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Challenges We Face to Supply Globally – Can Regulatory Convergence Help?

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Panel Discussion: Challenges we face to supply globally – can regulatory convergence help?

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Regulatory convergence to facilitate global supply

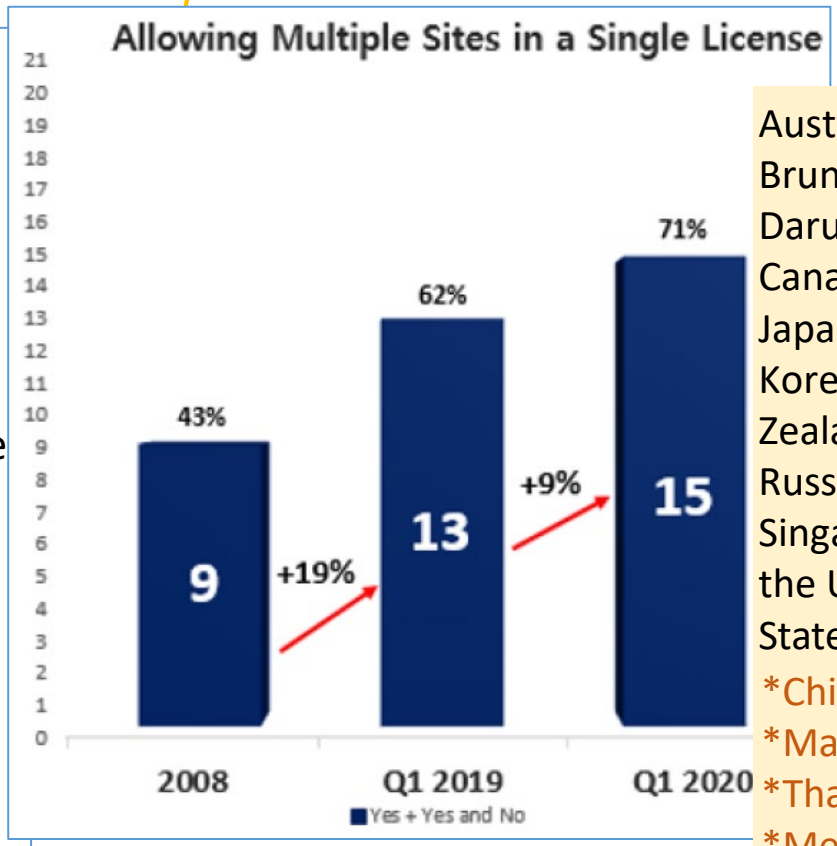
Key Performance Indicator #1: multi-sites-1-licence best practices

- The use of more than one manufacturing site is critical for pharmaceutical supply (to meet demand). The use of additional production sites at different stages of operation is common industry practice
- Challenges to ensure a reliable supply e.g. for vaccine, production is complex which can pressurise the supply chain and lead to shortages
- Regulation of 1-site-1-licence adds complexity (1 vaccine with multiple licences) and time lag (takes years to get a new licence) without enhancing the value of regulatory oversight
- KPI #1 shows that:

- 9 APEC economies practice multi-sites-1-licence

- *6 APEC economies permit that for some types of products only

- Continual efforts to simplify the supply processes in APEC economies that practice 1-site-1-licence



Australia; Brunei Darussalam; Canada; Japan; Korea; New Zealand; Russia; Singapore; the United States

*China
*Malaysia
*Thailand
*Mexico
*Chinese Taipei
*Indonesia

Source: APEC News Release (2019). https://www.apec.org/Press/News-Releases/2019/0819_LSIF

Source: Chong S-SF, Lim J-CW, TT (2018) Developing key performance indicators to measure the progress of regional regulatory convergence and cooperation in Asia-Pacific Economic Cooperation (APEC). American Association of Pharmaceutical Scientists (AAPS) Open, V**ol 4** Article number: 4 https://doi.org/10.1186/s41120-018-0024-2

