Dec. 2014. The rules of free medical management and financial compensation on 122DAB(30 Jan 2013) was ammended. Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the Sponsor to Chairman of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority as defined under rule 21(b) under Appendix XII with a copy of the report to the Licensing Athority and the head of the Institution where the trial has been conducted within 14 calendar days of occurrence of the serious adverse event. While current provisions require payment of compensation in cases of injury or death of a subject occurring in a clinical trial due to the failure of an investigational product to provide the intended therapeutic effect, the notification changed this clause with adding supplementary item. It is effective from 12 Jun. 2015.	Investigator should report all serious unexpected adverse event to sponsor /CRO as soon as possible after known it, if there are some next adverse event, report a.s.a.p. until end of event. Sponsor should report all serious adverse event in Clinical Trial include death to Head of NAFDC and Ethics Committee within 15 days start from known the event , if there is next event, report it a.s.a.p until end of event.	Case of death by unknown adverse event have to be reported to PMDA within 7 days. Case of death by known adverse event and unknown serious adverse event have to be reported within 15 days.	• Death or life-threatening SUSARs: within 7 days from the moment that the sponsor recognizes (the detail information should be additionally reported within 8 days from the first report) • Other SUSARs: within 15 days from the moment that the sponsor recognizes it	Death or possibly leading to death SAEs within 7 days, other SAEs within 15 days in CIOMS-I Form. Pls refer to Malaysian Guideline for Safety Reporting of Investigational Products for more details.	SAE: report to Authority within 3-7 days. Please see FDA Circular 2012-007 (p.9-10) Comment: As per A.O. 2014-0034	Fatal or life-threatening unexpected ADRs: within 7 calendar days. All other serious unexpected ADRs: within 15 calendar days. (See Guidance for Industry: Safety Reporting Requirments for Clinical Drug Trials)	SUSAR: report to Authority within 7 days for death and life threatening case, within 15 days for other cause. It is same as international rule.	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) To site IRB/EC: Death or life-threatening within 7 days , other SAE within 15 days (FERCIT)	- For all SAEs: Principle investigators are responsible to expedite report to Sponsor and Site Ethic Committee within 24 hours upon awareness. Based on SAE type, the reporting to Ethical evaluation Board of MOH and related organizations as below: a) For death or life-threatening SAE: principle investigators cooperate with Sponsor to complete and send report to Ethical evaluation Board of MOH. Initial reports in writing must be submit as soon as possible but no later than 7 calendar days when having SAE information. The content of initial report followed Report Form (Appendix 1) but no need to have all information at reporting time. Follow-up report must have all information of Report Form (Appendix 1) and forward within 15 calendar days when having SAE information. *b)* For other SAE which do not result in death or life-threatening: principle investigators cooperate with Sponsor to complete and send SAE report (Appendix 1) to Ethical evaluation Board of MOH as soon as possible but no later than 15 calendar days when having SAE information.
	GCP site inspection		-GCP inspection There are 30-50 cases per year of Triggered Inspection conducted by CFDA or PFDA which are triggered by complaints/requests from CDE/CFDA. Annual inspection plan-based Routine Inspection conducted by PFDA is also available. -Clinical trial data inspection Since Jul.22, 2015, CFDA conducted clinical trial data inspection for each NDA to improve the clinical trial quality in China. Only pass the inspection, drug can be approved for marketing. The criteria for inspection is not GCP but the key points for clinical trial data inspection (No.228) issued by CFDA.	Accreditated to the sites by separate parties	Yes.	NAFDC will do GCP site inspection during clinical trial	After NDA, PMDA inspects the applicant and 2-4 medical institutions based on GCP.	Yes	Yes		Will be conducted by the HSA Clinical Trial Branch, on locally conducted clinical trials.	TFDA is planning to conduct overseas GCP inspection for CSRs submitted for Taiwan NDA registration. Details pending discussion between authority and industry.	Yes	Yes GCP inspection is limited to domestic clinical site only.

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Manu -facturing	Acceptance test for Import drug	How the specifications & test methods for acceptance test of import drugs are set in your country?	QC test for 3 batches should be conducted by NIFDC. Specification and test methods should be approved by CFDA at the stage of NDA.	Based on the approved particulars.	Specifications and test methods are to be set according to registered specifications. Official in pharmacopoeia or in-house specifications with validation data are available.	Specification and test methods are following Indonesian Pharmacopoeia, 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 to be set according to registered specifications.	To be tested according to approved specifications & test methods	There is no need to have acceptance test in Taiwan except for vaccine and plasma produced products. TFDA will provide certification seal after TFDA acceptance test.	Both compendial and non-compendial method are acceptable	Yes. Request sample in first time dossier of NDA. Review based on reference Pharmacopoeia and Vietnamese Pharmacopoeia.
	Pharmacopeia	What is standard pharmacopeia? What is other accepted pharmacopeia? ex. USP/NF, JP, EP	All import drugs and domestic drugs should follow Ch.P2015.	BP, USP, EP and JP. In-house specification for NCE would be accepted by DOH.	If a DP/DS is official in the Indian Pharmacopoeia(IP) than must conform to IP if not official in IP than BP/USP/EU Pharmacopoeia standards are to be followed	Standard Pharmacopoeia : Indonesian Pharmacopeia Other accepted Pharmacopoeia : USP/NF, BP, EP, JP	JP (Japanese Pharmacopeia)	Standard : KP Accepted : JP, Ph. Eur(EP), USP(NF), BP, Deutshces Arzneibuch, Pharmaacipee Francaise	The main pharmacopieal references are BP and USP. Others are JP and EP	JP, USP/NF, EP, BP, PP (Philippine Pharmacopoeia)	Pharmacopoeias accepted by HSA are Ph. Eur., USP, BP, and JP	USP/NF, EP, JP, and Ch.P. are all acceptable.	USP 34, NF 29 and supplements, BP 2011 volume 1-5 and Addenda, the fourth edition of IP and supplements, Thai-pharmacopoeia II volume I part 1 and supplements, the seventh edition of EP and supplements plus updated revision	Standard: Vietnam Pharmacopoiea Reference (USP/NF, JP, EP, BP, USP, Ph.Eur)
	GMP system	What is current GMP requirements? ex. PIC/S	Chinese GMP 2010 version(MOH order 79)	PIC/S has been adopted for local manufacturer and overseas manufacturer.	Indian GMP as outlined in Schedule M of DRUGS AND COSMETICS RULES, 1945 Then, these regulations and guidelines (Schedule M) were revised in order to be based on WHO-GMP in 2003.	PIC/S GMP requirements	Japan has been a member of PIC/S GMP since July in 2014.	As South Korea joined to PIC/S membership in July, 2014, MFDS has been prepared a provision to harmonise the Korea Good Manufacturing Practice (KGMP) of Pharmaceutical Drugs with PIC/s guidelines and issued, MFDS Notification No. 2015-35 in June, 2015. The validation of GMP certificate is for 3 years from the completion of GMP inspection.	The current PIC/S Guide to GMP for Medicinal Products and its Annexes have been adopted as the standard used by NPRA to assess the GMP conformity of manufacturers.	Philippine applied for membership in the PICS (June 2009) --> PFDA has offically adopted the PICs Guidelines for GMP of medicinal products as per AO 2012-0008	PIC/S GMP requirements	Taiwan is one of the PIC/s member countries since Jan 2013. Sourcing country drug substance GMP certificates (original and legalized by Taiwan Embassy) are required in the application of NDA and drug substance post-approval changes (including drug substance license or drug product license), and license renewal. The detail requirements of the qualification of sourcing country GMP certificates, please refer to TFDA website. (http://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=9897&chk=666e6379-8ed5-4983-9c21-553c03d00144&param=pn%3d1%26sid%3d301#.WBFY1k3_rIX) Q&A section (http://www.fda.gov.tw/TC/siteContent.aspx?sid=4601#.WBFYqC197IU)	Thai FDA is PIC/s country member effective from 1 Aug 2016.	Current regulation (Circular) on GMP requirements being drafted following the new Pharma Law (effective 1 Jan 2017). Previous regulation: a) Local manufacturer must have the certificate of eligibility for drug trading and "Good Manufacturing Practice" certificate (abbreviated as GMP) according to the schedule of the applicable GMP by Ministry of Health or the certificate of eligibility for drug trading in case the manufacturer must validate the production conditions when being granted the certificate of eligibility for drug trading. b) The foreign drug manufacturers must have the criteria "Good Manufacturing Practice" - GMP equivalent or higher principles and standards "Good Manufacturing Practice" as recommended by the World Health Organization international (WHO-GMP). In case of the certification "Good Manufacturing Practice - GMP" or certificate of pharmaceutical products - CPP doesn't not specify that the manufacturer got GMP-WHO certificate, the applicant must provide the evidence to prove the principle, GMP standard that manufacturer got not less than GMP-WHO standard. For in vitro diagnostic biologicals, manufacturer must get GMP standard or ISO standard or other equivalent certificate. In case of doubt about the condition of production or drug quality, Drug Administration or the Department of Medical device and Construction (for in vitro diagnostic biologicals) will conduct audits manufacturing facility before or after granting the registration number.

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Manu -facturing	GMP system	Please describe GMP evaluation process by the authorities. ex. GMP clearance/ accreditation required before NDA ex. On-site or document inspection ex. Acceptability of GMP certificate from original country	1)For local drugs, GMP compliance is pre-requisite to obtain a Product Marketing Approval in China (see "NDA" - GMP inspection). GMP inspection to licensed manufacturer is carried out every five years by on-site inspection. An application for GMP renewal should be submitted 6 months before GMP expiration. 2)For import drugs, GMP on-site inspection started recently. Some selected drugs were inspected at foreign site after license approval.	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, 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.	GMP inspection will be arranged before granting the manufacturing license and periodically The Licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority of India may inspect the manufacturing premises of mfg units outside India on need basis.	The manufacturer which is first time register export product to Indonesia should provide SITE MASTER FILE (SMF) for GMP evaluation. After evaluation of SMF, the NADFC will approve to continue registration process of NDA or request site inspection. Before inspection, the manufacturer should provide Pre-inspection document for preparation of the site inspection . After inspection, the NADFC 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	GMP compliance is pre-requisite for obtaining a Product Marketing Approval in Japan (see Pre-approval inspection, GMP). GMP inspection to licensed manufacturer is carried out every five years either by on-site or document inspection.	Pre-approval GMP review: 1) documents (Minimum requirements) -based 2) Site inspection. In case MFDS visits the same site within 5 years for another products and submitting PIC/S country's inspection report (contents should be detail enough to fulfill MFDS requirement), on-site inspection could be waived. (In case of sterile product (DS & DP), waiter within 3 years. In case of biologics, exemption period is maximum 2 years.) Even though MFDS does not visit the site, documents for GMP review should be submitted. 3) Supplementary request after site inspection	NPRA is a PIC/S member and follows the PIC/S Guide to Good Manufacturing Practice for Medicinal Products. PRH must provide acceptable evidence to show that the manufacturer of the product follows an internationally accepted standard of Good Manufacturing Practice (GMP) and recognized by the Authority in Malaysia. NPRA will perform GMP Inspections on facilities in non-PIC/S countries, unless exempted.	GMP compliance (or better yet GMP Clearance) is a pre-requisite for the site registration of the manufacturing site and source into the License to Operate, which then is a requirement in obtaining a Product Marketing Approval in Philippines. Current evaluation for foreign sites is based on documentation review but the FDA may require on-site inspection depending on results of documentation review. GMP inspection of licensed local manufacturer is conducted by local FDA every 2 years, GMP recognition system of overseas manufacturing sites was introduced as per AO 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, May 2016	PMF registration: For manufacturing plants located in PIC/s member countries, it can be applied either by documents review or by on-site inspection. For manufacturing plant located in non-PIC/s member countries, it can be applied by on-site inspection. GMP follow-up: It will be taken every 2-4 years depending on the TFDA risk management assessments. Applicants can apply GMP follow-up by document review or on-site inspection (sometime TFDA will proactively request on-site inspection around 1 year before the periodic follow-up). Sourcing country GMP certificates are mandatory documents for PMF registration. PMF registration and NDA are individual applications and their reviews / approvals are in parallel. (PMF approval letters can be supplemented before NDA approval)	GMP Accreditation is required for new overseas manufacturer.	Current regulation (Circular) on GMP requirements being drafted following the new Pharma Law (effective 1 Jan 2017). Acceptance of GMP certificate from original country.
		Please describe frequency/number of on-site inspections to domestic/overseas manufacturers by the authorities. ex. number of inspections conducted in last year	The overseas manufactures for 34 products of some foreign companies were inspected by CFDI in 2015. 28 products were inspected in 2014. (http://www.cfdi.org.cn/ccdweb/view?oid=menunews&ntyp=D01) The list of products to be conducted overseas GMP on-site inspections by CFDA in 2016 is issued and includes 49 import drugs. (http://www.cfdi.org.cn/ccdweb/main?fid=open&fun=show_news&nid=7210)	Since the manufacture license valids for only 1 year, inspection will be made at least on annual basis for local manufacturers	Annually. For overseas, CDSCO started inspection of Pharmaceutical firms for import registration of drugs. Six on-site inspections in 2011 for DS manufacturing site in China, and four China drug manufacturing sites in 2012.	Every month there are on site inspection to domestic and overseas manufacturers by the Authorities. Almost Asia countries are inspected.	Number of on-site GMP inspection to overseas manufacturer in FY 2014 was 74. About 70% are in Asia. On-site inspection to Japanese domestic manufacturer by PMDA in FY 2012 was 132.	Number of on-site inspection to overseas manufacturers in 2011 was 90. Domestic manufactures in 2011 : 232 by MFDS (90 by other authorities, e.g. FDA, EMA)	The number of GMP Inspections conducted in 2014 was 360. Of these, the number of inspections on pharmaceutical premises was 68.	No details as of this moment. For overseas manufacturing sites, please note that FDA Phils may require conduct of on-site inspection where GMP certificate submitted was issued by a non-PICs member Regulatory Authority.		Overseas inspection in 2016: 31. No domestic data publication available.	- Domestic: Non-sterile drug: every 3 years Sterile drug: every 1.5 year - Overseas: if needed FDA's plan on inspection: (Note: The FDA is working on the update of this regulation, but not come out yet at time of report) • Routine Inspections ~ 60-70 plants/year • Special inspection in special case • And there will be Follow up Inspection which they are setting on criteria (may be from Risk Assessment).	N/A Current regulation (Circular) on GMP requirements being drafted following the new Pharma Law (effective 1 Jan 2017).

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Manu -facturing	DMF system	Please describe DMF system (or plan for introduction). Is DMF mandatory or optional?	"Bundling Review and Approval of Pharmaceutical Packaging Materials, Pharmaceutical Excipients and Drugs" was issued by CFDA in Aug 2016. But it isn't DMF system. It is applicable to pharmaceutical packaging materials and pharmaceutical excipients developed, manufactured, imported and used within China. Pharmaceutical packaging materials and pharmaceutical excipients used for imported drugs is not in the scope.	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.	The submission of MF (Master File) is optional. Drug substance, Intermediate, New excipients, Packaging materials etc. are subjects of MF.	NCE and API for generics should be submitted DMF since 2002. But all APIs should be registered by 2015, but not completed yet. (Every year, MFDS announced the list of APIs which should be registered.) Only drug substance(API) is subject of DMF. API for newly registered sterile injection should be submitted DMF since 2017.	A DMF is required for API registration, and may be replaced by a CEP or full details of Part II S ACTD. API registration is being implemented in phases.	With the adoption of the ASEAN CTD, maintenance of DMF is mandatory based on requirements stipulated on the ASEAN Variations Guideline.	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. Appendix 11 describes the DMF process and documentary requirements for DMF submission	DMF is only applied to chemical drug substance and their drug products. Drug substance DMF is mandatory for NDA approval. DMF dossier can be reviewed during NDA review process or can be applied as a separated application.	No DMF system	N/A
		Annual or periodical update reporting required?	DMF system is not implemented yet.	Not specified	N/A	N/A	No annual updated system. Partial change application or notification is required for changes.	Annual report should be submitted by Jan. 31 every year if the relevant changes are applicable for the subject of annual report	DMF is one of the 3 options for Regulatory Control of APIs. Assessment of APIs data and information include changes and variations submitted by the product registration holder (PRH)/API Manufacturer. Assessment of an API will also be performed for a registered product prior to a product renewal application, which is required every 5 years presently.	N/A As applicable	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 – refer to Chapter F of this guidance for more information on the post-approval process.	The DMF approval will be valid for 5 years and combined with NDA drug license. There is no annual update reporting mechanism in Taiwan. Detail post-approval major / minor change classification, please refer to appendix 12 of "Drug Review and Registration Guidance."	Not required	N/A for imported products.

