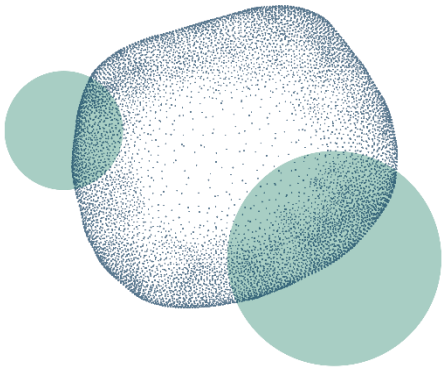
Achieving the 100 Days Mission for Pandemic Preparedness in South and Southeast Asia



A Participatory Discussion and Listening Exercise – Summary of Proceedings

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Event summary

The event took place on 13th July 2023 and was attended by 26 experts drawn from a diverse range of sectors, representing 11 countries from across the region. The event was co-hosted by the International Pandemic Preparedness Secretariat (IPPS) and the Singapore Ministry of Health in partnership with Pandemic Action Network, and participants were invited to reflect the full diversity of pandemic preparedness expertise available in the region.

The event began with brief presentations from Haskan Kaya (IPPS Science Policy Officer) and Heulwen Philpot (IPPS Head of Secretariat). These presentations provided participants with an overview of the IPPS and the 100 Days Mission (100DM) and outlined the purpose and scope of the day's discussion. The purpose being to strengthen collaborative networks within the region and to gain a deeper understanding of how the region might work towards, and benefit from, a '100 Day mission approach' to medical counter measure development. The scope of the discussion being the diagnostics, therapeutics, and vaccines (DTVs) value chain from R&D through to distribution (see Figure 1), with a particular focus on ensuring there is rapid and equitable access to DTV products.

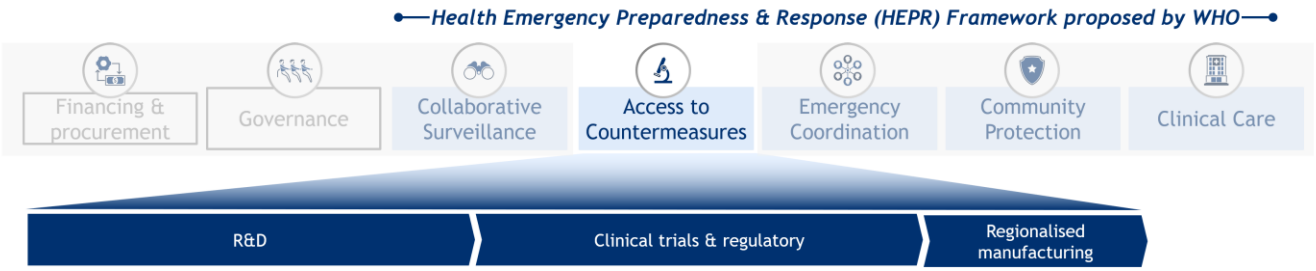

Figure 1: The DTV value chain and focus of the day's discussion.

The IPPS presentations were followed by a presentation from Professor Tan Chorh Chuan (Chief Health Scientist, Singapore Ministry of Health). Professor Tan thanked invitees for their attendance and acknowledged the significant progress the region has made in pandemic preparedness over the past twenty years. He then presented a summary of the findings of a pre-event survey that invitees had completed prior to joining the event (see Table 1).

Professor Tan closed his presentation by underlining the collective nature of the 100DM and expressing his desire to learn more about how the region can both contribute to and benefit from greatly accelerated development of pandemic countermeasures.

Regional Challenges that Remain	Possible Approaches to Tackling these Challenges
Limitations in R&D capabilities & biotech ecosystem Lack of funding/investment Availability of skilled workforce Regulatory barriers	Mutually beneficial sharing of data and specimens Regional collaboration in research and DTV development Clinical research networks Harmonisation of regulatory requirements

Table 1. Regional challenges and possible approaches.

