Simplified Progress Feedback Table

2021

Y: Yes

N: No

M: Maybe or Partially

1. Good reliance practice for medicines regulations should be optimized in accordance with WHO recommendations

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

		Progress 2021
MY	N	Currently the CPP is a mandatory requirement but does not reduce the scope of review by the HA. A full review is still conducted (under the standard pathway) and GMP certificates are still requested.
TH	N	CPP is used for MA, MAV (site change), and GMP clearance application. CPP is used for renewal only but for new manufacturing site needs full documents.
TW	Y	Taiwan FDA allows them to use assessment reports for partial reliance for drugs other than COVID?. MA: if 2 CPP provided, the HA will use as reliance tool for the assessment. GMP: if A10 (specific 10 countries) CPP provided, can reduce the assessment partially.
HK	Y	Two or more CPPs are required for NDA submission as an evidence of approval from reference countries instead of primary assessment. Special consideration for 1 CPP may be only acceptable in the situation of local unmet medical need for public health emergency, communicable diseases emerging infectious diseases and antimicrobial resistance.
ID	N	There are some reliance pathways under the regulation. However, submission of CPP from reference countries is not to replace full / partial assessment, but it will save/reduce the assessment timeline, but full data is still need to be submitted.
VN	N	2 CPPs are required for registration of new medicines and renewal of Marketing Authorizations (once every 3 or 5 years). If the CPP is issued by EMA, only 1 CPP is required (shorter time for dossier prep). CPP is a mandatory requirement, as part of the administrative documents but does not reduce the scope of review by the HA.
PH	N	FDA released its first draft policy to implement a reliance for MA in Sep., '21. In the draft, CPP is considered an acceptable proof of approval to qualify for abridged or verification.
SG	N	It's not applicable.
SK	N	The mandatory requirement for the submission of CPP for NDA application was deleted as of Apr 2021.
CN	N	For new Cat.5.1 CPP should be submitted at the submission of CTA and NDA. From Nov.27 2020, in view of the FDA policy adjustment on CPP issuance,
JP	N	It is not applicable, because part or all of the examination / GMP surveillance cannot be replaced by CPP or GMP certification of another country.

1. Good reliance practice for medicines regulations should be optimized in accordance with WHO recommendations

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

		Progress 2021
MY	Y	Full reliance has been utilized for Covid-related registrations with very short approval timelines (conditional registration). However, NPRA still performs a thorough review and applicants are expected to address additional NDA queries post-approval.
TH	Y	Yes
TW	Y	EUA mechanism exists for COVID-19 vaccine, and reliance is partially accepted.
HK	Y	Yes
ID	Y	BPOM issued a regulation on Emergency Use Authorization (EUA) for expedite Covid related drug registration.
VN	Y	Yes
PH	Y	FDA instituted a semi-reliance mechanism for issuing EUAs on the COVID-related technologies, where assessment reports are being utilized.
SG	N	The requirements are stipulated under the Pandemic Special Access Route (PSAR) for Supply of Emergency Therapeutic Products which the authority makes independent decision.
SK	Y	MFDS established a "Dedicated review team for the approval of COVID-19 vaccine" and proceeded with "Accelerated review process".
CN	N	Assessment reports of other SRAs might be a reference but not a necessary for NMPA when considering whether to approve the applications or not. The application will not be approved if any incompliance with Drug Administration Law (DAL) and Drug Registration Regulation (DRR) existed.
JP	Y	Assessment of reference countries will be used for review, however the final assessment will be made by MHLW/PMDA, and necessary measures are taken for use. For Covid related registration, Special Approval for Emergency (SAE) system exist in Japan. Under article 14-3 of the Pharmaceutical and Medical Devices Act, a certain medical product may be approved, through an expedited process (grace of data submission, etc.), when; 1. an emergency situation requires an unapproved medical product to be used to prevent damage to the public health caused by the spread of diseases, 2. such emergency situation cannot be managed appropriately by any means other than the use of the unapproved product, and, 3. such product is legally available in a country(USA, UK, Canada, Germany, France) with a regulatory system for medical products that is equivalent to Japan. MHLW can request a MAH, as an additional obligation, to implement appropriate safety monitoring and other measures as necessary.

