Part I Questionnaire
Survey on Regulatory Agilities

1a. Use of CPP as reliance tool for full or partial assessments of MA or GMP compliance.

Options	Economies	Remarks (if any)
CPP is either removed/not required or to replace all reviews fully or partially	CN, HK, JP, SG, SK	
CPP is used to replace some reviews fully or partially	None	
CPP is part of standard registration/reliance but does not replace reviews fully or partially:	ID, MY, PH, TW, TH, VN, IN	HK: 2 CPP with the normal way. Nov 2023 alternative route 1 CPP+ clinical trials/RWE/Recommendation letters IN: CPP of any major reference country is acceptable. JP: The CPP is not required for a regulatory submission in Japan, however, there is no review discount by reliance/MRA/CPP. PMDA does their review by themselves. MY: PhAMA has submitted a reliance proposal on CPP and is currently pending feedback from NPRA. TW: Reason: CPP is still required for registration in Taiwan, although CDE conducts full review. Although Taiwan has abbreviated review partway which can review partially, unredacted assessment reports will be required in addition to CPPs. TH: Full unredacted assessment report only for partial assessment

1b. Utilize assessments made by stringent NRAs for COVID19 registrations.

Options	Economies	Remarks (if any)
All Medicines	HK, ID, MY, SG, PH, TW, TH	MY: Based on the principle of the Facilitated Registration Pathways since March 2019 with the use of un-redacted assessment reports and Q&As PH: Moved to all medicines previously only 'Covid medicines only' in the first survey SG: No longer applicable now for Covid-19 drugs as the pandemic situation is over.
For COVID Only	SK, VN, JP	JP: Emergency Use category drugs only SK: It can be referenced, however, not replacing the requirements or review. SK: It can be referenced, however, not replacing the requirements of review
Not available	CN, IN	IN: Emergency Use Authorization are granted during COVID-19 registrations. However, CDSCO still performs a thorough review and applicants are expected to address additional queries on a case-to-case basis.

1c. Use reliance to eliminate redundant re-testing upon importation and overseas site inspections.

Options	Economies	Remarks (if any)
Local re-testing is not required or is applicable to vaccines and blood products and can be waived/simplified based on reliance/MRA	HK, ID, JP, MY, SG	JP: Blood products are limited to stable medicinal products derived from human blood or human plasma.
Local re-testing is only applicable to	PH, TH, TW, VN	TH: Re-testing = local lot release test

vaccines and blood products		VN: Local re-testing is applicable to vaccines, biological products which are serum containing antibodies; and other products determined by the Minister of Health based on the assessment of quality risk or issues arising upon importation/production.
Local re-testing is required for all biologicals and vaccines	CN, IN, SK	CN: 1. Registration testing by China HA lab is required (3 batches of drug products for chemical drugs; 3 batches of drug substance and 3 batches of drug products for biological products and vaccines). 2.Each imported commercial batch of biologicals should be tested by China HA lab. Each commercial batch of vaccines and blood products should be tested by China HA lab for release in China. 3. Overseas site inspection is risk-based for each application or product. IN: For marketed products: All vaccine commercial batch require testing in CDL before release in market. Biological products testing is needed once in a year or based on risk-based approach.

1d. Use reliance principles for new indications and post-approval variations.

Options	Economies	Remarks (if any)
Yes	HK, ID, PH, SG, TH	PH: Reliance is now used for new indications and post-approval variations TH: Need more clarification on how to manage new indications and post-approval variations
Under Discussion	IN, MY	IN: Some of the additional indication approvals are granted basis global data and major agency approvals (USFDA, EMEA)
No	CN, JP, TW, SK, VN	CN: For new indications, the situation is the same as the initial indication (see 1a). For post-approval variations, CPP or approval by reference country is required for some of the variations, but it does not replace any technical review by the NMPA/CDE

		TW: CDE conducts full review although CPP is required. VN: Reliance remains a subject for discussion during the Pharma Law revision.

