South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

Bangkok, Thailand, 19–21 September 2023
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
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<tr>
<td>BIRAC</td>
<td>Biotechnology Industry Research Assistance Council</td>
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<td>BMGF</td>
<td>Bill &amp; Melinda Gates Foundation</td>
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<td>BNA</td>
<td>Bottle Neck Analysis</td>
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<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
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<td>cGMP</td>
<td>Current Good Manufacturing Practices</td>
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<td>DGDA</td>
<td>Directorate General of Drug Administration</td>
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<td>GOI</td>
<td>Government of India</td>
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<td>GPO</td>
<td>Government Pharmaceutical Organization</td>
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<td>GSPA-PHI</td>
<td>Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property</td>
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<td>ICMR</td>
<td>Indian Council of Medical Research</td>
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<td>IHPP</td>
<td>International Health Policy Program</td>
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<td>IPR</td>
<td>Intellectual Property Rights</td>
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<td>IVI</td>
<td>International Vaccine Institute</td>
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<td>LDC</td>
<td>Least Developed Countries</td>
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<td>LMIC</td>
<td>Low- or Middle-Income Country</td>
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<td>MOPH</td>
<td>Ministry of Public Health</td>
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<td>MPP</td>
<td>Medicines Patent Pool</td>
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<td>MS</td>
<td>Member State</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NMQAL</td>
<td>National Medicines Quality Assurance Laboratory</td>
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<td>NRA</td>
<td>National Regulatory Authority</td>
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<td>PLI</td>
<td>Production Linked Incentives</td>
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<td>SCTIMS</td>
<td>Sree Chitra Tirunal Institute for Medical Sciences</td>
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<td>SDG</td>
<td>Sustainable Development Goals</td>
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<td>SEARO</td>
<td>Southeast Asia Region Office</td>
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<td>SEA ICRN</td>
<td>Southeast Asia Influenza Clinical Research Network</td>
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<td>SMS</td>
<td>Strategic Management System</td>
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<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
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<td>Abbreviation</td>
<td>Full Name</td>
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<tr>
<td>TT</td>
<td>Technology Transfer</td>
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<td>UHC</td>
<td>Universal health coverage</td>
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<td>UNESCAP</td>
<td>United Nations Economic and Social Commission for Asia and the Pacific</td>
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<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WIPO</td>
<td>World Intellectual Property Organisation</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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Executive Summary

SE Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products, Bangkok, 19–21 September 2023

1. Introduction

The Southeast Asia Region of WHO (SEARO) organized “SEA Regional workshop to accelerate technology transfer for local production and improve access to medical products, Bangkok, 19–21 September 2023”. The consultation workshop was conceived for sharing knowledge and best practices to enable SE Asia Regional countries to implement two major World Health Assembly (WHA) resolutions.

In May 2022, the Seventy-fifth WHA extended the time frame of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), WHA 75.14 from 2022 to 2030, that is, co-terminus with the Sustainable Development Goals (SDG2030). In the previous year in May 2021, in WHA74.6 “Strengthening local production of medicines and other health technologies to improve access” the WHA committed to strengthening local production including cooperation with, support to and development of voluntary patent pools and other voluntary initiatives for promoting access to medical products (medicines, vaccines, diagnostics, devices).

The background to GSPA-PHI, WHA 75.14 is as follows: In 2008, the World Health Assembly (WHA) adopted the GSPA-PHI with the aim to promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases that disproportionately affect developing countries. The GSPA-PHI has eight elements which are designed to promote innovation, build capacity, improve access and mobilize resources. The principles and elements of the GSPA-PHI guide and frame the work of the World Health Organization (WHO) on access to medicines and other health products.

In 2015, the World Health Assembly decided, inter alia, to undertake an overall programme review of the GSPA-PHI. In 2017, the report of the review panel recommended a way forward, including details of that elements or actions should be added, enhanced or concluded in the next stage of implementation of the GSPA-PHI, until 2022.
Progress has been made in certain aspects of both innovation and access, however, many of the challenges that motivated formulation of the GSPA-PHI remain and new challenges have emerged. These include a lack of new health products in areas of need and of sustainable financing, the unaffordability of many new medicines, a lack of essential health products and inappropriate use, ineffective delivery and supply chain infrastructure and the absence of robust regulatory frameworks and trained personnel, mainly but not exclusively in developing countries. In addition, the pandemic triggered a massive global demand for existing health technologies to combat COVID-19, including diagnostics, medicines, ventilators and other medical devices.

During COVID 19, to take forward the mandate of GSPA and universal health coverage (UHC) principles that imply all people have access to essential, safe, affordable, effective and quality medicines and vaccines, without financial hardship, SE Asia Regional Office engaged with all three levels of WHO (HQ/SEARO and WHO Country Office, India, WCO) for quality local production. Six virtual current good manufacturing practices (cGMP) were conducted online in collaboration with JSS Academy of Higher Education & Research, Mysuru, India, Indian Pharmaceutical Association and MOH, India. Virtual workshops of this kind have not been held before. The workshops explored critical areas like formulations, active pharmaceutical ingredients, medical devices, and diagnostics, benefiting 1115 individuals from 323 pharmaceutical units. These workshops fed into a mentorship programme, that aimed at assisting select participants with comprehension of cGMP within a risk-based and quality system-based framework. The virtual workshops provided facility systems upgradation, improved the understanding of cGMP in the context of a risk-based and quality system-based approach, improved knowledge to meet WHO prequalification requirements and other world class quality standards beginning with a pilot phase in India and presently being followed by a rollout to other South-East Asia member states.

The virtual workshops contributed to global thinking towards developing the WHA74.6 “Strengthening local production of medicines and other health technologies to improve access”.

Further, during COVID-19, WHA73.1 called on international organizations and other stakeholders to work together to develop, test and scale-up production of diagnostics, medicines and vaccines for the COVID-19 response, including existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access1. The objective of COVID-19 Technology Access Pool (C-TAP) is to accelerate product development and to facilitate access to the resulting

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health technologies by pooling IP, data, regulatory dossiers and manufacturing processes and other kinds of ‘know-how’.  

In “SEA Regional workshop to accelerate technology transfer for local production and improve access to medical products, Bangkok, 19–21 September 2023”, to the Member States representatives deliberated on activities of the technology transfer hub to build capacity in low- and middle-income countries to produce mRNA vaccines through a centre of excellence and training (the mRNA vaccine technology hub). The hub, launched in July 2021, was supported by WHO, the Medicines Patent Pool and the Act-Accelerator/COVAX and is located at Afrigen, Cape Town, South Africa, and works with a network of technology recipients (spokes) in low- and middle-income countries.

1.1 Approach of the Workshop

The workshop brought together diverse stakeholders. Many collaborative initiatives emerged during COVID-19, and national and international organizations played an important role encouraging technology transfer to developing countries, especially in times of crisis. The workshop deliberated on the issues to align to regional and country necessities and capabilities. It will also provide useful information about partnerships between agencies and firms in acquiring technologies and the terms involved during the pandemic. The information will inform policy for access to medical products by the countries in our region.

The general and specific objectives of the Workshop are as follows:

1.2 General objective

To explore and facilitate capacity-building for technology transfer to accelerate local production and access to medical products (medicines, vaccines, diagnostics, devices) in the SE Asia Regional countries.

1.3 Specific objectives

The specific objectives of the workshop and expected outputs were to

- Discuss implementation and learning in GSPA-PHI in COVID-19 and outline technology transfer initiatives relevant to the SE Asia Regional countries.
- Reflect on open innovation in local manufacturing and capacity-building and advance collaborative models with national and international agencies.

2 Operationalising The COVID 19 Technology Access Pool (C TAP) A Concept Paper

Deliberate on proposed publication for 2023 as regional public good: The Global Strategy and Plan of Action on Public Health and Intellectual Property, the COVID-19 pandemic, technology transfer for local production.

Discuss the outline of a possible roadmap of next steps as an outcome of the workshop.

The following SE Asia Regional countries attended the meeting:

- Bangladesh
- India
- Maldives
- Nepal
- Sri Lanka
- Thailand
- Timor Leste

**Deliberations of the workshop**

Dr. Olivia Nieveras, acting WHO Representative, Thailand, gave the inaugural address of the Regional Director. It was emphasized that the workshop would promote discussions and regional consensus in a global perspective and develop possible next steps on the two resolutions for the SE Asia Regional countries. The RD speech encouraged active participation to make the consultation fruitful in the GSPA and local production processes for the Member States in the Region and at the global level.

The meeting was chaired by Dr. Mukadavan Prakobvaitayakit, Deputy Managing Director, Government Pharmaceutical Organization (GPO), Thailand. It was attended by 45 participants and technical experts from the Member States of the Region, WHO-HQ, Geneva, WHO Country offices, and other organizations such as National Institutes of Health (NIH), Medicines Patent Pool (MPP), Bill & Melinda Gates Foundation (BMGF) and Wellcome Trust.