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Manu -facturing	Contents of packaging label and language	Please describe required contents of packaging label and language to be used. ex. refer to guidance document	The required contents are described in CFDA order 24. The contents should be written in Chinese	English or English and Chinese, requirements decribed in Guidelines on the Labelling of Pharmaceutical Products	The required contents are described in rule 96 & Schedule D2 of the Drug and Cosmetic Rules 1945. PI and packaging labels should be written in English	New guideline 2011 for labeling prescription drug : request to provide Package insert (English or Indonesia), Patient Information Leaflet (Indonesian), outerbox should following packaging requirement (name of the product, active substance, volume, indication, contraindication, dosage and administration, storage condition, manufacturing name & address , imported by,) also retail price, Registration number, Harus dengan resep dokter, Logo of prescription drug. In the label, after product name should follow active substance names, Label also following regulation on registration. Guideline for OTC : inner box and all product information should be in Indonesian language	The required contents are described in Article 50 of the Pharmaceutical Affairs Act. The contents Should be written in Japanese.	For pharmaceutical products including prescription only, OTC drugs and quasi-drugs, the labelling is the summarized indication of efficacy and safety that must be exactly same to the registered/approved product information by the Korean Health Authority. This is presented through three types of labelling like the following: • Package leaflet • Container • Carton (outer package) The required information including product name, lot number, dosage form, name and address of manufacturer or importer, etc. is defined in Articles 56, 57, 58, 59, 60 and 65 of the PAA and Articles 69, 70, 71, 74, 75, 76 and 77 of the Regulation on Safety of Pharmaceutical Drugs etc.	The labeling content is stated in Drug Regulatory Guidance Document. The labeling for pharmaceutical products are in English or Bahasa Malaysia. Some labelling statements are mandatory in Bahasa Malaysia, eg for “Keep medicine out of reach of children”.	The required contents are described in Generic Labeling Law. The contents Should be written in English. (see A.O. 55, series 1988)	Refer to: GUIDANCE ON MEDICINAL PRODUCT REGISTRATION IN SINGAPORE APPENDIX 7 Points to Consider for Singapore Labelling, 1 Nov 2016. 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	The required package label contents are described in Article 20 of “Regulations for Registration of Medicinal Products.” The contents of outer box should be 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.	Follow ASEAN labeling requirements Thai language required for - category of drug - expiration date - special warning package leaflet in Thai.	Vietnamese. Current regulation (Circular) on Labelling requirements being drafted following the new Pharma Law (effective 1 Jan 2017). Previous regulation: 1. *Outer package labels* For drugs, including finished drugs, vaccines, antiserums, and therapeutic biologicals: a) Drug name; b) Drug composition: including full information of active ingredient composition, strength or concentration including salt forms of active ingredients (if any) for the smallest dosage unit or the smallest packaging unit, with no compulsory requirements for excipient’s composition and strength; c) Dosage form (except for in vitro diagnosis biologicals), packaging specifications; d) Indications (including for oriental and herbal medicines), route of administration, and contraindications; e) Batch number, date of manufacture, expiry date, and storage conditions; f) Visa number or import visa number; g) Warnings and precautions; h) Name and address of organization and/or individual responsible for the drug; i) Country of origin of drug. 2. *Intermediary package labels* 2.1. Intermediary package labels of finished drugs must present as minimum requirements the following: a) Drug name; b) Name of manufacturing establishment; c) Batch number, expiry date. 2.2. In case an intermediary package is made of a transparent material which allows for information on the direct package to be seen, the intermediary package is not required to present information specified under clause 1 of this article. *3. Label for package with direct exposure to a finished drug* 3.1. Label for package with direct exposure to a drug must provide in full the following compulsory contents: a) Drug name; b) Drug composition: - For drugs that are a combination of more than 3 active ingredients: no compulsory presentation is required for the composition, strength and/or concentration of each active ingredient and/or excipient. In case composition and strength of the active ingredients are presented, the composition and strength of each of the active ingredients must be presented, including any salt forms of such active ingredients (if any); - For mono-substance drugs and drugs that are a combination of less than 3 active ingredients: full information is required for the composition, strength or concentration of each of the active ingredient(s) (including the salt forms of the active ingredient(s) (if any). - For in vitro diagnosis biologicals: no information is required for the composition of the active ingredient and/or excipient. c) Net weight or volume (not applicable for blister pack labels); d) Batch number, expiry date; e) Name of manufacturing establishment: The name of the manufacturing establishment can be provided in abbreviation or in English name used for business purposes, but must ensure ability to identify such name of the manufacturing establishment. In case many manufacturing establishments are involved in manufacturing a drug, labeling can follow either of the following ways: - Providing in full manufacturing establishments involved in manufacturing the finished drug; - Providing the name of the establishment responsible for the drug batch ex work. 3.2. In case of drugs without outer package, the direct package shall have to provide in full all the contents of an otherwise outer package label as specified under article 7 of this circular

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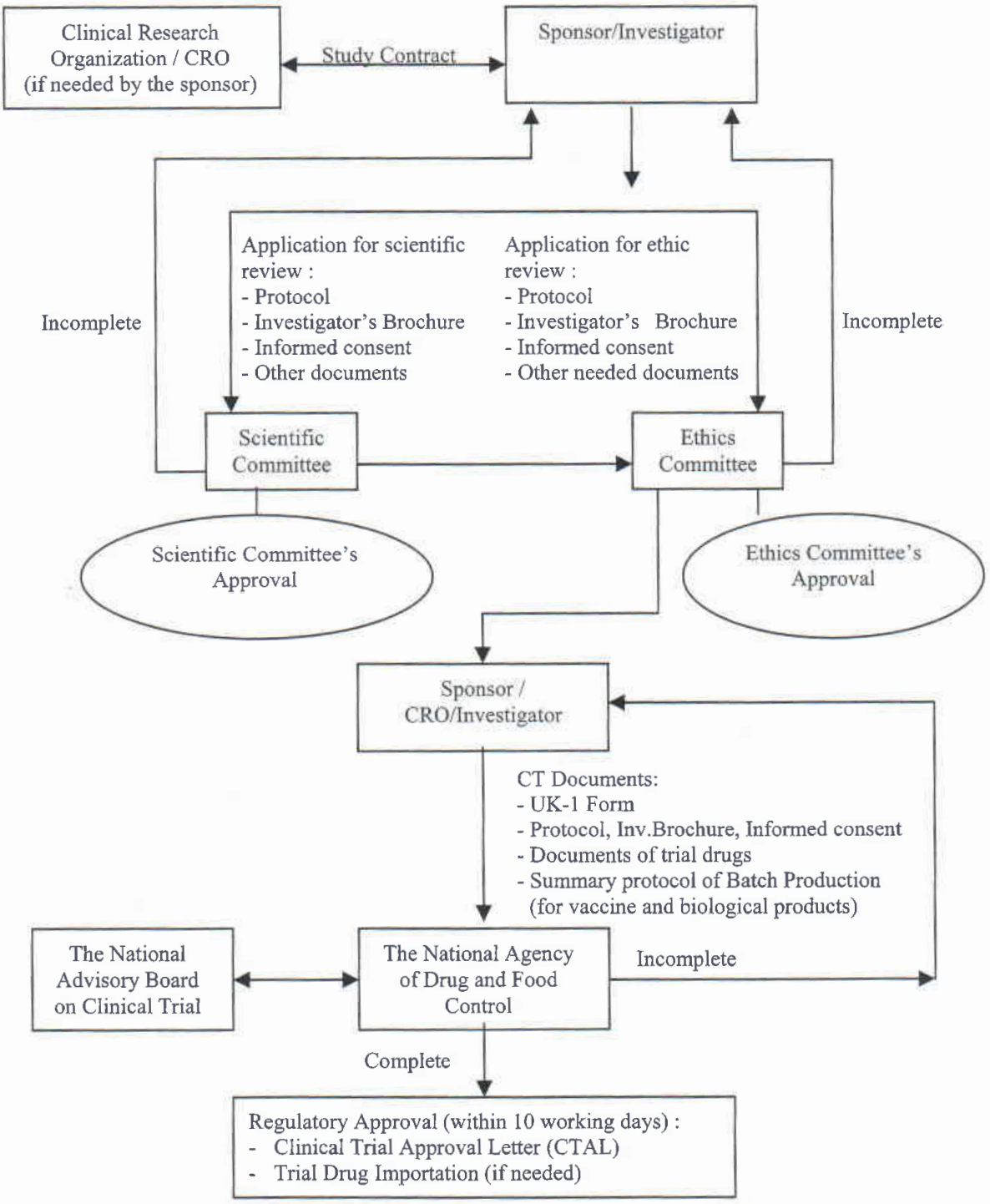
Manu -facturing	Bar code on packaging materials	Please describe requirements of Bar Code on packaging materials and concerned regulations.	CFDA issued the notification that bar code on packaging material was temporarily suspended, then the requirements of bar code are deleted from the revised GSP. Company will take the main responsibility to establish the drug tracing system. Bar code is not mandatory to be used in the future.	For product registration, no concern. For supply to government hospital: GTIN barcode as issued by GS-1	For product registration, no concern. For supply to government hospital: GTIN barcode is required Barcode requirements using GS1 identification standards has been implemented. (reference: The Office Memorandum No: Z-16025/02/08-EPW dated 6th May 2011 by MoHFW). For local Indian market, it is still not made mandatory	No regulatory requirement on bar code. It is an internal company logistics requirement.	The contents Should be written in Japanese.	MOHW Notification No. 2013-63 was issued to build the base of distributional information of domestically manufactured or imported pharmaceuticals by determining identification with barcodes/RFID tag. Except several products, all pharmaceutical drugs including the imported products must adhere a barcode since 2009. There are three codes of GS1 system, which can be used on the barcode.	Bar code is an optional information.	Barcode is required per SKU. It is a requirement upon submission of new drug applications with effective date on June 2015.	No regulatory requirement on bar code. It is a internal company logistics requirement.	TFDA will announce barcode standard-in on-01-Jul-2017. By 01 Jan 2019, the barcode system should include GTIN+ LOT+ Expiry date data on the shipping package and sale-unit package. Barcode system implementation to dispensing package is not mandatory.	No regulatory requirement for Bar code But some hospitals require barcode	Not a requirement. Organizations and individuals who are responsible for drugs are encouraged to write bar codes or paste anti-counterfeit stamps with confidential, anti-counterfeit information related to their products on drug labels to prevent counterfeits or allow for easy product recognition.
Post approval	Renewal system of approved license	Please describe renewal system of marketing authorization or manufacturing license. ex. renewal required every 5 years ex. re-evaluation system	Manufacturing license system is adopted for registration management. So, renewal system is based on manufacturing license. Renewal is required every 5 years, and should be submitted within 6 months before expiration date of license.	Renewal required every 5 year.	Renewal system has been implemented for the followings. 1) Import license (Every 3 years. Renewal application should be made three months before the expiry of the existing license.) 2) Registration certificate (Every 3 years. Renewal application should be made nine months before the expiry of the existing license.) 3) Manufacturing license (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.	Marketing Authorization: - Renewal application is required every 5 years. Renewal application needs to be submitted by 120 working days-prior to license expiry. If needed, the NADFC conducts re-evaluation. Renewal of Import Product should attach new CPP (Certificate of Pharmaceutical Product). Manufacturing License: Renewal application is required every 5 years for-every GMP facility and dosage form. Sometimes the NADFC will inspect the GMP facility before granting the renewal of Manufacturing license.	Not renewal but 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 for orphan drug.	Renewal system of approved licenses will be implemented from drugs which would be approved in 2013 (applicable for existing drugs as of Jan. 1, 2018). Documents should be submitted : 1) Summary reports on Safety and Efficacy of the drug product including the last 5-year 2) Usage in foreign countries, Any action related to safety in foreign countries 3) Data on Product Quality 4) Safety update report 5) In case anything would be changed from approval, its evidential data 6) Document on Drug Display (Label in carton, PI and so on) 7) Manufacturing or Importing records during the last five-year 8) Product Permission letter issued by MFDS	Renewal is required every 5 years of a product registration. Renewal needs to be submitted 6 months prior to registration expiry. (NOTE: Pre-renewal requirements eg for stability data at zone IVb, GMP inspection etc must also be fulfilled.)	Renewal system is being implemented. Renewal for products under Monitored Release status is after 3-5 years. Products on regular registration status, i.e. under Initial or Renewal status, renewal is done every 5 years. .	Reference to “RETENTION OF THERAPEUTIC PRODUCT ON THE PRODUCT REGISTER TPB-GN-002-000”. 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 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 procedure is required for approved license (every 5 years).	There are 3 kinds of license in Thailand which are Manufacturing license, Import license and Sale license, all of which require annual renewal. Based on current Thai Drug Act, the product license is life-long, no requirement of renewal, except for drug classified as narcotics and psychotropics shall subject to renewal every 5 years. Product license will be automatically withdrawn if no production/importation every 2 consecutive years.	MA validity is from 3-5 years (3 years: 1st time registered in VN; 5 years: renewals). MA extension/Renewal is mandatory. Renewal is applied to drugs which was granted MA but the MA expires and does not meet the conditions to extend MA.
	Post marketing surveillance or safety monitoring program	PSUR submission required? Other post-approval safety requirements? ex. Safety monitoring program/ monitored release	Annual PSUR submission is mandatory until the first renewal date, and it becomes every 5 years after the first renewal date. Mandatory special monitoring is performed over drugs within the new drug monitoring period as well as drugs imported for the first time within 5 years. The monitoring results shall be summarized, analyzed, evaluated and reported as required.	For NCE only. 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: Schedule Y of the Drugs and Cosmetics Rules amended in 2005) PSURs due for a period must be submitted within 30 calendar days of the last day of the reporting period. For conditional approval, there is a case where Phase IV crinical trial imposed.	PSUR submission is required only for NCE and certain product if it is required by HA. There is an obligation to report all Adverse Events (unexpected/expected , serious/ non serious in Indonesia or foreign countries) to NADFC	PSUR submission is mandatory every 6 month in first two years and annually after two years. Use-result survey data should be submitted together.	PSUR submission is mandatory every 6 month in first two years and annually after two years. Use-result survey data should be submitted together.	PSUR/BPRER is mandatory for NME: 6 months once in the first 2 years, and 12 months once in the subsequent 3 years.	As per PFDA Circular 2013-004, the post marketing surveillance system was enhanced to cover all registered products. Periodic (minimum on annual basis) submission of PSUR/ PBRER, and AE reports and submission of RMP are required.	Reference to: GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS, 1 Nov 2016 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 (e.g. during variation application review or when new significant safety issues are identified). Include the following: ・ Records of adverse effects; ・ Serious adverse reaction (SAR) reporting; ・ Risk management plans (RMPs); ・ Periodic benefit-risk evaluation reports (PBRERs); ・ Updates on actions taken by other regulatory authority or company in response to safety issues.	Pharmacovigilance period is first 5 years for NCE drugs. PSUR should be submitted every 6 months in the first 2 years and annually for the rest 3 years. PSUR submission period can be adjusted based on global international birthday (IBD) and its data lock point (DLP) within 3 months of drug license collection.	New drug approval will be with “conditional approval” requiring Safety Monitoring Program for 2 years. After 2 years, the application for “Unconditional approval” (or SMP releasing) is needed. Apart of local data, one of the document required is worldwide safety data and the PSUR for all relevant periods will be used for submission at this step. Actually, there is no PSUR regulation.	Periodic ADR report (PSUR, PBRER, report safety, effectiveness)

Item	Contents	Detail or Example	China RDPAC	Hong Kong HKAPI	India OPPI	Indonesia IPMG	Japan JPMA	Korea KPMA/KPPIA	Malaysia PhAMA	Philippines PHAP	Singapore SAPI	Taiwan IRPMA	Thailand PReMA	Vietnam PG
Post approval	Risk Management Plan (RMP)	Please describe requirements of RMP/REMS. ex. Mandatory at NDA, submit up on request from the authorities	Not yet officially implemented. For the product which is accepted for special review procedure, Risk Management and Implementation Plan should be submitted at NDA.	One of the mandatory requirements for NCE registration	N/A at present	Not required yet. RMP regulation will establish later on. RMP is necessary for the application of category 1. (Article33, No.HK.03.1.23.10.11.0848 1)	RMP document is mandated for NDA as M1.11.	For improved management and control for known or potential risk of post-approved drug product, a risk management plan (RMP) was introduced from 01-Jul-2015. For approval of new drugs and orphan drugs, the Risk Management Plan (RMP) should be submitted with application form in accordance with amendment made by MFDS Notification No. 2015-27. The scope of drugs required to submit the risk management plan will be expanded annually step by step by 2018.	RMP is listed as a requirement in the DRGD for biological products, including biotech products, biosimilars, vaccines and blood products. An RMP on any product may need to be submitted on request from the authorities, eg when there are safety concerns affecting the benefit-risk assessment that require specific risk minimisation activities.	RMP is required for submission of NDAs (FC-2013 004). There's no local format of RMP.	Reference to “APPENDIX 16 GUIDELINE ON THE SUBMISSION OF RISK MANAGEMENT PLAN DOCUMENTS”, 1 Nov 2016. All NDA-1 and biosimilar product applications must have an accompanying RMP submitted. For other application types such as NDA-2 or 3, major variation application (MAV) or generic drug application (GDA), RMP documents may be requested by HSA on a case-by-case basis: ・ For NDA-2, the request for RMPs may be in response to a new safety concern arising from a new route of administration; ・ For MAV, the request may arise as a result of a new safety concern associated with a new indication that may require additional PV activities and/or RMAs ・ For GDA, a RMP may be required if the innovator or reference product has safety concerns that have been identified to require additional local PV activities and/or RMAs.	The necessary of local RMP will be decided by TFDA during the NDA review. RMP protocol will be discussed and finalized between TFDA and NDA applicants.	There is no RMP regulation. The RMP is required only for some product group i.e. Biosimilars or if needed in specific drug e.g. Thalidomide. A public hearing just called in January on RMP, of which is anticipated to implement within 2017.	Not a mandatory requirement. The request could be given following the decision of Advisory Council for the Grant of Drug Registration License. Risk management plan for a drug should include the following information: - Overview of drugs - Safety information -Pharmacovigilance Plan - Plan of Post-marketing studies - Risk minimization activities - Summary of the plan
	Adverse drug reaction reporting after marketing	Please describe reporting requirements of ADR for marketed products.	Reporting is mandatory for ADR observed in post-marketing period including PMS. Reporting period of Serious ADR and unknown ADR are within 15 days and death should be reported immediately (30 days for non-Serious ADR for drugs within the new drug monitoring period or imported drugs within 5 years from the date of initial import permission).	SUSARs have to be reported within 15 calendar days from date of first receipt.	Serious unexpected adverse reactions: must be reported to the licensing authority within 15 calendar days of initial receipt of the information by the applicant. Other: to be reported in PSUR.	Reporting is mandated for ADR observed in post-marketing products. 1. AE Spontaneous serious unexpected in Indonesia , as soon as possible, not more than 15 calendar days. 2. AE spontaneous non-serious unexpected in Indonesia, report every 6 months. 3. AE Spontaneous serious expected in Indonesia, as soon as possible, not more than 15 calendar days. 4. AE spontaneous serious unexpected in froiegn countries, as soon as possible, not more than 15 calendar days	Reporting is mandated for ADR observed in 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 next year Feb from reported day	The PRH (product registration holders) shall inform the HA immediately of any adverse reaction arising from the use of the registered product. All PRHs must ensure that a pharmacovigilance system is in place by the company and appropriate action is taken, when necessary. PRHs are required to monitor and report any product safety issues that arise locally or internationally to the NPRA as well as comply with all safety-related directives issued by the Authority. The timeline for ADR reporting differs by reporter category. (Malaysian Pharmacovigilance Guidelines 2nd Edition 2016)	Reporting is mandated for ADR observed in post-marketing products including PMS. Reporting period of Serious ADR/AE, ICSR is within 5 days and serious one must be reported promptly.	Reference to “GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS, 1 Nov 2016. Upon becoming aware of any SARs, the company must report the event to the Vigilance and Compliance Branch as soon as possible within 15 calendar days. The regulatory reporting time clock starts as soon as any personnel of the company is aware of the SAR.	ADR reporting is mandatory for approved drug products. SAE of death and life-threatening cases should be reported within 7 days. Within 15 days for others SAE.	Follow Guidance for Industry Post-marketing Safety Reporting Requirements for Human Drug and Biological Products Including Vaccines (Annex 19)	Follow Ministry of Health guidance for ADR report. - Patient information (Initials, gender, age/date of birth, weight) - Details of AE* Date of onset/latency, concise description of AE (e.g. type of rash), severity Suspected health products Brand name or active ingredient(s), dosage form, strength, manufacturer, batch number, - Administration route - Concomitant health product - Reporter’s details Name, profession, place of practice, contact no., email address