2a. e-labelling

Options	Economies	Remarks (if any)
Yes for all medicines	JP, TH, SG	TH: Execution under discussion
Yes for COVID/selected medicines	ID, MY, PH, TW, VN, CN, SK	CN: e-labelling is just started in pilot program, and printed package inserts still need to be provided with e-labelling in the pilot program. On October 31, 2023, National Medical Products Administration issued the announcement of < the pilot work plan for the reform of drug labels for aging and accessibility > (No. 142 of 2023), which decided to carry out the pilot reform of drug labels for aging and accessibility in some oral and external drug preparations, and can choose to provide paper drug labels (simplified version) and electronic drug labels (complete version). On November 24, 2023, Centre For Drug Evaluation issued the announcement of < the Format Requirements for Electronic Drug Labels (Complete Version)> (No. 56 of 2023), electronic drug labels should comply with the requirements IN: Hard copy PI is required for submission; additionally, while , e-labeling is possible, it is not mandatory and does not substitute the requirement of a hard copy PI MY: Voluntary e-labeling has been implemented in phases for Scheduled Poisons category, i.e. Group B (Prescription Only Medicine) and Group C (medications dispensed by pharmacists), since May 2023. SK: There is the pilot program ongoing for e-labelling for some selected products (hospital only product like parenteral products) currently VN: Applied during the Covid pandemic and for Covid vaccines only. For other medicines, awaiting further guidance and roadmap from the MoH for the implementation
Not implemented	HK, IN	

2b. Serialization/Track and Trace

Options	Economies	Remarks (if any)
Serialization implemented	SK	SK: Serialization/Track and Trace in place, however, no opportunity to engage with e-label currently
Traceability initiated through barcodes for all/selected medicines	ID, JP, CN, TH, TW, VN	CN: Traceability has been implemented, and the detailed implementation requirements are different based on the types of medicines. Barcoding systems which comply with the NMPA's technical requirements, such as Alibaba barcode and GS1 barcode, can be used. TW: Track and trace system don't synergize with e-label.
Voluntary compliance for barcoding	HK, IN, MY, PH, SG	IN: No change in response as submitted in May 2023 MY: The implementation of track and trace in Malaysia is pending further actions by the Ministry of Health Malaysia. SG: Not mandatory

3a. eCPP and eGMP

Options	Economies	Remarks (if any)
When applicable, eCPP and eGMP are applicable as is without additional legalization	CN, HK, ID, JP, MY, SG, SK, TW, TH	HK: eCPP is only requested for reliance JP: Japanese authority does GMP inspection by themselves. SK: eCPP and eGMP could be accepted for COVID-19 situation, but not practical after COVID19.
eCPP is accepted as is but eGMP certificate requires additional legalization	IN, PH, VN	IN: eCPP and e GMP are acceptable but companies need to submit apostilled copy of eCPP and GMP VN: eCPP and eGMP are accepted but subject to legalization requirement.
Not Acceptable	None	

4a. Multiple sites in single registration license

Options	Economies	Remarks (if any)
Allowed for all or selected medicines	CN, HK, IN, JP, MY, SG, SK, TH, TW	HK: Only for biologics and vaccines MY: Multiple site registration is only allowed for biological products presently. Previously there was on-going discussions with NPRA to allow multiple site registration for other products, however, due to the delay in the upgrade of the regulatory electronic submission system, this is currently on hold. SK: Multiple sites allowed for DP manufacturers if GMP review/inspection is done. But it is partially allowed for DS manufactures, i.e., chemical DS should have same specification TW: Biological products is allowed for multiple DS, DP in single registration. Chemical drugs is only allowed for multiple DS in single registration.
Allowed for COVID products only	PH, VN	VN: In Vietnam, for DP: one step of production can be undertaken by one only manufacturer. Alternative site is not allowed in one single registration license. However, for DS: multiple sites are acceptable in one single registration license. For products other than COVID products: multiple DS sites in single license.
Not allowed for multiple DS, DP, or both	ID	

