Vaccine manufacturing workshop
for South-East Asia and the Western Pacific Regions

Meeting report

21–22 February 2022
Vaccine manufacturing workshop
for South-East Asia and the Western Pacific Regions

Meeting report

21–22 February 2022
Vaccine manufacturing workshop for South-East Asia and the Western Pacific Regions: meeting report, 21–22 February 2022

ISBN 978-92-4-005201-7 (electronic version)
ISBN 978-92-4-005202-4 (print version)

© World Health Organization 2022

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (http://www.wipo.int/amc/en/mediation/rules/).


Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see https://www.who.int/copyright.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers’ products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviations</td>
<td>iv</td>
</tr>
<tr>
<td><strong>1.0 Introduction</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>2.0 Workshop proceedings – Day 1</strong></td>
<td>2</td>
</tr>
<tr>
<td>2.1 Objectives</td>
<td>3</td>
</tr>
<tr>
<td>2.2 WHO policies, support and landscape on vaccine R&amp;D, production, and access</td>
<td></td>
</tr>
<tr>
<td>2.2.1 Global COVID-19 vaccines: Demand and supply and anticipated regulatory challenges</td>
<td>3</td>
</tr>
<tr>
<td>2.2.2 Regional landscape: South-East Asia region</td>
<td>4</td>
</tr>
<tr>
<td>2.2.3 Regional landscape: Western Pacific region</td>
<td>4</td>
</tr>
<tr>
<td>2.2.4 Update on WHO activities for strengthening the local vaccine production: HQ activities – Local Production and Assistance unit</td>
<td>5</td>
</tr>
<tr>
<td>2.3 Introduce and review the CEPI 2021 vaccine manufacturing survey data identifying gaps/ opportunities across South-East Asia and Western Pacific regions</td>
<td>6</td>
</tr>
<tr>
<td>2.4 Brainstorm on future activities to support improving vaccine manufacture capacity/ capability and/ or efficiencies in South-East Asia and Western Pacific regions</td>
<td>7</td>
</tr>
<tr>
<td>2.5 Day 1 Wrap up</td>
<td>8</td>
</tr>
<tr>
<td><strong>3.0 Workshop proceedings – Day 2</strong></td>
<td>9</td>
</tr>
<tr>
<td>3.1 Core features of a roadmap to establish and/or expand vaccine manufacturing capacity and capability</td>
<td></td>
</tr>
<tr>
<td>3.1.1 Scientific and technical considerations</td>
<td>9</td>
</tr>
<tr>
<td>3.1.2 Business model and market considerations</td>
<td>9</td>
</tr>
<tr>
<td>3.1.3 Infrastructure, regulatory systems, workforce, and partnerships</td>
<td>10</td>
</tr>
<tr>
<td>3.2 Part 1: Presentation</td>
<td>10</td>
</tr>
<tr>
<td>Plan towards improving vaccine development/ manufacturing capacity/ capability and/ or efficiencies in South-East Asia and Western Pacific regions</td>
<td></td>
</tr>
<tr>
<td>3.2.1 Government of Indonesia</td>
<td>11</td>
</tr>
<tr>
<td>3.2.2 Government of Philippines</td>
<td>11</td>
</tr>
<tr>
<td>3.2.3 Gennova Biopharmaceuticals, India</td>
<td>12</td>
</tr>
<tr>
<td>3.2.4 Serum Institute of India Pvt. Ltd., India</td>
<td>12</td>
</tr>
<tr>
<td>3.2.5 Siam Biosciences, Thailand</td>
<td>12</td>
</tr>
<tr>
<td>3.2.6 Asian Development Bank</td>
<td>13</td>
</tr>
<tr>
<td>3.2.7 International Vaccine Institute</td>
<td>13</td>
</tr>
<tr>
<td>3.2.8 Developing Countries Vaccine Manufacturers Network</td>
<td>13</td>
</tr>
<tr>
<td>3.3 Part 2: How local vaccine manufacturing can address vaccine access gaps in Asia</td>
<td>14</td>
</tr>
<tr>
<td><strong>4.0 Day 2 wrap up, conclusion and next steps</strong></td>
<td>14</td>
</tr>
</tbody>
</table>
Abbreviations

ADB  Asian Development Bank
BOI  Board of Investments
BPOM  Indonesia Food and Drug Administration
BSL2  Biosafety Level 2
CEPI  Coalition for Epidemic Preparedness Innovations
cGMP  Current Good Manufacturing Practice
CHAI  Clinton Health Access Initiative
CMC  Chemistry, Manufacturing, and Controls
COVID-19  Coronavirus disease
DCVMN  Developing Countries Vaccine Manufacturers Network
DOST  Department of Science and Technology
DTI  Department of Trade and Industry
EUA  Emergency Use Authorization
EUL  Emergency Use Listing
FDA  Food and Drug Administration
GAVI  Global Alliance for Vaccines and Immunization
GBT  Global Benchmarking Tool
GCP  Good clinical practice
GLP  Good laboratory practice
GMP  Good Manufacturing Practice
HIC  High-income country
HPV  Human Papillomavirus
HQ  Headquarters
IFPMA  International Federation of Pharmaceutical Manufacturers & Associations
ISO  International Organization for Standardization
IVI  International Vaccine Institute
LIC  Low-income country
LMICs  Low- and middle-income countries
LPA  Local Production & Assistance
MIC  Middle-income country
MRA  Medical Regulatory Agency
mRNA  Messenger ribonucleic acid
NCL  National Control Laboratories
NDC  National Development Company
NRA  National Regulatory Agency
PCV  Pneumococcal Conjugate Vaccine
PQ  Prequalification
R&D  Research & development
RITM  Research Institute for Tropical Medicine
RVAG  Regional Vaccine Advisory Group
SII  Serum Institute of India
SOPs  Standard operating procedures
UN  United Nations
VSRP 1  Vaccine Self Reliance Project 1
WHO  World Health Organization
1.0 Introduction

