The United States Pharmacopeial Convention (USP) thanks DFAT for the opportunity to provide our perspective on key policies and investments that Australia can make in international development cooperation to support a peaceful, stable, and prosperous Indo-Pacific.

## What key challenges will shape Australia's engagement in our region and globally over the next five to 10 years?

In DFAT's own words, the Indo-Pacific is facing the triple challenges of climate change, COVID-19 recovery, and strategic contest. Individually, each challenge along has a significant effect on global health security in the region. Combined, the challenges raise the stakes exponentially. Climate change exacerbates the emergence of novel pathogens and the risk of cross-species viral transmission.[1] Severe weather resulting from climate change results in supply chain interruptions.[2] Meanwhile, COVID-19 recovery is hampering health system ability to provide routine care, as is evidenced with declines globally in routine immunization, worsening coverage for tuberculosis and malaria patients, and fewer people on antiretroviral therapy.[3,4]

Substandard and falsified medication flowing into the Indo-Pacific from China and India[5] further complicates combatting malaria, tuberculosis, and HIV in the region. Furthermore, surges in demand for medicines during outbreaks increase the prevalence of substandard and falsified medicines and medical products, a practice that skyrocketed as a result of COVID-19.[6] Finally, the fact that the world's supply chain for global health commodities—from active pharmaceutical ingredients to fully finished pharmaceuticals—is concentrated in the hands of large countries like China and India will make it more challenging for countries in the region to respond to the next outbreak with appropriate medical countermeasures.[7,8,9]

Fortunately, the Indo-Pacific region possesses key factors to building resilient and equitable global health supply chains, capable of withstanding pandemic shocks: A range of quality pharmaceutical manufacturers, from nascent to established; strong regional cooperation bodies; a wealth of human capital; and a robust investment landscape. With additional targeted development assistance and effective public-private partnerships that open the door for blended financing, there is significant opportunity to help Indo-Pacific countries to better prepare for the next pandemic.

## What opportunities does this present for Australia's development assistance?

COVID-19 has made clear to every country in the world—whether low-, middle- or high-income economies—that a new approach to global health supply chains is needed. The World Health Organization itself convened countries around the world in 2021 for the World Local Production Forum to explore how localized and regionalized global health supply chain models could help create more resilient and equitable health systems, more capable of responding to the next pandemic.[10]

### *Local and Regional Global Health Commodity Manufacturing and Procurement*

While pharmaceutical supply chains have become increasingly complex, the supply of many essential health products is constrained by a limited number of producers from a handful of manufacturing hubs. The challenge extends beyond limited sources of finished products: Few sources exist for starting and raw materials, as well as active pharmaceutical ingredients. Such over-consolidation makes supply chains vulnerable to disruptions, handicaps the ability of nations to prepare and respond to health emergencies, and imperils access to essential medicines, including novel medical countermeasures

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required to respond to a new pandemic threat. Local manufacturing is key to expanding access to medical products, averting supply chain shortages, advancing health security, and assuring equitable responses during health emergencies.[11,12]

Support for local manufacturing in the Indo-Pacific can include:

- Targeted technical assistance to pharmaceutical manufacturers to ensure compliance with international standards and product prequalification/approval;
- Regulatory advisory support to ensure manufacturing quality/GxPs, from dossier preparation to full product life cycle management, depending on existing manufacturer capabilities;
- A range of technology transfer support, including feasibility analysis, product and process knowledge transfer, and skills transfer for workforce development;
- Mitigating essential medicines shortages by sourcing and upscaling manufacturers for essential medicines in short supply;
- Developing novel synthetic routes for essential medicines and enabling alternate raw material sourcing.

Furthermore, in many Indo-Pacific countries, the supply of medicines and medical products is heavily dependent on imported products and vulnerable to supply shocks. Many nations lack the purchasing power to negotiate the best prices for health commodities. Locally produced medicines that meet international standards, in combination with stronger collective bargaining power, can help countries lower drug costs, spur local innovation, improve public health, and enable communities to prepare for the next pandemic.

Medicines procurement support in the Indo-Pacific can include:

- Procurement optimization efforts at country, subregional, and regional levels that can include baseline analyses of country national procurement agencies, develop institutional development plans, and harmonized KPIs to track efficiencies and improvements;
- Pooled procurement, including assessing enablers and bottlenecks, developing and harmonizing procurement frameworks to strengthen collective bargaining power, and developing strategies to address bottlenecks and increase purchasing power at the country and/or regional levels.

### *Regional Regulatory Convergence and Harmonization*

Localized/regionalized global health supply chains and procurement practices are necessary but not sufficient in addressing emerging pandemic threats in the Indo-Pacific. There is a need for a common regulatory framework that will allow for such efforts to take place. Since its establishment in 1998, the ASEAN Pharmaceutical Product Working Group has engaged in the region to harmonize technical procedures and quality requirements as they relate to pharmaceuticals.[13] The June 2022 adoption of the jointly developed ASEAN Pharmaceutical Regulatory Policy (APRP) by ASEAN Health and Economic Ministers has moved the region closer to having an ASEAN Pharmaceutical Regulatory Framework that will provide a common reference for implementation of APRP principles.[14]

Among the principles of the APRP[15] are those that DFAT has been supporting in the region to develop the capacity of National Regulatory Authorities (NRAs) to cover all elements related to regulation of quality, safety and efficacy of pharmaceuticals throughout the pharmaceuticals lifecycle. This includes implementing practices and guidelines aligned with international standards, practices and guidelines for

pharmaceutical products, including those developed by the World Health Organization, Organization for Economic Co-operation and Development, International Council for Harmonization, and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme for Pharmaceutical Products.