Item	Contents	Detail or Example	China	Hong Kong	India	Indonesia	Japan	Korea	Malaysia	Philippines	Singapore	Taiwan	Thailand	Vietnam
			RDPAC	HKAPI	OPPI	IPMG	JPMA	KPMA/KPPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Post approval	Variation guideline	Is there any guideline document for post-approval changes? If yes please show the title.	The variations to be approved or filed are listed in Drug Registration Regulation order 28. Meanwhile, Guideline for Variations of Post-market Chemical Drug Products has been implemented.	Please refer to the guidelines for Change of particulars (Guidance Notes on Change of Registered Particulars of a Registered Pharmaceutical Product ; issued by Drug Office, Department of Health of Hong Kong).	Chemical products: In case major change, approval is needed within 30 days by submission of variation application. For minor change, it should be notified to the authorities within 30 days. (See Drugs and Cosmetics Rules, 1945) Biological products: LEVEL I - Supplements (Major Quality Changes); LEVEL II - Notifiable Changes (Moderate Quality Changes) LEVEL III - Annual Notification (Minor Quality Changes) (See Guidance for Industry: Post approval changes in Biologic Products – Quality, Safety and Efficacy Documents)	Regulation of the Head of National Agency of Drug and Food Control No HK.03.1.23.10.11.08481 : Criteria and Procedure of Drug Registration, 12 Oct 2011, variation is defined as a change to any aspect of a marketing authorization, including but not limited to a change to formulation, methods, and site of manufacturer, specifications (both for finished product and ingredients), container, packaging, labeling, manufacturing process and product information.	Partial change application should be submitted for approval of changes. For minor changes, notification system can be applied. Scope and handling of these changes are stipulated in the Pharmaceutical Affairs Law and several notices.	Changes in post-license should be applyed to MFDS according to the level of the changes. Pharmaceutical Affairs Act, Several notices and Guidelines exist.	Malaysian Variation Guideline For Pharmaceutical Products This guidance document is adopted from the ASEAN Variation Guideline for Pharmaceutical Products 2012 incorporating Malaysia's specific requirements.	FDA Circular No. 2014-008: Application Process and Requirements for Post-approval Changes of Pharmaceutical Products, 28 Feb 2014, which was effective on 1 April 2014. Almost the same with "Asean variation guideline" , but a country specific request was added.	Reference to "GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE TPB-GN-005-000"; Chapter F Post-Approval Process.	Please refer "Regulations for Registration of Medicinal Products for post-approval changes application"	As per ASEAN Variation Guideline (AVG).	Yes. As ASEAN harmonization. Current regulation (Circular) on Registration which includes Variation being drafted following the new Pharma Law (effective 1 Jan 2017). Previous regulation: Appendix II issued together with Circular 44 on Drug Registration (Major variation, minor variation and others).

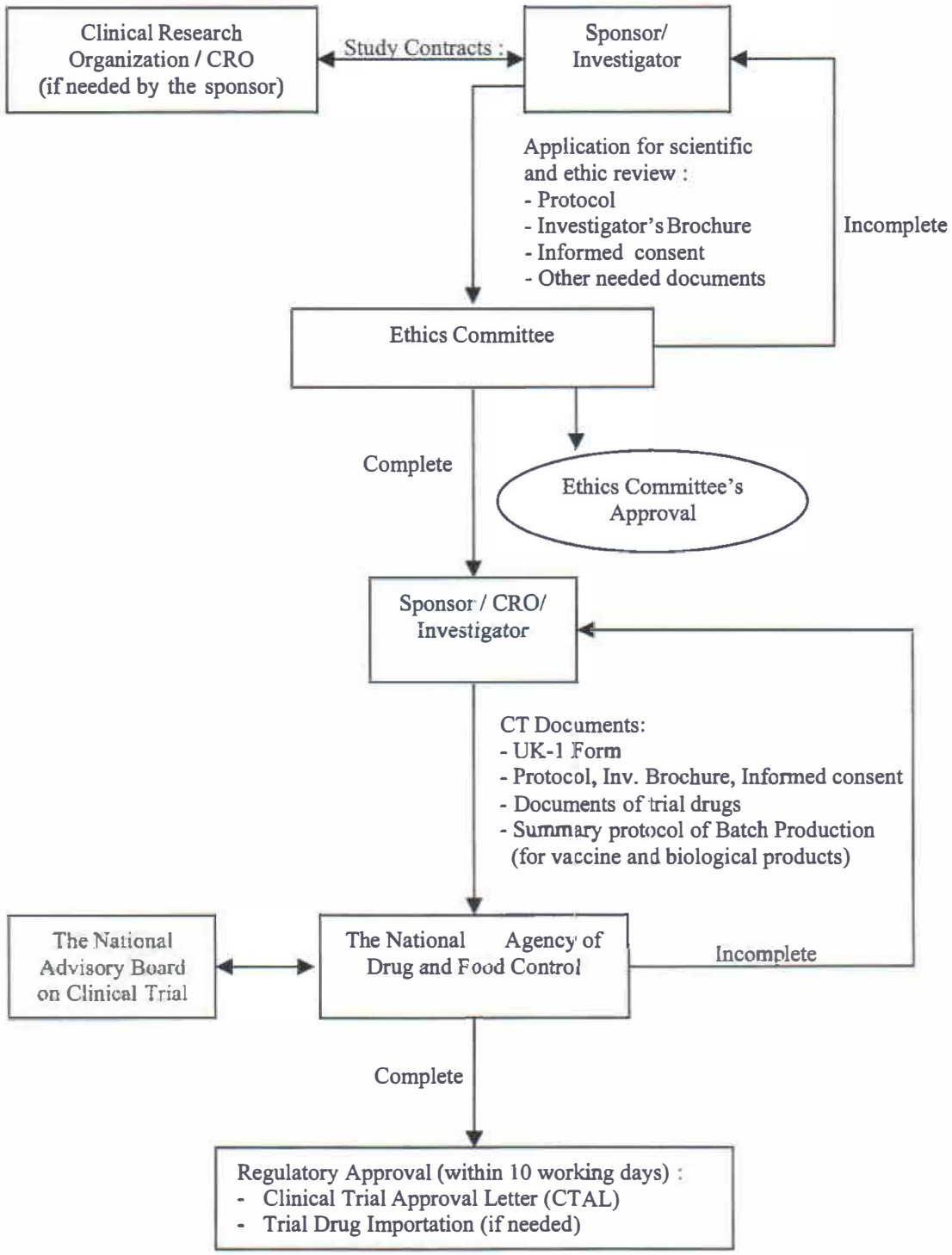
ATTACHMENT IIa
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Pre-Marketing Trial



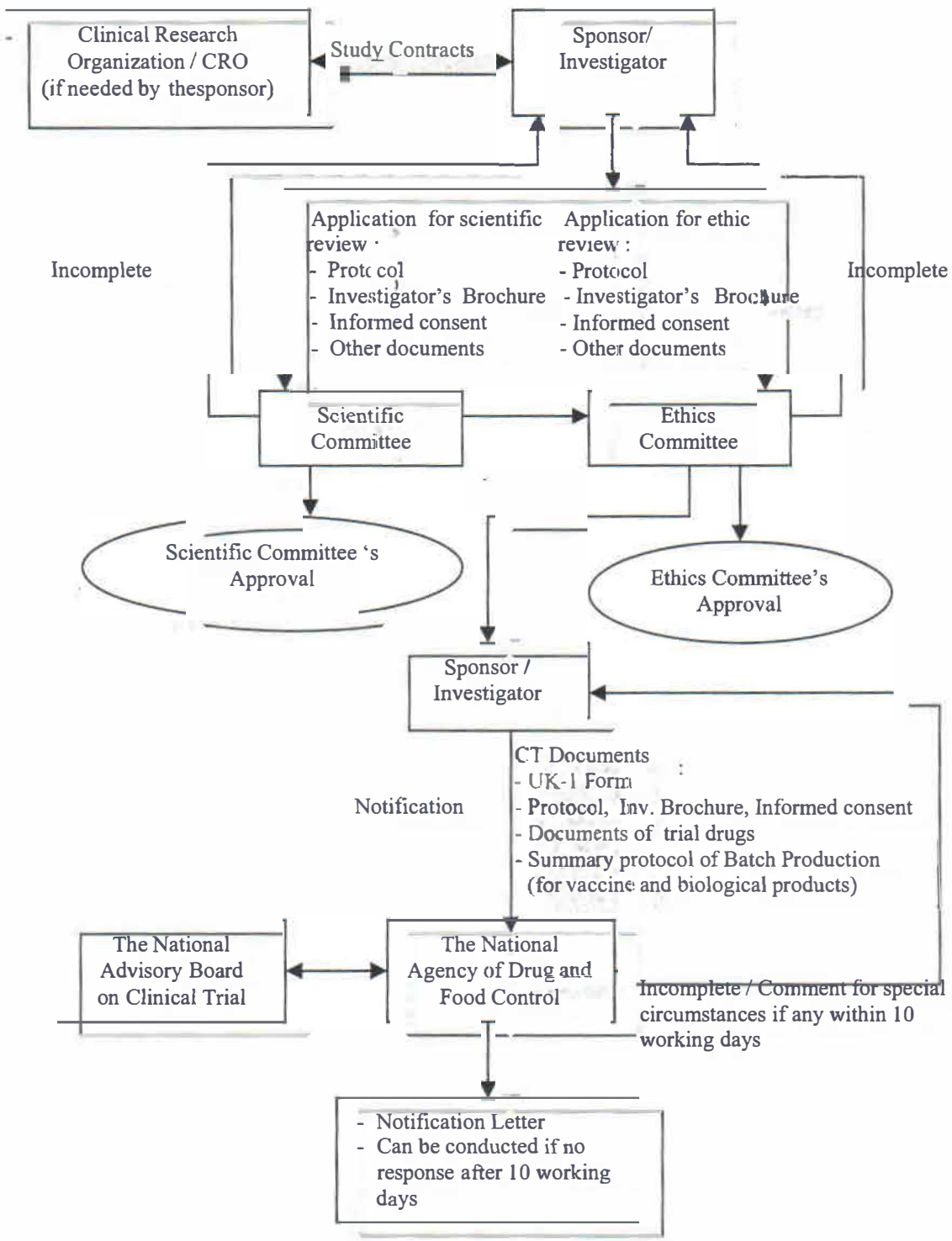
ATTACHMENT IIb
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Pre-Marketing Trial
(Inseparate Scientific and Ethics Committee)



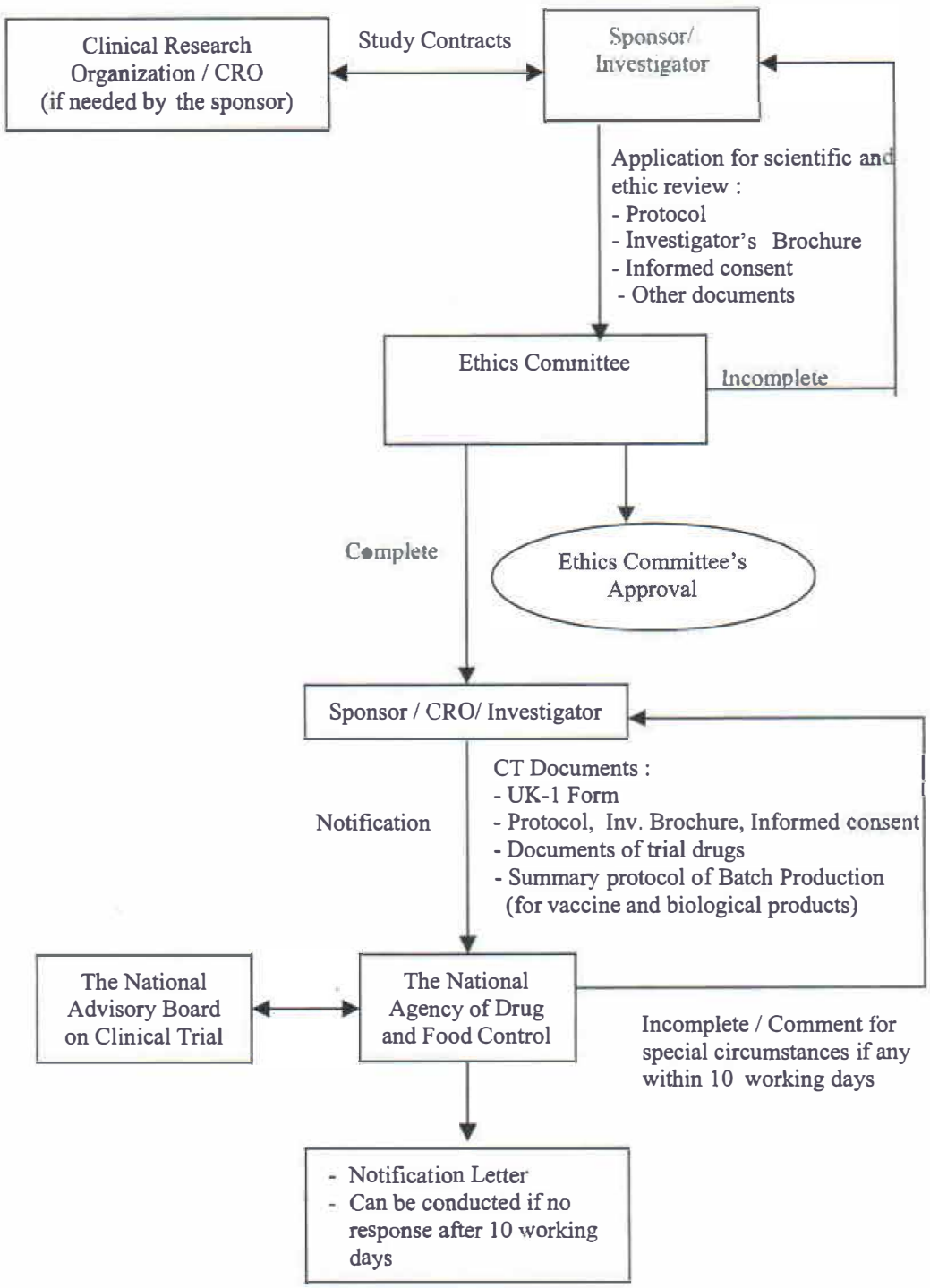
ATTACHMENT IIIa
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Post-Marketing Trial
(Separate Scientific and Ethics Committee)



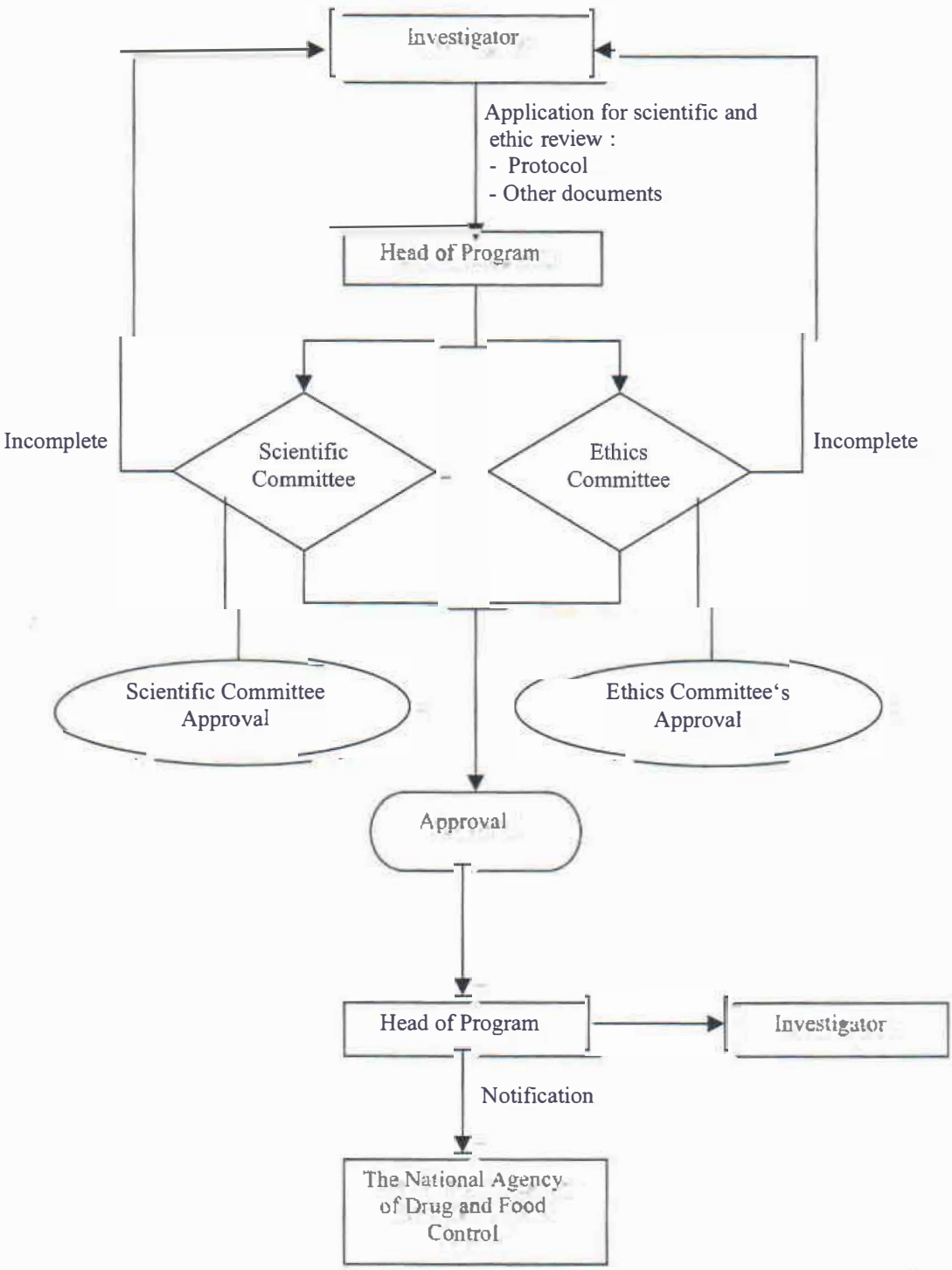
ATTACHMENT IIIb
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Post-Marketing Trial
(Inseparate Scientific and Ethics Committee)