A lesson learnt from the COVID-19 pandemic is the importance on diversification of vaccine production geographically to meet the local demands and enhance vaccination uptake, especially in the low- and middle-income countries (LMICs). Equitable access of affordable and quality-assured vaccines continues to be at the forefront of initiatives in driving vaccine manufacturers to partake actively in producing routine vaccines and increase adaptability to new technologies to address current and future pandemics/epidemics. World Health Organization (WHO) Local Production and Assistance (LPA) Unit in close collaboration with WHO Regional Office for South-East Asia and WHO Regional Office for the Western Pacific with technical support from Coalition for Epidemic Preparedness Innovations (CEPI) organized this workshop to bring about a platform for stakeholders to engage, dialogue and collaborate towards preparedness and response to current and future epidemics/pandemics to coronavirus and other priority pathogens to improve public health security in LMICs.

A series of topics is aimed at addressing the specific needs for a robust and sustainable local production environment at country and regional levels and to deliver regional roadmaps in South-East Asia and Western Pacific regions to improve vaccine production capacity/capability through strategic WHO policies and guidelines, research and development, financial investment, political and government commitment. This workshop has the following core principles:

i. Examine and prioritize factors that affect production sustainability and efficiency
ii. Understand manufacturing gaps and instigate developing a roadmap to improve epidemic/pandemic vaccine preparedness and response capacity and capability in each region
iii. Review WHO’s activities from headquarters and regional offices in strengthening local vaccine production
iv. Review CEPI’s 2021 vaccine manufacturing landscape survey data collected from South-East Asia and Western Pacific regions
v. Establish strategic partnerships with existing/new networks and stakeholders to build/improve capacity for outbreak preparedness and address vaccine manufacturing gaps
vi. Brainstorm future activities to support establishing/improving vaccine manufacture capacity and capability in the South-East Asia and Western Pacific regions, focusing on:
   - Championing, oversight, and leadership requirements to deliver objectives per region to ensure “local ownership” of established manufacturing capacity/capability
   - Potential business models and public-private (investment) initiatives to ensure future manufacturing sustainability of developed and/or established facilities
   - Required infrastructure, workforce training, regulatory needs, and public-private partnership networks

Around 300 participants from South-East Asia and Western Pacific regions attended the 2 days’ workshop to review the needs and requests to deliver a robust vaccine manufacturing ecosystem that is capable and efficient in the production of routine vaccines and outbreak preparedness at country and regional levels. This meeting report is developed by the Local Production and Assistance Unit, WHO headquarters, as a summary of the workshop discussions, and was circulated and accepted by the WHO Regional Office for South-East Asia, WHO Regional Office for the Western Pacific, partners and speakers.
2.0 Workshop proceedings – Day 1

Dr Rogério Gaspar, Director, Regulation and Prequalification Department, Access to Medicines and Health Products Division, WHO headquarters, chaired Day 1 with an introduction of Dr Poonam Khetrapal Singh, Regional Director, WHO Regional Office for South-East Asia, Dr Takeshi Kasai, Regional Director, WHO Regional Office for the Western Pacific, Dr Mariângela Batista Galvão Simão, Assistant Director-General, Access to Medicines and Health Products, WHO headquarters, Dr Soumya Swaminathan, Chief Scientist, WHO headquarters, and Dr Frederik Kristensen, Deputy Chief Executive Officer and Director of People, Planning and Policy, CEPI, to deliver welcome and opening remarks.

Dr Poonam Singh revealed that high-income countries (HICs) have received 13 times more doses per person compared to low-income countries (LICs), 27 LMICs have less than 10% of their population vaccinated while 78% have vaccinated less than 40%. Such inequities are unethical and unsustainable, and directly beat WHO’s goal of ensuring at least 70% of eligible populations are vaccinated in all countries globally by mid-2022. There are 5 priorities to be addressed, namely to consider commercial viability, agility of manufacturers to adopt newer technologies, need for transparent information and data exchange while respecting intellectual property rights, optimize human and financial resources with a focus on public-private partnerships, and strengthen oversight and leadership in local ownership and centers of excellence. Dr Takeshi Kasai highlighted 6 countries, namely, Australia, China, Japan, Republic of Korea, Viet Nam and recently Malaysia, have contributed to the national, regional and global supply of vaccines. Over the past decade, the region’s contribution to the global supply base of vaccine has increased through the strengthening of National Regulatory Agencies (NRAs). In 2017, Member States in the Western Pacific adopted the regional action agenda on regulatory strengthening, convergence and cooperation for medicine and health workforce at the 68th Regional Committee meeting which led to the formation of Regional Alliance of NRAs. Dr Mariângela Simão shared that diversification of production and supply globally could contribute toward reducing a dependency on imports, securing supply chains and improving timely access. Global attention continues to focus on strengthening production capacity of COVID-19 and other vaccines but vaccine manufacturing is complex. WHO provides support to Member States with feasibility assessments to identify gaps in the ecosystems, specialized technical assistance to help speed up attainment of WHO Prequalification (PQ) or Emergency Use Listing (EUL), and capacity building to improve understanding and compliance with WHO and international regulatory standards and requirements for sustainable local production of quality-assured vaccines and other health products. Strengthening local production go hand-in-hand with strengthening regulatory systems in ensuring quality, safety and efficacy of vaccines. Dr Soumya Swaminathan emphasized that we have many other large public health problems in the region, both infectious diseases as well as non-communicable diseases for which there is always being a shortage of medicines, biotherapeutics and in some cases quality-assured and effective vaccines. Uninterrupted supply chain and trade, research and development (R&D), academic centers, clinical sites and others in the value chain of vaccine manufacturing can be tackled at regional levels. Dr Frederik Kristensen expressed that the workshop’s intent enables discussion on how to support the establishment of a geo-diverse manufacturing network to mitigate the reliance on manufacturing facilities from a handful of countries to have more of a broader base, both for annual routine as well as epidemic/ pandemic manufacturing capabilities to solve public health needs.
2.1 Objectives

Dr Jicui Dong, Unit Head, Local Production and Assistance Unit, WHO headquarters, introduced the objectives of the Vaccine Manufacturing Workshop for South-East Asia and the Western Pacific Regions.