The overview of the workshop, progress was presented by Dr. Manisha Shridhar, WHO-SEARO. The participants were requested to actively debate a set of recommendations from the workshop that could define future work on the two important World Health Assembly resolutions in the Region. The workshop discussed various mechanisms related to access to medicine for public health in the changing legal landscapes in the context of post COVID-19. The issues in relation to reach the next steps in technology
transfer and local production through the workshop were discussed around the following points:

- C-TAP
- Policy coherence in UN / WHO / WTO / intergovernmental organizations
- Vaccine nationalism practiced by countries during the pandemic.
- Is local production the complete answer?

The eight elements of the WHO GSPA-PHI were discussed:

1. Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity
4. Transfer of technology
5. Application and management of intellectual property to contribute to innovate and promote public health
6. Improving delivery and access
7. Promoting sustainable finance mechanisms
8. Establishing monitoring and reporting systems
Dr. Erika Dueñas, WHO-HQ discussed the implementation of GSPA-PHI and next steps in view of extension of the resolution to 2030. It was reiterated that the GSPA represents an international consensus of priority actions to be taken, to promote new thinking on needs-driven innovation and access to diseases that disproportionately affect developing countries. The progress in reviewing GSPA-PHI and designing activities, indicators, and the implementation plan 2024–2026 – Dr Erika highlighted the following:

- A report on outputs from the 1st WHO HQ and Regional Office joint workshop is circulated for feedback
- Internal analysis of outputs and gaps under review with relevant HQ teams is underway that should be complemented by work in the regions
- A questionnaire has been circulated to collect responses on implementation of GSPA
- A Member State consultation document would be sent out in coming weeks
- In-person workshop with Regional Offices and some Country Offices from each Region planned for 1–2 November 2023
- Progress report and draft implementation plan of GSPA 2024–2025 will be presented to EB 154

On the WHA Resolution, WHA74.6: Strengthening local production of medicines and other health technologies to improve access Dr Erika referred to:

- the use of the TRIPS flexibilities to promote equitable access
- the voluntary mechanisms to promote technology transfer, including WHO C-TAP

Roadmap of alternatives to access COVID-19 therapeutics
The discussion on “Strategies to facilitate sharing of technology and knowledge” centered on incentives for voluntary transfer of technology with C-TAP for global equitable access to essential health technologies. New recent licenses added to the COVID-19 Technology Access Pool (C-TAP) outlined were with:

- Medigen Vaccine Biologics Corp.
- Spanish National Research Council (CSIC)
- University of Chile

C-TAP General Collaboration Agreements with public health research institutes were also discussed relating to:

- University of Cape Town
- Sree Chitra Tirunal Institute for Medical Sciences and Technology

The licences and collaborations were discussed as tools to mitigate future pandemic risks.

- Dr. Anoopkumar Thekkuveettil, Sree Chitra Tirunal Institute for Medical Sciences (SCTIMS) and Technology made presentation on Technology Development and Commercialization bringing medical technologies to the market with focus on:
  - Molecular Neurobiology – especially focuses on information storage in brain
  - Diagnostics – focus is on infectious diseases

Technologies developed and commercialized during COVID-19 with SCTIMS were highlighted such as:

- Agappe Chitra Magna RNA isolation kit (ICMR approved)
- COVID-19 Chitra Multiplex RT PCR kit (ICMR approved) – communalized by Huwel Life Sciences
- Chitra Multiplex RT-PCR kit for Covid 19

The following challenges in technology development and transfer were discussed:

- Achieving high accuracy of detection with excellent sensitivity and specificity
- Requires lot of standardization.
- Finding industry interested in the product.
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- Academy to industry transfer of technologies is more effective - gives more confidence to the industry on the technology.
- WHO initiatives like C-TAP are an important stride towards equity in access to technologies and health.

It was emphasized to make technology affordable including by need for automation in medical technologies for example, COVID-19. Technologies should allow capacity-building and optimal use of human resources taking away risks and reducing the widening gap between rich and poor countries.

- Dr. David Atchoarena, WHO Academy presented the work being taken up by WHO Academy that seeks to build skills and competencies for a healthier world. The Academy would tackle the challenges in improving global health outcomes in the following areas:
  - Global workforce shortage
  - Distribution of health workforce
  - Changing needs and opportunities for skills and learning

In 2017, WHO began an organization-wide transformation. Improving access to learning for the global health workforce to address challenges have been identified. With the use of AI, machine learning and other web assistive technologies, the Academy delivers a personalized learning journey to accommodate the needs and ability level of each learner.

The WHO Academy learning is based on the following methods:

- Competency based - Learners will not only acquire knowledge, but the Academy will also support them to apply new competencies in their daily work.
- Personalized - Academy learning journeys adapt to the evolving needs of each learner.
- Accredited - Learners will build a portfolio of credentials to demonstrate the competencies they have acquired.
- Impact driven - The success of the WHO Academy will be measured by the extent to which our learners are able to improve health in their communities.

WHO Academy vision: A world in which all health- and care- workers, practitioners, policy-makers and WHO staff have the skills and competencies they need to achieve health for all.
The WHO Academy will work like a unified learning platform addressing the larger WHO agenda to address its key strategic priorities and would work closely with WHO regional offices.

- Dr. Roger Kampf, WTO presented on ‘Taking GSPA-PHI to 2030: trade aspects and updates on TRIPS Covid-decision’ He focused on the need for partnerships with other international organizations and development partners to improve the capacity of developing economies and LDCs to participate more fully in international trade. The lessons from the pandemic highlighted were:
  - The pandemic confirmed importance of preserving global trade in goods
  - Production of medical goods has been highly concentrated in certain countries
  - Export restrictions caused disruptions in supply chains
- Identify and address supply chain bottlenecks
- Make appropriate use of IP regime, including understanding and implementing flexibilities, in support of public health objectives
- Strengthen/streamline regulatory cooperation and coherence for access to medical products
- Ensure transparency
- Ramp up and diversify (vaccine) manufacturing capacities
- Enable transfer of know-how and technology

Technology Transfer as an enabler of Local Manufacturing, examples during pandemic were:

- CUBA - PI Iran SOBRERANA® - Vaccines for COVID-19
- FIND, UNITAID & DIATROPIX - Diagnostics for COVID-19
- CSIC, MPP & C-TAP Diagnostics for COVID-19

Barriers to Technology Transfer discussed were – (FIND/UNITAID/Diatropix example):

- Lack of adequate funding for R&D
- Manufacturing bottlenecks relating to
- Trained personnel
- Dependency on manual manufacturing input
- Speed of implementation for technology transfer
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- Unpredictable demand of medical products leading to lack of adequate planning for manufacturing and distribution through supply chains
- Need for robust Quality assurance and regulatory regimes
- Competition amongst global manufacturers (such as between originator and generic producers)

Why WTO & Trade Have an Important Role to Play for the Implementation of GSPA-PHI

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<th>Tools</th>
<th>Possible Contributions</th>
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<tr>
<td>Select WTO agreements</td>
<td>- Preserving supply chain integrity</td>
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<td></td>
<td>- Facilitating trade</td>
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<td></td>
<td>- Fostering regulatory cooperation</td>
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<tr>
<td>TRIPS Agreement</td>
<td>- Supporting innovation, technology transfer and partnerships</td>
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<td>- Implementing and using TRIPS policy options</td>
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<td>TRIPS COVID-19 Decision</td>
<td>- Promoting the understanding of what the Decision does (not)</td>
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<td>- Taking a decision on the extension to COVID-19 diagnostics &amp; therapeutics</td>
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<td>WTO Pandemic Declaration</td>
<td>- Mapping manufacturing capacities/demands in collaboration with WHO/other IOs</td>
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<td>- Facilitating and diversifying manufacturing capacities</td>
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<td>- Promoting technology transfer</td>
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<td>Trilateral Cooperation</td>
<td>- Ensuring coherence, applying an integrated approach, including procurement, competition, etc.</td>
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<td>- Providing data for evidence-based decision-making</td>
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<td>- Building capacity in Members, including as regards TRIPS flexibilities</td>
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<td>WTO Secretariat (see background)</td>
<td>- Ensuring transparency</td>
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<td>- Providing analysis and policy support</td>
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<td>- Engaging with IOs and other key stakeholders</td>
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Following further steps were suggested:

- Creating synergies building on coordination and cooperation, including Intergovernmental Negotiating Body (INB) to draft and negotiate a convention, agreement or other international instrument under the Constitution of the World Health Organization to strengthen pandemic prevention, preparedness and response. Preserving and building on existing collaboration networks - and lose what has been carefully built during the COVID-19 pandemic
- Ensuring sustainability of diversified manufacturing projects
- Considering the most effective approach: local, subregional or regional approaches for R&D and manufacturing
- Learning from experiences regarding technology transfer, voluntary partnerships and manufacturing capacities – and build on description of existing domestic frameworks
- Engage to provide clear guidance to governments
- Dr. Tara Kirby, NIH presented on Making Technology Transfer and Licensing Work for Access to New Drugs and Vaccines.