4b. Waiver of site-specific stability data or stability batches be reduced

Options	Economies	Remarks (if any)
Not Required	HK, JP, SG, SK	SK: Site-specific stability data is not always mandated HK: Site specific stability data is not required
Required	CN, IN, ID, MY, PH, TW, TH, VN	CN: 1. Site-specific stability data are required, 2: Need to be compliance with ICH, such as the zone IV stability study. IN: Site-specific stability data is required for each site. If tech transfer is established, data can be extrapolated

4c. Harmonization of post approval changes procedures and guidelines to align with ICH Q12

Options	Economies	Remarks (if any)
Yes	JP	
Under review for alignment	CN, SG, SK	CN: In April 26, 2023, in order to promote the implementation of ICH Q12, CDE issued the implementation proposal of ICH Q12, there will be a transition period of 24 months from the date of this announcement.
No	HK, IN, ID, MY, PH, TW, TH, VN	TH: PReMA shared experience ICHQ12 with among members. VN: Some variations are required to submit as new registration as minor variations, not follow ICH/ASEAN guideline. IN: Harmonization of post approval changes procedures is still not followed or implemented.

4d. Desktop GMP inspection or utilization of GMP inspection reports by PIC/S Agencies be formalized post-COVID pandemic

Options	Economies	Remarks (if any)
Yes	HK, ID, JP, MY, PH, SG, SK, TW, TH, VN	JP: For the sites in partner countries that have concluded MRA, in principle, based on the provisions of MRA, by submitting a GMP certificate or a copy of the GMP inspection report by the partner country, etc. based on the provisions of MRA, the results of the GMP inspection in the partner country, etc. will be accepted, and the inspection will be conducted only in desktop writing. SK: Remote inspection had been available for pandemic situation, however, it is not available from later this year. TH implement Desktop GMP inspection by ASEAN listed authority, PIC/S, certify by PIC/S. Non-PIC/s either desktop or onsite inspection. No remote inspection available. TW: Remote inspection will not be available in Taiwan now. VN: GMP certificates and Inspection Reports from manufacturers belong to ASEAN member countries under ASEAN GMP MRA. Manufacturers belong and/or certified by ICH member countries, US FDA; EU; EMA; TGA; PMDA; Health Canada are being accepted for desk assessment.

No	CN, IN	CN: 1. The NMPA submitted the application for accession to PIC/s in Jul 2023, and received PIC/S' confirmation of its applicant role in Nov 2023. 2. Remote inspections have been conducted by the NMPA/CFDI since COVID-19 pandemic. In 2021 and 2022, the CFDI conducted 6 and 11 remote oversea site inspections, respectively. 3. Desktop assessment should be adopted if utilizing GMP inspection reports by PIC/S 4. Agencies in some low risk cases. Remote inspection should be promoted.

Part II A Questionnaire
Survey on Regional Reliance Pathway

1) Awareness and Interest in ASEAN Joint Assessment (AJA) Procedure

a. Are your member companies aware of the AJA Procedure?

Options	Economies
Yes	ID, MY, PH, SG, TH, VN, TW
No	SK

b. Please rate the level of interest of your member companies in participating in the AJA Procedure where 1 = not interested at all and 5 = very interested

Options	Economies
5 = Very Interested	ID
4 = Interested	MY, TH, PH
3 = Moderately Interested	None
2 = Slightly Interested	SG, VN, SK
1 = Not Interested at all	None

2) Optimizing AJA Procedure

a. Which of the following areas do you perceive as an issue in the current AJA Procedure? Please check as many as applicable:

Options	Economies
Long timeline, i.e. not competitive with local reliance procedures	ID, MY, PH, SG, TH
Non-optimal use of the online submission platform (i.e. Joint Assessment Information Management System [JAIMS])	ID
Additional country-specific questions may be received, not from the lead ASEAN National Medicines Regulatory Authority (NRA)	ID, MY, PH, SG, TH, VN
Unclear status of AJA implementation at the country level	ID, PH, VN