Small Group Discussions Round 1: Identifying what has been working well

In the first of three breakout room activities, participants worked in small groups to consider Prof Tan's theme of progress in the face of significant challenge. The participants were asked to share a previous case of an infectious disease outbreak in there region where, despite significant challenges, some parts of the infectious disease product development ecosystem worked well.

19 regional cases of infectious disease outbreak were discussed by the participants. The most commonly discussed disease was COVID-19; however, participants also shared the learnings from a number of other disease outbreaks (including, SARS CoV-1, MERS; Zika; hand, foot and mouth; and malaria). The participants stated that the following areas of the product development ecosystem were instrumental in controlling the outbreaks: global collaboration and partnerships, early identification and surveillance, equitable access to diagnostics and treatments, clear communication and public engagement, prior investments in research and development, and robust regulatory support and accelerated approvals.

Two exemplar case studies are provided below:

Exemplar case 1: Rapid development and delivery of a serology test to differentiate between SARS infections

Working on SARS-CoV-2 in January 2020 required accurate serology to differentiate between SARS-CoV-1 and SARS-CoV-2 infections. One participant described how a beta test was developed, a patent was applied for, and regulatory approval was received - enabling delivery within 70 days.

This was made possible so rapidly because of pre-existing connections with an industry partner who believed in the beta test, who had resources to help develop it, and trusted it was the right thing to do, despite economic profit not being guaranteed. It was also critical to begin discussions with regulatory bodies and other partners in the value chain before the product was finalised so there was sufficient data and familiarity with the product to enable rapid approval.

This example highlights the importance of developing cross-sectoral networks during inter-pandemic periods that can be drawn on when accelerated approaches are needed. Although this product was developed, approved and delivered in 70 days for one country, it took 3 years to get approval for use in other countries in the region showing the importance of regional regulatory harmonisation.

Exemplar case 2: Enabling rapid regulatory approval of a novel malaria therapeutic via the Indo-Pacific Regulatory Strengthening Program

A new malaria treatment, Tafenoquine, offers a radical single dose cure with several advantages over the current 14-day course of treatment with the existing product Primaquine. This product was developed through a multi-stakeholder collaboration with private sector (GSK), product development partnership (MMV) and supported by the Gates Foundation.

Australian regulatory agencies approved the use of the product in Australia. The Australian Therapeutic Goods Administration (TGA) through its Indo-Pacific Regulatory Strengthening Program (IPRSP) then provided technical assistance to other countries in the region to fast-track the regulatory review process for Tafenoquine.

This fast-tracking was achieved through multiple videoconferences which involved technical discussions around the TGA's evaluation and a visit of Thai delegates to the TGA, resulting in an expedited approval. This resulted in Thailand being one of the first countries in Asia Pacific to follow Australia in approving use of this product for vivax malaria.

This example underscores the importance of intra-regional cooperation. It shows how national regulatory authorities can connect with regional programs, such as the IPRSP, to provide public health benefit beyond national borders. The expert-to-expert discussions referred to in this example, also highlight how the soft outcomes of trust and mutual confidence are built between nations.

Small Group Discussions Round 2: Identifying existing Rate-limiting stages within the product development pipeline

In this second round of small group discussions, participants were asked to respond to two questions focusing on which areas of the product development pipeline needed the most attention in their region.

Question one required participants to consider the end-to-end ecosystem of pandemic product development as a relay race, and asked what stages and handovers of the relay need the most strengthening in their region to ensure sustainability and efficiency.

In response to this question participants reported that pan-regional collaboration was seen as crucial to strengthening many stages of the pandemic product development race. Collaboration was framed in many ways. For example, encouraging research collaboration through open science and the sharing of data and know how; and improving funding coordination through shared decision making (e.g. on priority pathogens).

The need for regulatory harmonization and simplification was an issue that was discussed by a number of the groups. Several participants in these groups stated that harmonization of regulatory systems across countries would facilitate a common product registration process. Streamlining regulatory pathways and expedited approvals were seen as critical to speeding up the development and approval of new products.