Dr Jicui Dong stated that local production has been the subject of discussions in World Health Assemblies for over 4 decades. The number of Member States embarking on local production have been increasing in the last decade, particularly in the last 2 years. The COVID-19 pandemic has challenged the world’s ability to produce and supply life-saving health products and had rallied the global community to seek global solutions.

Currently, 10 COVID-19 vaccines have been granted WHO EUL. Manufacturing sites, producing drug substances, drug products, or both, in the South-East Asia Region and Western Pacific Region contributed to 8 of the 10 vaccines. And to date, over 10 billion vaccine doses have been administered globally, but more vaccine doses are needed.

The objectives of the workshop were to:

- Explore the regional landscape of vaccine production capacity/ capability as well as challenges and gaps in South-East Asia and Western Pacific regions
- Present WHO’s activities from headquarters and regional offices in strengthening local vaccine production
- Share CEPI’s 2021 vaccine manufacturing landscape survey data collected from the WHO South-East Asia and the Western Pacific regions
- Examine ways to improve vaccine development and manufacturing capacity, capability and/or efficiencies in South-East Asia and Western Pacific regions

2.2 WHO policies, support and landscape on vaccine R&D, production, and access

2.2.1 Global COVID-19 vaccines: Demand and supply and anticipated regulatory challenges

Speaker: Dr Rogério Gaspar, Director of the Regulation and Prequalification Department, Access to Medicines and Health Products Division, WHO headquarters

There is a huge inequity problem in access, distribution, and public health goals implemented in different regions and countries that was not covered adequately. With set goals of at least 10% or 40% to be established by September and December 2021 respectively, there are 6 Member States currently below the 40% threshold in Western Pacific Region and 2 countries in South-East Asia Region. WHO has worked on a widespread of initiatives, including active participation of regulatory authorities with International Coalition of Medicines Regulatory Authorities and COVAX Regulatory Advisory Group to support the Science Division and Emergencies Division in WHO for the R&D Blueprint, internal work in terms of the WHO EUL, cooperation with a wide number of experts from different NRAs and a number of documents that were established applying the principles of convergence and reliance between regulatory authorities. Despite some NRAs incapacity to deal with all these to streamline authorizations, the active implementation of the Global Benchmarking Tool (GBT) and a huge number of institutional development plans to strengthen the regulatory systems of NRAs bring us to more than 3500 national regulatory authorizations in more than 150 countries of the 10 vaccines approved through the EUL. This is a widespread regulatory work that is starting at the WHO headquarters that goes through the three levels and to the NRAs and is a very good model of cooperation for all other areas of WHO intervention.
Identified regulatory challenges now being managed at WHO headquarters through the 3 levels and to the NRAs are: 1. Need to implement international regulatory standards to assess quality, safety and efficacy, 2. Improved timelines for EUL approval, 3. Regulatory alignment on the candidates in clinical phase, 4. Assay standardization, 5. Standardized methodologies, 6. Speeding up manufacturing, clinical research, regulatory processes whilst maintaining quality, safety and efficacy of medical products.

2.2.2 Regional landscape: South-East Asia region

**Speaker:** Dr Sunil Bahl, Coordinator (COVAX, Immunization & Vaccine Development), WHO Regional Office for South-East Asia

On the historical perspective of the vaccine manufacturing in the South-East Asia Region, until the 90’s, public sector manufacturing units led and supplied to national programs. In the post 90’s, private sector entered vaccine manufacturing in the region with a major focus on production of vaccines like polio, BCG etc. In 2000 onwards, the WHO PQ and the United Nations (UN) agency supplies of several of these vaccines from the region has commenced. Now, South-East Asia Region is a major contributor to the global vaccine supplies at nearly 1.6 billion doses.

India is the country of origin for several named vaccines, in collaboration with another collaborator or an indigenous manufacturer on different platforms being used, some having completed phase 3 clinical trials and many of them granted the emergency use authorization (EUA) and/ or EUL by WHO. The same scenario and processes are seen in other countries within South-East Asia Region. On the COVID-19 front, there are ongoing talks for technology transfer between manufacturers in the region.

On regulatory system strengthening for the COVID-19 vaccine deployment in the region, recent actions or best practices include high quality national deployment and vaccination plans developed by all countries of the region, assessments of regulatory preparedness, conduct of standardized tools and simulation exercise, followed by timely corrective actions, and workshops and webinars organized in the region for vaccine regulators and manufacturers. There was also the deployment on the safety surveillance, on expediting regulatory pathways, introductions of expedited market authorization procedures with quality management systems and enhanced standard operating procedures (SOPs) being put in place, and a recognition and reliance on the WHO PQ or the EUL with risk-based application in the region coupled with regulatory agility to assess the quality, safety and efficacy of the vaccines. A roadmap was also developed for the technology transfer of COVID-19 vaccines based on some of the novel platforms, like messenger ribonucleic acid (mRNA).

