APAC
Asia Partnership Conference of Pharmaceutical Associations

18 May 2021

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Dr. Roshayati Mohamad Sani, Acting Director of National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia.
Dr Ir. Penny K Lukito, MCP, Head of National Agency of Drug and Food Control, Indonesia
Minister Jiao Hong, Commissioner of China's National Medical Products Administration, China
Minister Kim Kang-lip, Ministry of Food and Drug Safety, South Korea
Dr Mimi May Ling Choong, Chief Executive Officer of Health Sciences Authority, Singapore
Dr Paisarn Dunkum, Secretary General, Food and Drug Administration, Thailand
Dr Rolando Enrique D. Domingo, Director General of FDA, the Philippines
Ms. Shou-Mei Wu, Director General, Taiwan FDA
Mr Vu Tuan Cuong, Director General, Drug Administration of Vietnam
Dr. Yasuhiro Fujiwara, Chief Executive, Pharmaceuticals and Medical Devices Agency, Japan

Dear Mr Frank Chan, Dr. Roshayati Mohamad Sani, Dr Ir. Penny Lukito, Minister Jiao Hong, Minister Kim Kang-lip, Dr Mimi Choong, Dr Paisarn Dunkum, Dr Rolando Domingo, Ms. Shou-Mei Wu, DAV Director General Vu Tuan Cuong and Dr Yasuhiro Fujiwara,

We, the representatives of the R&D-based pharmaceutical industry thank our National Regulatory Authorities (NRAs) for responding to our letter dated 27 July 2020. We truly appreciate NRAs for taking action in implementing regulatory agility to facilitate the availability of medicines in the midst of COVID-19 pandemic, including:

- NRAs of ASEAN in expanding the products list to allow more disease areas to be eligible for ASEAN Joint Assessment Coordinating Group
- NRA of the Philippines in introducing the concept of reliance pathway
- NRA of Malaysia and Indonesia in accepting eCPP
- NRA of South Korea for exempting obligation of CPP submission

We applaud and deeply appreciate all our NRAs' excellent efforts. It appears critical not to go back to the former practices required in the pre-COVID time, we sincerely ask for regulatory agility to be the permanent ways of working moving forward. Specifically, we believe there are residual challenges that stifle regulatory agility that we can work through collectively as areas for improvement:

(1) Good reliance practices in medicines regulations should be optimized in accordance with WHO recommendations

The NRAs have made great strides towards collaborative assessment, although there continues to be long review and approval process in countries that require CPP. We would like to recommend the use of CPP as a reliance tool based on its original intent defined by the WHO[1]. Accordingly, CPP is to replace full or partial assessment for marketing authorization (MA) and GMP compliance status, resulting in a much shorter timeline in granting MA. In the event that the role of CPP differs from its original intent, then removing CPP ensures that NRAs will eliminate resource wastage in redundant document review activities.

In the absence of CPP, we support NRAs in implementing reliance pathways by taking into account the stringent assessments performed by the reference agencies in reaching their own decisions within a shorter timeline than that of their standard pathways. The introduction of reliance pathways in the Philippines is a welcome development. We hope that these be fully operationalized soon, aligned with the COVID-19 registration experience where reliance on stringent regulatory authorities helped facilitate the process.

In addition, we recommend expansion of reliance principle to waive off redundant re-testing upon importation and overseas site inspection[1]. Given the powerful role reliance can play in accelerating the availability of vaccines, treatments and diagnostics, NRAs might consider to expand reliance pathways to also approving new indications and post-approval variations. A good example is the verification route of the Singapore NRA for approving post-approval variations[1].

(2) Digital use should be enhanced for communication

Similar to the NRAs of Japan, Taiwan and Singapore, we recommend that NRAs prioritize moving forward with e-labeling initiatives. Under the COVID-19 pandemic, digitalization should be enhanced in the pharmaceutical area and e-labeling initiatives should be one of them. e-labeling improves the accessibility and understanding of approved medical product information, thereby enhancing adherence to medicines and patient outcomes. The availability of the latest labeling on a publicly accessible website is an important first step in improving patient safety and trust in medicines. The adoption of e-labeling will enhance the user's ability to navigate the product information on how to use, handle, and to better understand safety information. Eventual removal of the paper from the pack will reduce the lead time to launch new products, make efficiencies on reducing operational steps for inserting paper labeling in packs, and support environmentally friendly practices. In the future, e-labeling will be integrated with the wider digital healthcare system such as electronic medical records, bringing efficiencies, and opportunities across a spectrum of healthcare. The collaboration between agencies and industry associations is an important factor in moving the e-labeling initiative forward in Asia.