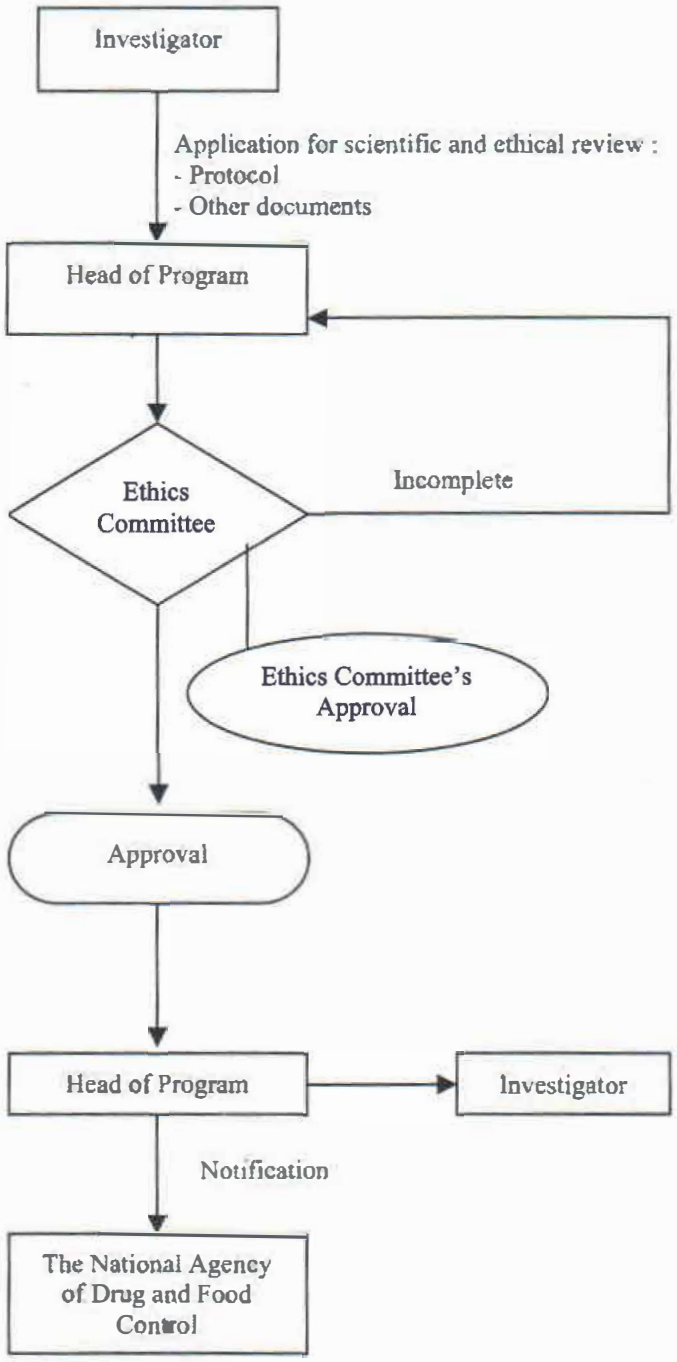
ATTACHMENT IVa
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Trial for Educational Purpose
(Separate Scientific and Ethics Committee)



ATTACHMENT IVb
DECREE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURE

Flow Chart
Trial for Educational Purposes
(Inseparate Scientific and Ethics Committee)



UK-1 FORM

ATTACHMENT I
DECRRE OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NO 02002/SK/KBPOM
REGARDING CLINICAL TRIAL PROCEDURES

To:
The Head of the National Agency of Drug and Food Control Republic of Indonesia
Percetakan Negara 23
JAKARTA

☐ Pre-Marketing Clinical Trial ☐ Post-Marketing Clinical Trial

I. GENERAL INFORMATION

1. Title of Clinical Trial:
2. Protocol number and dated (final protocol) :
3. Objective of the trial :
4. Phase of the trial (I, II, III, IV) :
5. Design :
6. Use of comparator drug (s) Yes ☐ No ☐
7. Use of placebo Yes ☐ No ☐
8. Number of Subject :

9. Protocol, Investigator's Brochure, Informed Consent and amandements (if any)

Yes ☐ No ☐

10. The categories of study medications used in the clinical trial

☐ Category I
New study medication that has never been studied in human before.

☐ Category II
New study medication that phase I, II, or III trials is still being conducted.

☐ Category III
Study medication has been marketed and this trial is to be conducted for new indication, new administered, and/or new strength.

☐ Category IV
Study medication has been marketed and its trial is being conducted as Post-Marketing Trial.

II. INSTITUTIONS

Multi-center Clinical Trial

Yes ☐ No ☐

Local Center:

Overseas Center:

Name of the (Principle) Investigators, Sub/Co Investigators, and their institution respectively and coordinating investigator (if any):

III. STUDY DRUG

Study medication	: Imported	☐
	Local	☐

1. Generic name :
2. Trade name :
3. Chemical name :
4. Pharmacological Class :
5. Dosage form and strength :
6. Packaging :
7. Route of Administration:
8. Expiry date :
9. Batch number :
10. Certificate of analysis :
11. GMP certificate :
12. Imported drug (s) (Name and amount):
13. Manufacturer (Name and address):
14. Imported by :
15. Marketed in other countries (if any):

IV. COMPARATOR DRUG

Study medication	: Imported	☐
	Local	☐

1. Generic name :
2. Trade name :
3. Chemical name :
4. Pharmacological Class :
5. Dosage form and strength :
6. Packaging :
7. Route of Administration:
8. Expiry date :
9. Batch number :
10. Certificate of analysis :
11. GMP certificate :
12. Imported drugs (Name and amount):
13. Manufacturer (Name and address):
14. Imported by :
15. Marketed in other countries (if any):

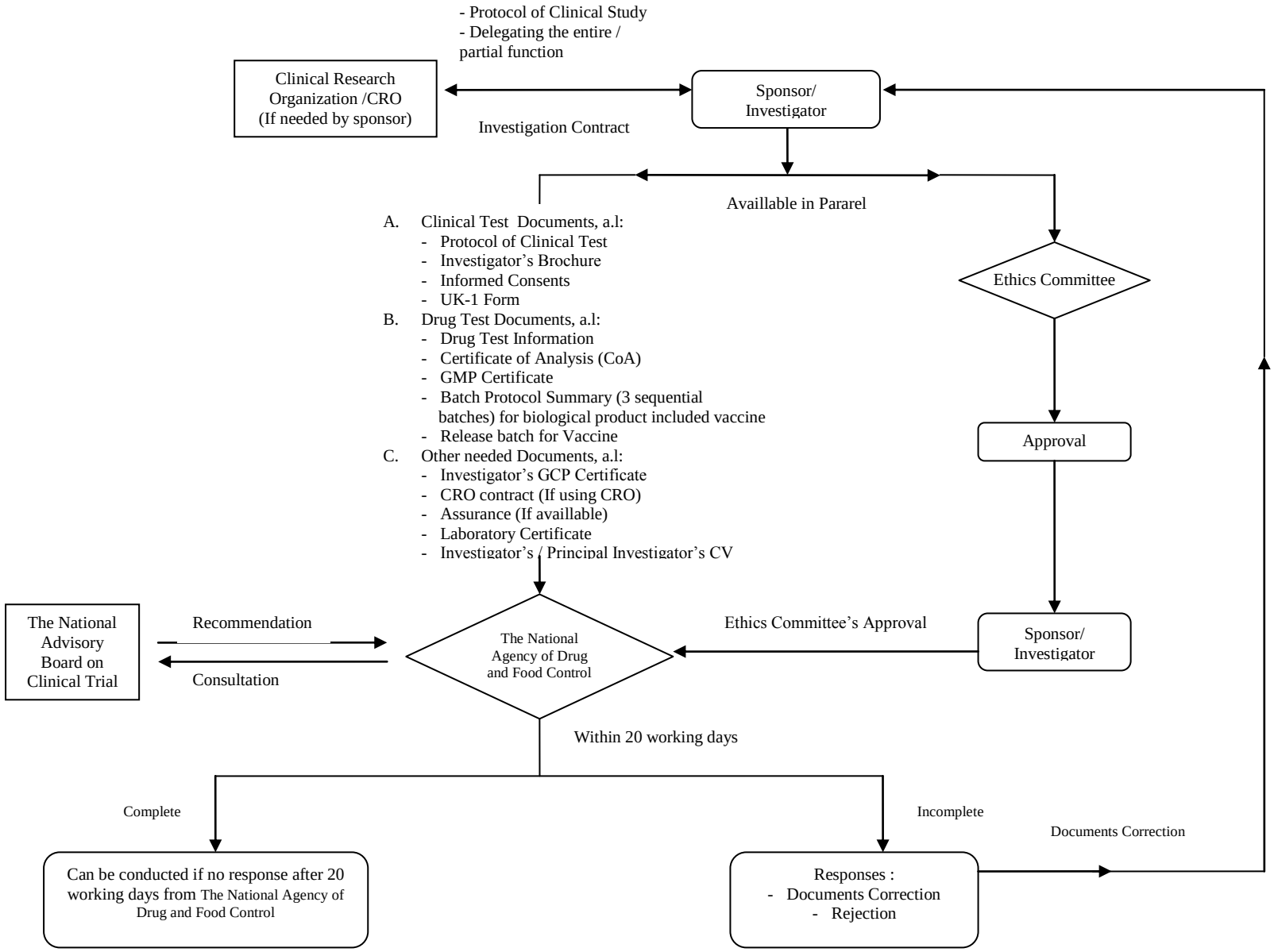
V. SPONSOR

1. Name and address :
2. Sponsor's representative (name and telephone) :
3. Contract Research Organization, (if any, Name and address):

VI. SCIENTIFIC COMMITTEE AND ETHIC COMMITTEE' S APPROVAL

Conclusion of scientific review (attached)
Conclusion of ethical review (attached)
Scientific Committee's approval (attached) - Number and date : - Name and address of Institution :
Ethics Committee' s approval (attached) - Number and date : - Name and address of Institution :

Flow Chart Post-Marketing Trial



MFDS IND Approval Process

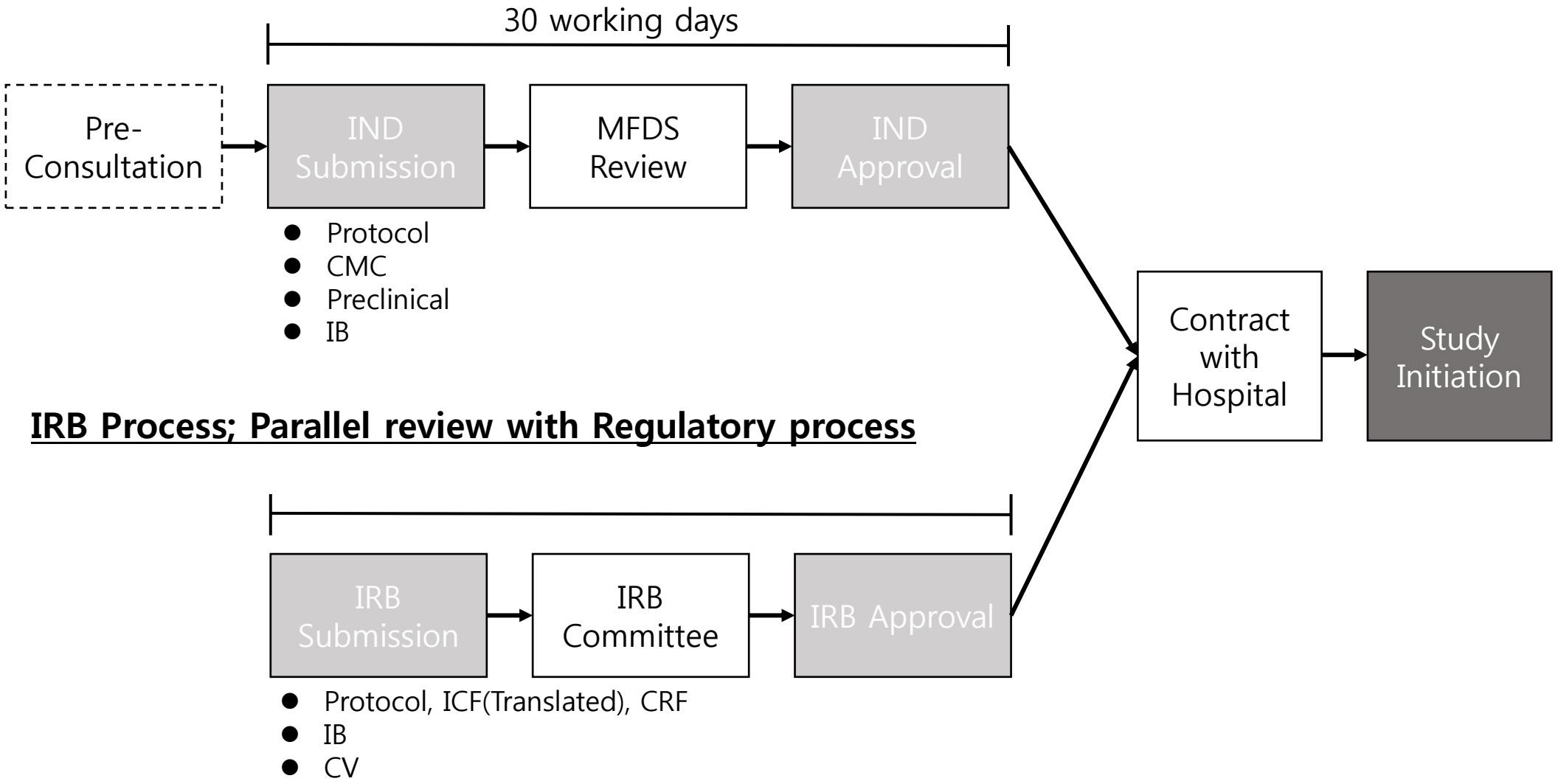
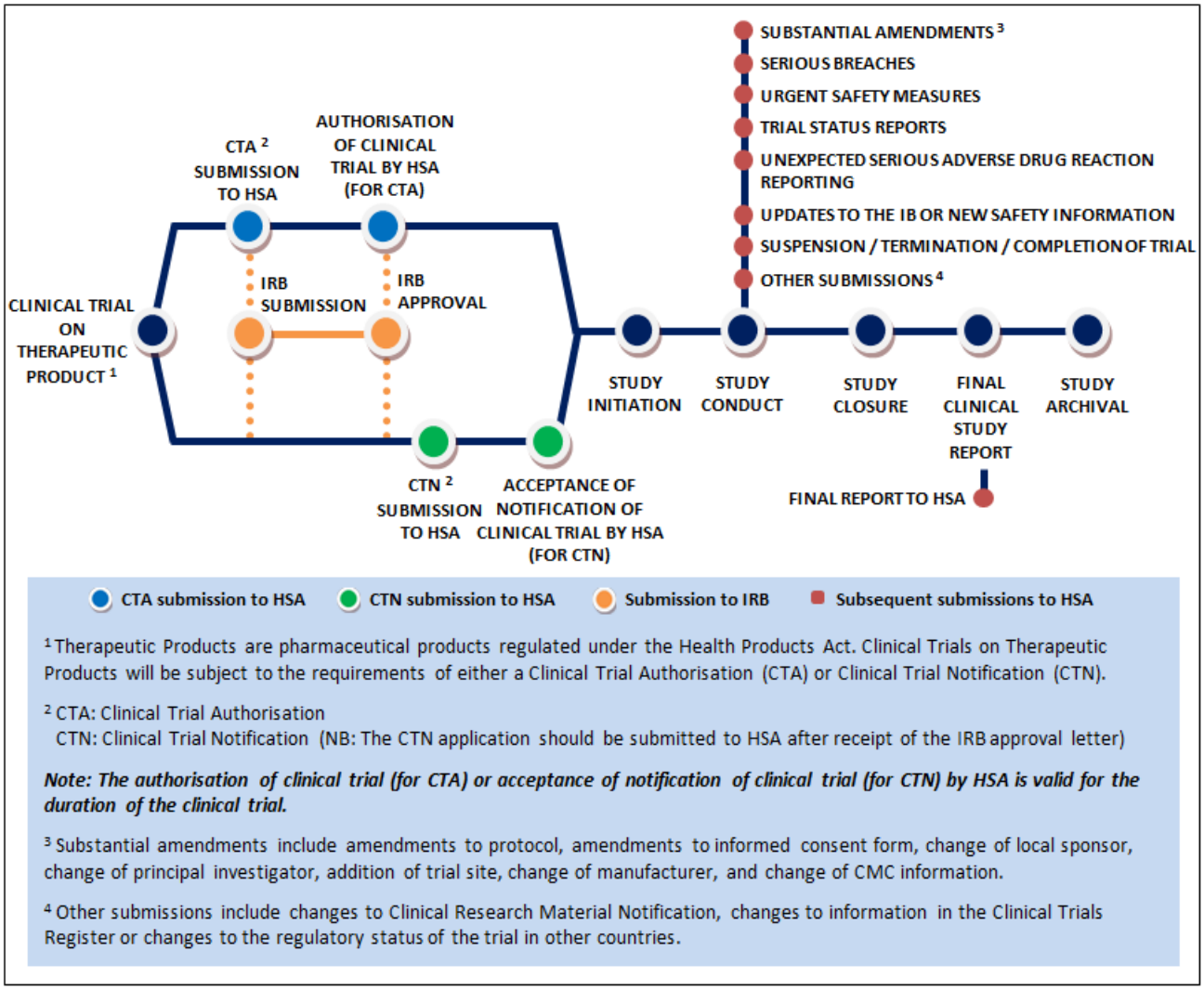


Figure 1. Regulatory roadmap for clinical trials on therapeutic products



[1] Therapeutic Products are pharmaceutical products regulated under the Health Products Act. Clinical Trials on Therapeutic Products will be subject to the requirements of either a Clinical Trial Authorisation (CTA) or Clinical Trial Notification (CTN).

