Introduction

While thrusting the world into a health crisis, the COVID-19 pandemic has simultaneously highlighted numerous global economic, social and political vulnerabilities and the desperate need to secure global value chains for a range of health and non-health-related products. Many countries have significantly benefited from the rapid development and production of novel vaccines and other essential health products (“EHPs”) such as therapeutics, diagnostics (e.g., polymerase chain reaction and rapid antigen testing kits) and personal protective equipment. However, gross inequities in the availability of these health products across countries and regions have left much of the developing world without access to them. At a time when these products are most needed, international trade and global supply chains have suffered immensely.

Supply levels for EHPs have not matched global demand, primarily because of the following factors:

- limited global production capacity and insufficient technology transfer, especially for local production in diverse regions;
- the continuing emergence of new variants of concern, and thus growing demand for vaccine booster doses in developed countries;
- procurement by developed countries of many more vaccines than they need to vaccinate their populations;
- logistical, transportation and supply chain constraints, such as shipment and customs clearance delays;
- lockdowns, travel and border restrictions, and staff shortages;
- trade barriers such as export restrictions, and protectionist measures such as stockpiling and export bans;
- poor existing domestic health infrastructure; and
- limited access to intellectual property (“IP”) rights or other IP barriers.

These factors have contributed to inequities in EHP access and distribution across different regions, with countries in Asia-Pacific and Africa being amongst the worst affected. Although some developed countries are approaching or celebrating ‘COVID normal,’ every country is facing its own unique situation and challenges. 11 billion COVID-19 vaccine doses have been
administered globally, but 22 WHO member states have vaccinated less than 10 per cent of their populations and 75 states have vaccinated less than 40 per cent.

The COVID-19 pandemic and the fragility of global value chains and cross-regional trade have revealed the crucial role of intra-regional trade, investment, research and development (“R&D”), and innovation flows in fighting the pandemic. Open trade in vaccines and other health product inputs, strong flows of capital, and the smooth transfer of technology and know-how is needed to enhance the availability and distribution of EHPs.

**Key take-aways**

There is a pressing need for:

- the even distribution of production capacity within the region, where feasible;
- the transfer of R&D;
- the availability and movement of raw materials and inputs;
- the mobility of global talent and expertise;
- regulatory harmonization for trade and transport procedures, clinical trials, and medical products; and
- a strengthening of investment facilitation, including through streamlining investment approvals and providing tax incentives and allowances.

- Small and medium-sized enterprises (“SMEs”) in the region play a critical role in ensuring equitable access to EHPs but have been the most significantly affected by trade measures and high costs.
- Partnership at every stage of the production and distribution process is vital; no firm or government can alone play a significant role in the global and regional pandemic response without the assistance and cooperation of others.
- Both public-private and private-private partnerships can play an equally important role in boosting the development and distribution of EHPs. Cooperation amongst private and public enterprises throughout the whole manufacturing, distribution and delivery ecosystem – and across the entire supply chain – is required. As in-house end-to-end production of vaccines and other EHPs is uncommon, this applies equally in the manufacturing context.

**Procurement**

- Small island states in the Pacific are at a disadvantage in accessing quality and affordable health products because of supply chain and logistics challenges associated with transportation to remote areas, delays in air transport, and financing constraints.
- There is no ‘one-size-fits-all’ approach for countries in the region, and each has its procedures. To ensure a stable supply, some countries are adopting a portfolio approach to procurement, with no preference being maintained for particular manufacturers. This strategy can generate demand and highlights the need for further geographical diversity in manufacturing.
• Small island states, such as Tuvalu, are seeking and will continue to seek the support of international organizations such as the World Health Organization and UNICEF, as well as initiatives such as the WHO COVID-19 Vaccines Global Access ("COVAX") Facility, United Nations Patent Pool, and Asian Development Bank’s Asia Pacific Vaccine Access Facility ("APVAX").

• Regional cooperation in the form of pooled procurement of EHPs can increase economies of scale and reduce the prices of EHPs for less-developed nations, especially in more remote regions.

• The development of a Tuvalu National Trade Development Strategy, in partnership with ESCAP, is an example of the kind of initiatives that can be undertaken to facilitate trade domestically and internationally.

Supply Chain, Logistics and Trade Regulation

• The availability and predictability of the supply of EHPs have been a common challenge for many developing countries. Disruptions to both the supply- and demand-side resulted from rebounded demand in the early pandemic stages and operational disruptions brought on by lockdowns, port closures, weak logistics infrastructure, and protectionist measures such as export restrictions and high duties on EHPs.

• ASEAN constituents have taken concerted action to strengthen supply chain connectivity and ensure the smooth flow and transfer of EHPs. Initiatives like the Hanoi Plan of Action on Strengthening ASEAN Economic Cooperation and Supply Chain Connectivity in Response to the COVID-19 Pandemic and the Memorandum Of Understanding on the Implementation of Non-Tariff Measures on Essential Goods have been at the forefront of ASEAN’s efforts.

• However, customs procedures must be simplified even further. Digital transformation of trading processes is key to enabling faster and cheaper cross-border trade and transport of EHPs. One underutilized option is greater investment in digital infrastructure, including through the adoption of paperless trade, electronic pre-arrival processing, and open data exchange between authorities.