Limited scope and not allowing applicants to select participating ASEAN NRA	ID, MY, PH, SG, VN
Additional multiple country-specific requirements	ID, MY, PH, VN
Duplicative requirements (e.g. WHO Certificate of Pharmaceutical Product (CPP), GMP Certificates, Testing, among others)	MY, PH
Others: At this moment since BPOM consider they already have acceleration Pathway in Indonesia (Pathway 2/Reliance), therefore BPOM consider not necessary to include AJA pathway. In the reality AJA will be longer than Path 2	ID
Others: Based on our experience in Thailand with AJA, it's challenging to evaluate accurately due to delayed AJA participation. The current approval lead time exceeds the lead time proposed by NRA. Additionally, there is a list of queries that need to be addressed during the NRA process	TH
Others: Lack of human resources at the country level	VN

b. Which of the following reforms are needed to improve the AJA Procedure. Please check as many as applicable:

Options	Economies
Reduction in timelines	ID, MY, PH, SG, VN
Submission of M2-M5 through JAIMS and only M1 to be submitted locally to participating NRAs	ID, PH, SG
Issuance of a single, consolidated list of questions for the AJA Procedure	ID, MY, PH, SG, TH, VN
Official adoption of AJA Procedure, guidelines, and timelines into individual national policies	ID, PH, SG, TH, VN
Ability of applicants to select which ASEAN NRA to file/register	ID, MY, PH, SG, VN
Non-requirement of CPP	MY, PH, TH, VN

Acceptance of Multiple Drug Substance and/or Drug Product manufacturing sites under 1 product license	ID, MY, PH, TH
Better alignment to ICH and WHO guidelines, e.g. about stability data	ID, TH, VN
Expanding AJA scope to post-approval changes	ID, MY, PH, SG, TH
Better coordination between participating AMS	ID, MY, PH, SG, TH, VN
Others: Required similar understanding/ knowledge among NRA on the data evaluation, for example why in Singapore can accept stability data that not site specific, while Indonesia insist to have the stability data site specific. Also for the safety efficacy aspect, why other country can accept data based on pharmacokinetic extrapolation for paed indication, while for Indonesia insist to have independent clinical study for paed indication.	ID
Others: Addition of Observer Roles to allow exposure and upskilling of developing countries or countries that wish to subsequently recognize the AJA assessment outcome without actually participating in the review.	MY

b.1. For your selection in item 2) b, kindly identify the top 3 reforms that will have the highest impact:

Economies	Responses
Indonesia	1. Reduction in timeline 2. Required similar understanding/ knowledge among NRA on the data evaluation, for example why in Singapore can accept stability data that not site specific, while Indonesia insist to have the stability data site specific. Also for the safety efficacy aspect, why other country can accept data based on pharmacokinetic extrapolation for paed indication, while for Indonesia insist to have independent clinical study for paed indication

	3. Better alignment to ICH and WHO guidelines, e.g. about stability data
Malaysia	1. Ability of applicants to select which ASEAN NRA to file/register 2. Significant reduction of timelines 3. Issuance of a single, consolidated list of questions for the AJA Procedure
Philippines	1. Significant reduction of timelines 2. Ability of applicants to select which ASEAN NRA to file/register 3. Issuance of a single, consolidated list of questions for the AJA Procedure
Singapore	1. Significant reduction of timelines 2. Ability of applicants to select which ASEAN NRA to file/register 3. Issuance of a single, consolidated list of questions for the AJA Procedure
Thailand	1. Official adoption of AJA Procedure, guidelines, and timelines into individual national policies 2. Non-requirement of CPP 3. Expanding AJA scope to post-approval changes
Vietnam	1. Official adoption of AJA Procedure, guidelines, and timelines into individual national policies 2. Ability of applicants to select which ASEAN NRA to file/register 3. Better coordination between participating AMS

b.2. For your answer in item 2) b.1, kindly provide the reason why you think it will have the highest impact:

Economies	**Responses**

Indonesia	To increase approval probability, because due to different understanding to assess the data can lead the product rejection.
Malaysia	To ensure that we encourage more participation of AJA, there will need to be value of investing interest as demonstrated by the significance of the approval timelines. Greater industry participation in the AJA will contribute to capability building of NRAs and support progress of AJA as a viable regional collaboration procedure.
Philippines	Reduction in timelines: This will make AJA more attractive as a submission pathway of choice if the timelines will be as competitive as the local reliance pathways. Ability of applicants to select which ASEAN NRA to file/register – address prevalent disease burden that may differ across AMS Issuance of a single, consolidated list of questions for the AJA Procedure – for efficiency
Singapore	These will streamline submission processes and increase transparency in the review process, thereby encouraging more companies leveraging ASEAN JA for submissions.
Thailand	1. The NRA should receive the adequate training on the procedure, guideline before adopting AJA. And should get alignment with ASEAN NRAs who participating in the AJA procedure on the committed timelines. Additionally, the additional NRAs should not be accepted after the process starts to ensure no impact to the committed timeline. 2. The NRA can consult directly to the SRA where the registration is approved, and the SRA can share their

	assessment report to ASEAN NRA. The CPP is not necessary. 3. To maintain the end-to-end record of registered product, the post-approval changes should be made in the same platform so that NRA can effectively monitor the product life cycle management.

c. Which aspects of current regulatory schemes (e.g. ACCESS Consortium, among others) can be adapted for the current AJA Procedure?

Economies	Responses
Malaysia	Single consolidated dossier and transparency in the timelines to the applicants Work sharing practiced by ACCESS consortium (divide the and assign NRA to review a specific Module). Reliance principle practiced by ACCESS Consortium (rely and trust assessment performed by participating NRAs).
Philippines	Risk-Based Approach: The ACCESS Consortium focuses on a risk-based approach to regulatory assessment, where the level of scrutiny is tailored to the potential risks associated with a product. This approach could be applied to the AJA to prioritize assessments for high-risk products or for products with significant differences between manufacturing sites. Scientific Expertise Sharing: The AJA could encourage collaboration among NRAs to share expertise and resources for complex assessments. This could involve establishing working groups or secondment programs for regulatory personnel. Training and Capacity Building: The ACCESS Consortium provides training and capacity building programs for member states. The AJA could implement similar programs

	to ensure that all NRAs have the necessary skills and expertise to participate effectively in the joint assessment process. Mutual Recognition Agreements (MRAs): The AJA could leverage existing MRAs between ASEAN member states and other countries with robust regulatory systems e.g. HSA Singapore. This could allow for reliance on regulatory assessments conducted by trusted partners.
Thailand	1. Aligning regulatory standards and requirements across participating ASEAN NRAs to facilitate smoother approval processes. 2. Engaging in joint reviews and assessments with the SRA to leverage expertise and resources from multiple countries.

Part II B Questionnaire
Survey on Digital Transformation

1) e-Submission including ICH eCTD Implementation

a. Is e-submission currently available in your country?

Options	Economies
Yes, completely paperless	CN, IN, ID, JP, PH, SG, VN
Yes, but physical documents are still required	HK, MY, SK, TW, TH
No	None

b. Are submissions in ICH e-CTD format accepted?

Options	Economies
Yes	CN, JP, SK, TW, TH
No	HK, IN, ID, MY, PH, SG, VN

If you answered 'no', could you inform:

b.1. Which dossier structure is accepted in your country?

Options	Economies
ICH CTD (International Standard)	HK
ACTD (For ASEAN Nations)	
Both ICH CTD (International Standard) and ACTD (For ASEAN Nations)	ID, MY, PH, SG, VN
Country Specific (where M2-M5 are not as per ICH nor ACTD)	IN

b.2. What is the dossier format accepted in your country?