[2] CTA: Clinical Trial Authorisation
CTN: Clinical Trial Notification (NB: The CTN application should be submitted to HSA after receipt of the IRB approval letter)

Note: The authorisation of clinical trial (for CTA) or acceptance of notification of clinical trial (for CTN) by HSA is valid for the duration of the clinical trial.

[3] Substantial amendments include amendments to protocol, amendments to informed consent form, change of local sponsor, change of principal investigator, addition of trial site, change of manufacturer, and change of CMC information.

[4] Other submissions include changes to Clinical Research Material Notification, changes to information in the Clinical Trials Register or changes to the regulatory status of the trial in other countries.

Source:
CLINICAL TRIALS GUIDANCE REGULATORY REQUIREMENTS FOR NEW APPLICATIONS AND SUBSEQUENT SUBMISSIONS, HSA
GN-CTB-2-003A-001

ATTACHMENT XII

BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA

Attachment XII
Decree of the Head of National Agency of Drug and Food Control
Number HK 03/23.10.11.08481 year 2011
on Criteria and Procedure of Drug Registration

COMPLETENESS OF NEW PRE-REGISTRATION DOCUMENTS

A. ADMINISTRATION DOCUMENTS

1. Introduction letter
2. Certificate and other administrative documents in accordance to attachment 5.
3. Documents of consideration to stipulate the evaluation paths *)

3.0.0.1 100 (hundred) working days path.

- Justification that drug is indicated for serious diseases or an orphan drug, and/or
- Justification that drug is indicated for serious diseases/ therapeutic effect for human/life saving and/or contageous diseases and/or on other/less therapeutic choice that effective and safe, and/or
- Supporting documents for public health program

3.0.0.2. 150 (one hundred and fifty) working days path

3.0.1. Marketing status information that is completed with valid proof.

3.0.2. Assessment report from related authority agencies of other countries which have implemented established evaluation system

3.0.0.1. 1 (one) document of the status of registration approval in the countries which have implemented harmonized evaluation system and 1 (one) document of the status of registration approval in the countries with established evaluation system completed with minimal 1 (one) independent assessment report from a

group of countries which have implemented harmonized evaluation system, or

3.0.0.2. 3(three) documents of the status of registration approval in the countries with an established evaluation system completed with minimal 2 (two) independent assessment reports from mentioned documents.

4. Documents of patent related drug (if necessary)
   4.1. Statement letter of related patent
   4.2. Results of patent searching from Ditlen HKI
   4.3. Self assessment patent

B. QUALITY DOCUMENTS

1. Quality overall summary
2. Information regarding source of animal used in the manufacturing process of active ingredient and drug product.
3. Name and full address including the country of the manufacturer that involved in the manufacturing process of active ingredient, bulk, drug product, primary packaging material and/or secondary packaging material, responsible for the batch released and/or solvent.
4. Flowchart and description of manufacturing process of raw material to finished drug.
5. Result of raw material of active ingredient and finished drug batch analysis.
6. Drug master file from the manufacturer of active ingredient for active ingredient of a drug product which is not yet approved in Indonesia.
7. Study protocol of a validation process [b)]
8. Study protocol of validation of an analytical procedure
9. Study protocol of drug stability test [b)]
10. Equivalency data (summary/study protocol) or justification, it is not necessary of an equivalency test [b)]
11. Site Master File (SMF) of overseas Pharmaceutical Industry which has no product with the similar criteria for marketing authorization in Indonesia (include SMF of active ingredient manufacturer for

BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA

biological product)

C. NON CLINICAL DOCUMENTS (IF NECESSARY)

1. Nonclinical overview
2. Nonclinical tabulated summary

D. CLINICAL DOCUMENTS (IF NECESSARY)

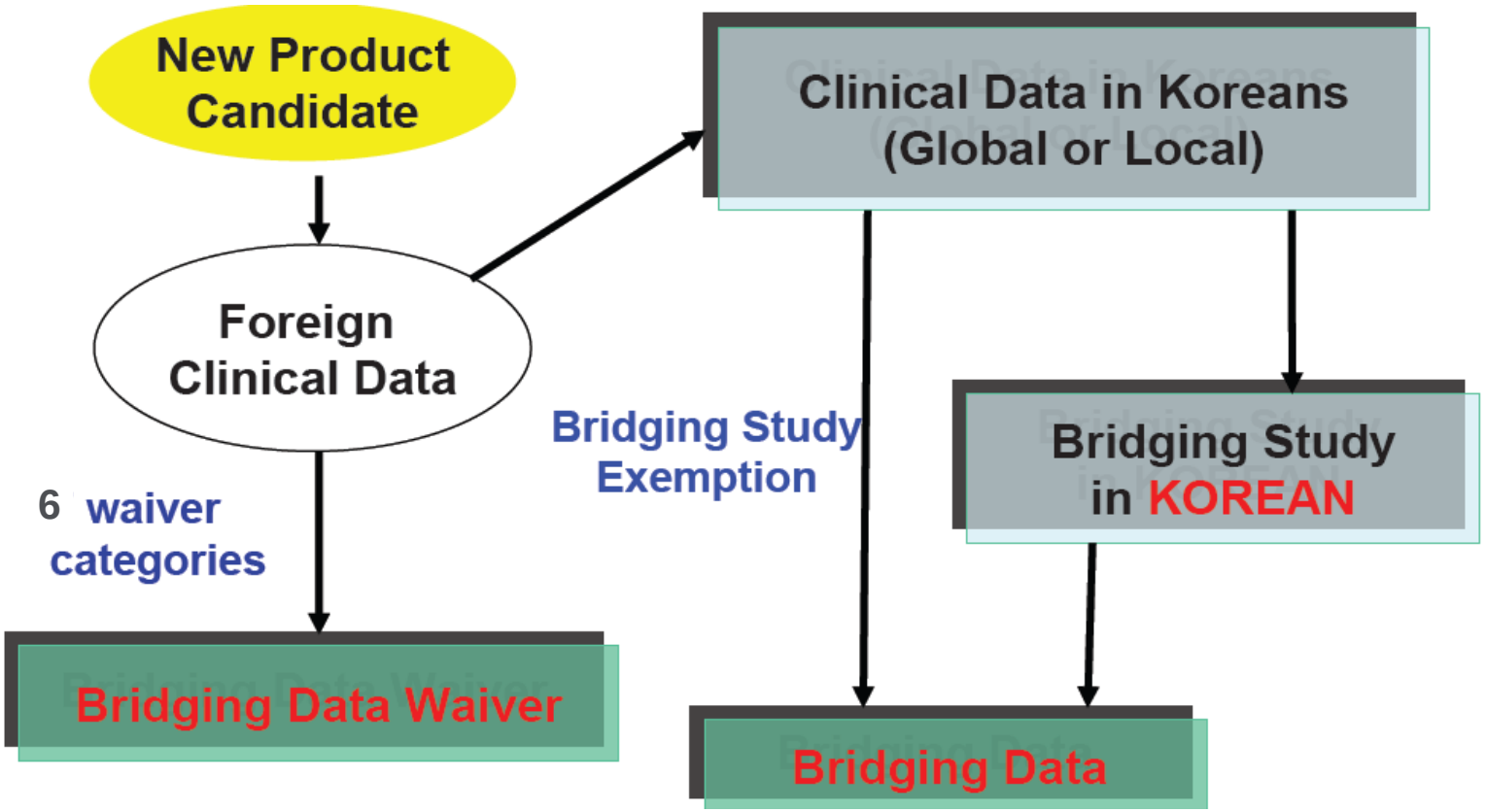
1. Clinical overview
2. Tabulated study synopsis

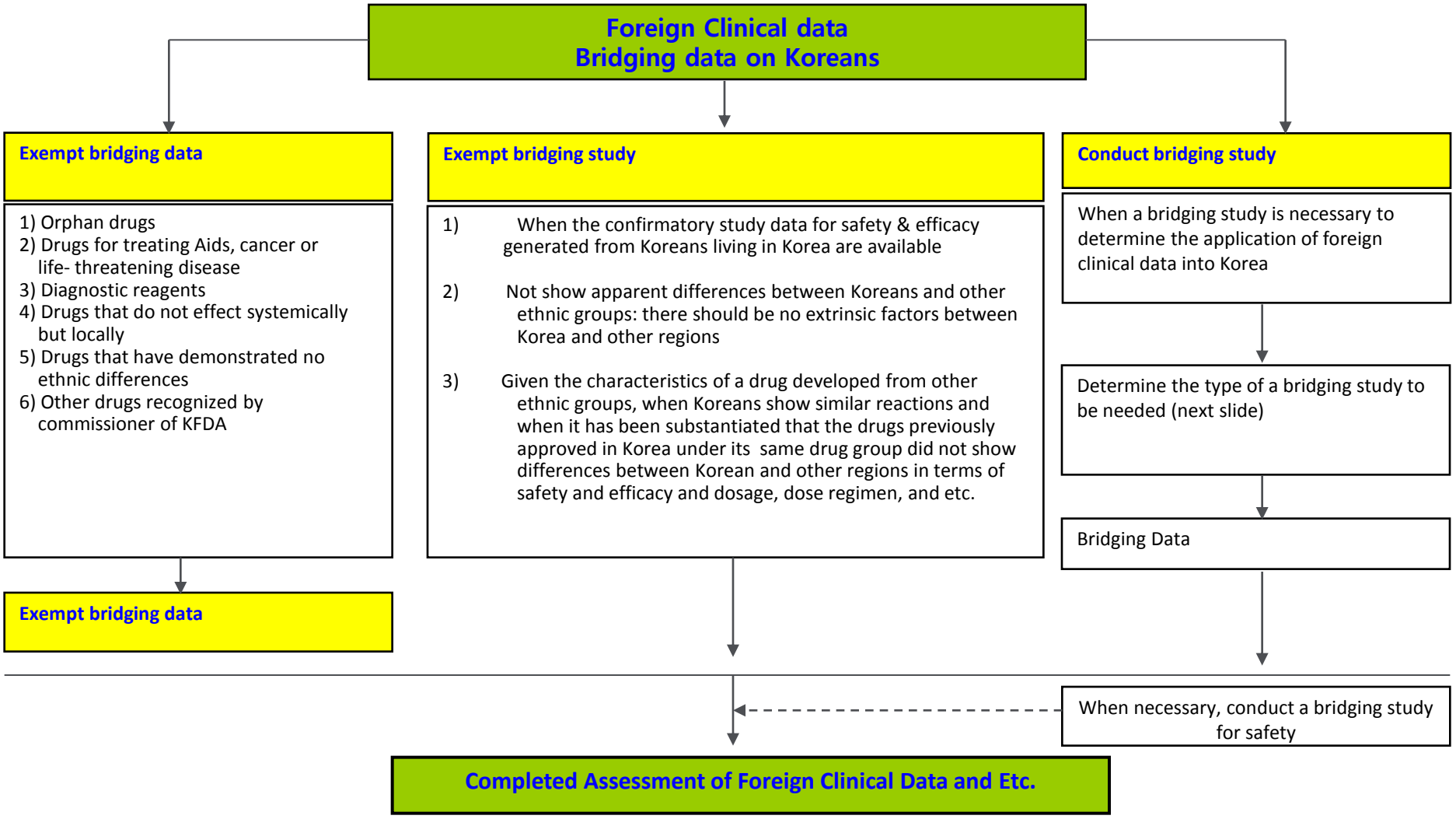
Note:

a) For new drug and biological product
b) For domestically manufacturing drug

THE HEAD OF NATIONAL AGENCY OF DRUG
AND FOOD CONTROL OF THE REPUBLIC OF INDONESIA

KUSTANTINAH


New Product Candidate
Foreign Clinical Data
6 waiver categories
Bridging Data Waiver
Clinical Data in Koreans (Global or Local)
Bridging Study Exemption
Bridging Study in KOREAN
Bridging Data


Foreign Clinical data
Bridging data on Koreans
Exempt bridging data
1) Orphan drugs
2) Drugs for treating Aids, cancer or life- threatening disease
3) Diagnostic reagents
4) Drugs that do not effect systemically but locally
5) Drugs that have demonstrated no ethnic differences
6) Other drugs recognized by commissioner of KFDA
Exempt bridging data
Exempt bridging study
1) When the confirmatory study data for safety & efficacy generated from Koreans living in Korea are available
2) Not show apparent differences between Koreans and other ethnic groups: there should be no extrinsic factors between Korea and other regions
3) Given the characteristics of a drug developed from other ethnic groups, when Koreans show similar reactions and when it has been substantiated that the drugs previously approved in Korea under its same drug group did not show differences between Korean and other regions in terms of safety and efficacy and dosage, dose regimen, and etc.
Conduct bridging study
When a bridging study is necessary to determine the application of foreign clinical data into Korea
Determine the type of a bridging study to be needed (next slide)
Bridging Data
When necessary, conduct a bridging study for safety
Completed Assessment of Foreign Clinical Data and Etc.

Number of reviewers	New Drugs							New Generic (NG)	Generic (G)	Biologics		
	NCE	NI	NCO	ND	NR	NDOS	NS			NB	BF	B
CMC	2	-	2	2	2	2	2	2	2	2	2	2
Clinical	2	2	2	2	2	2	2	2(BA/BE)	-	2	1	
Non-clinical	2	2*	1*	1*	1*	-	1*	(labelling,efficacy&safety	(labelling,efficacy&safety	2	1	1(labelling,efficacy&safety)

* If applicable

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
NB = New Biological drug
BF = New Generic of Biological drug

BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA

PERATURAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA
NOMOR 3 TAHUN 2013
TENTANG
PERUBAHAN ATAS PERATURAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN NOMOR HK.03.1.23.10.11.08481 TAHUN 2011 TENTANG KRITERIA DAN TATA LAKSANA REGISTRASI OBAT

DENGAN RAHMAT TUHAN YANG MAHA ESA

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA,

Menimbang : a. bahwa pengaturan registrasi obat sebagaimana telah diatur dalam Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.1.23.10.11.08481 Tahun 2011 tentang Kriteria dan Tata Laksana Registrasi Obat perlu disesuaikan dengan kondisi terkini terkait dengan registrasi obat generik;

b. bahwa berdasarkan pertimbangan sebagaimana dimaksud dalam huruf a perlu menetapkan Peraturan Kepala Badan Pengawas Obat dan Makanan tentang Perubahan Atas Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.1.23.10.11.08481 Tahun 2011 tentang Kriteria dan Tata Laksana Registrasi Obat;

Mengingat : 1. Ordonansi Obat Keras (*Sterkwerkende Geneesmiddelen Ordonnantie, Staatsblad* 1949:419);

2. Undang-Undang Nomor 5 Tahun 1997 tentang Psikotropika (Lembaran Negara Republik Indonesia Tahun 1997 Nomor 10, Tambahan Lembaran Negara Republik Indonesia Nomor 3671);

3. Undang-Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen (Lembaran Negara Republik Indonesia Tahun 1999 Nomor 42, Tambahan Lembaran Negara Republik Indonesia Nomor 3821);

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4. Undang-Undang Nomor 35 Tahun 2009 tentang Narkotika (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 143, Tambahan Lembaran Negara Republik Indonesia Nomor 5062);
5. Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 144, Tambahan Lembaran Negara Republik Indonesia Nomor 5063);
6. Keputusan Presiden Nomor 103 Tahun 2001 tentang Kedudukan, Tugas, Fungsi, Kewenangan, Susunan Organisasi, dan Tata Kerja Lembaga Pemerintah Non Departemen sebagaimana telah beberapa kali diubah terakhir dengan Peraturan Presiden Nomor 3 Tahun 2013;
7. Keputusan Presiden Nomor 110 Tahun 2001 tentang Unit Organisasi dan Tugas Eselon I Lembaga Pemerintah Non Departemen sebagaimana telah beberapa kali diubah terakhir dengan Peraturan Presiden Republik Indonesia Nomor 4 Tahun 2013;
8. Peraturan Menteri Kesehatan Nomor 1010/Menkes/Per/XI/2008 tentang Registrasi Obat sebagaimana telah diubah dengan Peraturan Menteri Kesehatan Nomor 1120/Menkes/Per/XII/2008;
9. Keputusan Kepala Badan Pengawas Obat dan Makanan Nomor 02001/SK/KBPOM Tahun 2001 tentang Organisasi dan Tata Kerja Badan Pengawas Obat dan Makanan sebagaimana telah diubah dengan Keputusan Kepala Badan Pengawas Obat dan Makanan Nomor HK.00.05.21.4231 Tahun 2004;
10. Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.1.23.10.11.08481 Tahun 2011 tentang Kriteria dan Tata Laksana Registrasi Obat (Berita Negara Republik Indonesia Tahun 2011 Nomor 634);
11. Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.01.23.12.11.10217 Tahun 2011 tentang Obat Wajib Uji Ekivalensi (Berita Negara Republik Indonesia Tahun 2012 Nomor 120);

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12. Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.1.34.11.12.7542 Tahun 2012 tentang Pedoman Teknis Cara Distribusi Obat Yang Baik (Berita Negara Republik Indonesia Tahun 2012 Nomor 1268);
13. Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.1.33.12.12.8195 Tahun 2012 tentang Penerapan Pedoman Cara Pembuatan Obat yang Baik (Berita Negara Republik Indonesia Tahun 2013 Nomor 122);

MEMUTUSKAN:

Menetapkan : PERATURAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN TENTANG PERUBAHAN ATAS PERATURAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN NOMOR HK.03.1.23.10.11.08481 TAHUN 2011 TENTANG KRITERIA DAN TATA LAKSANA REGISTRASI OBAT.