The best way to support preparedness for regional regulatory convergence frameworks that emerge from ASEAN are to strengthen NRA regulatory maturity and effectiveness in individual countries in the Indo-Pacific. Australia's regulatory System strengthening support can include:

- Using the World Health Organization's Global Benchmarking Tool to objectively evaluate national regulatory systems across the nine function areas to identify strengths and areas for improvement; and provide technical assistance to formulate institutional and development plan to build upon strengths and address the identified gaps, prioritize institutional development plan interventions, and monitor progress and achievements.
- Supporting good governance and transparency best practices, including data standardization and sharing; multisectoral stakeholder engagement and standards; and integrated regulatory information management systems.
- For pandemic preparedness, support NRA efforts to ensure robust yet rapid Emergency Use Authorization processes, mutual recognition, reliance, and variation reporting.

### *Capacity Strengthening in Professional Education*

Despite considerable human capital investments in the region, gaps remain in key professional knowledge and skills required for resilient, robust, localized global health supply chains. As such, supporting the development of state-of-the-art undergraduate and postgraduate curricula and professional development materials for regulatory, laboratory, pharmacy, and public health staff in national medicines regulatory authorities, Ministries of Health, national quality control laboratories, and Food and Drug Administrations can go a long way to developing additional human capital in the region to be effective stewards of national health systems, and effective responders to emerging pandemic threats.

Professional Education support in the Indo-Pacific can include a range of short or long courses, whether for formal degrees or continuing professional development, such as:

- Technical assistance to define appropriate undergraduate and graduate degree program content in selected programs (e.g., regulatory sciences);
- Technical assistance to develop curriculum, define competencies, for selected undergraduate and graduate degree programs (e.g., regulatory affairs, vaccinology);
- Support for developing evidence-based continued competency learning programs for NRA professionals.

### *Robust Investment Landscape*

The dynamic economic landscape in the Indo-Pacific—despite COVID-19—provides Australia the opportunity to leverage its health security investments. For example, DFAT can crowd in additional private capital from impact investors who have patient capital, and are willing to forego higher gains when their investment bears a social good. Furthermore, such capital can be used to structure pay for performance awards where Australia reimburses initial investors only if pre-determined milestones are

achieved. With COVID-19 making importance of pandemic preparedness painfully aware to everyone, we expect there to be a strong appetite among the investment community to strengthen health systems' capacity to prevent, detect, and respond to the next pandemic. The Global Impact Investing Network and Intellecap estimate at least 60 different private impact investors have invested USD 904 million in 225 deals in Southeast Asia between 2007 and 2017.[16] Core areas of investment and interest include manufacturing, human capital development, and healthcare. Such investors could be key to Australia implementing a successful localized/regionalized global health commodity manufacturing strategy in the Indo-Pacific.

## What lessons from Australia's past development efforts should inform the policy?

A robust foundation has been laid through Australia's recent DFAT Health Security Initiative investments for regulatory systems strengthening (RSS), laboratory systems strengthening (LSS), and medicines quality programs. Lessons learned from these programs can support expanded Australian health security efforts in the Indo-Pacific region. Investments Australia has made in both RSS and LSS have strengthened regulatory systems and medicines testing capacity in the Indo-Pacific, preparing regulators for ensuring better quality medicines and strengthening the human, technical and material resources for the next pandemic or crisis. Still, a critical need exists to build capacity to respond rapidly and with agility to prepare for the next pandemic or crisis. There is also a critical need to strengthen post-marketing surveillance to ensure drugs on the market are safe and effective and to prevent antimicrobial resistance in antibiotics which are increasingly produced locally, and where antimicrobial testing is often spotty or non-existent.

### *Regulatory and Laboratory System Strengthening*

Strong regulatory systems help people access safe, effective, and quality-assured medical products, guard against harmful substandard and falsified products, and help foster a reliable supply chain of medicines. They also provide a crucial enabling environment function for local pharmaceutical production. A critical link in the supply chain, strong NRAs promote health security and improve equitable responses in routine times and in health emergencies alike. Strong laboratories help ensure medical products are of assured quality and are critical to the detection, prevention, and control of global health diseases; and help identify and contain antimicrobial resistance. As critical components of the health system, laboratories—including quality control and microbiology laboratories, and clinical and diagnostic laboratories—are all strengthened by robust, effective and continuous capability building through quality management systems that help ensure reliable and consistent results.

DFAT's investment to date in supporting the quality, resilience, and sustainability of clinical and diagnostic laboratories is increasing Indo-Pacific countries capacity to prevent, detect, and respond to current and emerging diseases. Based on our experience implementing these efforts for DFAT and other donors in low- and middle-income countries, we recommend the following next steps for additional DFAT support:

- Developing NRA capacity for biologics and vaccines microbiological laboratories in lot release testing, and to enable quality-assured, local good manufacturing practices for the export of quality-assured biologics and vaccines;
- Increasing the maturity levels of NRAs in the Indo-Pacific in a stepwise process to Maturity Level 3 status;

- Introducing advanced analytical methods for impurities, trace elements, etc.;
- Improving internal quality control and participation in external quality assurance and regional inter-laboratory comparison testing schemes;
- Linking testing services to post-market surveillance to ensure quality, efficacy, cost effectiveness and sustainability, especially for quality medicines for key diseases: HIV/AIDS, tuberculosis, Malaria, COVID, non-communicable diseases, and for antimicrobial resistance testing;
- Ensuring national testing laboratories and diagnostic laboratories have in place effective, practical institutional development and strategic plans for resource mobilization and sustainability; and that they are both accredited and re-accredited in a timely manner so as to maintain and not lose their international accreditation status;
- Supporting biosafety, biosecurity, and proper laboratory waste management.

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