The necessity for regional regulatory reliance in ASEAN

– *an APACMed perspective*

In March 2020, the National Academies of Sciences, Engineering, and Medicine published Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators (2020), a Consensus Study Report promoting the benefits of regulatory reliance. The Study Report was drafted and reviewed by contributors including the European Medicines Agency, the Medicines & Healthcare Products Regulatory Agency, the World Health Organization, the Bill & Melinda Gates Foundation, Japan Self-Medication Industry, University professors, and representatives from the healthcare industry.

In June 2020, the World Health Organization issued the first version of Good Reliance Practices in Regulatory Decision-Making: High-level Principles and Recommendations with the objective to encourage the practice of regulatory reliance. WHO also conducted a webinar on the launch of the guidance on good reliance practices on June 29, 2021 and advocated for regulatory reliance where markets see fit. WHO's endorsement has come at an opportune time, and I am hoping this would act as a catalyst to persuade stakeholders to gather together to explore how reliance can be developed and best implemented within APAC.

Regulatory reliance, as defined in the Study Report published by the National Academies of Sciences, is a tool that allows Regulators to take into consideration assessments performed by other Regulators, fully or partially, for the approval of product registrations. It is important to highlight that, as the "relying" Agency retains complete jurisdictional independence in approving products, a legislative framework may not be required for the implementation of regulatory reliance because the reliance concept does not oblige the "relying" Agency to recognize the decisions made by the "reference" Agency, in contrary to recognition.

Below are the excerpts of the definitions for "recognition" and "reliance" from the Study Report:

Recognition

The routine acceptance by the regulatory authority (RA) in one jurisdiction of the work products and regulatory decisions of another RA or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Recognition may be unilateral, bilateral, or multilateral, although recognition is usually manifested as the subject of mutual recognition agreements.*

Reliance

The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to (i.e., totally or partially rely on work products by) another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

APACMed has been working closely with Health Sciences Authority (HSA), Singapore and Thai FDA to successfully implement regulatory reliance pathways for medical device and in vitro diagnostic products since last year. Thailand FDA - HSA Singapore Regulatory Reliance is an expedited medical device registration program where the manufacturer or importer can request permission for faster (applicable to Class 4 medical devices at present). In this program, Medical Control Division will assess the performance and safety of the medical device based on the results of the safety assessment and performance of the medical device from HSA, Singapore.

In ASEAN Regulatory reliance (RR) for medical device regulations are entirely dependent on the Global Harmonization Task Force (GHTF) model. The International Medical Device Regulators Forum (IMDRF) officially uses the GHTF acronym to indicate benchmark countries for RR protocols. These include United States (US), European Union (EU), Canada, Japan and Australia. Most of regulatory reliance in ASEAN is restricted to pre-market compliance only. This scenario compels two pressing questions:

What if ASEAN had its own regional regulatory reliance protocols?

Is it possible for ASEAN to have mutual recognition regulatory model as in the EU?

The two questions above triggered APACMed to conduct investigative research. It required the perceptions and opinions of various stakeholders in the ASEAN medical devices regulatory space that include regulators, industry personnel, and authorized representatives. If there is an understanding of perceptions and opinions towards a regional regulatory reliance framework, then pilot studies could be conducted for a holistic harmonization of regulatory process in ASEAN. These opinions and cooperative interests – across Malaysia, Philippines, Singapore, Thailand, and Vietnam – have been translated to preparedness scores. Perceptions may be subjective but a quantified metric – in the guise of a preparedness scores – would influence organized decision making towards qualitative pilot studies.

While opinions and perceptions towards a regional reliance were investigated from a people-centric perspective, redundant regulatory policies were also scrutinized to understand pain points that delay stipulated registration timelines. On the contrary, the research was also attempted to understand key metrics of emergency use authorizations (EUA) in each country that expedited approvals of certain medical products. For example, Singapore has pre-defined clauses in their regulatory policies for both immediate and expedited approvals for certain class of devices, and this provision compliments EUA. However, other ASEAN nations also authorized immediate approvals during the Covid-19 pandemic. What was their basis for EUA? Understanding such scenarios will be beneficial for regulatory convergences while executing pilots for regional reliance, especially if synergies exist in applications of EUA approved and general devices.

Lastly, both regulators and industry personnel were interviewed on regulatory models – work sharing, abridged pathways, regional reliance, unilateral recognition or mutual recognition – compliant in ASEAN and what they want implemented for expedited regulation. While everyone favors the mutual recognition model as the ideal choice, the framework that made this model successful – like in EU – was investigated and consensus was drawn on whether similar frameworks can be implemented in ASEAN.

Challenges as described above are abound, in attempting to harmonize the ASEAN regulatory process and introduce a regional reliance model, but these challenges are addressable. This is based on the conclusive evidence disclosed in this report. Regulators and Industry personnel have expressed their willful cooperation towards initiatives that pave way to establishing regional regulatory compliance in ASEAN. APACMed is committed to making this vision a reality by assisting regulators and medical device manufacturers both strategically and methodically.

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