That said, challenges for NRAs and manufacturers exist in the region. To address them, key areas need to be tackled from sustainable local production for eligible countries, regional collaborations to maximize output of the manufacturing facilities, strengthening of the NRA for mandatory regulatory functions, and a regional network for deregulatory exchange and surrogacy, as well as the public-private partnerships for funds pooling and the focusing of resource utilization.

2.2.3 Regional landscape: Western Pacific region

**Speaker:** Dr Socorro Escalante, Team Coordinator, Universal Health Coverage, WHO Country Office in Viet Nam
There is a global resolution on strengthening local production of medicines and other health technologies in the vaccines vision and strategy, that inputs into the global goal of immunization agenda in 2030 as well as the roadmap for mitigation of vaccines and health products from 2019 to 2023. At regional level, Member States have adapted the regional strategic framework for vaccines, preventable diseases and immunization in the Western Pacific Region. For the year 2021 to 2030, within this framework, there is a strong emphasis on vaccines and securities complemented by adaptation of the regional framework for regulatory authority strengthening, cooperation and convergence to assist local production in countries.

On regional vaccine manufacturing landscape, types of vaccines manufactured in the Western Pacific Region are a mix of vaccines for COVID-19, influenza, and immunization program for key public health diseases. Broadly, the status of manufacturing capacity of countries in the region were categorized into non-producing, medicines-producing and vaccines-producing, and importing, importing and producing, and importing, producing and exporting as a stepwise approach to the development of regulatory authorities.

Amongst the regional initiatives to support local vaccine development and production, they are strengthening of regulatory system through the benchmarking, establishing minimum capacity for vaccines production for countries that have been assessed, and cooperation across the region bringing together regulatory strengthening on one hand and capacity building on the other. The regions focused on the big picture on the sustainability of all local pharmaceutical production, including capacities of clinical trials, manufacturing of vaccines for neglected tropical diseases, as way forward in the region. The approach mechanism, either at regional or country level, is ongoing in the Western Pacific Regional Alliance.

2.2.4 HQ activities – Local Production and Assistance Unit

Speaker: Mr David Woo, Technical Officer, Local Production and Assistance Unit, WHO headquarters

A landmark resolution on strengthening local production was adopted in the 74th World Health Assembly in May 2021 with more than 100 Member States co-sponsoring this resolution. In this resolution, Member States requested WHO to explore a global platform to promote technology transfer and local production. A WHO new initiative, the World Local Production Forum (WLPF): Enhancing access to medicines and other health technologies is a regular forum for the global community of foremost government leaders, industry, technology experts, international organizations and other stakeholders to stimulate high-level dialogue and action to mitigate the global challenges, leverage on the opportunities and shape the direction globally in promoting local production of quality health products. The LPA Unit is the WLPF Secretariat. The first WLPF was convened virtually after the 74th World Health Assembly in June 2021, with Ministers and heads of national regulatory authorities, heads of UN agencies, delegates from over 100 Member States and other stakeholders in the global community discoursing on key issues, such as building the business ecosystem, regulatory systems, licensing and technology transfer, innovation, and financing. There was a session dedicated to look at vaccines at different angles for COVID-19 and beyond, such as the vaccine ecosystem, innovation and technology transfer. Three actionable recommendations resulted from this WLPF and the Netherlands announced they will be the hosting country for the next WLPF.

The LPA Unit supports Member States in strengthening local production in a holistic and strategic manner. The LPA Unit fosters partnerships and collaborations, and the Regulation and Prequalification Department is actively involved with the COVAX manufacturing taskforce workstream working groups. The LPA Unit conducts feasibility assessments and situational analyses for sustainable local production to identify gaps
in key areas, prioritize actions and inform the development of strategies/roadmaps for strengthening sustainable local production. The LPA Unit also provides specialized technical assistance to manufacturers to help speed up attainment of WHO PQ or EUL of health products (medicines, vaccines, in-vitro diagnostics, etc.) and develops guidelines, tools and other global resources on local production and technology transfer for Member States. One important area of work by the LPA Unit is capacity building of manufacturers, regulators and other stakeholders in areas such as Good Manufacturing Practice (GMP), product quality and Chemistry, Manufacturing and Controls (CMC), technology transfer, policy coherence and the business ecosystem, such as the Virtual cGMP Training Marathon for Vaccine Manufacturing for vaccine/biopharmaceutical manufacturers and regulators in the 6 WHO regions, which was completed in November 2021. Holistic training workshop on key enabling factors on successful local production leveraging on policy, business and technical enablers for sustainable quality local production were also organized. In parallel with strengthening local production, the Regulation and Safety Unit in the Regulatory and Prequalification Department supports Member States on strengthening regulatory systems of the NRAs.

2.3 Introduce and review the CEPI 2021 vaccine manufacturing survey data identifying gaps/opportunities across the South-East Asia and Western Pacific regions

**Speaker:** Dr Matthew Downham, Manufacturing & Supply Chain Networks, Coalition for Epidemic Preparedness Innovations (CEPI)

The CEPI undertook a vaccine manufacturing survey in 2021 to determine vaccine manufacturing site capacity and capability per region where it exist today, whether it requires development to improve epidemic/pandemic preparedness and response options or countries aspiring to establish manufacturing capacity/capability currently absent or limited. Questions on core capabilities, platform technologies, site capacity, and pathogen were asked.

There were 22 respondents from South-East Asia and Western Pacific spanning across 10 different countries of the total 96 respondents from all regions. The respondents were either from vaccine and pharmaceutical manufacturers, research and veterinary institutes, organized manufacturing facilities that is committed for making vaccines for animals to making vaccines for humans, and government agencies. Most respondents are willing to utilize their capabilities to support addressing pandemic vaccine preparedness and/or responses in the future. The survey data revealed there is a very well-established human vaccine manufacturing capacity and capability across South-East Asia and Western Pacific, predominantly in China and India. Most of the respondents have got that diversified end to end capability with more than one platform technology and have medium to large manufacturing capacity.