Pasal I

Beberapa ketentuan dalam Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.1.23.10.11.08481 Tahun 2011 tentang Kriteria dan Tata Laksana Registrasi Obat diubah sebagai berikut:

1. Setelah Pasal 21 ditambah Bagian Kesepuluh Pasal 21A yang berbunyi sebagai berikut:

Bagian Kesepuluh

Registrasi Obat dengan Nama Generik

Pasal 21A

(1) Obat yang diregistrasi dengan nama generik harus mempunyai spesifikasi dan mutu yang sama dengan obat dengan nama dagang atau sebaliknya yang dibuat oleh industri farmasi yang sama.

BADAN PENGAWAS OBAT DAN MAKANAN
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(2) Spesifikasi sebagaimana dimaksud pada ayat (1) meliputi:

a. ukuran;

b. bentuk;

c. warna;

d. aroma; dan

e. rasa.

2. Diantara Pasal 24 dan Pasal 25 disisipkan 1 (satu) pasal, yakni Pasal 24A yang berbunyi sebagai berikut:

Pasal 24A

(1) Untuk menjamin kestabilan obat dalam bentuk sediaan oral padat, registrasi obat dengan kemasan botol berisi paling banyak 100 (seratus) sediaan.

(2) Registrasi obat dengan kemasan botol sebagaimana dimaksud pada ayat (1) hanya dapat dilakukan untuk obat dengan zat aktif yang stabil.

(3) Jika industri farmasi melakukan registrasi obat yang memiliki lebih dari 1 (satu) kekuatan zat aktif, maka harus memiliki perbedaan paling sedikit salah satu spesifikasi sebagaimana dimaksud dalam Pasal 21A ayat (2).

(4) Khusus registrasi obat dengan nama generik, dokumen penandaan sebagaimana dimaksud dalam Pasal 24 ayat (3) harus mencantumkan:

a. harga eceran tertinggi sesuai dengan ketentuan peraturan perundang-undangan; dan

b. logo generik yang berwarna hijau sebagai contoh berikut:

(5) Logo generik sebagaimana dimaksud pada ayat (4) dicantumkan secara proporsional sesuai dengan ukuran kemasan.

(6) Jika industri farmasi melakukan registrasi obat dengan nama generik lebih dari 1 (satu) kekuatan zat aktif, maka pada kemasan harus mencantumkan kekuatan zat aktif setelah bentuk sediaan dengan ukuran huruf sesuai ukuran huruf nama generik.

BADAN PENGAWAS OBAT DAN MAKANAN
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3. Mengubah ketentuan Pasal 46 ayat (1) dan antara ayat (2) dan ayat (3) disisipkan 1 (satu) ayat yakni ayat (2a) sehingga berbunyi sebagai berikut:

Pasal 46

(1) Persetujuan sebagaimana dimaksud dalam Pasal 45 ayat (3) diberitahukan kepada Pendaftar secara tertulis berupa:

a. pemberitahuan persetujuan (*approvable letter*);

b. persetujuan Izin Edar;

c. persetujuan impor dalam bentuk ruahan;

d. persetujuan impor Khusus Ekspor;

e. persetujuan Khusus Ekspor.

(2) Persetujuan Registrasi Variasi berupa persetujuan Izin Edar atau surat persetujuan perubahan yang merupakan adendum dari persetujuan Izin Edar yang telah diterbitkan.

(2a) Pemberitahuan persetujuan sebagaimana dimaksud pada ayat (1) huruf a merupakan surat pemberitahuan persetujuan untuk melakukan persiapan pembuatan obat dengan skala komersial atau persiapan pelaksanaan importasi obat sebelum diterbitkan persetujuan Izin Edar.

(3) Persetujuan sebagaimana dimaksud pada ayat (1) huruf b menggunakan format sesuai Lampiran XVII yang merupakan bagian yang tidak terpisahkan dari Peraturan ini.

4. Diantara Pasal 46 dan Pasal 47 disisipkan 1 (satu) pasal, yakni Pasal 46A yang berbunyi sebagai berikut:

Pasal 46A

(1) Pemberitahuan persetujuan (*approvable letter*) sebagaimana dimaksud dalam Pasal 46 ayat (1) huruf a bukan sebagai pengganti Persetujuan Izin Edar.

(2) Pemberitahuan persetujuan sebagaimana dimaksud dalam Pasal 46 ayat (1) huruf a berlaku 2 (dua) tahun sejak tanggal surat diterbitkan.

(3) Persetujuan Izin Edar sebagaimana dimaksud dalam Pasal 46 ayat (1) huruf b diterbitkan apabila hasil pembuatan obat skala komersial memenuhi persyaratan atau telah menyerahkan bukti importasi obat.

BADAN PENGAWAS OBAT DAN MAKANAN
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Pasal II

Peraturan ini mulai berlaku pada tanggal diundangkan.

Agar setiap orang mengetahuinya, memerintahkan pengundangan Peraturan ini dengan penempatannya dalam Berita Negara Republik Indonesia.

Ditetapkan di Jakarta
pada tanggal 26 Maret 2013
KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA,

ttd.

LUCKY S. SLAMET

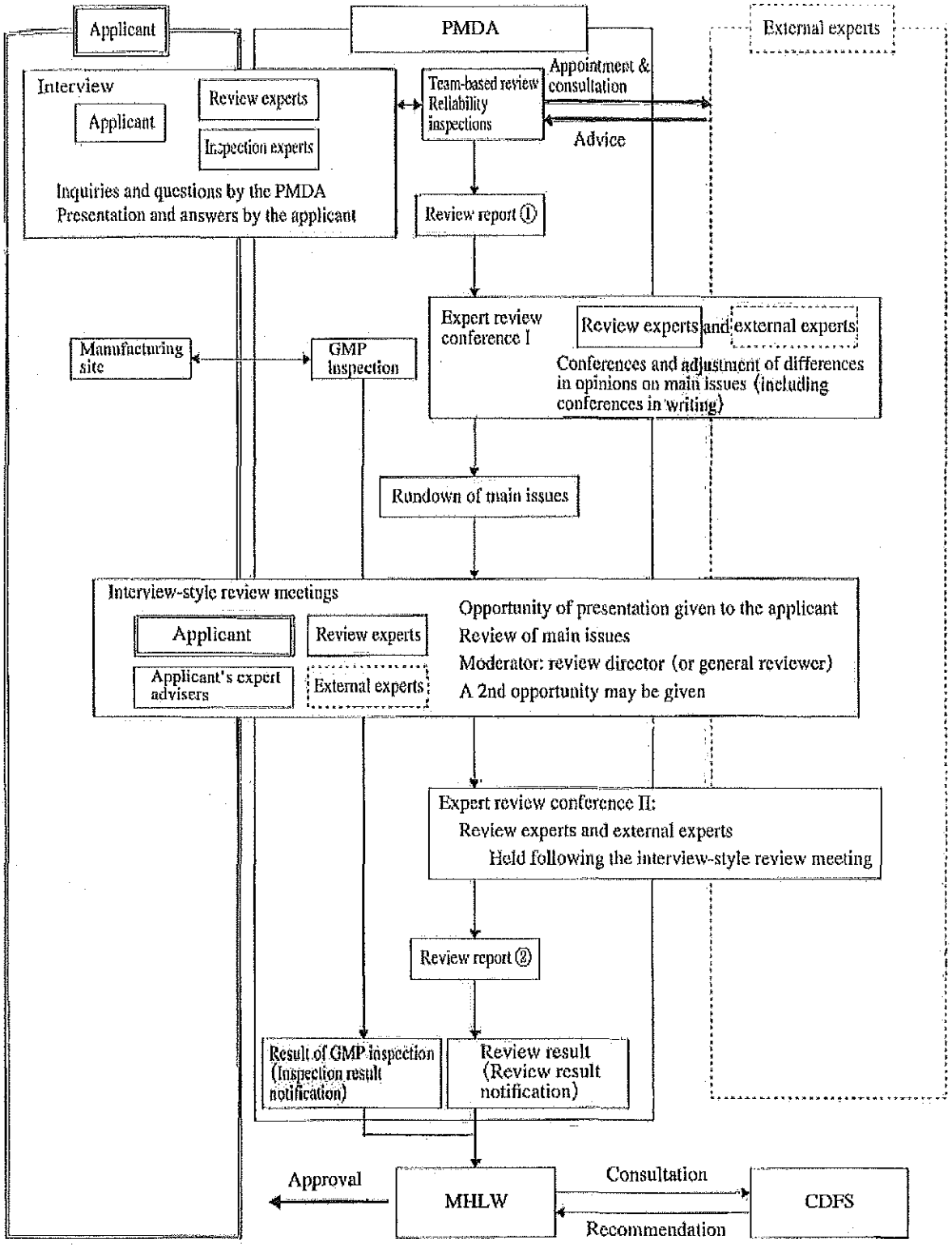
Diundangkan di Jakarta
pada tanggal 4 April 2013
MENTERI HUKUM DAN HAK ASASI MANUSIA
REPUBLIK INDONESIA,

ttd.

AMIR SYAMSUDIN

BERITA NEGARA REPUBLIK INDONESIA TAHUN 2013 NOMOR 540

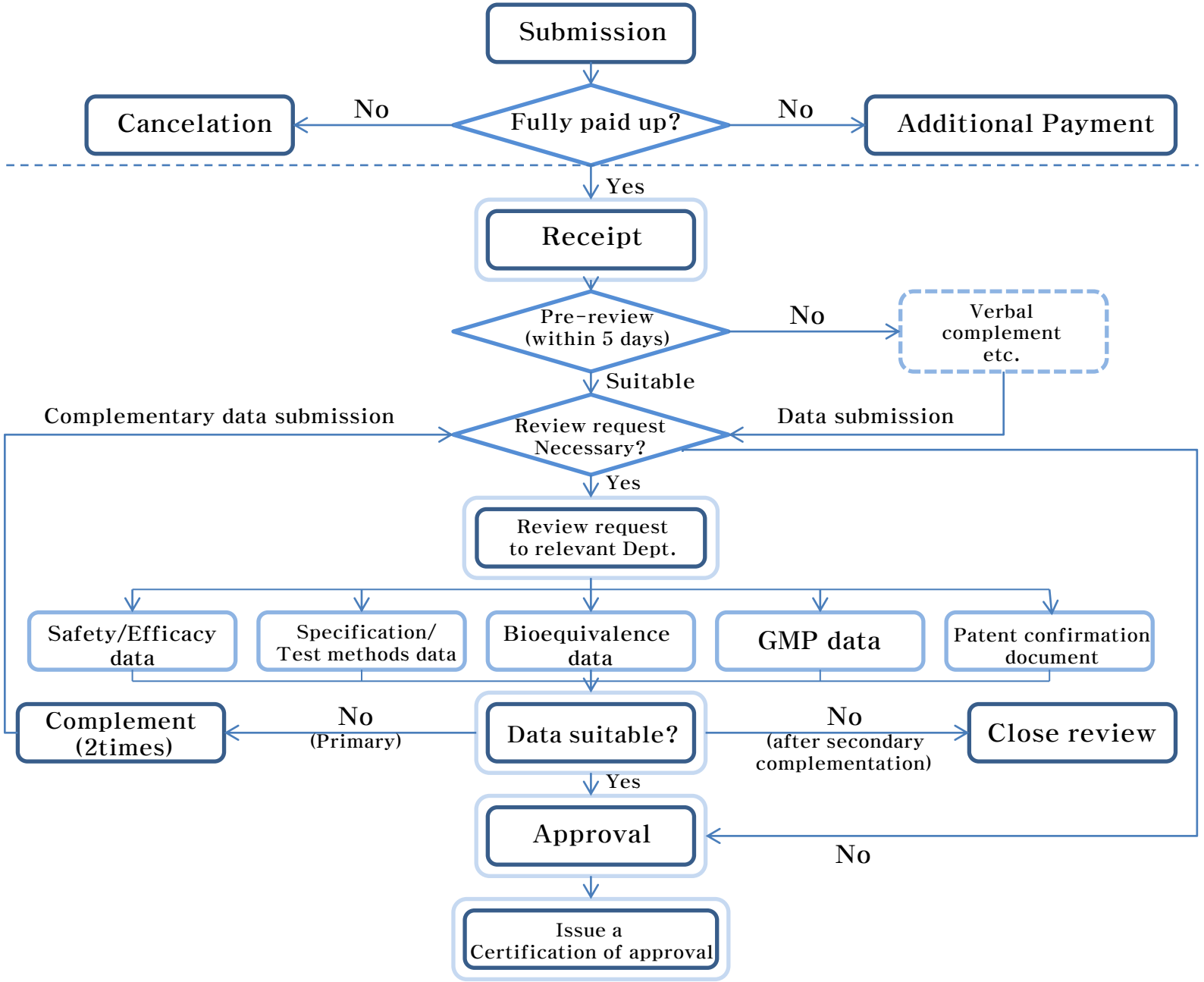
Application Review Process



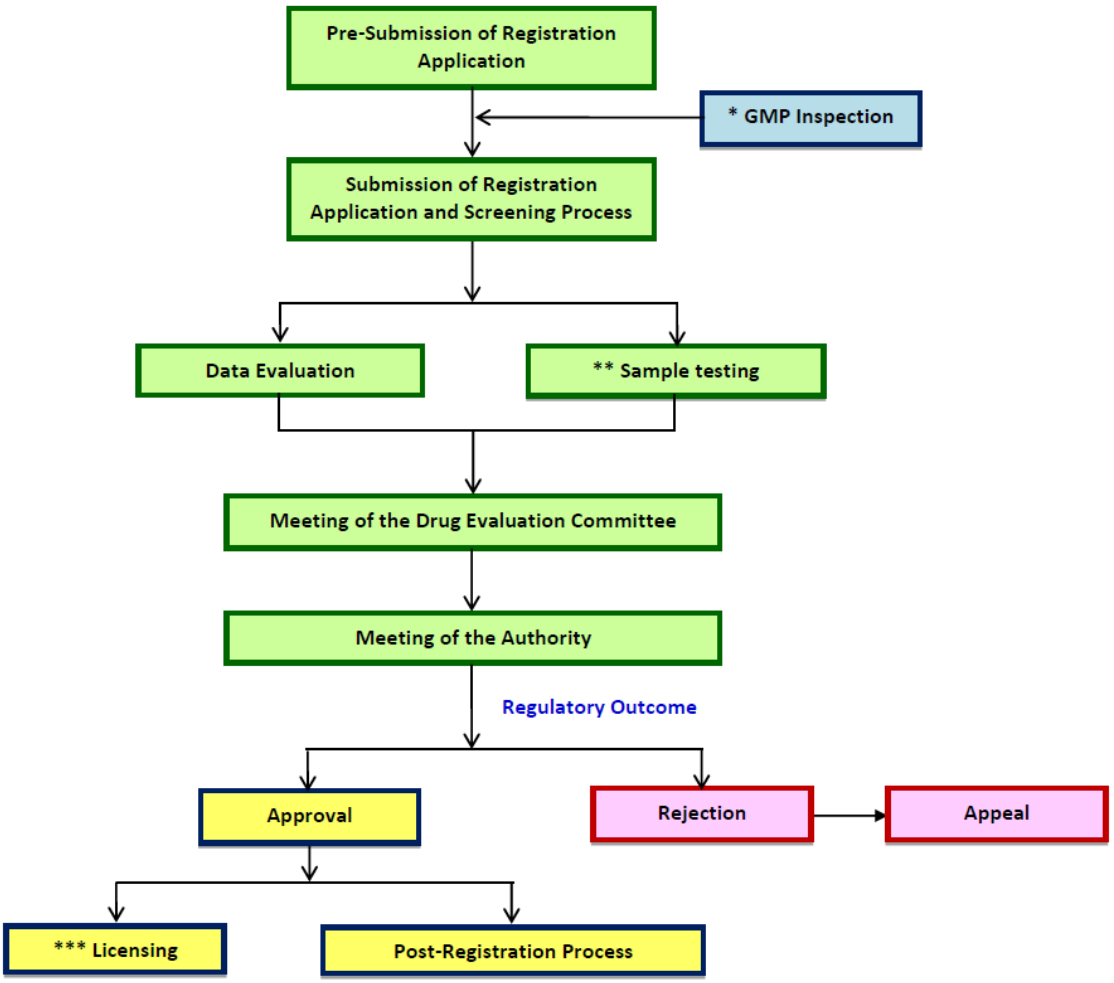
(Source: Jiho. Drug Approval Licensing Procedures in Japan 2010. Tokyo. Jiho, Inc, 2011; P. 489.)