Dr. Tara Kirby, NIH presented on Making Technology Transfer and Licensing Work for Access to New Drugs and Vaccines.
Dr. Tara Kirby mentioned how international organizations could work with NIH through:

- Fogarty International Center programmes
- Research collaborations
- Licensing initiatives

NIH engages in global licensing based on the following considerations to promote access:

- Long-term collaborative partnerships work best
- Preference for non-exclusive or partially exclusive licenses
- In cases where typical licensing strategy may not apply
- Consider regional / local licensing strategies
- Look for local (non-U.S.) manufacturing capability
- The strategy for patent protection is carefully planned
- For technologies with global market potential, licensee development plan needs to address developing countries
- Consider incentives to facilitate availability in LMIC through licensing in other jurisdictions.
Additional NIH Strategies for facilitating access to medical products discussed were:

- Patent pools such as:
  - Medicines Patent Pool (HIV medicines)
  - MPEG LA/Librassay® (diagnostic technologies)
  - WHO COVID-19 Technology Access Pool (vaccines)
- Public-Private Consortia, for example,
  - WIPO Re:Search Consortium for neglected tropical diseases, malaria, and tuberculosis
- Through Trans-National Networks such as:
  - Southeast Asia Influenza Clinical Research Network (SEA ICRN)

Dr. Tara Kirby focused on the efficient ways to promote Technology Transfer and Licensing Work for Access to New Drugs and Vaccines

- Dr. Rupa Chanda, UNESCAP made a presentation on regional integration and cooperation to promote affordable and equitable access to vaccines, diagnostics and therapeutics in the Asia-Pacific region.

Overview of the book was shared From Lab to Jab: Improving Asia-Pacific’s Readiness to Produce and Deliver Vaccines Aimed at helping developing countries in the region was shared. The aspects highlighted to:

- Improve their understanding of the vaccine landscape and suitability/readiness to be part of it
- In policy thinking to improve vaccine trade and transport connectivity and stakeholder engagement, including through regional cooperation
- Better prepare for the next pandemic as well as fight other communicable disease

The structure of the book was outlined comprising:

Part I: Research and Development of Vaccines

Part II: Production, Trade and Transport of Vaccines

Part III: Regulatory Cooperation and Accessibility of Vaccines
Certain policy recommendations and areas for further study and action from book were:

- Diversify vaccine/essential medical products import sources, reduce tariffs, ease export restrictions, improve logistics, better utilize trade and investment facilitation and agreements, manage IP rights and flexibilities, enable technology transfer, implement universal health coverage and strengthen health systems.
- Increase regional cooperation in the prioritization of diseases for vaccine/essential medical products R&D, and the coordination of their production, taking into account varying capacities among different countries.
- Increase regulatory cooperation and coherence within the Region, which will help to enhance intra-regional trade in vaccines/essential medical products and their inputs.
- Regional organizations and development partners can play a more active role in pooled/coordinated mechanisms for R&D financing and procurement, and in aiding the improvement of transportation and storage capabilities in countries.

Based on the publication, an overview of an ongoing project was also shared:

Objectives: Strengthen capacity of countries in Asia and the Pacific to develop policies and strategies in trade, investment, technology transfer and regional cooperation to address inequities in availability of and access to essential medical products (vaccines, diagnostics and therapeutics), within broader objective of enabling greater inclusivity and resilience in national health systems.

- Consideration of countries based on:
  - Potential for production capacity
  - Scope to participate in various stages of the value chain
  - Significance of imports
  - Some are LDCs
  - Needs, challenges, and scope to improve access to essential medical products and health services through regional cooperation, and cooperation with ESCAP and development partners
- Timeline: 2023 – mid 2026
- Activities and deliverables
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- Policy studies
- Build, utilize and/or enhance online tools
- Regional and national multi-stakeholder meetings/consultation workshops
- Draft national strategies
- Stakeholders
- Government officials in ministries, agencies Policy analysts, researchers, academia & think tanks
- Private sector actors
- Partners: international organizations, regional organizations, development partners
- UNESCAP: TIID, SDD, SROs, APCTT
- Dr. Matthias Helble, WHO-HQ presented on Covid-19 pandemic lessons to healthcare, R&D and innovation. Understanding Vaccine R&D (Postigo, 2023) was discussed:

The challenges of Traditional vaccines (based on biological process) are as follows:

- Slower design & production
- Higher variability in yield & performance
- Slower regulatory approval
- Uncertainty & economic disincentives for vaccine R&D

The advantage of the Latest vaccines (based on chemical processes) are:

- Faster design
- Faster scale up & production
- Easier re-design

Mechanisms to close the Vaccine R&D Finance Gap

Source: Yamey et al. (2023)
The main policy dimensions of significance are:

- **R&D priority setting:** Beyond disease burden, the priorities depend on technological and research capabilities of countries, as well as the position in the R&D value chain and in global research efforts.

- **Skills development and training:** Beyond training of selected researchers, governments need to ensure that school and university curricula respond and are adapted to R&D needs. Furthermore, talents need to be pulled into the research system.

- **R&D Funding:** Public sectors, governments and social donors are essential to fund R&D efforts. In addition, new financial models are needed, catering to the national context.

- **Public and private institutions:** Given the dominant role of the public sector in the first episodes of the development of research systems, as well as regulator and buyer of health technologies, its efficiency is crucial, as well as its interaction with the private sector.

- **International coordination, cooperation and network integration:** The success of R&D depends to a large extend on the successful integration into national, regional and international knowledge and R&D networks. R&D policies also need to be coordinated across countries to be synergistic.

- **Intellectual property, data and access:** Intellectual property rights are a central instrument in developed R&D system and a key incentive mechanism as well as an enabler of markets for technologies.

- **Policy coherence:** R&D systems policies need to be coherent with other domestic policies, such as procurement policies. R&D efforts need to be aligned with local or regional production capabilities and lead to better access to health technologies.
The following noteworthy suggestions are made:

- Vaccine market has its own dynamics with several competitive production hubs in Asia-Pacific.
- Bilateral and multilateral aid has predominantly focused on regulatory strengthening and promoting local production, rather than R&D.
- Improved pandemic preparedness requires build-up of entire biomedical eco-system (end-to-end) and R&D expansion is costly.
- Explore ways for increasing participation by LMICs in global biomedical R&D.
- Additional public (including with multilateral development banks - MDBs) and philanthropic investment needed to advance R&D in LMICS.
- More innovative and regional solutions needed.
- Dr. Shirshendu Mukherjee, Mission Director, BIRAC made a presentation on Academia Industry Inter Linkages to Translate Knowledge into health products. He focused on how technologies work towards fostering knowledge exchange and technology transfer between domestic and international institutions. Collaboration with global partners to leverage existing expertise and resources, accelerate development, and share best practices was highlighted.

Challenges to Innovation were discussed in the context of discovery, development and delivery:
Various programmes under BIRAC were highlighted indicating the manner in which lab- to final- market support is provided. The programmes discussed were: BioNEST, BIRAC-PATH, National Biopharma Mission, Regional Technology Transfer Offices (RTTOs), Mission COVID Suraksha – The Indian COVID-19 Vaccine Development Mission, Biotech First Hub, IP & Technology Management Law Clinic Connect.

Suggestions for the way forward were as follows:

- Encourage collaboration among academia, public health agencies, and medical products manufacturers with focus on Translation Research Consortia.
- Promote indigenous development of raw materials essential medical products development pipeline.
- Foster knowledge exchange and technology transfer between domestic and international institutions. Collaboration with global partners can help leverage existing expertise and resources, accelerate development, and share best practices.
- Protect and enforce intellectual property rights to incentivize innovation and provide a framework for indigenous vaccine developers to commercialize their products.
- Dr. Isariya Techatanawat, GPO made presentation on Agile Scrum Management in GPO Vaccine Development and Production. The vision of Government Pharmaceutical Organization is to be an organization for maintaining drug &
medical supply security of the country with valuable and sustainable innovation.

GPO Pharmaceutical Products and Medical Supplies cover the following products:

![Diagram of medical products](image)

Thailand’s aim is to be self-sufficient in Pandemic Vaccines the focus on construction sites began in 2009–2018. This was followed by developing WHO GMP compliance, Biosafety level 2 plus, Solar power, Zero-waste concept and securing FOYA 2021 Award (Social Impact)

Agile is the ability to create and respond to change. It is a way of dealing with, and ultimately succeeding in, an uncertain and turbulent environment.

**Agile Way**

- Rapidly changing circumstances
- Be prepared for another emerging disease
- Further tasks on variant strain

Lesson learnt from Agile: are the following: fail fast, learn faster, find critical step of work, prioritize work tasks, cross-functional team working toward the same goal
Dr. Navneet Tewatia & Dr. Mila Maistat, MPP presented the Role of Medicines Patent Pool in accelerating access to medicines and other health products through voluntary licensing and technology transfer. MPP works to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries (LMICs) through voluntary licensing and technology transfer.