Dominantly expressed by the South-East Asia and Western Pacific region, many of the respondents have attained WHO PQ of vaccines, up-to-date regulatory inspection records and uniquely demonstrated the strength of the NRA network throughout both of the respective regions.

Vaccine manufacturing capacity is spread well across South-East Asia and Western Pacific regions with well-established end to end capability and diversified technology capability which indicates a very strong training element. However, there is a need to support in terms of coordinating collaborations, particularly global stakeholders, and to encourage in-region champions and local ownership. To sum up the aspirational plans, there is plan to further implement new technologies, whether viral vaccines or mRNA vaccines, or upgrading and/or expanding existing manufacturing capacities and facilities, and to get further financial support, whether from government, investors, development banks, and philanthropic
and non-government organizations. The identified key gap is the requirement to coordinate across regions and opportunities are to deliver efficiencies and improve capacity/ capabilities through regional vaccine manufacturing collaborative partnerships/ associations, and this opens up the possibilities for government and political commitment moving forward.

2.4 Brainstorm on future activities to support improving vaccine manufacture capacity/capability and/ or efficiencies in South-East Asia and Western Pacific regions focusing on: (Breakout & main plenary session)

**Moderator:** Dr Matthew Downham, Manufacturing & Supply Chain Networks, Coalition for Epidemic Preparedness Innovations (CEPI)

Participants were directed into breakout groups for 15-minutes, followed by a 20-minutes main plenary discussion to brainstorm and discuss the assigned question for each group.

This session was intended to brainstorm on below 3 questions in breakout rooms:

1. What are the requirements to address and mitigate the identified vaccine manufacturing gaps and opportunities?

The group identified main gaps as:
- Government commitment to purchase locally-produced vaccines,
- Lack of trainings,
- Need for coherent policies,
- Lack of availability to raw materials (mainly post-pandemic),
- Disturbed supply chain for packaging, requirement for collaboration with NRAs, and
- Gap in educational system.

On addressing the gaps, it was proposed that:
- Countries need to develop capability to produce their own vaccines,
- Have WHO and regional coordination, and
- Government commitment.

2. How to effectively improve vaccine manufacturing production and efficiencies in South-East Asia and Western Pacific including e.g. collaboration with Member States government bodies?

Several of the described measures were:
- Listing existing and new facilities, as well as existing products and pipeline,
- Focus on mRNA-like platforms and transfer of technology for shortlisted facilities and qualify them,
- Focus on local and regional needs in terms of vaccines needed,
- Identify potential issues/ concerns for each scenario (regional vs country), e.g., decision making ownership,
- Strengthen existing NRAs through the GBT prioritizing those closest to reaching Maturity Level 3,
- Support NRAs through capacity building, training and experience sharing,
- Sharing capacities between NRAs, e.g., for testing, facilitate information sharing between NRA/ National Control Laboratories (NCLs) also to support reliance,
- Strengthen cooperation between governments and private companies through public-private partnerships,
Consider a regional approach within a global production network where countries take part in
different parts/ phases of the process.

3. What are the expectations of global stakeholders to support addressing the identified gaps/
opportunities?

There were vast expectations on roles of stakeholders. To name a few of expectations for the described
stakeholders as below:

- **For government department/ ministries,**
  - Translucent or transparent trade data on the demand and supply of vaccine,
  - Sense of urgency to come up with local production capacity,
  - Interest in mRNA vaccine manufacturing,
  - Assistance through tax incentives and procurement etc.

- **For NRAs,**
  - Stringent enforcement of standards,
  - Capacity and independence of NRAs,
  - Standardized regulations/ expedited reviews, and
  - Streamlined process on the approval of the vaccines etc.

- **For non-governmental organization and other partners,**
  - Require cooperation and support,
  - Collaboration opportunities,
  - Training support, and
  - Sharing of technical knowledge etc.

- **For WHO,**
  - Technical guidance, assistance, coordination and support on trainings,
  - Discussion platforms,
  - Networking, and
  - Intellectual patent coordination etc.

Other stakeholders who should play a role in vaccine manufacturing were also identified, namely
ministries, research agencies, academia, networks such as DCVMN and IFPMA, pharmaceutical
companies and associations on technology transfer etc.

2.5 Day 1 Wrap Up

**Dr Suman Rijal, Director, Department of Communicable Diseases, WHO Regional Office for South-East
Asia** summarized the key points for each session of Day 1 and covered the workshop objectives, need for
strengthening of NRAs and the strategies in place, regional vaccine manufacturing landscape in the South-
East Asia and Western Pacific regions, WHO headquarters activities with emphasis on strengthening local
vaccine production, CEPI 2021 vaccine manufacturing survey data followed by brainstorming activities for
future support in improving vaccine manufacturing capacity/ capability and/ or efficiencies in the 2
regions. **Dr Jinho Shin, Coordinator, acting interim, Essential Medicines and Health Technologies,
Division of Health Systems and Services, WHO Regional Office for the Western Pacific** touched briefly
on the agenda for Day 2 before the workshop ended on Day 1.
3.0 Workshop proceedings – Day 2

Mr Martin Robert Taylor, Director, Division of Health Systems and Services, WHO Regional Office for the Western Pacific, and Dr Suman Rijal, Director, Department of Communicable Diseases, WHO Regional Office for South-East Asia, co-chaired Day 2 of the workshop.