Flow of Application process

Annex 10 Korea



Registration process includes quality control, inspection & licensing as well as post-registration process of medicinal products is illustrated in **Figure 2** below:



* Good Manufacturing Practice (GMP) Certification
** For natural products only
*** Application for Manufacturer, Import and/or Wholesale License

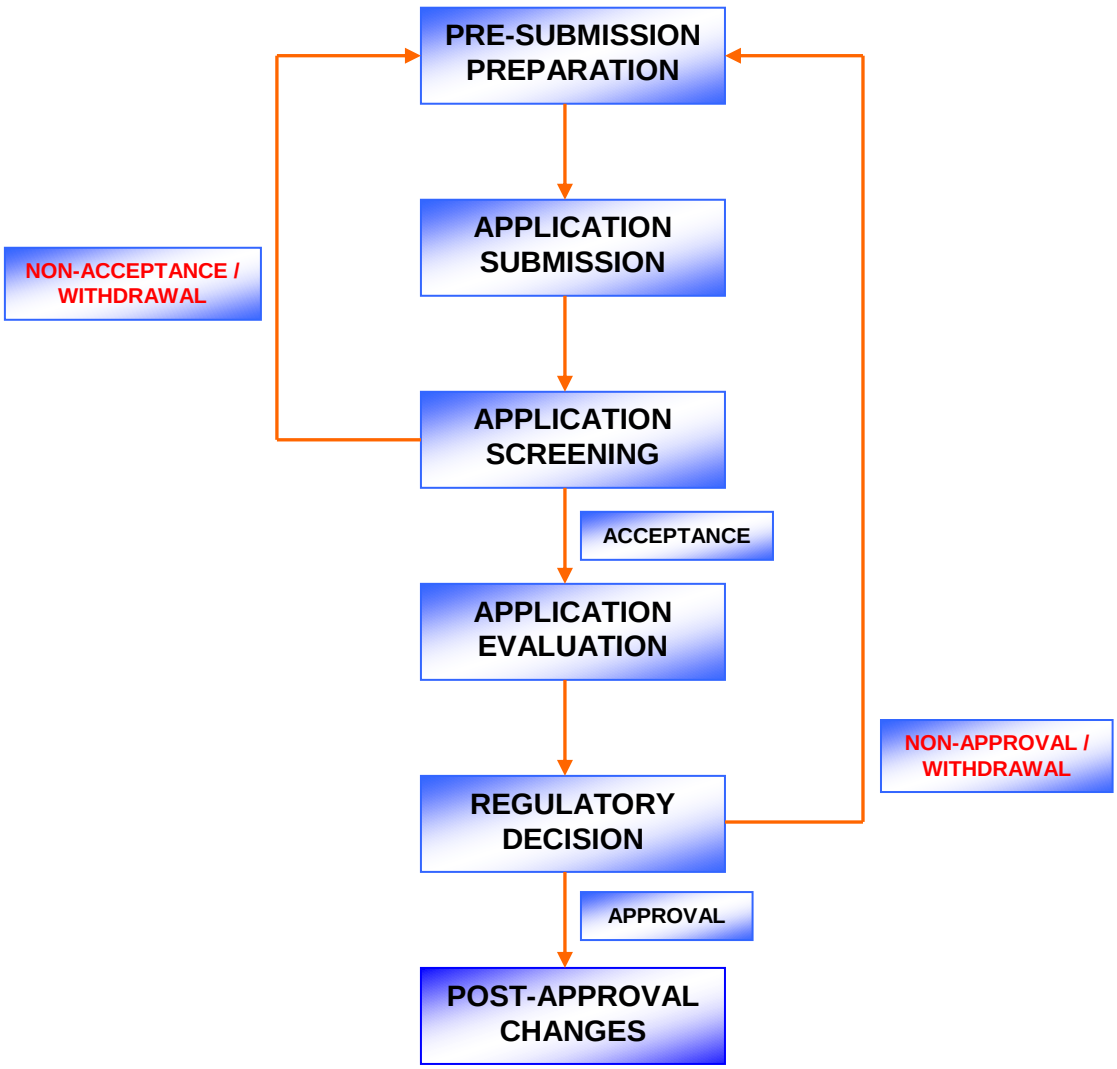


Figure 1 Registration Process for a Therapeutic Product

Source : GUIDANCE ON MEDICINAL PRODUCT REGISTRATION IN SINGAPORE, HSA

New Drug Registration
Thailand

REGISTRATION PROCEDURE

Annex 13 Thailand

FDA Drug Bureau

Step I

Application for Importing of Drug Sample

Submit Application

Permit for Importing Drug Sample

1 days

Step II

Application for Registration

Submit Registration File

Document Checking and Preliminary Review

Experts and/or Subcommittee

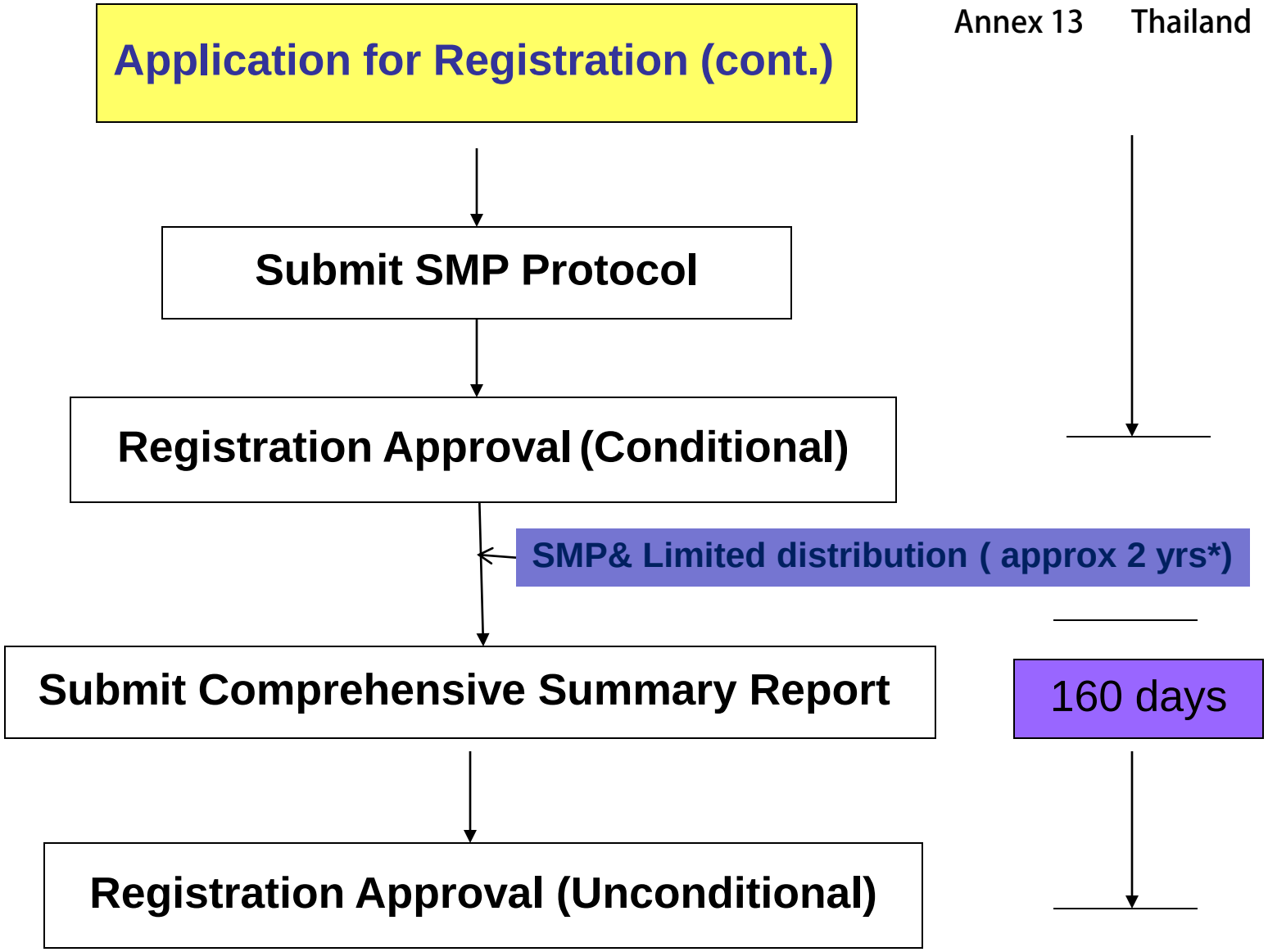
Accept

Revise or Request for Add. Document

Review

Accept

280 wd



Note: *Time can be extended from 2 years up to 4 years if justified

NATIONAL AGENCY OF DRUG AND FOOD CONTROL
OF THE REPUBLIC OF INDONESIA

REGULATION OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL OF THE REPUBLIC OF INDONESIA NUMBER 17 IN 2016
CONCERNING
THE SECOND AMENDMENT TO THE REGULATION OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL NUMBER HK.03.1.23.10.11.08481 IN 2011 ON THE CRITERIA AND PROCEDURES OF DRUG REGISTRATION

WITH THE BLESSING OF GOD ALMIGHTY

THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL OF THE REPUBLIC OF INDONESIA,

Considering: a. that in order to improve public service in drug and food monitoring, especially in drug registration process, it is necessary to change several stipulations in the Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.1.23.10.11.08481 in 2011 on the Criteria and Procedures of Drug Registration which has been amended with the Regulation of the Head of the National Agency of Drug and Food Control Number 3 in 2013;

b. that based on the considerations stated in letter a, it is necessary to stipulate a Regulation of the Head of the National Agency of Drug and Food Control concerning the Second Amendment to the Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.1.23.10.11.08481 in 2011 on the Criteria and Procedures of Drug Registration;

In view of:

1. Ordinance on Hard Drugs (*Sterkwerkende Geneesmiddelen Ordonnantie, Staatsblad* 1949:419);
2. Law Number 5 in 1997 on Psychotropic Drugs (State Gazette of the Republic of Indonesia in 1997 Number 10, Supplement to the State Gazette of the Republic of Indonesia Number 3671);
3. Law Number 8 in 1999 on Consumer Protection (State Gazette of the Republic of Indonesia in 1999 Number 42, Supplement to the State Gazette of the Republic of Indonesia Number 3821);
4. Law Number 35 in 2009 on Narcotics (State Gazette of the Republic of Indonesia in 2009 Number 143, Supplement to the State Gazette of the Republic of Indonesia Number 5062);
5. Law Number 36 in 2009 on Health (State Gazette of the Republic of Indonesia in 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia Number 5063);
6. Presidential Decree Number 103 in 2001 on the Position, Tasks, Function, Authority, Organizational Structure, and Work Procedures of Non-Departmental Government Agencies which has been amended several times, the last of which was with the Presidential Regulation Number 145 in 2015 on the Eighth Amendment to the Presidential Decree Number 103 in 2001 on the Position, Tasks, Function, Authority, Organizational Structure, and Work Procedures of Non-Ministerial Government Agencies (State Gazette of the Republic of Indonesia in 2015 Number 322);
7. Presidential Decree Number 110 in 2001 on Organizational Units and Tasks of Echelon I Non-Departmental Government Agencies which has been amended several times, the last of which was with the Presidential Regulation Number 4 in 2013 on the Eighth Amendment to the Presidential Decree Number 110 in 2001 on Organizational Units and Tasks of Echelon I Non-Ministerial Government Agencies (State Gazette of the Republic of Indonesia in 2013 Number

11);

8. Health Ministerial Regulation Number 1010/Menkes/Per/XI/2008 on Drug Registration which has been amended with the Health Ministerial Regulation Number 1120/Menkes/Per/XII/2008;
9. Decree of the Head of the National Agency of Drug and Food Control Number 02001/SK/KBPOM in 2001 on the Organization and Working Procedures of the National Agency of Drug and Food Control which has been amended with the Decree of the Head of the National Agency of Drug and Food Control Number HK.00.05.21.4231 in 2004 concerning the Amendment to the Decree of the Head of the National Agency of Drug and Food Control Number 02001/SK/KBPOM in 2001 on the Organization and Working Procedures of the National Agency of Drug and Food Control;
10. Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.1.23.10.11.08481 in 2011 on the Criteria and Procedures of Drug Registration which has been amended with the Regulation of the Head of the National Agency of Drug and Food Control Number 3 in 2013 concerning the Amendment to the Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.1.23.10.11.08481 in 2011 on the Criteria and Procedures of Drug Registration (Official Gazette of the Republic of Indonesia in 2013 Number 540);
11. Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.01.23.12.11.10217 in 2011 on Equivalence Testing-Mandatory Drugs (Official Gazette of the Republic of Indonesia in 2012 Number 120);
12. Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.1.34.11.12.7542 in 2012 on the Technical Guide of Proper Drug Distribution Methods (Official Gazette of the Republic of Indonesia in 2012 Number 1268);
13. Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.1.33.12.12.8195 in 2012 on

the Implementation of Proper Drug Manufacturing Methods (Official Gazette of the Republic of Indonesia in 2013 Number 122);

DECIDED:

To enact: REGULATION OF THE HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL CONCERNING THE SECOND AMENDMENT TO THE FOOD AND DRUG MONITORING AGENCY HEAD REGULATION NUMBER HK.03.1.23.10.11.08481 IN 2011 ON THE CRITERIA AND PROCEDURES OF DRUG REGISTRATION.

Article I

Several stipulations in the Regulation of the Head of the National Agency of Drug and Food Control Number HK.03.1.23.10.11.08481 in 2011 on the Criteria and Procedures of Drug Registration which has been amended with the Regulation of the Head of the National Agency of Drug and Food Control Number 3 in 2013 are amended as follows:

1. Article 30 is changed into the following:

Article 30

(1) Excluded from the terms stipulated in Article 28 are Registration of Variation for category 4, category 5, and category 6 drugs as stipulated in Article 5 verse (3) letter a, letter b, and letter c, as well as Re-Registration of category 7 as stipulated in Article 5 verse (4).

(2) Registration of Variation for category 4 drugs as stipulated in verse (1) only applies to registration of variation in relation to drug quality which does not require clinical testing.

2. Article 31 is changed into the following:

Article 31

The evaluation tracks as stipulated in Article 28 verse (1) consist of:

1. The 7 (seven)-day track covering registration application for export-only drugs

2. The 10 (ten)-day track covering re-registration without any changes
3. The 40 (forty)-day track covering registration of minor variation which requires approval;
4. The 100 (one hundred)-day track covering:
   a. New Registration of New Drugs and Biological Products indicated to be used to treat diseases that are life-threatening, and/or highly communicable, and/or do not yet have or lack other options of safe and effective treatments;
   b. New Registration of New Drugs and Biological Products which based on justification are indicated to be used for serious and rare diseases (orphan drugs);
   c. New Registration of New Drugs, Biological Products and Copy of Generic Drugs intended for public health programs that are equipped with documents supporting the programs' needs or data supporting the drugs as essential drugs;
   d. New Registration of New Drugs and Biological Products which have undergone a process of new drug development by the Pharmaceutical Industry or a research institution in Indonesia with all stages of clinical testing performed in Indonesia;
   e. Registration of major variation of new indication/new posology for the intended drugs as stipulated in letter a, letter b, letter c, and letter d;
   f. Registration of major variation which is not included in letter e.
5. The 150 (one hundred and fifty)-day track covering:
   a. New Registration of New Drugs and Biological Products, and registration of major variation of new indication/new posology which have been approved in countries that have applied a harmonized evaluation system and in countries with a well-known evaluation system;

b. New Registration of New Drugs and Biological Products, and registration of major variation of new indication/new posology which have been approved in at least 3 (three) countries with a well-known evaluation system;

c. New Registration of Copy Drugs.

6. The 300 (three hundred)-day track covering New Registration of New Drugs, Biological Products and Similar Biological Products, or registration of major variation of new indication/new posology which are not included in evaluation tracks stipulated in numbers 4 and 5.

3. Article 35 is changed into the following:

Article 35

(1) Registration of variation for category 6 as stipulated in Article 5 verse (3) letter c is applied for by filling in a form, an example of which is included in Appendix I, and enclosing a Registration of Variation document as stipulated in Article 34 verse (3).

(2) The applicant may make the changes stated in verse (1) and report to the National Agency of Drug and Food Control every 6 (six) months cumulatively for all of the changes.

(3) Implementation of the changes stated in verse (2) is done through a mechanism of change control.

(4) If the reported changes are not in accordance with the type of changes stipulated in Appendix XV letter B number 3, then the registration shall be processed according to the determined registration of variation category.

(5) Appendix XV letter B number 3 is changed into that which is included in the amendment to Appendix XV letter B number 3, which forms an inseparable part of this Agency Head Regulation.

Article II

This Agency Head Regulation takes effect at the time it is stipulated.

So that everyone is aware of it, this Agency Head Regulation is published in the Official Gazette of the Republic of Indonesia.