Options	Economies
NeeS (Structured PDFs with hyperlinks and table of contents)	None
Both NeeS and PDF	ID, PH, SG, VN
PDF documents	HK, IN, MY

Paper submission	None

c. On re-formatting:

c.1. Is additional workload required by applicants to re-format the M2-M5 of the ICH CTD to meet local e-submission requirements?

Options	Economies
Yes	IN, MY, PH, SG, VN
No	CN, HK, IN, JP, SK, TW, TH

c.1.1. If additional work is needed, please specify at which level it is being done:

Options	Economies
At country level	IN, MY, VN
At global level	PH, SG, VN

c.1.2. If additional work is needed, please indicate which module(s) require reformatting. Please check as many as applicable:

Options	Economies
M2	IN, PH, SG, VN
M3	IN, MY, PH, SG, VN
M4	IN, PH, SG, VN
M5	IN, PH, SG, VN

c.2. Is baseline requirement for existing products mandated for conversion into e-submission?

Options	Economies
Yes	HK, IN, ID, TH, VN
No	CN, JP, MY, PH, SG, SK, TW

d. Which is the most burdensome additional requirement for e-submission? Please select the top 3:

Economies	Responses
China	• Mandatory use of country-specific software for electronic submission implementation (e.g., eCTD) • Non-English-dossier

	• eSeal is required on all the PDF documents for eSubmission (incl. eCTD) in China
Hong Kong	• Complex dossier structure based on country-specific requirements • Management of multiple strengths/pack sizes/sites/dosage forms under multiple applications • Lack of a single submission mechanism directly to the Health Agency (e.g., M1 in paper/portal, M2-M5 in media)
India	• Mandatory use of country-specific software for electronic submission implementation (e.g., eCTD)
Indonesia	• Management of multiple strengths/pack sizes/sites/dosage forms under multiple applications • System BPOM frequently get error and cause delay in submission and approval.
Japan	• Non-English-dossier • Complex dossier structure based on country-specific requirements
Malaysia	• Management of multiple strengths/pack sizes/sites/dosage forms under multiple applications • Lack of a single submission mechanism directly to the Health Agency (e.g., M1 in paper/portal, M2-M5 in media) • Complex dossier structure based on country-specific requirements
Philippines	• Management of multiple strengths/pack sizes/sites/dosage forms under multiple applications • Lack of a single submission mechanism directly to the Health Agency (e.g., M1 in paper/portal, M2-M5 in media)

	• FDA online platform not yet optimized, needs improvement
Singapore	• Management of multiple strengths/pack sizes/sites/dosage forms under multiple applications • Lack of a single submission mechanism directly to the Health Agency (e.g., M1 in paper/portal, M2-M5 in media) • Mandatory use of country-specific software for electronic submission implementation (e.g., eCTD)
South Korea	• Mandatory use of country-specific software for electronic submission implementation (e.g., eCTD) • Non-English-dossier • Complex dossier structure based on country-specific requirements
Taiwan	• Management of multiple strengths/pack sizes/sites/dosage forms under multiple applications
Thailand	• Lack of a single submission mechanism directly to the Health Agency (e.g., M1 in paper/portal, M2-M5 in media) • Changing process and regulations frequently, unclear the evaluation process and approval timeline. • Thai FDA still require for removable disk/USB for MAA application. • Require certificate of translator for non-English translated document of inspection report/CAPA for GMP clearance.
Vietnam	• Management of multiple strengths/pack sizes/sites/dosage forms under multiple applications • Complex dossier structure based on country-specific requirements

	• Mandatory print-out of specific modules of a dossier for submission

e. For countries that have not implemented ICH eCTD yet, is the trade association engaging or planning to engage the Health Agency to discuss ICH eCTD implementation in the next 1–3 years?

Options	Economies
Yes	IN, MY, SG
No	HK, ID, PH, VN

2) Real-World Evidence

a. Is a guideline relating to real-world evidence (RWE) available?

Options	Economies
Yes	CN, JP, TW
No	HK, IN, ID, MY, PH, SG, SK, TH, VN

b. Does the Health Agency support discussions with applicants about new applications that contain RWE dataset?