MPP’s role in local and regional production is as follows:

- Engage with local and regional medicine manufacturers to flag opportunities to apply for MPP licenses and to broaden the geographical spread of MPP’s manufacturing partners
- Partner with organizations working to improve capacity of local/regional manufacturers so they can qualify for MPP licences
- Work with WHO and others to build capacity to manufacture mRNA vaccines in LMICs

MPP provides Technology transfer by:

- Providing technology transfer assistance by supporting the development of technology transfer packages and assisting the recipient companies in acquiring the necessary expertise
- Focus on supporting technology transfer for mRNA vaccines, biotherapeutics and complex small molecule formulations

The mRNA technology transfer programme aims to contribute to enabling equitable access to mRNA vaccines, by increasing the distribution of sustainable manufacturing capacity across countries, enhancing regional and inter-regional collaborations by developing and empowering local workforce through tailored and inclusive trainings and expert support. The purpose of the mRNA programme R&D network is based on the following:

- Programme’s initial focus on COVID-19 remains important for proof of concept
- Increasing interest from programme partners in applying technology platform to other disease targets (endemic diseases as well as diseases of pandemic potential)
- Work ongoing in parallel on 2nd generation mRNA vaccine technology to address: (i) thermostability, (ii) reduced cost of goods (iii) freedom to operate

MPP’s contributions in licensing and technology transfer enabled the following:
Licensing has facilitated sustainable and equitable access to innovative treatments in LMICs for certain diseases (e.g. HIV or viral hepatitis)

- It has also led to development of needed new formulations (such as HIV combination “TLD” or new paediatric formulations)

- Licensing and technology transfer can also play a critical role in facilitating affordable access to pandemic countermeasures in new pandemics - need to establish mechanisms to accelerate availability of generics

- Increasingly, licensing is being explored as an access mechanism in other disease areas - cancer, diabetes or maternal health and for more complex technologies such as biologics, long-acting medicines and mRNA vaccines, for which technology transfer can be critical

- Significant interest among countries in having local sustainable capacity for the manufacturing of health products to ensure supply security and address health emergencies

- Dr. Jicui Dong, WHO-HQ, joined virtually and presented on updates and next steps WHA 74.6 “Strengthening local production of medicines and other health technologies to improve access”.

- Dr. Gangandeep Kang, BMGF, joined virtually and made a presentation on Research & Development and innovation for access to health products. She stressed to build ecosystems for innovation by creating hybrid framework in the following manner:
  - The university takes on a role of starting businesses
  - Firms collaborate and share knowledge
  - Government encourages this interplay both by providing a regulatory environment that stimulates interchange and by acting as public venture capitalist.

The way to enable R&D ecosystem in India was shared. Innovation has been identified as priority by the Government of India. Key policies and government actions in this regard relate to:

- Decades of innovation 2010–2020 – national strategy to strengthen science, technology and innovation as a part of increasing gross expenditure on R&D
- Atal Innovation Mission – government initiative to create platforms, opportunities & oversight for innovation
Startup India Seed Fund – government effort to build ecosystem for innovation through funding & resource/information sharing

Key Organizations collaborating in this respect are: Indian government and international organizations (USAID Women connect & BMGF Grand Challenges)

The Challenges for R&D roll out are:

- Limited manufacturing capabilities
- Access to capital is limited – leading to missed opportunities
- Covid related disruptions for startups

To access to novel products or scale up products available the following points were summarized:

- Understanding process and opportunity is essential for interventions in R&D.
- There are Multiple players, so competitive advantage is a key driver.
- Affordability and fit for purpose products are essential for access.
- Important to take care of procurement and supply chain which have further complexities.
- Dr. Shobana Balasingam, Wellcome Trust, made a presentation virtually on Establishing human challenge in endemic settings to bring vaccines for target populations. The challenges – regulatory, clinical, manufacturing, market and finance faced by vaccine developers were discussed. Wellcome’s human infection study programme’s utility was highlighted as follows;
South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

The following recommendations were suggested to make progress:

WHO to engage with Member States for

- Strengthening NRAs where vaccine manufacturers exist
- Strengthening in country regulatory systems and harmonisation with other NRAs
- Streamline WHO PQ and requirements e.g. data from human infection studies
- Interpreting Trade agreements, encouraging research, innovation and intellectual property engagements to provide incentives to developers
- Dr. Anh Wartel, International Vaccine Institute (IVI) on capacity-building programmes for Promoting Access to Vaccines. The vision to promote local production of vaccine or biologics to bring the world closer to equitable access to vaccines and biotechnologies, and to ensure better preparedness to tackle future pandemics.

The International Vaccine Institute (IVI) has the expertise, talent, and track record to help build tomorrow’s vaccine manufacturing workforce and complement global efforts to increase vaccine production in LMICs. In 2021, the WHO established the first mRNA technology transfer hub in South Africa to help increase local production of vaccines and biologics.

While strengthening R&D and manufacturing capacity in low- and middle-income countries IVI works in the following areas:

**Training and education**

- International Vaccinology Course

---

Utility of Challenge Studies

Challenge studies can be completed with fewer number of volunteers, generate efficacy data generally faster than field trials and are less expensive.

Uniqueness of Challenge Studies – Time of Infection and dose of pathogen is known

- Allow for a better understanding of the pathogenesis and immunity to the organism to provide insight into vaccine development
- De-risking vaccine development by down-selecting vaccines allowing most promising to be progressed
- Proof of Concept to assess whether a vaccine provides protection
- Identifying correlates of protection
- Can be the basis of licensure – e.g. Vaxchora licensed by the FDA for travellers
South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

- Global Training Hub for Biomanufacturing

**Global Health strategic working groups**

- Global Health Security Agenda
- ASEAN Vaccine Security and Self Reliance

**Technology transfer**

- Oral cholera vaccine
- Vi-DT typhoid conjugate vaccine

IVI partner with qualified vaccine manufacturers from LMICs and transfer know-how to partners so they can lead the vaccine development process and help manufacturers and sponsors of new vaccines navigate the path to regulatory approval.

Global Training Hub for Biomanufacturing created and comprised of Introductory Course for Biologics Development and Manufacturing, Introductory Course for Standard Practice, Onsite consultations and future trainings

- Fostering Local Production and Access to Quality Medical Products to meet National and Global Needs - India Experiences was presented by Dr. Madhur Gupta, WHO India Country Office. Current Good Manufacturing Practices (cGMP) Workshops were conducted in India (2020–2022). WHO engaged at all three levels of WHO (HQ/SEARO and WCO) for promoting access to quality medicine production. First-of-its-kind virtual current good manufacturing practices (cGMP) set of online workshops were held in collaboration with IPA. More than 38 technical subjects focusing on quality production were covered in each of the workshops for Indian pharmaceutical manufacturers. The Active Pharmaceutical Ingredients (APIs) and Formulations workshops were for 12 days each over 6 workshops.

The background to the workshops are as follows:

- SEARO and WCO India WHO had undertaken a joint Survey on Pharmaceutical Enterprises in India. As part of the key recommendations from the Survey, action for several ministries for pharmaceutical enterprises engaged in manufacturing APIs, formulations, and medical devices was proposed to promote access to medical products for meeting national and global health needs.
Indian Ministry of Health and partners, USAID funded programmes, MTaPS and PQM+.

The objective of the online workshops was to promote access to affordable medical products of assured quality, safety and efficacy in all countries through adoption of WHO cGMP in pharmaceutical units.

The outcomes of the virtual cGMP workshops were:

1. Facility/systems upgradation of manufacturers of medicines (formulations and APIs)/biologics/medical devices for cGMP.
2. Understanding cGMP in terms of risk-based and quality system-based approach, principles behind key aspects of cGMP including utilities, water systems, HVAC, process validation, cleaning validation among others for non-sterile and sterile products.
3. Pharmaceutical units have improved knowledge to meet WHO Prequalification requirements and other world class quality standards beginning with a pilot phase in India and to be rolled out to other SE Asia Regional Office Member States.
4. Building capacity and upgradation of Quality Culture and Quality management in medical products including medicines, vaccines, antisera and medical devices manufacturing facilities.
5. Understanding of the use of Artificial Intelligence in Drug Design and Development and Clinical Trial Data Analytics.
6. Promoting availability, affordability and access to quality-assured medicines and medical products.