1. Good reliance practice for medicines regulations should be optimized in accordance with WHO recommendations

1c. Use reliance to eliminate redundant re-testing upon importation

		Progress 2021
MY	Y	Local quality testing is not required for chemical pharmaceuticals. However, local lot release testing is still required for some biologics and vaccines.
TH	Y	
TW	Y	
HK	Y	
ID	Y	For vaccines, local lot release is necessary. Exception for lot release testing for COVID products.
VN	Y	Testing upon importation are not required for pharmaceuticals but required for vaccines (takes ~4 weeks). GMP certificates are utilized to replace overseas site inspections
PH	Y	Previously, FDA requires lot release testing for all biologicals. But in August 2021 FDA clarified that lot release is now only required for vaccines, toxoids, and immunoglobulins. Upfront quality testing for pharmaceuticals not required for registration. Overseas site inspection currently waived due to COVID, but pre pandemic inspection is required for Non-PICS.
SG	Y	Yes
SK	N	No
CN	N	For biologics (including COVID-19 vaccines), it's required to have testing for each batch before releasing. For chemical drugs, it's required to test 3 batches of commercial verification batches. Overseas site inspections is very limited due to the COVID-19 pandemics. We are exploring more possibility of remote inspections under the pandemic.
JP	N	Except for the product tested by MOU and MRA exchanged countries, local re-test is required at product release.

1. Good reliance practice for medicines regulations should be optimized in accordance with WHO recommendations

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

		Progress 2021
MY	N	Reliance principles have been built into current guidelines, but NPRA still performs a thorough review. For post-approval variations, work in progress to formalize reliance pathway within the Malaysia Variations Guideline.
TH	M	No. They can use package insert from stringent countries for their reference for indication and post-approval variations.
TW	N	No
HK	Y	Same requirement of 2 CPP for new indication as NDA. Acceptance of reference country approval as evidence of some post approval variations including labelling and CMC changes.
ID	Y	BPOM issued a guidance for reliance pathway 120 BD include new registration and registration major variation for new indication/ posology for new product and biological products approved at least in 1 (one) country with well-known accepted evaluation system (EU, US, Australia, Canada, England & Japan).
VN	Y	Same requirements of 2 CPPs for new indication but does not reduce scope of review by local HA, same as NDA. Acceptance of host country approval for reference for indication and some post approval variations including labelling changes.
PH	N	FDA released draft policy, reliance will cover post-approval variations. But it is still a draft.
SG	Y	Yes
SK	M	In principle, MFDS reviews documents independently. But if foreign clinical trials were performed, the reliance principle may be necessary. For an example, by submitting a document that proves an approval with the submitted data in other jurisdiction, GCP inspection can be waived for clinical data conducted only in other countries. Regarding COVID-19 vaccines, reliance principle is only used for emergency use approvals, which are different from usual approvals and triggered by the government.
CN	N	Independent review by NMPA is needed.
JP	N	Independent review is made by PMDA.