Mr Martin Robert Taylor and Dr Suman Rijal welcomed the floor to start Day 2 of the workshop. Mr Martin Taylor re-iterated an overarching common objective that is, "Moving towards filling vaccine equity gaps and increasing health security through strengthening local production". A few salient points for private, public, and non-profit non-governmental sectors were raised including long term commercial viability for private sectors that calls for contractual advance purchasing agreement with public sectors, competitiveness and longevity of technologies being considered, justification for legitimate use of taxpayers' money and building social consensus towards developing governmental policy, investing in innovative regulatory guidance and facilitating public-private partnerships, investing in multi-disciplinary vaccine manufacturing workforce training and education for public sectors, and for non-profit, non-governmental sectors, demand from private and public sectors on strengthening local production, and higher priority of such demands against other competing demands are to be considered.

3.1 Core features of a roadmap to establish and/or expand vaccine manufacturing capacity and capability

3.1.1 Scientific and technical considerations

Speaker: Dr Simone Blayer, Global Head, Chemistry, Manufacturing, Control and Nonclinical Toxicology, Essential Medicines, Center for Vaccine Innovation and Access

The science and technical considerations to establish or expand vaccine manufacturing capacity and capability is made up of country infrastructure, import and export, sustainable pharmaceutical supply chain, technical expertise, manufacturing technology access, quality control, quality assurance, GMP, NRA, licensing, WHO PQ, and access to key materials such as antigen and adjuvant. Supply chain analysis for current state and future state needs to include the complete cycle from raw materials, vaccine manufacturing and distribution to create a sustainable environment. A project portfolio approach in the CMC area focuses on a few key components: training, technology transfer hubs, innovation, predictable and consistent supply, and vaccine life cycle. The immunization supply chain also has its own pillars and portfolio from primary packaging, cold chain/thermostability, route of delivery, method of delivery and waste disposal.

3.1.2 Business model and market considerations

Speaker: Ms Casey Selwyn, Special Initiatives Lead & Senior Officer, Bill & Melinda Gates Foundation

In vaccine manufacturing, the cycle of ‘panic and neglect’ and ‘build and decay’ should focus on ‘build and sustain’ instead. As manufacturers are in it for the long haul, there is a need to produce products that drive revenue back into the facility and keep costs low. Currently licensed mRNA vaccine is for COVID-19, and so it may not be sustainable for this to be the only platform for the future.
For long term viability from a regional block, huge volume doses and population is needed to sustain facility costs by coordination between more units, states and entities to take advantage of the different locations across facilities. On ways to look at the market, approaches taken can be categorized by platform, analysis of supply gaps, review of market health and dynamics, complexity ranking of vaccine manufacturing, inclusion of novel products, and expert input and review. This was summarized to emphasize on shift of mindset to ‘build and sustain’ to focus on manufacturing facilities sustainability in the time between pandemics, conduct of market assessment to identify platform and product to invest and manufacture, and to think regional and global to ensure financial sustainability.

3.1.3  Infrastructure, regulatory systems, workforce, and partnerships

Speaker: Dr Jicui Dong, Unit Head, Local Production and Assistance Unit, WHO headquarters

Fundamental considerations for a national or regional roadmap were highlighted, including government commitment, a wider viewpoint toward improving access, buy-in from stakeholders, a strong case for value for vaccine production with positive impact for stakeholders and countries, and feasibility assessments/situational analyses to identify barriers in developing vaccine production.

Infrastructure needs to be in place. Water, power and roads are essential. Other infrastructure along the value chain should also be considered, such as buildings for sterile production, equipment suitable to produce the targeted vaccine(s), R&D facilities, clinical trial centers, supply chains with cold chain capabilities, and a national quality control laboratory. Regulatory systems for oversight of quality, safety and efficacy is another important component of a roadmap. If there is a goal for vaccines to be WHO prequalified, the NRA need to achieve ML 3 after assessment from the WHO GBT. A roadmap could consider strengthening regulatory systems and promoting regulatory reliance, convergence and harmonization. Lack of skilled human resources is a continuing bottleneck, which was highlighted at the first WLPF.

As more countries and companies seek to produce vaccines, ready-to-use talent may not be available to recruit. That said, vaccine manufacturing requires diverse skills and know-how. A roadmap should consider available talent in the country and region and workforce development in the short, medium and long-term. The importance of partnerships and collaboration were also recognized by the WLPF. Trust and confidence will sustain relationships, drive collaborations and technology transfer, and build a sustainable ecosystem. It is of key importance for relevant public and private stakeholders to be identified and involved in developing the roadmap and ensuring implementation. Other essential core features to consider include a governance structure and coordination mechanism, policy coherence, and roadmap objectives to achieve public health goals and sustainability.

3.2  Part 1: Presentation

Plan towards improving vaccine development/ manufacturing capacity/ capability and/ or efficiencies in South-East Asia and Western Pacific regions.
3.2.1 Government of Indonesia

**Speaker:** Dra Mayagustina Andarini, Deputy for Drug, Narcotic, Psychotropic, Precursor, Addictive Substance Control, Indonesia Food and Drug Administration (BPOM)

The Indonesian NRA is moving towards self-reliance of national pharmaceutical product and has released self-assessment tools in R&D of Vaccine for Research Centre as a guidance in implementing GMP, Good laboratory practice (GLP) and Good clinical practice (GCP) on vaccine development. Indonesia is also building its National Biological Product Development Ecosystem and its vaccine research center through the National Research and Innovation Agency. In terms of vaccine manufacturing capacity and efficiencies, considerations for facility sharing of fill and finish activities are in place and so is the provision of technical guidance on personnel competency improvement and personnel’s understanding of regulation related to GMP.