Enacted di Jakarta

on May 24, 2016

HEAD OF THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL OF THE REPUBLIC OF INDONESIA,

signed

ROY A. SPARRINGA

Stipulated in Jakarta
on August 4, 2016

DIRECTOR GENERAL OF REGULATORY LAW
JUSTICE AND HUMAN RIGHTS MINISTRY
OF THE REPUBLIC OF INDONESIA,

signed

WIDODO EKATJAHJANA

OFFICIAL GAZETTE OF THE REPUBLIC OF INDONESIA IN 2016 NUMBER 1140

ATTACHMENT
DECREE OF THE HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL
NUMBER 17 YEAR 2016
ON SECOND CHANGES TO
HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL REGULATION
NO: HK. 03.1.23.10.11.08481 OF 2011
ON THE CRITERIA AND PROCEDURE OF DRUG REGISTRATION

Category 6: Registration of Drug Minor Variation which
Need an Approval (VaMi-A)

No	Type of Modification	Criteria	Submit Documents
Modification of relevant product information and/or labelling			
1	Modification or adding of trademark (logo) (including trademark/logo of the company)	1. Claims in product information are unmodified 2. Specification of the packaging is unmodified	Picture of primary and/or secondary packaging to be marketed from all angles (including product information).
2	A stringent additional claims of side effects and/or contraindication in the product information		Picture of primary and/or secondary packaging to be marketed from all angles (including product information).
3	Decreasing of manufacturing location/space (including active ingredient, intermediate product or finished drug, packaging location, batch released location	1. Manufacturing location still available with the same usage/function (including: active ingredient, intermediate product or finished drug, packaging location, batch released location) has been approved 2. Decreasing of manufacturing location is not due to the critical factor relevant to manufacturing procedure	
4	Modification of the	1. Active ingredient is	Picture of primary and/or

	name of active ingredient	unmodified 2. The new name of active ingredient should be in lined with INN/Pharmacopoeia	secondary packaging to be marketed from all angles (including product information).
5	Modification of the primary packaging that is not contacted with the drug (such as the color of flip-off caps, the color of the ring on the ampule, modification on the shield of the needle, used different plastic)	1. Not important past of packaging material that affect to: distribution, usage, safety or drug stability 2. Specification of primary packaging material that contacted with the drug is unmodified	Specification and analytical method of packaging material
6	Eradication of foreign language of drug labelling	1. Claims in product information are unmodified	Picture of primary and/or secondary packaging to be marketed from all angles (including product information).
7	Modification of the dimention of packaging	1. Not for sterile preparation 2. Not any modification or the specification of packaging material except dosage form and/or the dimension 3. Not for head space or surface/volume ratio 4. Claims on product information are unmodified	1. Picture of primary and/or secondary packaging to be marketed from all angles (including product information). 2. Specification of packaging material
8	Modification of design of packaging	1. Claims in product information and claims in labelling are unmodified 2. Valid only for the	Picture of primary and/or secondary packaging to be marketed from all angles (including product

		modification of text located and picture (graphic), color and line 3. Not included the modification of the picture (graphic) 4. Not content the sentences/ information that are characterized of promotion	information).
9	Modification of the address (written) of the applicant/ pharmaceutical industry/license	1. Location of applicant/ pharmaceutical industry/license are unmodified	1. Letter of information of changing address 2. Picture of primary and/or secondary packaging to be marketed from all angles (including product information).
10	Modification of batch number system		1. Explanation of new batch number system
A. Modification related to the quality of active ingredient			
1			
2			
3	Modification of the name and/ or address of the manufacturer of active ingredient	1. Location of the manufacturer of active ingredient is not changed	Supporting document of the modification of name and/or address of active ingredient manufacturer
4	Update Ph. Eur. Certificate of Suitability (CEP)	1. Not included biological product 2. Specification of drug (released and shelf life) are unmodified 3. Manufacturing procedure	New Certificate of Suitability (Ph. Eur.)

		of active ingredients are not used human/animal sources which need viral safety data	
5	Modification of Pharmacopoeia edition stated for active ingredient	1. Analytical method of active ingredients are unmodified 2. Specification of active ingredient and finished drug are unmodified	Refrences of relevant Pharmacopoeia
6	Fixing the limit of specification of active ingredients	1. Modification is still in the limit of valid standard 2. Analytical procedure is unmodified	1. Specification of the active ingredient 2. Certificate analysis of active ingredient
7	Modification of the specification of active ingredient to fulfill the criteria of new Pharmacopoeia	1. Specification of drug (released and shelf life) are unmodified 2. Specification of impurity and active ingredient are unmodified (particle size profile, polymorphism form) 3. Addition of validation from the new method of Pharmacopoeia or modification is not necessary	1. Specification and analytical method of active ingredient 2. Certificate analysis of active ingredient 3. Result of batch analysis of 2 batches of active ingredient of production scales for all analysis in new specification 4. References of relevant Pharmacopoeia
8	Addition of analytical parameters and limit of specification in process control of manufacturing procedure of active ingredient	1. The modification is not due to the affect to drug manufacturing procedure 2. The specification of active ingredients are unmodified 3. The specification of active	1. Manufacturing procedure 2. Details of analytical procedure and validation data of new analytical method/procedure 3. Batch analysis data using 3 batches of active

		ingredients are unmodified	ingredients for all study in new specification
9	Minor modification of analytical procedure of active ingredient	1. Analytical method is unmodified (inexample, modification in the length of coloumn or temperature, but the method and type of coloumn are unchanged) 2. Study of revalidation has been conducted conformed to the study protocol 3. Result of validation method appointed that new analytical procedure is similar/equivalent with the former procedure 4. Specification of drug (released and shelf life) are unmodified 5. Not valid for addition of analytical procedure	1. Specification and analytical method of active ingredient 2. Certificate of analysis of active ingredient 3. Comparison of the result of validation or comparison of the result of drug analysis that the new analytical procedure and the former procedure are similar/equivalent
10	Modification of analytical method to determine the concentration of active ingredient conformed to fulfill the criteria of Pharmacopoeia	1. Specification of active ingredient are unmodified 2. Specification of drug (released and shelf life) are unmodified	1. Analytical method of active ingredient 2. Verification of analytical procedure of active ingredient 3. Certificate analysis of active ingredient 4. Standard reference
11	Modification of storage condition of active ingredient	1. Result of stability study specification still fulfilled approved criteria formerly 2. The modification is not	1. Report of the stability of active ingredient 2. Specification of active ingredient

		due to the affect in manufacturing procedure of active ingredient or the problem of stability 3. No modification of repeated study period of active ingredient	3. Result of batch analysis of finished drug
12	Modification of working cell/ seed bank	1. Manufactured of approved working cell/seed bank and using approved master cell seed bank and approved SOP with the similar passage level of approved working cell/seed bank 2. Statement that specification of drug released and shelf life of finished drugs are unmodified	1. Comparative batch analysis data (tabulated) of minimally 3 batches of active ingredients from the new and submitted cell seed bank 2. Comparative batch of active ingredients shows a comparable result
13			
B.Modification relevant to the quality of finished product			
1	Minor modification of drug manufacturing	1. Not includes biological product and sterile preparation 2. Principally the whole manufacturing is still similar 3. New process gives the similar result from the aspect of quality, validity, specification of drug, safety and efficacy 4. No modification of qualitative and	1. Drug manufacturing procedure 2. Batch analysis data of drug 3. For all solid preparation, dissolution profile data comparable from 1 batch production representative and comparisons of 3 batches of last production of mnaufacturing procedure of former drug 4. Report of drug stability

		quantitative of impurity profile or physicochemical chaacteristics 5. Drug stability study has been conducted on minimally 3 months from 1 batch of pilot scale or production scale 6. Manufacturing location is not modified 7. Dissolution profiles are unmodified	and commitment of drug stabiity if the report of drug stability has not completed 5. Justification of not conducted BE study
2	Modification of addition of drug study location	1. Transfer of drug analytical method from former location to the new location has fulfilled the criteria 2. Specification of drug is unmodified 3. Product owner is still similar 4. Study location has been registered	1. Result of batch analysis of new drug 2. Specification of the drug 3. Reference standard 4. Result of batch analysis of the drug 5. Report of transfered of drug analytical procedure
3	Fixing the limit of specification of drug released	1. The modification is still in the range of approved specification limitation 2. Analytical procedure is unmodified, or only minor modification of analytical procedure	1. Specification of drug 2. Certificate analysis of new drug
4	Addition of parameters of analysis and limit of specification or process control in drug manufacturing	1. The modification is not due to the affect to drug manufacturing procedure 2.Specification of drugs are unmodified	1. Manufacturing procedure 2. Details of analytical procedure and validation data of new analytical

	procedure	3. Vallidation of analytical method has been conducted	method/procedure 3. Batch analysis data using 3 batches of active ingredients for all study in the specification of new drug
5	Fixing the limit of specification of in-process during drug manufacturing	1. The modification is not due to the affect of drug manufacturing procedure or problem of stability 2. Specification of drug (released and shelf life) are unmodified 3. The modification is still in the limit of valid standard 4. Analytical procedure is unmodified for only a minor modification	1. Specification of in-process during manufacturing of new drug
6	Addition of parameters of drug analysis	1. Modification is not due to the affect of drug 2. Specification of drug besides the additional parameters of drug analysis are unmodified	1. Specification of drug 2. Drug analytical procedure 3. Result of batch analysis of finished drug (2 batches) 4. Report of validation of drug analytical procedure (if necessary)
7	Fixing the limit of specification of inactive ingredient	1. Modification not due to the affect of drug manufacturing procedure 2. The modification is still in the limit of valid standard 3. Analytical procedure is unmodified	1. Specification of new active ingredient 2. Certificate analysis of inactive ingredient with new specification
8	Minor modification of analytical procedure of	1. Analytical procedure is unmodified (for example,	1. Specification and analytical method of

	inactive ingredient	modification of coloumn length or temperature, but no different in the method and type of coloumn) 2. Analytical procedure is not biological/immunological / immunochemistry analytical procedure or analytical procedure using biological reagents	inactive ingredient 2. Certificate of analysis of inactive ingredient
9	Modification of analytical procedure of inactive ingredient conforme to compendial monography or relevant one	1. Specification of inactive ingredient is unmodified (such as: particle size, polymorph form)	1. Specification of active ingredient 2. Analytical procedure of inactive ingredient 3. Certificate of analysis of inactive ingredient 4. Compendial references or relevant supporting documents
10	Addition of study parameters of the specification of inactive ingredient	1. Modification not due to the affect of drug manufacturing procedure 2. The modification is still in the limit of valid standard	1. Specification and analytical procedure of inactive ingredient 2. Batch analytical data of inactive ingredient with former specification that is submitting
11	Modification of analytical procedure of inactive ingredient, including the changement of analytical procedure	1.Re-validation study has been conducted conformed to the study protocol 2. Result of validation method appointed that new analytical procedure	1. Specification and analytical procedure of inactive ingredient 2. Review of specification of drug impurities (if any)

		is similar/equivalent to former procedure 3. Specification of drug (released and shelf life) are unmodified	
12	Modification of the specification of inactive ingredient to fulfill the compendial criteria	1. Specification of drug (released and shelf life) are unmodified	1. Specification and analytical procedure of inactive ingredient 2. Certificate of analysis of inactive ingredient 3. Result of batch analysis of finished drug from 2 batches of 2 batches of drugs of production scales 4. Relevant compendial references
13	Modification of the sources of inactive ingredient or reagent with Transmissible Spongiform Encephalophaties (TSE)/ Bovine Spongiform Encephalophatis (BSE) risks	1. Specification of inactive ingredient released and drug released and specification of shelf life are unmodified 2. Not for inactive ingredient or reagent that are used in manufacturing biological product or drugs containing biological active ingredient	A. Quality documents 1. Statement of inactive ingredient or reagents manufacturer that the sources are herbal, animal, or synthesis 2. Certificate of free from BSE/TSE
14	Major modification of heavy tablet coating or heavy capsule shell of the oral preparation immediate release	1. Drug dissolution profile with new heavy tablet coating or heavy capsule shell (minimal 2 batches of pilot scales) equivalent to former drug	1. Description and formula 2. Specification of the drug 3. Result of batch analysis of the drug with old and new heavy tablet coating/capsule shell

		2. Specification ofdrug, only weight and dimention modification 3. Coating is not a critical factor for drug released mechanism	4. Comparable dissolution test data of minimal 1 batch of pilot scale between approved and submitted drug and formula, if required 5. Report of drug stability and commitment of drug stability if the report of drug stability has not completed
15	Modification or adding imprint, bossing or other signs (except middle line of tablet of printing or the capsule, includes the substitution or addition olink used to label the product	1. Specification of drug (released and shelf life) are unmodified 2. The ink which is used should fulfill the criteria and Pharmaceutical regulation 3. The new description not induce ambiguous with registered drug	A. Quality documents 1. Specification of the drug 2. Certificate of analysis of ink/printing material 3. Product information and its photo (if necessary)
16	Modification or inactive ingredient synthesis (non compendial)	1. Not included inactive ingredient of biological product (adjuvant, absorbent, preservative) 2. Not affected to the specification of inactive ingredient 3. No qualitative and quantitative modification of impurity profile or physicochemistry characteristic 4. Route of synthesis and specification of inactive	1. Comparison of batch analysis data of inactive ingredient of minimal 2 batches of drugs of pilot scales which are manufactured using manufacturing procedure of new and old inactive ingredient 2. Comparison of drug's dissolution profile data of minimal 2 batches of drugs of pilot scales

		ingredient are similar and no modfication of impurity profile qualitatively or quantitatively	
17	Subsitution for enlargement of drug secondary location packaging	1. The result of last 2 (two) years inspection and satisfied 2. Manufacturing location is registered	Product information (if necessary) and labelling on the secondary package (if necessary)
18	Fixing the limit of primary packaging specification of drugs	1. The modification is in the range of valid standard 2. Analytical procedures are unmodifie, or only minor modification in the manufacturing procedure	Specification of the packaging
19	Modification of qualitative and quantitative composition of drug primary packaging material	1. Not included biological product and sterile product 2. Modification onlyon the type and material of the same packaging 3. Submitted packaging material similar/equivalent with the approved packaging material	
20	Addition of substitution of measureing device that is not as part of primary packaging (not included spacer device for metered dose inhaler)	1. Submitted measurement device should include accurate dose in lined with approved posology and support by appropriate study data 2. New measurement device compatible with the drug	1. Specification and analytical method of packaging material 2. Data of the result of measurement device calibration 3. Product information and labelling on the primary

		3. Modification not induce the modification of drug information	and secondary package
21	Modification of analytical procedure of primary packaging material of drug including substitution or addition of analytical procedure	Specification of drug are unmodified	Specification and analytical method of packaging material
22	Modification or addition of supplier of the component of packaging or health device associate to drug, not including supplier spacer devices for metered dose inhaler	Specification of packaging material or health device are unmodified	1. Letter of information of substitution or addition of supplier 2. Biological product only complete with comparison result of the study (control) of the component of packaging or health device associate with drug between new supplier and approved supplier
23	Decrease of supplier component of packaging or health device that associated with drug, not included supplier spacer devices for metered dose inhaler	1. Modification not due to the affect of drug manufacturing procedure	
24	Addition of parameters of analytical method of primary packaging of drug	1. Modification is not due to the affect of manufacturing process of drug	A. Quality documents 1. Specification and analytical method of packaging material 2. Report of validation of primary packaging

25	Decreasing the limit of drug expiration date: packaging has not been opened	1. Specification of drug (released and shelf life) are unmodified 2. Stability study has been conducted conformed to the approved study protocol and the result fulfilled the criteria of specification	1. Product information and photo (if necessary) 2. Specification of drug 3. Report of drug stability
26	Reduction of the limit of drug expiration date after the package has been open	1. Specification of drug (released and shelf life) are unmodified 2. Stability study has been conducted conformed to the approved study protocol and the result fulfilled the criteria of specification	1. Product information and photo (if necessary) 2. Specification of drug 3. Report of drug stability

The Head of National Agency of Drug and Food Control
of the Republic of Indonesia

Roy A. Sparringa

Table 2. Supporting documents for CTA, CTN and CTC applications to HSA

Supporting Document	Clinical Trial Authorisation (CTA)	Clinical Trial Notification (CTN)	Clinical Trial Certificate (CTC)
Clinical Trial Protocol	✓	✓	✓
Informed Consent Form (English)	✓	✓	✓
Investigator's Brochure	✓	✗	✓
List of Overseas Trial Site, where applicable	✓	✓	✓
Principal Investigator's CV	✓	✗	✓
Good Manufacturing Practice (GMP) Certificate[1]	✓	✗	✓
Certificate of Analysis (COA) for study batches of Investigational Products	✓	✗	✓
Chemistry. Manufacturing and Control (CMC) information, if requested by HSA	✓	✗	✓
Approved Product Label	✗	✓	✗
IRB Approval Letter	✗	✓	✗

Source : GUIDANCE ON MEDICINAL PRODUCT REGISTRATION IN SINGAPORE, HSA

Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
(Office of DCGI)

FDA Bhavan, Kotla Road,
New Delhi-110002.

Dated: 26th March, 2016

NOTICE

The Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2012 are in the process of revision. The proposed revised Guidelines on Similar Biologics 2016 are uploaded for suggestions/ comments of the stakeholders.

All the stakeholders are requested to submit their suggestions or comments to the Office of Drugs Controller General (India) by 30th April, 2016 through e-mail (dci@nic.in) or fax (no.011-23236973) or by post to the address as under:

Central Drugs Standards Control Organization HQ,
Office of DCG (I),
FDA Bhavan,
Kotla Road, New Delhi – 110002

Office of Drugs Controller General (India)

Table 3. Labelling elements for registered investigational product which fulfils the three conditions, and registered auxiliary product

	Labelling Element	Wholesale Supply	Supply to Subject	
			Investigational Product	Auxiliary product
(a)	the words “For clinical trial use only” or similar wordings;	X	✓	X
(b)	a clinical trial reference code allowing identification of the trial, site, investigator and sponsor;	X	✓	X
(c)	the name of the person to whom the product is to be administered or the trial subject identification number;	X	✓	✓
(d)	the name, address and any identification number or logo of the licensed healthcare institution, licensed retail pharmacy, or trial site where the product is supplied or dispensed;	X	✓	✓
(e)	the name of the product, being the appropriate non- proprietary name and the proprietary designation;	✓	✓	✓
(f)	where the appropriate non-proprietary name is included on the label of the product, the appropriate quantitative particulars of any active ingredient of the product;	✓	✓	✓
(g)	the directions for use of the product;	X	✓	✓
(h)	an appropriate control number, such as a serial number, batch number or lot number;	✓	✓	✓
(i)	the expiry date of the product;	✓	✓	✓
(j)	the date that the product is dispensed;	X	✓	✓
(k)	where the product is registered/ approved, the registration number/ product licence number assigned to the product by the Authority.	✓	✓	✓

Source : GUIDANCE ON MEDICINAL PRODUCT REGISTRATION IN SINGAPORE, HSA

[emblem]

The Announcement of Food and Drug Administration

Title: Guidance for Market Authorization Holders on Post-Marketing Safety Reporting for Human Drugs, Narcotics, and Medicinal Neuropsychotropic Substances

In order to provide the single direction and standard as well as the definite working procedure of post-marketing adverse events reporting and monitoring related to health products to Market Authorization Holders consequence to their compliance and optimizing the pharmacovigilance effectiveness, therefore Food and Drug Administration of Thailand has been issued the announcement entitled “Guidance for Market Authorization Holders on Post-Marketing Safety Reporting for Human Drugs, Narcotics, and Medicinal Neuropsychotropic Substances” as detail enclosed.

Hence, this will be effective from now on.

The announcement on 18 December 2015

[signature]

(Mr. Boonchai Somboonsook)

General Secretary of Food and Drug Administration

The enclosure of

the Announcement of Food and Drug Administration

Title

Guidance for Market Authorization Holders on

Post-Marketing Safety Reporting for

Human Drugs, Narcotics, and Medicinal Neuropsychotropic Substances

Dated 18 December 2015

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Review Process