2. Digital use should be enhanced for communication

2a. e-Labeling

		Progress 2021
MY	M	Electronic PI and PIL are available on NPRA's website. However, hard copy PI is still required to be included into product carton box (except for COVID-19 vaccines where e-labelling fully adopted). Proposal to replace hard copy PI with e-label will be discussed further. NPRA has agreed to establish a Joint Committee for e-labeling to review this matter further with Industry.
TH	N	In the discussion process with Thai FDA. e-Labeling is allowed for COVID vaccines only.
TW	M	Pilot plan is under discussion, expected to be effective in 2022 Q1.
HK	N	No
ID	M	BPOM accept e-labelling for COVID vaccine which is globally manufactured. However, no establish regulation on e-labelling. IPMG Regulatory Association initiate to discuss e-labelling within members and plan to approach BPOM on e-labelling by establishing e-labelling working group (WG). Approximately PI for HCP is available in BPOM website (not always updated). Ref : http://pionas.pom.go.id/ (BPOM website for PI information)
VN	N	No
PH	M	Philippines FDA accept e-labelling for COVID vaccine which is globally manufactured. However, e-labelling is not yet acceptable for other drug. Paper PI are still required as part of the registration. But recent discussions with FDA have opened up opportunities to move forward, including conduct of a pilot.
SG	M	e-Labeling is voluntary for prescription only medicine.
SK	M	Some medical devices allowed.
CN	N	e-labeling system construction is still ongoing and not completed in China, so currently no products is applicable to e-labeling system.
JP	Y	As from August 1, 2023, package insert will be provided by e-labeling, and hardcopy will not be included in the product. Transition period is until July 31, 2023.

2. Digital use should be enhanced for communication

2b. Serialization/Track and Trace (opportunities to synergize with e-label)

		Progress 2021
MY	N	Potentially, with track & trace target to go live in 2023. Further discussion with NPRA is needed. Barcode is optional and voluntary; no specific product.
TH	M	In the discussion process with Thai FDA. Barcode is now used for logistics purpose only. Just started to implement only cannabis medicinal product.
TW	M	Pilot plan is under discussion, expected to be effective in 2022 Q1.
HK	N	Not a requirement yet. Require approval if related 2D matrix is added on outer packaging
ID	Y	BPOM issue 2D barcode serialization regulation and already implemented.
VN	N	No
PH	N	Voluntary compliance as of the moment.
SG	N	Currently it is not mandatory requirement for serialisation and barcode. Companies may choose to do so voluntarily.
SK	Y	Pharmaceutical companies must attach a serial number when manufacturing or importing pharmaceuticals, and report the serial number to the government at the first step of shipping pharmaceuticals.
CN	N	Traceability system is under construction by NMPA. Each product has a barcode on the package (minimum sales unit) and could be scanned by using an Alibaba APP named Taobao in mobile phone. Alibaba is supporting NMPA to maintain this barcode system. General information of the product are included in the barcode, such as drug expiration date, approval number, manufacturing date, registration category, MAH info. etc.
JP	M	Partially

3. Electronic documents should be widely accepted

3a. eCPP and eGMP

		Progress 2021
MY	Y	Fully accepted by NPRA. eCPP without legalization is accepted.
TH	Y	Yes
TW	Y	Yes
HK	Y	eCPP and eGMP are acceptable with electronic signature verifiable.
ID	Y	Electronic CPP is acceptable by Indonesia FDA (BPOM). GMP Certificate and some supporting documents are still necessary to be submitted for drug/ site registration. Ref: Indonesia Drug registration guideline No. 24 year 2017
VN	Y	eCPPs issued by EMA are accepted yet paper documents (accompanying the e-documents) are still required.
PH	Y	eCPP acceptable to FDA, but eGMP required to be legalized.
SG	Y	Accept eCPP without legalization.
SK	Y	Yes
CN	Y	Since May 13 2020, accept eCPP issued by overseas NRA. Not yet for eGMP, required to have legalization.
JP	N	It is not applicable, because there is no electronic certificate like eCPP or eGMP.