In the way forward for Indonesia, Indonesia Food and Drug Administration (FDA) continuously puts all the efforts to oversee the safety, efficacy and quality, prior to EUA of COVID-19 vaccines. Close intersectoral cooperation and collaboration nationally, regionally, and internationally are essentially required to fight against COVID-19 pandemic notably by providing equitable access to vaccines. Also, the Government of Indonesia is committed to actively support in development and manufacturing of COVID-19 vaccines to fulfill local and global needs.

3.2.2 Government of Philippines

**Speaker:** Her Excellency Dr Rowena Cristina L. Guevara, Undersecretary for Research and Development, Department of Science and Technology

The Task Group on Vaccine Evaluation and Selection composed of the Department of Science and Technology (DOST), Department of Health, Department of Trade and Industry (DTI), Board of Investments (BOI), Department of Foreign Affairs, Research Institute for Tropical Medicine (RITM) and the FDA in the National Development Company (NDC), works on the plans for accelerating vaccine development and manufacturing capacity of the Philippines. A vaccine development and manufacturing roadmap containing short-, medium- and long-term plans to achieve vaccine self-reliance for the Philippines in preparation for future pandemics and national immunization program that is in place was explained.

Currently, FDA is on track with the roadmap, with the WHO planned mock audit in April 2022 and full audit scheduled in September 2022 for the biosafety level 2 (BSL2) biologics laboratory. DTI-BOI and NDC negotiation with the private sector for the establishment for a local fill and finish facility is ongoing, and the ADB-RITM Vaccine Self-Reliance Project 1 (VSRP 1) study will guide on the models to pursue for vaccine manufacturing. That said, challenges and gaps remain to be addressed by the task group member agencies.

**Speaker:** Ms Jesusa Joyce N. Cirunay, Director IV, Center for Drugs Regulation and Research, Philippines Food and Drug Administration

Strengths and ongoing improvement in the Philippines FDA were looked at various angles of the FDA that is, ISO 9001:2015 certified, international membership of the inspectorate in ASEAN MRA on GMP Inspection and ISO 17020:2018 certification, ISO/IEC 17025:2017 accredited laboratory, data
management via available open data for transparency of services, and personnel and facilities through automation and expansion of services.

FDA is anticipating and preparing for fill and finish products/ facilities applications from local manufacturers. The umbrella of indicators according to WHO GBT of the FDA showed 2 indicators in ML 3, moving into ML 4 and the other indicators are at ML 1 with 90% progress in issuance of policies and record to comply and progress to ML 3.

3.2.3 Gennova Biopharmaceuticals, India

**Speaker:** Dr Sanjay Singh, Chief Executive Officer

A COVID-19 vaccine, Gemcovac-19 is based on mRNA platform and has completed Phase 3 trials and in the process of data submission to NRA. This product has received funding and technical support from the Government of India.

The future of the mRNA platform technology requires a lot of work to go to next generation level, including open research on the platform in cost effective and process efficiency, backward integration in the materials required for manufacturing, understanding of the disease biology, improvement of existing COVID-19 vaccine, and in search of novel vaccines for other disease areas. Gennova aims to go into mRNA Gigafactory, create national and regional stockpiling, technology transfer for ease of manufacturability, and deployability in terms of thermostable formulation.

3.2.4 Serum Institute of India Pvt. Ltd., India

**Speaker:** Dr Sunil Gairola, Executive Director

Across development of the COVID-19 vaccine, shortages of the raw materials were the main challenge that the Serum Institute of India (SII) suffered during the pandemic. SII has expertise working on multiple platforms and was a technology transfer recipient from Oxford and Astra Zeneca, performed virtually. The EUA and EUL procedures have fast tracked vaccine development under the NRA and WHO guidance.

At present, SII has delivered more than 2 billion doses of Covishield adenovector technology globally. Also in the portfolio is Covovax, a protein-based vaccine that obtained the EUA and EUL, and the Codigenix, Spycatcher technology and new adjuvants under development.

3.2.5 Siam Biosciences, Thailand

**Speaker:** Dr Songpon Deechongkit, Managing Director

Siam Biosciences has repurposed their facility for viral vector vaccine production for Astra Zeneca in collaboration with Thailand government through the National Vaccine Institute, an example of a public-private partnership. It is a commercial manufacturing facility of recombinant proteins from microbial and mammalian cells with complete analytical capabilities with international certification.

The technology transfer focused on 4M, that is method, man, materials and machine. The outcome was achieved in 7.5 months from the first kick-off call to delivery of the first dose to the public. Key lessons
shared include ready to be flexible and repurpose, borderless open innovation, virtual technology transfer and decentralized manufacturing, to improve readiness for the next pandemics.

3.2.6 Asian Development Bank

**Speaker:** Dr Benjamin Coghlan, Senior Health Specialist

The health sector strategic framework 2021 – 2030 comes under 4 domains. First is on vaccine regulation through governance, policy and public goods related to regulation, legislation, stewardship and accountability. The ADB’s Regional Vaccine Advisory Group (RVAG) provides advice on technical, scientific, regulatory and broader policy matters pertaining to COVID-19 vaccines. Second is architecture, built upon infrastructure, data systems and supply chains for vaccine manufacturing.

Next is finance and incentives that could be private- or public-led. Vaccine market dynamics and sustainability is considered with some vaccines having a broader utility in therapeutics. Lastly, it is the workforce in clinical, technical and managerial areas that requires a genuine understanding by governments and new manufacturers of vaccine markets, human resource needs, and regulatory, clinical and manufacturing standards.