The Team for the India Initiative
In medical diagnostics and devices, the key areas of focus identified for capacity-building are:

- Global standards & best practices for development & manufacturing of IVD,
- Current Good Manufacturing practices for IVDs,
- Assay Design, optimizations & analytical validations of IVDs,
- Clinical validations of IVDs,
- Global regulations and WHO PQ programme for IVDs,
- Technical documentation & dossiers for WHO Prequalification and other global requirements, and
- Post market surveillance of in-vitro diagnostics

The discussions in the September 2023 workshop strongly recommended to create a knowledge hub with international collaboration to scale up the access to quality medical products for the following:

1. Building capacity and upgradation of Quality Culture and Quality management in drugs and medical devices manufacturing facilities.
South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

(2) Advanced training programme for Mentors to strengthen in-country capacity pool for advanced topics in manufacturing and production

(3) Training and guidance for facility / systems upgradation of manufacturers of pharmaceuticals/diagnostics to international requirements and other world class quality standards

(4) Facilitating Technology Transfer of Health Products to Enable Affordable Access and foster international collaborations for enhanced access.

- Dr. Rubina Bose, Central Drugs Standard Control Organization (CDSCO), India made a presentation on Support for Manufacture and Product approvals in India for early Access to Vaccines.

It was highlighted that the CDSCO & entire regulatory system have worked as inherent part of these collaborative activities through the various regulatory enablers and tools for responding to combat the pandemic. Provisions for expedited regulatory processing & approval of Vaccines in special situations like emergency, pandemic etc. were explained. The vaccine lifecycle as well as the dossier requirement on Indian SUGAM online portal were elucidated.

Snapshot of key regulatory activities in tackling the public health emergency were discussed as follows:

XVIII. Dr. Cha-aim Pachanee, IHPP, Thailand, made a virtual presentation on Trade and Health Policy Coherence to support UHC and
health security. She covered the history of previous EB/WHA agenda on international trade and health as follows:

(1) The agenda on international trade and health was discussed at the 116th session of the WHO Executive Board in May 2005, with the draft resolution proposed by Thailand with support from Benin, Bhutan, Bolivia, Brazil, Canada, China, Iraq, Jamaica, Kenya, Nepal, Sudan, Tonga and Viet Nam. Please see B116_4 for the secretariat report on this agenda.

(2) The 116th Executive Board agreed to defer consideration of the draft resolution on international trade and health to the 117th Executive Board in January 2006 when the resolution was adopted (recommend the 59th WHA to adopt the resolution doc A59_15).

(3) The 59th WHA adopted the resolution WHA59.26 International Trade and Health. This Resolution suggests a constructive collaboration among ministries of finance, trade, foreign affairs and health to balance trade and health interests and create policy coherence between trade and health.

The rationale for policy coherence is:

➢ There is complex linkage between trade and health are more complex.
➢ New trade regimes that pose both opportunities and challenges to health.
➢ WHO’s support – WHA Resolution 59.26 on international trade and health in 2006 as well as other subsequent resolutions including Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), WHA 75.14 resolutions
➢ Paradigm shift toward working in complementarities to maximize the mutual benefits in support of global trade and health sustainable development.

The proposed agenda on ‘trade and health policy coherence to support UHC and health security’ will promote synergy and enable cohesive and concerted action at national and international level. With this perspective, the WHO and Member States will be well guided in fostering coherence between trade and health policies, as well as to strengthen necessary capacities. Therefore, it is timely and crucial for WHO and Member States to discuss this issue in the view of trade opportunities for health and vice versa.
Country Deliberations on Technology Transfer and Local Production of Medical Products

Bangladesh

The country has provision for promoting Technology Transfer under:

- National drug policy 2016: section 4.11(a) regarding technology and knowledge transfer
- Incepta Vaccine Limited is connected to the mRNA technology transfer hub and intended to start local production of mRNA vaccines in Bangladesh and included in COVID-19 Technology Access Pool (WHO C-TAP)

The availability of Health products:

- Locally made - Currently more than 97% of medicines (FP) are being produced in the country.
- Imported - Bangladesh is importing only 3% of the drugs required in the country.
- Constraints - Bangladesh needs to import around 80% of the APIs and raw materials for FP.
- Capability of manufacturing/testing - Manufacturing: Currently Bangladesh Pharma companies are manufacturing all ranges of Finished products with state of art facility and exporting 157 countries including USA.
- Testing - Well equipped testing facilities are available whatever are required to maintain quality of product. National control Laboratory of DGDA is also accredited by WHO and ANSI.
- Drugs for all Types I, II and III diseases are manufactured and available in Bangladesh
  
  (1) Type I diseases: are incident in both rich and poor countries, with large numbers of vulnerable populations in each. (Cancer)
  
  (2) Type II diseases: are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. (TB and AIDS)
  
  (3) Type III diseases: are those that are overwhelmingly or exclusively incident in developing countries. (infectious tropical diseases such as leishmaniasis or malaria)
    
    - Chronic diseases account for approximately 61% of total burden of disease and 54% of annual mortality in Bangladesh,
    
    - Top ten causes of death in Bangladesh;
South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

(4) Cancer 13%, Lower Respiratory Infections 7%, Chronic Obstructive Pulmonary Disease 7%, Ischemic Heart Disease 6%, Stroke 5%, Preterm Birth Complications 4%, Tuberculosis 3%, Neonatal Encephalopathy 3%, Diabetes 3%, Cirrhosis 3% (Ref.: CDC)

Steps for strengthening local production of medicines and other health technologies to improve access in the country are as follows:

- Currently government is developing API industrial park.
- Developing complex generic drug to make easy affordable to patients.
- Adaptation of new technology for manufacturing of different dosage form by collaborating with MNC's companies.
- Transferring and receiving new technology from neighboring countries like India, China etc.
- Mitigating 97% of domestic demand reflects local manufacturing strengths.

India

The country-initiated technology transfer and health technologies to neighboring countries during pandemic. Developed joint funding programmes for academia-industry, Industry-academia hubs-bio foundries & manufacturing hubs, India is now developing National Deep-tech startup policy.

OVERVIEW OF PHARMA INDUSTRY

<table>
<thead>
<tr>
<th>Key Highlights</th>
<th>Exports – by Segments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market size FY2022 ($50 Bn)</td>
<td>73.31%</td>
</tr>
<tr>
<td>Market size FY2030F ($130 Bn)</td>
<td>18.03%</td>
</tr>
<tr>
<td>Expected CAGR FY20-FY30 (~11-12%)</td>
<td>2.16%</td>
</tr>
<tr>
<td>Export to 200+ countries FY23: $25.4 Bn</td>
<td>2.49%</td>
</tr>
<tr>
<td>Largest no. of USFDA plants outside the US</td>
<td>4.01%</td>
</tr>
<tr>
<td>FDI Apr'00 - Mar'23 ($21.50 Bn)</td>
<td></td>
</tr>
</tbody>
</table>

exports – by segments

- **Surgicals**
- **Formulations & Biologicals**
- **Bulk Drugs & Intermediates**
- **Ayush & Herbals**
- **Vaccines**

Indian interventions to promote technology transfer:
South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

- Joint funding programmes for academia-industry
- Promote IP with institutions
- Initiated tech transfer and health technologies to neighboring countries during pandemic

Government Initiatives to promote Medical Devices:

- Production Linked Incentives (PLI) - Financial incentives worth US$ 456 million to promote domestic production
- Development of Medical Devices Parks - New Medical Devices Parks upcoming in Himachal Pradesh, Uttar Pradesh, Madhya Pradesh, & Tamil Nadu to provide plug & play infrastructure
- Policy Support - National Medical Devices Policy to enable strong collaborations for boosting medical devices ecosystem
- Boosting R&D - National R&D Policy to foster interdisciplinary collaborations to develop translational skills and start-up ecosystem

Government of India (GOI) initiatives to promote pharmaceuticals and APIs:

- Production Linked Incentives (PLI) - Financial incentives worth ~US$ 3 billion to promote domestic production
- Development of Bulk Drugs Parks - New Bulk Drugs Parks upcoming in Himachal Pradesh, Gujarat, & Andhra Pradesh to provide plug & play infrastructure
- Financial Assistance for Pharmaceuticals - Strengthen the existing infrastructure facilities by providing Financial Assistance to Pharma clusters for creation of Common Facilities

WHO-GOI Initiatives for fostering Local Production in Pharmaceuticals Enterprises - With an aim to promote access to affordable medical products of assured quality, safety and efficacy through adoption of WHO cGMP in pharmaceutical units (Revised Sch-M). Outcomes of the Virtual cGMP Workshops:

1. Facility/systems upgradation of manufacturers of medicines (formulations and APIs)/biologics/medical devices for cGMP.
2. Understanding cGMP in terms of risk-based and quality system-based approach, principles behind key aspects of cGMP including utilities, water systems, HVAC, process validation, cleaning validation among others for non-sterile and sterile products.
(3) Pharmaceutical units have improved knowledge to meet WHO Prequalification requirements and other world class quality standards beginning with a pilot phase in India and to be rolled out to other SEARN Member States.

(4) Building capacity and upgradation of quality culture and quality management in medical products including medicines, vaccines, antisera and medical devices manufacturing facilities

(5) Understanding of the use of Artificial Intelligence in drug design and development and clinical trial data analytics.