• Strategies for long-term resilience during and beyond the pandemic are a priority. Such strategies should involve better risk management, cross-sectoral coordination between trade, health and logistics supply chain players, and public-private cooperation.

• There is a need to maintain and develop open trade settings and a real-time understanding of challenges in the supply chain so that relevant and informed action can be taken. A global market information system and/or a supply chain watchtower could enable greater visibility over essential medical supply chains, strengthen private-public cooperation, enable removal of potential bottlenecks, increase trade facilitation measures, bolster long-term resilience and ultimately intensify the production and distribution of EHPs.

• Rapid regulatory changes and a lack of consultation and cooperation between policy-makers, the private sector and governmental agencies lead to misunderstandings, uncertainty and delays at the industry level. Clearer legal guidance and harmonization around regulatory approval requirements are needed, and these requirements should not lead to transit delays.
In this regard, attention must be paid to regulatory barriers that limit the distribution of ancillary as well as primary health products and inputs.

- Countries take a varied approach to clearance and transport procedures and security risks, with some utilizing military escorts for cargo. Moreover, remote and hard-to-reach countries require distinct distribution models.
- Advanced planning must consider the need to produce and mobilize large volumes of goods using limited capacity transit networks in both accessible and remote areas. Planning must also consider regulatory and operational requirements associated with the physical movement of EHPs, including dangerous goods used to facilitate temperature control, the approval of data loggers, and packaging standards.
- Domestic health systems should be seen as an integral part of RVCs and the distribution of EHPs. Health system limitations, such as a lack of trained personnel, inadequate health infrastructure and supply chain and logistics challenges, may limit the success of vaccine rollouts even if sufficient doses are available.

**Production, Investment, R&D and Clinical Regulation**

- Diversification of production is key to the reliability and resilience of EHP supply chains and can also introduce economic opportunities and spill-over effects, such as increased jobs and higher domestic revenue streams for developing nations.
- Future planning around financial and timeframe elements must be carried out in advance of potential health or other emergencies to ensure production and distribution of EHPs can occur in a timely manner.
- Existing manufacturing and distribution infrastructure should be repurposed where possible to reduce financial and timeline challenges associated with EHP delivery.
- There is a need to consolidate the currently fragmented, highly uncoordinated and under-resourced R&D ecosystem, enable closer coordination of clinical trials, and harmonize clinical trial regulation. The focus should be placed on improving both research and regulatory capacity, as well as managing the logistical challenges in conducting clinical trials. Such challenges include mobilizing large numbers of trial participants to diverse regional areas.

**Policy recommendations**

**Short-term**

- Governments should remain vigilant, keep vaccinating their populations, and apply public health measures with a commonsense approach.
- Small nation-states and developing countries should continue to utilize pooled procurement methods to leverage economies of scale and ensure access to EHPs for their populations.
- Governments and international development banks should support SMEs and solidify their role in EHP supply chains by offering them appropriate funding. Funding should be extended to:
valuable initiatives such as the Access to COVID-19 Tools (ACT) Accelerator, COVAX and APVAX;
- manufacturing facilities in the least Developed Countries for vaccines and a wide variety of platform technologies;
- the development of domestic public health infrastructure, including trained personnel, vaccine delivery facilities and transport networks.

- Governments should **remove measures that limit the supply of EHPs**, such as export restrictions, bans and tariffs. Technical regulations for EHPs should be no more trade-restrictive than necessary to ensure the safety and efficacy of EHPs or their transportation.
- Governments should **simplify customs and other transport procedures** and requirements and **avoid unnecessary or burdensome regulatory changes**.
- Governments should provide **clearer legal guidance** around regulatory approval requirements for EHPs when changes are made and **consult with the private sector and subordinate government agencies** prior to implementing new rules and regulations.
- Governments in the region should seek to **harmonize**, amongst other things:
  - import standards and regulations and flight crew restrictions for a more optimized distribution capability;
  - technical regulations and packaging requirements for medical products;
  - clinical trial regulations and standards; and
  - investment policies and requirements.

**Mid- to long-term**

- **Small island states should strengthen their relationships** with other nearby island states and neighboring nations, as well as their relationships with suppliers and supply management systems.
- Governments should commit to **greater investment in digital infrastructure** and implement measures that facilitate the adoption of paperless trade, electronic pre-arrival processing, and open data exchange between authorities.
- Governments should **streamline the adoption of the WTO Trade Facilitation Agreement** to enable smoother trade processes and digital trade.
- Governments and the private sector should collaborate on a **global market information system** and/or a **supply chain watchtower** that could enable greater visibility over EHP supply chains for both the current pandemic and future health crises.
- Private firms operating at the production stages should **plan in advance for the production of EHPs**, taking into account financial and timeframe requirements and the potential need for adequate investment. Firms should work with private sector partners and governments to repurpose existing manufacturing infrastructure to reduce financial and time challenges associated with EHP delivery.
Private firms operating at the distribution stages should **plan in advance for the mobilization of large volumes of goods** using limited capacity transit networks in both accessible and remote areas, taking into account the need to address a wide range of regulatory and operational requirements. The private sector and governments should collaborate in this regard where appropriate.

**Research institutions** and **private firms** should aim to **collaborate on R&D** more closely and widely with other institutions and firms in different regional or global areas to ensure confidence in the safety and efficacy of health products and streamline the transfer of technology.

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