3.2.7 International Vaccine Institute

**Speaker:** Dr Jean-Louis Excler, Program Director, New Initiatives

IVI is an UN chartered international organization dedicated to accelerating vaccine R&D for global health that contributed along the process of R&D, clinical trial, surveillance to registration and delivery of a vaccine. Through its role, IVI promotes understanding of disease burden and health economics, and provides translation and support services to accelerate vaccine development by catering potential partners to select the activities that align to our shared goals.

Major IVI partners come from the industry, governments, academia, philanthropic institutions, and global health organizations. IVI has helped to build the Korean vaccine manufacturing capacity, by producing vaccines through partnerships with Korean manufacturers and agencies since 2016. Adding on to that, IVI ADB-RITM VSRP 1 project also enables global partners in COVID-19 vaccine development including, pre-clinical and international standard serum and assay development, clinical development and capacity building by supporting epidemiology and phase 3 site development.

3.2.8 Developing Countries Vaccine Manufacturers Network

**Speaker:** Mr Rajinder Kumar Suri, Chief Executive Officer

DCVMN is a public health driven international alliance of manufacturers working to strengthen vaccine manufacturers through the provision of information and professional training programs, innovative vaccine R&D, encouraging technology transfer initiatives and educational trainings.

Amongst the observations in a recent survey circulated to DCVMN members are that, on average, manufacturers from South-East Asia and Western Pacific regions have more than 4 vaccine products with 5 candidates in pre-clinical trial or clinical trials. A majority of manufacturers in South-East Asia and Western Pacific regions utilizes 3 or more technology platforms and have end-to-end capabilities. For the
future, most of the vaccine manufacturers in the 2 regions are looking forward to scale-up production and plan to acquire new technology platforms within 5 years. The survey also revealed regulatory challenges, vaccine demand uncertainty and others as challenges to sustainable production.

3.3 Part 2: How local vaccine manufacturing can address vaccine access gaps in Asia

**Speaker:** Mr Joshua Chu, Executive Vice President, Vaccines and Non-Communicable Diseases, Clinton Health Access Initiative (CHAI)

South-East Asia and Western Pacific regions have a high routine coverage for traditional vaccines, however, lack benchmarks for newer routine vaccines, compared to GAVI and non-GAVI middle-income countries (MICs). MICs in Asia have not introduced Pneumococcal Conjugate Vaccine (PCV) and Human Papillomavirus (HPV) vaccine, in part due to the lack of benefit from GAVI funding and support. While current market factors inhibit access to some vaccines, the supply and affordability are expected to improve for vaccines such as Pentavalent, PCV, HPV. The aggregated global supply in the regions is expected to exceed demand in 2022, whilst sufficient supply of preferred vaccines platform is possible with active supply management.

Future pandemic preparedness efforts should leverage on existing manufacturing activities in the 2 regions. Further diversifying supply of HPV, PCV, and other routine vaccines is unlikely to enhance access to vaccines, and fragmentation of supply base may increase costs and deteriorate market health. Manufacturers with regional and global ambitions are recommended to identify novel vaccines where significant access gaps remain unaddressed, and develop a wide portfolio of pandemic platforms, such as mRNA and viral vector. Also, improved ability of regional suppliers to absorb technology transfer and increased speed of global regulatory approvals will improve the access.

4.0 Day 2 wrap up, conclusion and next steps

**Dr Jicui Dong, Unit Head, Local Production and Assistance Unit, WHO headquarters**, delivered a wrap up of Day 2 and concluded the workshop with some key messages and next steps. The workshop continued on day 2 with a forward-looking view at local vaccine production and core features to improve vaccine manufacture capacity, capability and/or efficiencies in South-East Asia and Western Pacific regions. Perspectives shared from Member States, vaccine developers, manufacturers, and partners resonated with some of the core features required in a roadmap.

Among the key messages from the 2-day workshop, **Dr Jicui Dong** mentioned that local production of vaccines could improve access, strengthen public health, and enhance industrial and economic development. Local production of vaccines is complex and resource-intensive and it is essential to have collaboration among many actors. Government commitment and support are needed. Feasibility assessments are also needed to build a conducive ecosystem. Workforce training and capacity building for manufacturers and NRAs are essential and regulatory systems should be strengthened. Strengthening local vaccine production should consider commercial viability along with production efficiency and sustainability, such as viewing the demand for vaccines at a regional level. New and existing strategic partnerships are vital at a national, regional or global level. Development of a national or regional roadmap for sustainable local vaccine production should consider a variety of key elements.

WHO works collectively at 3 levels (global, regional, and national) as one WHO to support Member States. Next steps identified in the workshop are described below:
- Conducting feasibility assessment/situational analyses of the ecosystem to identify gaps and provide recommendations (per Member States request),
- Strengthening regulatory systems to reach ML 3,
- Building capacity in sustainable local production of quality vaccines, including GMP, CMC, technology transfer, key enablers, among others, in a tailored manner to meet country and regional needs, including hands-on training,
- Developing global and regional resources, which might include a model strategy for strengthening local production; guidance on roadmap development; exploration of public-private partnerships for funds pooling for vaccine development and production,
- Supporting Member States to develop a strategy or roadmap for local production by piloting the model strategy (per Member States request),
- Supporting Member States to strengthen infrastructure to sustainable local vaccine production based on Member States or regional needs,
- Specialized technical assistance to manufacturers for WHO PQ or EUL,
- Compiling the comments/feedback from the breakout sessions for follow-up discussions,
- Potentially leveraging on the WLPF by the 2 regions to foster partnership for regional and cooperation, enable integration of a national approach in strengthening vaccine production into a regional/global approach, explore the establishment of a regional network for key governmental agencies and the private sector for promoting vaccine development and manufacturing, and
- Organizing regular regional fora to share success stories of vaccine manufacturing technology transfers and strengthen partnerships.

Dr Jicui Dong closed the workshop.