(6) Promoting availability, affordability and access to quality-assured medicines and medical products

**Maldives**

The country has health research priority areas identified for 2022 to 2025 which includes separately, health research priority areas and clinical research priority areas. Maldives health research bulletin published annually which includes the research articles published that year with detailed guidance on how registration and approval of research proposals are carried out. Country interventions to promote technology transfer:

- Copy right law finalized and implemented,
- Trademark law in process of finalization, and
- Industrial property right law in the process of stakeholder consultation

Priorities for next steps:

- To finalize the industrial property right law with stake holder comments, and
- Training and awareness for stakeholders on IPR and patents

Countries priorities - WHA74.6 “Strengthening local production of medicines and other health technologies to improve access”:

- Maldives made efforts to implement bulk procurement for all essential medicines from reliable suppliers to ensure safety, quality and efficacy.
- Establish a robust government procurement system within the country to ensure availability of essential medicines of assured safety, quality, and efficacy.
- Enhance the testing capacity in National Health laboratory for medicine testing.
All medicines, vaccines, medical devices and diagnostics are imported to Maldives as there is lack of manufacturing capacity in the country.

**Nepal**

The country has made efforts to promote transfer of technology by landscape analysis of local pharmaceutical production done to identify gaps and needs to improve local medicines production and technologies. One industry Tizig ph (anti-cancer medicine) has established on basis of the technology transfer from Indian based company SPAL. eHealth strategy implementation roadmap 2019, to set actions on transfer of technology (transformed from traditional to techno-friendly and adoptive).

The availability of health products:

- Types I, II and III diseases: Imported except some medicines used in infectious diseases,
- Availability of diagnostics, vaccines and drugs,
- Locally made: Market share of domestic production is 45% (128 domestic mfg),
- Imported - market share of imported medicine is 55%, Rs 28.65 billion worth (505 international industries, 169 importers), specifically, vaccines, biotechnological products and modern technology related medicines; used for anti-cancer, ART, critical care etc.

**Constraints**

1. Inadequate Partnership and collaboration in priority areas of Health Research,
2. National quality control laboratory is not capable of testing all medicines like vaccines, biologicals, herbal medicines, cancer products, HIV., only one and centrally located,
3. Inadequate of robust regulatory frameworks and trained personnel, and
4. Lack of pricing regulation of medicines, medicine shortage management and irrational use of medicines including antibiotics.

   - Capability of manufacturing/testing

1. Nepalese pharmaceutical industry has a market of around Rs 2400 billion. Most of manufacturers are small and medium scales. (45.5% of the total market share)
Due to low revenue and limited capacity most of the industries are not able to carry on research & development activities, not even the reverse engineering of the molecule production.

The country’s priority - WHA74.6 “Strengthening local production of medicines and other health technologies to improve access”

- Develop National strategy for local production of quality, safe, effective and affordable medicines and other health technologies.
- Build a capacity of regulators, manufacturers and other stakeholders to cultivate and leverage on key enabling factors to strengthen local production towards quality-assurance, improve the understanding of cGMP, transferring technology.
- Promote local production of safe, effective and quality traditional medicines as an alternative source enforcing Ayurveda GMP.
- Strengthening NRA ability to provide effective regulation to ensure access to quality-assured medicines.
- Utilize the opportunity around in neighboring countries to collaborate for exchange of knowledge and technology transfer.

**Sri Lanka**

Sri Lanka is at the beginning stage of pharmaceutical manufacturing and therefore, R & D fund allocation should be increased.

The availability of health products:

- Types I, II and III diseases - Yes
- Availability of diagnostics, vaccines and drugs - Yes
- Locally made - No diagnostics and vaccines, drugs available
- Imported - 95% imported drugs and 100% diagnostics and vaccines are imported
- Constraints – economic crisis and less human capital
- Capability of manufacturing/testing - OSD-24 and Injectable-04
- Testing – National Medicines Quality Assurance Laboratory (NMQAL), SL

   The country’s priority - WHA74.6 “Strengthening local production of medicines and other health technologies to improve access”

- Government commitments,
- Accelerated regulatory review process for locally manufactured products,
Government procurement policy given priority for locally manufactured products, and

Increased the number of graduates in the field of pharmacy

**Thailand**

The country interventions to promote technology transfer:

- API: Technology sourcing from leading API manufacturers,
- Medicines: Adoption technology transfer from India to accelerate the product development of conventional medicines, improving access to essential medicines, and
- Biologics: Training on relevant courses organized by national and international agencies

The country’s intervention so far are as follows:

- **20-Year National Strategic Plan for Public Health (2017–2036)** to develop and implement a health system which is in line with the national policy, the national reform and health system reform agenda toward Thailand 4.0
- The strategic plan is run by creating and operating work plans and projects such as Plan 14 Development of health research study and innovation (Project 44 Development of research studies/innovations, health products, and medical technologies), established to promote research and development activities that will lead to innovations and to ensure that people have access to quality and affordable pharmaceutical drugs and vaccine products, thus reducing healthcare expenditures
- MOPH senior administrators conduct several informational meetings in different health zones across the country to transfer all the details of the plan to health officials and to create an understanding with the aim to ensure concerted efforts in the implementation of this public health strategic plan to achieve ultimate goal
- Roles and responsibilities of health agencies involved in translating the MOPH-drafted national strategic plan for public health into practice and in implementing monitoring and evaluation (M&E) programme

The countries priority for the next steps:

Ministry of Public Health (MOPH) has introduced a sophisticated and innovative M&E system known as Strategic Management System (SMS) for use in different health zones and provinces across the country
**Timor-Leste**

The country must improve on the following areas:

- Current legal framework outdated,
- Fragmented regulatory system of four core NRAs (NDFM, GIAS, GLRAS, and LNS/INSP TL, NDME with little autonomy,
- Insufficient channels of coordination and communication between each other,
- Overlaps in some responsibilities (e.g. marketing authorizations (GLRAS/DNFM), duplication of work between SAMES and DNFM), and
- Critical gaps in other functions: no authority responsible for laboratory testing and clinical trials.

The country’s priority - WHA74.6 “Strengthening local production of medicines and other health technologies to improve access”

- Strengthening local production of medicines: N/A
- other health technologies to improve access: N/A
- Production: N/A
- Currently: planning for O2 production in the near future in collaboration with GF & WHO

The country recommended:

- Support on the technical and financial on creating the NRA, NMP & NMDP, and
More participation of the health professionals on workshop, training and meeting related

**Group work facilitated by Experts**

The countries were divided into 3 groups as follows to deliberate on mechanisms of technology transfer and local production to enable access to medical products at national & regional levels.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
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<tbody>
<tr>
<td>• Bangladesh, Sri Lanka</td>
<td>• India, Thailand</td>
<td>• Maldives, Nepal, Timor-Leste</td>
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</table>

**Group 1: Bangladesh & Sri Lanka**

**Challenges**

- Patent protection of key medical products,
- Mechanisms to transfer of knowhow for new technologies,
- Country’s economic and human resources capacity,
- Limited infrastructure for manufacturing,
- Limited capacity of research institutes in LDCs, and
- Effective use of mandatory incentives to transfer technology to LDCs under article 66.2 of TRIPS
South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

Key Recommendations

- Develop capacity in reviewing Patent & Intellectual Property Regulations provisions,
- Develop pool of experts for Technology Transfer – “Technology Transfer Professionals”,
- Develop “Technology Transfer Facilitation Cell”,
- Develop Guidelines/SOPs for Technology Transfer through digital portal,
- Review and revise curriculum for B.Pharm/D.Pharm with chapter on TRIPS provisions,
- Develop guidelines for local production of new technologies,
- Monitor industry for quality production and GMPs, and
- Promote and protect local industry through trade incentives.