4. Regulatory processes should be adequately integrated and streamlined

4a. Multiple sites in single registration

		Progress 2021
MY	M	Multisite DP sites are accepted for biological products. For chemical products, in principle NPRA agrees on the allowance of DP multiple sites. However, NPRA will only consider the application once the QUEST3+ system is upgraded to facilitate these additional sites.
TH	M	Single license with multiple DP sites is not allowed for NDA but accepted for COVID-19 EUA license. In addition, multiple secondary sites per license is allowed.
TW	M	API: accepted. Biological products: accepted; Chemical products: not accepted.
HK	M	Relaxation in biological/vaccine to allow multiple sites. Issued a “Supplementary Notes for Application for Registration of Biological Products Involving Alternative / Back Up Manufacturer(s) for Manufacturing Steps” in Aug 2021. Other products is still single site for each manufacturing step.
ID	M	It is not allowed. However, exception may be given in certain case /case by case; eg. NHI (National Health Insurance) product.
VN	N	No
PH	M	It is allowed for COVID products.
SG	Y	Yes
SK	Y	If the requirements are met, multiple site in single registration is possible (e.g. in the case of the same specification, etc.).
CN	N	Multiple sites in single registration is not allowed, either API or DP of biologics.
JP	Y	Multi sites can be registered in single registration both for API and DP.

4. Regulatory processes should be adequately integrated and streamlined

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

		Progress 2021
MY	N	No
TH	N	3 batches with site-specific stability data are still required.
TW	N	3 batches with site-specific stability data are still required.
HK	N	There is “no requirement”.
ID	N	No
VN	N	No
PH	N	No
SG	Y	Yes
SK	N	No
CN	N	No
JP	Y	There is no requirement to request site-specific stability data.

4c. Harmonization of post approval changes procedures and guidelines to align with ICHQ12

		Progress 2021
MY	N	No
TH	N	No
TW	N	No
HK	N	No
ID	N	No
VN	N	No
PH	N	No
SG	M	Partially
SK	Y	Related regulations has been revised/enacted to be aligned with ICH Q12.
CN	M	ICH Q12 hasn't been effective in China yet. However, regulations issued by NMPA related to PAC are aligned with ICH Q12.
JP	Y	Yes

4. Regulatory processes should be adequately integrated and streamlined

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

		Progress 2021
MY	Y	Yes
TH	Y	Only desktop GMP inspection is required, while onsite inspection is not required for PIC/s member and PIC/s certified countries by utilizing GMP inspection reports by PIC/S Agencies. However, Thai FDA will conduct onsite inspection for non-PIC/s after COVID-19 as usual.
TW	Y	Yes
HK	Y	Yes
ID	M	BPOM issue a regulation on assessment on GMP compliance of imported drug manufacturing facilities. The steps are including document evaluation, desktop inspection and site inspection. BPOM also refer to PIC/S member inspection result, but this is not automatically accepted. Review/ assessment are still necessary for BPOM final decision.
VN	Y	Pre-COVID-19: Accept PIC/S GMP certificate to replace overseas site inspections. During COVID-19 and now: Accept official letters issued by overseas agencies for GMP validity extension.
PH	Y	Yes
SG	Y	HSA reserves the right to conduct an on-site inspection of an overseas manufacturing site, where deemed necessary. “Desktop GMP inspection pathway already existed prior Covid pandemic. There is no need to formalize what has been practiced prior. “
SK	Y	Yes
CN	N	Possibility of remote inspection is under exploration under pandemic, and PIC/s has not yet accepted by NMPA. NMPA has submitted the application for “pre-accession” to PIC/s in Sep. 2021. Therefore currently PIC/s has not yet accepted by NMPA.
JP	M	Even if you are a PIC / S member country and have a GMP certificate or inspection report, a GMP inspection (on-site or desktop) will be conducted in Japan. Instead of onsite inspections, remote inspections are currently in the pilot stage. For manufacturing sites overseas, determine whether to conduct onsite or desktop inspection, taking into consideration the GMP standards and their operation in that country, and the GMP compliance status of the sites overseas as appropriate. 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. For the sites other than the partner country such as MRA or MOU, in addition to the GMP certificate by the relevant partner country, WHO certificate, etc. shall be submitted, but these are for reference only. With that, it will not be immediately a written desktop inspection.