Another key theme that emerged in this second round of discussions was the need to exploit “peace time” to learn from past experiences with infectious disease and build regional capacities. It was suggested that keeping flexible platform-agnostic manufacturing facilities in readiness between pandemics, or redeploying existing capacity is one means of ensuring continuous supply chains are in place to meet the need for scale up during pandemics. The importance of training and development was also a key theme of many of the groups, some specifically noting the need for expertise in designing and running clinical trials.

The second question posed to participants in this round of small group discussions was “How can equity and accessibility be built into the early-stage R&D ecosystem in your region?”.

In response to this question there was a strong sense that equity and accessibility are driven by political will, and that it is not just global bodies that should be providing that will but bodies in the region such as the Association of Southeast Asian Nations (ASEAN) should also be driving this aim. One participant reported that there were conversations in progress to form a political consortium in the region to provide direction at this level.

The groups also provided a number of practical suggestions to address equity and accessibility. For example, it was suggested that terms and conditions in publicly funded R&D should explicitly state the need for equity and accessibility and that research should consider the availability of materials right from the start of the product development process. Collaboration in various forms was again seen to be key, with one group stating that good clinical trial networks are important for achieving early access to products in the region, and that more of these networks need to be set up.

Small Group Discussions Round 3: A focus on global mechanisms that support regional preparedness

In the final small group discussion of the event the focus shifted from regional capabilities to global frameworks that support regional pandemic preparedness. This section of the event began with a presentation by Heulwen Philpot (IPPS) that provided an overview of the global supporting frameworks and mechanisms that already exist or are in development. In particular, she highlighted that whilst organisations such CEPI and FIND are leading work in the areas of vaccines and diagnostics, the therapeutics space is more complex. Therefore, she invited

participants in the region working on research or access to therapeutics to contact IPPS as they are in the process of producing a 100DM roadmap for therapeutics development.

Following the presentation, a number of participants provided details of existing global mechanisms that they found helpful in supporting pandemic tool development. These mechanisms included the WHO emergency use listing, WHO prequalification, and WHO genomic surveillance strategy; APEIR, an Asian network for disease surveillance and member of CORDS (Coordinating Organization for Regional Diseases Surveillance); and GISAID, which was reported to have been an instrumental platform to exchange information.

The participants then moved into breakout rooms to discuss the answer to the following question: “What external normative frameworks, guidance or agreements would be most beneficial for your region’s preparedness?”

In this discussion, sharing, trust, and funding were the most frequently occurring themes. Again, sharing referred to both data and knowledge, with participants stating that data sharing frameworks and agreements would expedite the timely sharing of quality data, and that open access to biorepository samples and clinical data is crucial. In terms of building know-how across the region, one group stated that effective capacity building networks would involve not only knowledge sharing mechanisms but also mechanisms to share needs. IP was stated as a barrier to technology transfer, and participants wondered what frameworks or agreements might facilitate smaller or less well-resourced countries to build their local manufacturing capacity. A number of groups stated that trust was the key to building the types of effective collaborative networks that foster the sharing of data, knowledge and technology. They also stated that collective progress towards achieving the 100DM requires trust to be built in peace time so that, during a pandemic, new relationships are not being built from scratch.

Funding and its relationship to equity was highlighted in several discussions. It was stated that the global north is often funded to do work in the global south, and this does not work well for the region and this is not sustainable. To combat this, it was suggested that major global north funders should talk to each other in order to coordinate more effectively to reduce duplication. Furthermore, it was suggested that rather than the current colonial model of funding, it should be the global south that sets the funding priorities for the region – perhaps with the establishment of regional hubs for the Pandemic Fund with regions deciding on a set of “grand challenges” that should be put out in a regional funding call.

The event closed with organisers and participants signing off by sharing individual takeaways and stating how beneficial the day's discussions had been.

"It's been great sharing and learning from our different multidisciplinary experiences"

"I'm looking forward to even greater partnerships in our region that will strengthen our collective preparedness and response to the next epidemic"

"It's clear that, together, all counties can develop the roadmap based on recent learning to create a robust 100 Days Mission blueprint"