Governments and regulatory agencies around the world are developing regulations to enhance patient safety, secure pharmaceutical supply chains and counter illegal activities like: counter reimbursement fraud, counterfeiting, adulteration, theft and diversion of prescription drugs and other products. These regulations require serialization and other related abilities in order to track and trace product throughout the supply chain. We should consider how to leverage synergies between e-labeling and serialization to further enhance patient safety and the security of supply chains.

(3) Electronic document should be widely accepted

We are encouraged that NRAs of Indonesia, Malaysia, Thailand, China, Vietnam and Singapore decide to accept eCPP[2] and eGMP. We humbly ask for all the NRAs in Asia to do the same in confirming MA status and GMP compliance; thereby exempting applicants from submitting original certified papers with wet signatures and stamps, notification by public notary, or legalization by embassies.

(4) Regulatory processes should be adequately integrated and streamlined

Allowing a single license to cover multiple sites is a common practice of ICH members and most PIC/S members as well[3]. To increase supply, manufacturers need more sites to produce the drug products. The international standard of ICH and WHO recommends that an additional site to be approved as a post-approval variation, and as a result the additional site is to be included in the same license. In contrast, the one-site-one-license practice requires the new site to supply the full dataset as that required by a new drug application including but not limited to a minimum of 12-months' stability data, local testing and all country specific requirements. This approach complicates and hinders the addition of multiple sites, without enhancing the value of regulatory oversight[3]. The recommendation is therefore for NRAs to adopt the practice of multiple sites in a single license, in line with ICH and WHO guidance. Waiver of site specific stability studies on multiple product/drug substance sites need to be considered or batches reduced to ensure timely and stable supplies, and these best practices are essential to ameliorate the impact of the ongoing pandemic on availability of medicines and vaccines.

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To overcome the challenges mentioned above and deepen cooperation between NRAs, convergence and harmonization of requirements, standards and guidelines are important enablers of regulatory cooperation and reliance. ICH and PIC/S are platforms for disseminating regulatory information and for building knowledge and trust among NRAs. Therefore, we humbly highlight the importance of all countries rigorously implementing harmonised ICH principles as regulatory standards to facilitate the review and provide a single technical basis for approval. PIC/S has also issued guidance on inspection reliance, outlining a process for desktop assessment of compliance with GMP.

As for efficient measures taken to substitute on-site GMP inspections, NRA of South Korea has decided to accept inspection reports issued by other PIC/S member country, while NRA of Japan has adopted remote inspection. We earnestly hope that these temporary measures under COVID can become a long-term approach and to be formulated into the process of business as usual moving forward.

Finally, we would like to make a proposal for harmonization of post-approval changes processes and guidelines to align with ICHQ12 principles. In addition, Similar to the approach of the NRAs of China, Singapore, Japan and Malaysia, we recommend all NRAs to allow 'grace periods' for post approval changes implementation, which is the standard practice of ICH countries.

We hope that the above four areas proposed can be considered a pragmatic approach to enable efficient processes and system. We remain committed to work in partnership with NRAs to ensure the continual supply of medicines and treatment to patients in Asia.

We are at your disposal to organize constructive dialogue with the R&D-based pharmaceutical industry. We look forward to hearing your response and welcome any virtual meeting for further discussion.

Best regards,

George Nakayama
President, JPMA

On behalf of

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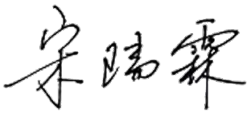

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sapi

Abbreviation:

APAC	Asia Partnership Conference of Pharmaceutical Associations
BPOM	Badan Pengawas Obat dan Makanan (Indonesia FDA)
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
KPBMA	Korean Pharmaceutical and Bio-Pharma Manufacturers Association
KRPIA	Korean Research-based Pharma Industry Association
PHAMA	Pharmaceutical Association of Malaysia
PHAP	Pharmaceutical & Healthcare Association Of The Philippines
PhIRDA	China Pharmaceutical Innovation and Research Development Association
PG	Pharma Group Vietnam
PreMA	Pharmaceutical Research & Manufacturers Association
RDPAC	R&D-based Pharmaceutical Association Committee
SAPI	Singapore Association of Pharmaceutical Industries

References:

[1] WHO good reliance practices 2021; Annex 10 in https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf
[2] EMA no longer issues paper CPP; EMA certification verification tool link
[3] Measuring progress of regulatory convergence and cooperation among Asia-Pacific Economic Cooperation (APEC) member economies in the context of the COVID-19 pandemic; SSF Chong, M Kim, M Limoli, E Obscherning, P Wu, L Feisee, N Nakashima, JCW Lim (2021). Therapeutic Innovation & Regulatory Science; DOI https://doi.org/10.1007/s43441-021-00285-w