Regulatory convergence to facilitate global supply

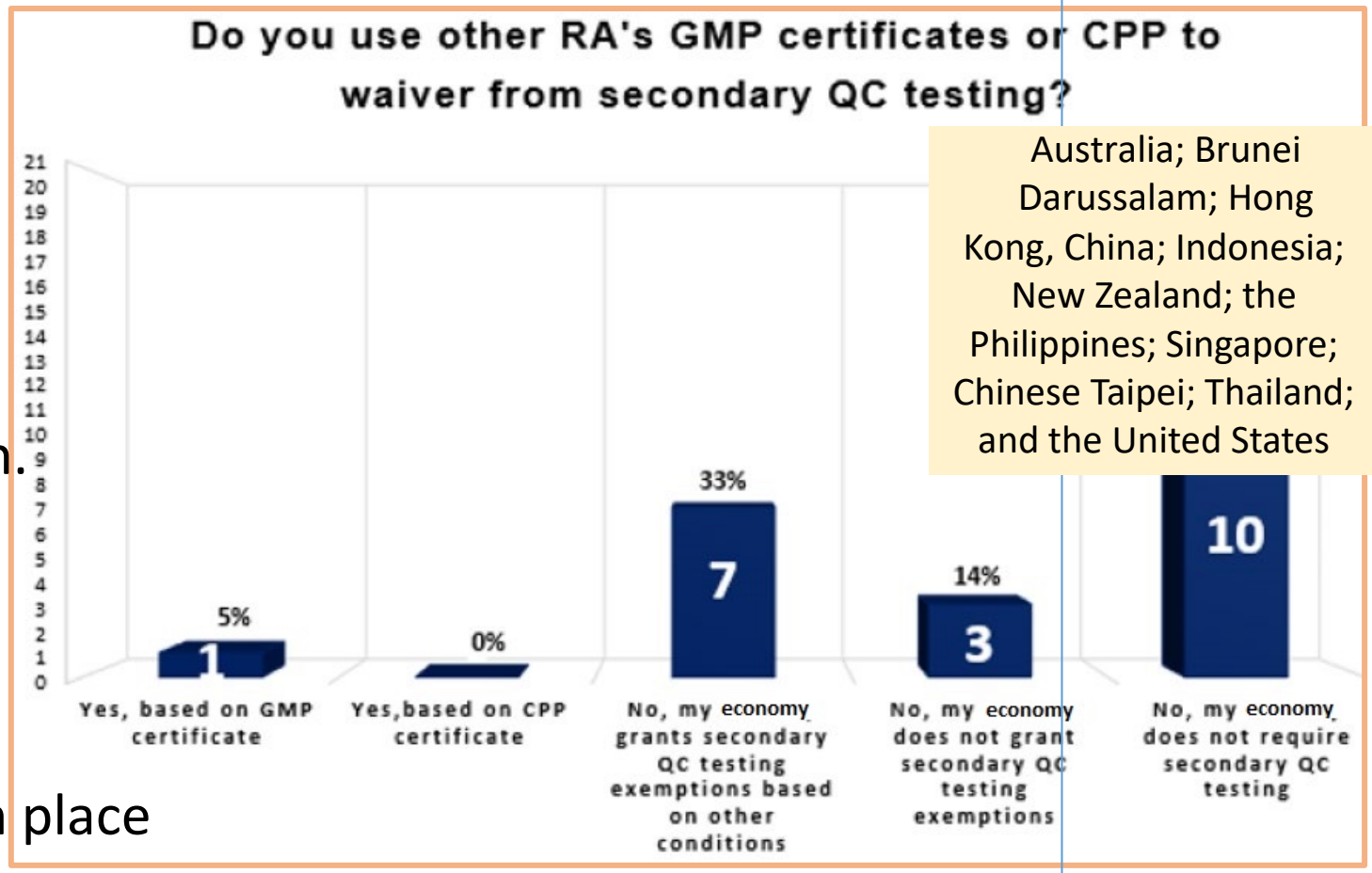
Key Performance Indicator #2: Good Reliance Practices to reduce duplication

- Rely on assessment performed by stringent Regulatory Agencies (RA) to reach its own decision
- Advantages

- Align/harmonize to high standard

- Minimize repeated testing

- 10 APEC economies do not require re-testing for importation or registration.
- Nearly 52% of the APEC economies continue to require import re-testing.
- Robust quality management systems, appropriate control strategies already in place to replace redundant, outdated practice that offers limited benefits to patients



Australia; Brunei Darussalam; Hong Kong, China; Indonesia; New Zealand; the Philippines; Singapore; Chinese Taipei; Thailand; and the United States

Source: J. Garbe, K. Ennis, G. Furer, M. Jacobs, S. Rönninger, **Import Testing of Pharmaceutical Products Has Limited Safety Benefits and Can Add Risk to Patients**, *Pharm. Tech. Europe*, 2015, 27(8):s6 - s20. (external link)

The New Normal that is fit for Purpose (patient safety)

Need of new KPIs to measure convergence to advance supply modernization

- Adoption of e-leaflets/e-package insert. Art work changes because of emerging safety information, new production sites.. and generally requires 9 to 12 months for a product. A lot of liaison for printing and verification is involved. Economy-specific requirement also leaves us limited choices but to re-address labels locally. This stifles access to important update (e.g. safety, medication instruction) in a timely manner. E-leaflets ensure flexibility in stock allocation across multiple economies and faster/more efficient updates for patients.
- Having digitized products (e.g. via a the GS1 2D DataMatrix barcode including e.g. serialized and links to product information (e-labelling/-leaflet) is a prerequisite for full Track & Trace. Acceleration of full Track & Trace to prevent counterfeits and illegal parallel imports; to protect our patients from counterfeits or parallel trade that may not hold the utmost highest quality standards as that required of pharma companies.
- Integrated blockchain solutions to connect supply chain solutions from manufacturers to wholesalers and hospitals/pharmacies: ensures safe and secure product data sharing.
- Think of new ways to bring products as close as we can to patients, e.g. home delivery, delivery to care centers etc. Consider also the need to introduce digital tools/apps that can connect back with patients on e.g. efficacy of the products, reminders to patients when to top up on their products, instructions on when to take the products, nearest location to get the replenishment of their products etc.