Expectation from WHO/International organization

- To facilitate creation and coordination of “Regional Forum” to discuss IPR, Patent related challenges and knowledge exchange,
- To provide technical support in developing and institutionalizing “Technology Transfer Facilitation Cell” at National Level,
- To provide technical support in building capacity through training programmes for Pharmacists/Regulatory Authority/Industry/Academia in Member States.
- To provide technical assistance in reviewing curriculum for Pharmacists/Biotechnologist/Bio-Chemist/Microbiologist to include TRIPS/IPR related material,
- Technical support in developing “Research & Development Strategy” for Member States,
- Technical support in developing guidelines for local production,
- WHO/WIPO/WTO Tri-Lateral cooperation to develop/review/revise applied course for competent authorities in Technology Transfer in Health Sector,
- The Tri-Lateral Cooperation to organize workshop/training for on health trade and IP officials and other relevant stakeholders,
- Knowledge exchange from various innovative institutional mechanism located in Member States, and
- Create a pool of resources to support Member States in producing medical products in emergencies through technology transfer.
Group 2: India & Thailand

Key Recommendations

- Both the countries have legal provisions and policies to enable Technology Transfer (TT) without much complications and follow WHO Technical guidelines (TRS) e.g. WHO TRS on TT,
- Further, TT policies have been also framed for Publicly funded R&D projects in India,
- All TT has to follow the applicable national regulations, hence, it was agreed that, the regulations and legal framework should not become a barrier for TT and should be agile and flexible to facilitate TT at different stages of development,
- There shall be information sharing platforms for regular and dynamic flow of information between all the parties for simplification and accessibility,
- TT can be possible based on capacities and capabilities of the receiving countries with its available infrastructure, trained competent manpower, resources,
- TT may not be a solution for a very small country with few millions population where it may be needed to rely on the regional capacities and it may be needed to develop a regional network to ensure that each country gets the desired medical products as per country’s need from identified manufacturing countries with adequate capacities and capabilities,
- As already mentioned, one size does not fit all, local production may not be the feasible solutions. Smaller countries may rely
upon the manufacturing capacities of other countries in the regions, and

- It may be prudent to identify such products which are of specific needs in the context of the country’s disease burden and affordability and to support research to commercialization of such products e.g investing in low cost, point of care screening innovative solutions e.g. TB

**WHO’s support**

- WHO can support by sharing the knowledge on Patents, epidemiology, disease burden, laboratory,
- Sequencing through a common platform, which can be accessed by all countries,
- Leveraging support from institutions like NIH, various COE, Research Centres etc. by the startup, innovators for novel technologies,
- Scaling-up initiatives for incubators till commercialization,
- Training solutions by WHO through in-house and outside experts,
- Translational research being the need of the hour, so wherever necessary the training support, may be through the WHO Academy would be the need of the hour,
- Facilitate sharing of expertise and best practices among Member States e.g. Clinical Research, Biomed Research, GMP, Pharmacovigilance programmes etc,
- WHO to facilitate linkages and collaboration with WHO Academy
- Leverage the existing trilateral cooperation between WTO, WHO and WIPO to accelerate the access to medical products,
- WHO to leverage collaboration with IVI Korea for technology transfer of some products,
- WHO to facilitate the technical and funding support from other organizations for researchers, innovators etc, and
- Member States to participate in the annual meetings of trilateral cooperation (WTO-WHO-WIPO) and WHO may facilitate such participation
Group 3: Maldives, Nepal & Timor-Leste

Technology Transfer - National/International context

- Policy advocacy and develop policies and legal framework for technology transfer. Capacity to accept and transfer technologies,
- Implementation gap: capacity-building of technology transfer in country context. Advocate the policy level - inter-sectorial collaboration between the ministries,
- Ministerial steering committee to be established and they will decide the roles and responsibilities and the committee will make the decision,
- Technology transfer a solution for the country to enable access to medical products,
- To have the internal capacity to absorb the technology in terms of infrastructure and skilled human resource,
- Expectation from WHO: Technical assistance,
- Expectation from international organization/partnerships/participants networking, establish a common platform with other countries of similar interest and analyze the national system by an international expert in the area,
- International constituents engage better: when the recipients are willing and eager to establish the system and the country to develop eligible criteria for tech transfer (here need international support TA),
- Active collaboration coordination and communication between recipient country and international agency,
South-East Asia Regional workshop to accelerate technology transfer for local production and improve access to medical products

- Challenges: Lack of expertise in the country, human resource, infrastructure, budget, political commitment,
- Possible solutions: policy advocacy, capacity-building, infrastructure, training, initiating PPP model and G to G model, and
- Expectation from WHO: technical assistance

**Local Production - National/International context**

- Policy advocacy and develop policies and legal framework for local Patent office dealing with IPR matters,
- Baseline analysis to find the GAPs in the country context - BNA (bottleneck analysis),
- Advocate the policy level – Inter-sectorial collaboration between the ministries,
- Ministerial steering committee to be established and they will decide the roles and responsibilities and will make the decision on this TOR prepared for better coordination,
- Local production a solution for the country to enable access to medical products,
- At National levels: Internal capacity development to produce,
- At Regional level: networking and collaboration between countries focal point,
- Shall have the internal capacity to absorb the technology in terms of infrastructure and skilled human resource,
- Expectation from WHO: Technical assistance,
- Expectation from international organization/partnerships/participants: networking, establish a common plat form with other countries of similar interest. Analyze the national system by an international expert in the area,
- International constituents engage better: when the recipients are willing and eager to establish the system and country to develop eligible criteria for local production (here need International support TA),
- Active collaboration coordination and communication between recipient country and international agency,
- Challenges: Lack of expertise in the country, political commitment, human resource, infrastructure, budget,
Possible solutions: Policy advocacy, allocation of resources, (funds, capacity-building, infrastructure, training, initiating PPP model and G to G model

Expectation from WHO: Technical assistance

**Observations and suggestions by Experts Panel: Technology Transfer & Local Production**

The discussions were moderated by Dr. Manisha Shridhar to provide insights into the observations and suggestions by distinguished panelists:

- **Dr. Erika Dueñas, WHO-HQ**
  
  Dr. Erika Dueñas strongly recommended for a specific assessment of the national laws and policies in the countries of this Region in order to promote transfer of technology. Laws and policies not only concerning public health but also related to industrial laws & policies, IP policies, R&D policies to be considered at the national level. Exchange between countries of the Region to align on laws and policies to meet public health needs. Assessment and exchange among the experiences of the countries in the Region to promote public health. Use of competition law and policies to promote public health and strengthen local production.

- **Dr. Tara Kirby, National Institute of Health (NIH)**
  
  Dr. Tara Kirby mentioned that NIH has a lot of capacity in terms of research materials and tools as they have contributed in CTAP and other programmes and licensed technologies relevant to public health needs. She encouraged the countries in the Region to take advantage of the available resources. To focus more on the specific needs of the countries by having a pool of experts to build capacity so that there will be expertise across the whole ecosystem. It becomes an important step to collaborate across region to identify the components and goals a country would fit into.
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**Dr. Mila Maistat, Medicine Patent Pool (MPP)**

Dr. Mila Maistat highlighted the importance of collaboration with government and stakeholders for the key medical products experiencing high prices should be taken up for licensing and technology transfer. Also, local production contributes to improve affordability and regions should identify priority products and regional manufacturing becomes essential. Government commitments needed to invest in procurement of essential recommended products so that efforts to support local manufacturing result in actual uptake and sustainable.

**Dr. Navneet Tewatia, Medicine Patent Pool (MPP)**

Dr. Navneet Tewatia emphasized that it’s important to have a pre-established list of regional manufacturers so that whenever needed, it can develop products and can get the regulatory approval faster and thus lead to generic production. MPP’s priority biotherapeutics a new area and would need support from Government for the promotion.

**Dr. Madhur Gupta, WHO India Country Office**

Dr. Madhur Gupta focused on the need for cross collaboration learnings, exchanging knowledge, leveraging the state of that institutions and centers of excellence. Collaboration with NIH as a possible example for countries to be facilitated by WHO and Member States and supported to take the early-stage solutions forward through incubators, startups innovator companies and faster access can be facilitated. Leveraging the trilateral cooperation of WTO WIPO and WHO is another cooperation or collaboration, which should be tapped into in proactive and dynamic manner. To explore a regional forum to be an agile and proactive structure and facilitate the collaboration acting as a knowledge hub in the Region where exchange of knowledge, best practices, workshops, capacity-building endeavors, study visits to countries, cross regional collaborations become easier, global meetings, cross regional meetings could be facilitated. So the regional forum for innovation, local production and technology should be explored. Scaling up initiatives for capacity-building have proven to be successful for fostering access to medical products, building capacities in good manufacturing practices in countries amongst manufacturers, innovators producing products of priority health needs for countries and WHO prequalification programme. Madhur Gupta also highlighted the lag, which all the regions except the developed world faces, a lag of about four to five years for all the cutting-edge medical products, which are limited to developed countries only. It’s essential to identify and bridge this lag of making it less than five years to one and a half years, so that new cutting-edge medical products discovered in the United States of America should reach to other parts of the world. For the capacity-building component linkages with WHO Academy are critical.
Dr. Roger Kampf, World Trade Organization (WTO)

Dr. Roger Kampf emphasised on assessment of legal frameworks and policies to better understand the gaps in the existing system and mapping of patents would be a good basis for technology transfer. It is important to map the manufacturing capacities so that the needs and strengths of countries are identified to build regional and national capacity. It becomes important to protect the local list of industry in relation to tariff policies and help from ministries must be sorted.

Dr. David Atchoarena, WHO Academy

Dr. David Atchoarena recommended capacity-building for development of technology transfer. WHO Academy to promote capacity-building, it will be important to be fully aligned with the authorities and the interventions and supported by WHO for the next two years until Academy is opened. WHO recently signed an agreement with the Republic of Korea when it comes to bio manufacturing and IVI is the technical arm of the Ministry of Health of Korea for developing the training programmes. The WHO Academy will be providing support for the review of the curriculum and certification. In terms of local production the regional scenario are as follows:

- India, Bangladesh and Thailand already producing not only for the domestic market, but also exporting a large scale of medical products.
- Nepal and Sri Lanka at intermediate position and requires support for capacity development in terms of manufacturing.
- Maldives and Timor Leste need more support in terms of procurement management of the supply chain.