Options	Economies
Yes	CN, IN, JP, MY, SG, TW, TH
No	HK, ID, PH, SK, VN

c. Can the Health Agency accept and approve new applications that contain RWE dataset through a reliance pathway, i.e. already approved by an SRA?

Options	Economies
Yes	CN, HK, IN, JP, PH, SG, TW, TH
No	ID, MY, SK, VN

d. For countries that do not have a RWE guideline, is the trade association engaging or planning to engage the Health Agency re RWE and/or Guidelines?

Options	Economies
Yes	HK, MY, SG, SK
No	ID, PH, TH, VN

3) Decentralized Clinical trials (DCTs) (ICH E6 (R3)

a. Is a guideline relating to decentralized clinical trials (DCTs) available?

Options	Economies
Yes	CN, JP, SG, TW
No	HK, IN, ID, MY, PH, SK, TH, VN

a.1. If yes, is there a major concern with any country-specific requirement not in line with the US and EU in the area of (please check as many as applicable:):

Economies	Responses
CN	• eConsent • Mobile nursing and use of local healthcare practices
JP	• No concern
SG	• eConsent • IMP (Investigational MP) Home delivery and administration
TW	• eConsent • Telemedicine and Virtual visit • Mobile nursing and use of local healthcare practices

a.2. If no, is the trade association engaging or planning to engage the Health Agency to discuss DCT guidelines in the next 1–3 years?

Options	Economies
Yes	MY, PH, SK, TH
No	HK, IN, ID, VN

a.3. If not in the next 1–3 years, what are the top 2 reasons for not doing that? Please specify in the box below.

Economies	Responses
HK	No request from member countries

	There are other higher priority initiatives that need to engage Health Agency for discussion
ID	Regulations on the material transfer agreement which have led to hinder of clinical trial in Indonesia
VN	Right now, we still have tremendous difficulties conducting clinical trial so we aim to address them first

b. In terms of urgency, what elements of DCTs do your Health Agency /trade association want to advocate? Please select the top 2:

Economies	Responses
China	eConsent Mobile nursing and use of local healthcare practices
Hong Kong	eConsent Mobile nursing and use of local healthcare practices
India	eConsent IMP (Investigational MP) Home delivery and administration
Indonesia	IMP (Investigational MP) Home delivery and administration Telemedicine and Virtual visit
Japan	eConsent Mobile nursing and use of local healthcare practices
Malaysia	eConsent IMP (Investigational MP) Home delivery and administration
Philippines	Telemedicine and Virtual visit Remote safety and efficacy assessments (digital endpoints /wearables)
Singapore	Mobile nursing and use of local healthcare practices

	Remote safety and efficacy assessments (digital endpoints /wearables)
South Korea	Mobile nursing and use of local healthcare practices Use of local imaging and local laboratories
Taiwan	IMP (Investigational MP) Home delivery and administration Telemedicine and Virtual visit
Thailand	eConsent Telemedicine and Virtual visit

c. Can the Health Agency accept and approve new applications that contain data coming from trials with DCTs elements by independent review?

Options	Economies
Yes	CN, HK, ID, JP, MY, PH, SG, SK, TW, TH
No	IN, VN

d. Can the Health Agency accept and approve new applications that contain data coming from trials with DCTs elements by reliance pathway?

Options	Economies
Yes	CN, HK, ID, MY, PH, SG, SK, TH
No	IN, JP, TW, VN

4) Paperless ePI

a. Does the Health Agency fully accept e-PI without the need for a physical paper copy?

Options	Economies
Yes	ID, JP, MY, SG, SK, TW
No	CN, HK, IN, PH, TH, VN

b. For countries that have not implemented paperless e-PI yet, is the trade association engaging or planning to engage the Health Agency to discuss implementation in the next 1 – 3 years?

Options	Economies

Yes	CN, HK, IN, PH, TH, VN
No	None