A need to keep diversity of context and priorities and needs as per the capacity of the countries in the Region when it comes to capacity-development. WHO Academy will be committed to support the countries in the region.

Dr. Anh Wartel, International Vaccine Institute (IVI)

Dr. Anh Wartel mentioned that to focus on technology transfer and local manufacturing it’s important to look beyond and see the critical ones i.e. vaccine and medicine and assess the robustness of the regulatory environment in the country. To bring vaccine to WHO prequalification level, it requires a regulatory agency to ensure that the product will be licensed for use implemented for vaccination and the demand generation. At the regional level if the volume of vaccines are produced and the markets not shaped properly at the country and regional level it will be a challenge to produce in the low demand. Therefore, it becomes crucial to match the demand with the supply, procurement agreement and the delivery part.
Need for robust training mechanism to ensure successful vaccine development training of scientists, research, safety cases, safety data etc. India, China already at advanced level in terms of biomanufacturing as they can produce with high quality. Sri Lanka can do clinical trials and they have learned that with dengue vaccine trial. Bangladesh has a renowned organization. Dr. Anh Wartel highlighted an integrated approach to leverage the strengths of each country having a consolidated regional plan to get all the ecosystem in place where the countries that have much more robust value manufacturing capabilities can tackle more complex issues and produce vaccine that can benefit specific diseases or disease affecting South-East Asia, as the Region in whole.

**Dr. Shirshendu Mukherjee, BIRAC**

Dr. Shirshendu Mukherjee stated that the research leads to development of intellectual property which converts into technology and further converted into other issues of bio productions and other things. It becomes important to achieve a good innovation management ecosystem for building of capacities to manage innovation which has been difficult to manage and needs people with cross-functional expertise a team 360-degree innovation management. Regulatory issues, regulated capacities, trial capacities and other things needs to be building for which capacity-building is the bottom line. A need to create a forum or a platform to share the experience and take the innovation from bench to the bedside for cross learnings, cross understanding, cross meetings together will be a very important step forward. Also, an important step to create local structural base for biomanufacturing where academic innovation can be validated through the infrastructure created at various levels biomanufacturing hubs, bio foundries, where the innovations taken up quickly at a controlled scenario.

**Dr. Matthias Helble, WHO – HQ**

Dr. Matthias Helble highlighted R&D ecosystem should be integral part of local production for which need to analyse the countries that can be medium to long run to build a certain capacity of local manufacturing. For local manufacturing need to import lot of capital goods that are produced outside the country so a global industry to be set up from which the regional and global corporation make efficient allocation of resources. Institutionalizing regional corporation to exchange ideas and make sure that these local productions are actually happening and also happening in a regionally coordinated fashion and will bring access to new health technologies in the fastest way possible.

**Dr. Isariya Techatanawat, GPO, Thailand**

Dr. Isariya Techatanawat emphasised the importance of IP at the university which builds the research ecosystem and initiate the new innovation and
prepare for the technology transfer. Creation of a network where manufacturers and stakeholders need to invest a big money to build up the new facility or to update the existing facility in our region and focus on the growth of the R&D and technology transfer, for example use of international laboratory for immunology testing so without building up laboratory can use this facility.

**Dr. Pallav Bhat, WHO Country Office, Bangladesh**

Dr. Pallav Bhat pointed out the regional disparity where the levels of the research and development, innovations and technology differ. Some are far ahead in terms of medical equipment production and innovation while others are lagging behind. Create a mechanism to develop capacity to knowledge exchange platform for competencies, workshops, and policy papers which will raise the level of development to collaborate with each other for technology transfer. Need government and political commitment and system readiness to develop sustainable financing for research and development in the country. To create a pool of resources to fund research initiatives in the region through the different partners, organizations jointly some kind of mechanism which will be sustainable in a sense, and will be shared among the Member States. There will be need to prepare the system for adapting to the new technology and framework through developing legislations and implementation framework and the monitoring mechanism for setting up medical technology park, SEZ to facilitate among the manufacturers and academia joint collaborations. Dr. Pallav Bhat also suggested that the importance of identifying 20 medicine which caters 80% of the outpatients in prescription and try to manufacture those medicines in the country to reduce the cost significantly and improve the access. High-cost medicines for cancer etc need regulatory mechanism to regulate the price of those products and use of HTA to assess the technology. There should be mechanisms at the national level and quality assurance agency which could be an autonomous body to evaluate the quality both as the private sector as well as the public sector mutually to so that the quality is assured.

**Dr. Md Khurshid Alam Hyder, WHO Country Office, Nepal**

Dr. Md Khurshid Alam Hyder emphasized to establish quality and sustainable local production and align them with national plans and regional policies and strategies related to local production and leverage regional economy integration and sustainability of finance. It becomes crucial to develop evidence based holistic approaches for the national policies to sustain the quality and effective mechanism to engage all the partners north-south, south-south, collaboration, partnership exchange, learning and helps to create the best practices and learn from each other. Dr. Md Khurshid Alam Hyder also mentioned the need of investments in the
country for policy coherence so that investors can come to the country and leverage production capacity like hub at Bangladesh which has established several exports.

**Dr. Anoop Thekkuveettil**

Dr. Anoop Thekkuveettil highlighted on the problems faced during COVID-19. It becomes essential to know how to write a good technology transfer document because that’s a lag and WHO should help to draft better technology transfer documents with the help of companies dealing with technology transfer. Also, the price of the product which entered the market should be mentioned in the technology transfer document to maintain a fair pricing. Development of research & development activities in all the countries of the Region an extremely important step towards local production.

**Vote of Thanks**

Proposing the vote of thanks, Dr Manisha appreciated all participants for their support and enthusiasm to have a very successful meeting and for spending their valuable time. She appreciated the Chair, co-chair and the rapporteur for their excellent contribution. She thanked the WHO team including the country office and Head Quarters and all the Member States. Finally she thanked everyone for their cooperation and contribution to make the meeting successful.

**Recommendation of the workshop**

The effective discussions by the experts led to well-informed and actionable recommendations.

**Action by Member States**

Member States stress the need for concerted action on the following:

- Build capacity through engaging in annual, cross-regional, HQ GSPA meeting/symposium/workshops to promote information sharing on IPR issues in technology transfer, research, innovation and product development for access to medical products.
- Provide capacity-building in IP management, technology, information management to maximize public health outcomes
- Develop mechanisms for collaboration among R&D institutions in academia public and private sectors and international organizations.
- Engage with WHO academy for institutional capacity-building programmes on access to medical products.
Promote exchange of information and capacity-building for R&D and protection of traditional, complimentary and integrative medicine

To develop and strengthen collaboration between academia and industry through development of incubators/accelerators and partnerships

To engage with state-of-the-art institutions, and partners such as NIH and international organizations for technology management, research, innovation and product development to promote technology transfer and local production of medical products including collaborative capacity building activities.

Promote inclusion of the outcomes of WIPO-WTO-WHO trilateral cooperation and other international organizations at national and regional levels.

Explore formation of a Regional Forum to engage in the areas of IPR, technology transfer and local production.

**Action by WHO**

WHO should support Member States by carrying out the following recommendations:

- Build capacity of the Member States through annual cross-regional and annual GSPA meeting/symposium/workshops to promote information sharing in technology transfer, research, innovation and product development for access to medical products (HQ/SEARO).

- Provide capacity-building and coordination mechanism for technology transfer for public health among countries and regions and develop guidelines for technology transfer among Member States and regions (including expansion of Covid Management Technology Access Pool/HQ).

- Support the linkages with state-of-the-art institutions and partners such as NIH and international organizations to for technology management, research, innovation and product development to promote technology transfer and local production of medical products including collaborative capacity-building activities.

- Support MS to engage with WHO Academy for programmes for developing national institutional capacity for effective solutions for access to medical products
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- Support MS for capacity-building for local production, technology transfer and R&D to promote innovation and improve access to medical products.
- Assist MS in their efforts to strengthen national biomedical R&D and innovation systems as a means to promote sustainable local manufacturing of health technologies.
- Support MS for technology development and strengthen collaboration between academia and industry through development of incubators/accelerators and partnerships.
- To facilitate participation of MS to engage in WIPO/WTO/WHO national/regional/cross-regional/global consultations in the context of trilateral cooperation,
- SE Asia Regional Office to engage with member countries for information sharing on WHO MPP programme for affordable, quality assured WHO-recommended essential medical products technology transfer programme with existing network of manufacturers to facilitate access to medical products (MPP)
- Support MS for the formation of a Regional Forum to engage in the areas of IPR, technology transfer and local production.