

Local Production and Assistance Unit: local production and technology transfer

WHO Technical Briefing Seminar

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Regulation and Prequalification

Access to Medicines and Health Products Division

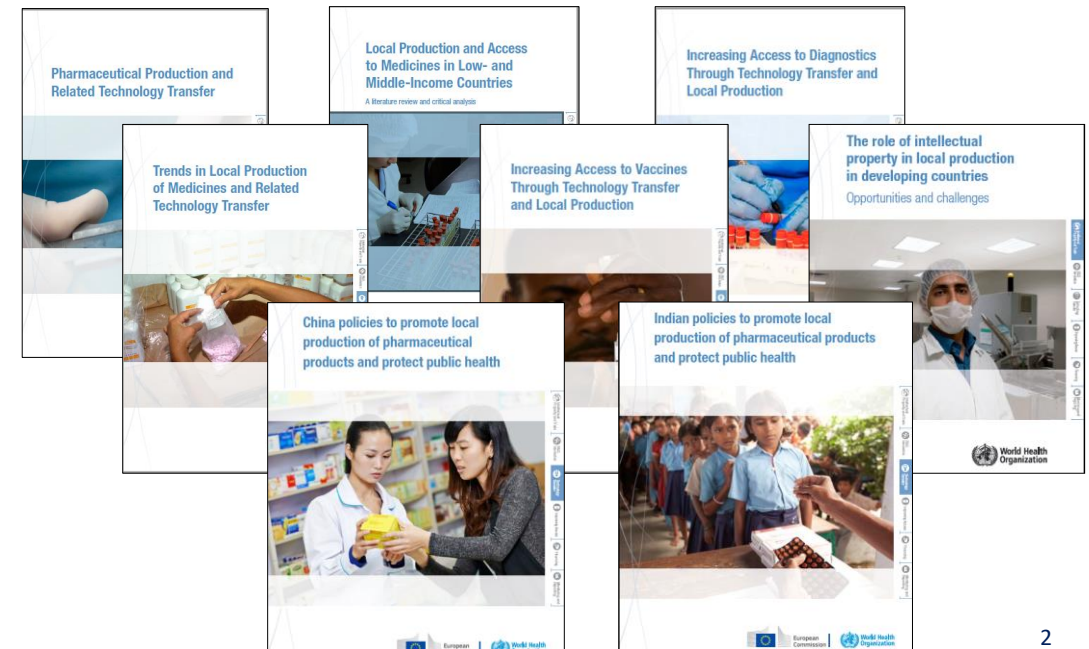
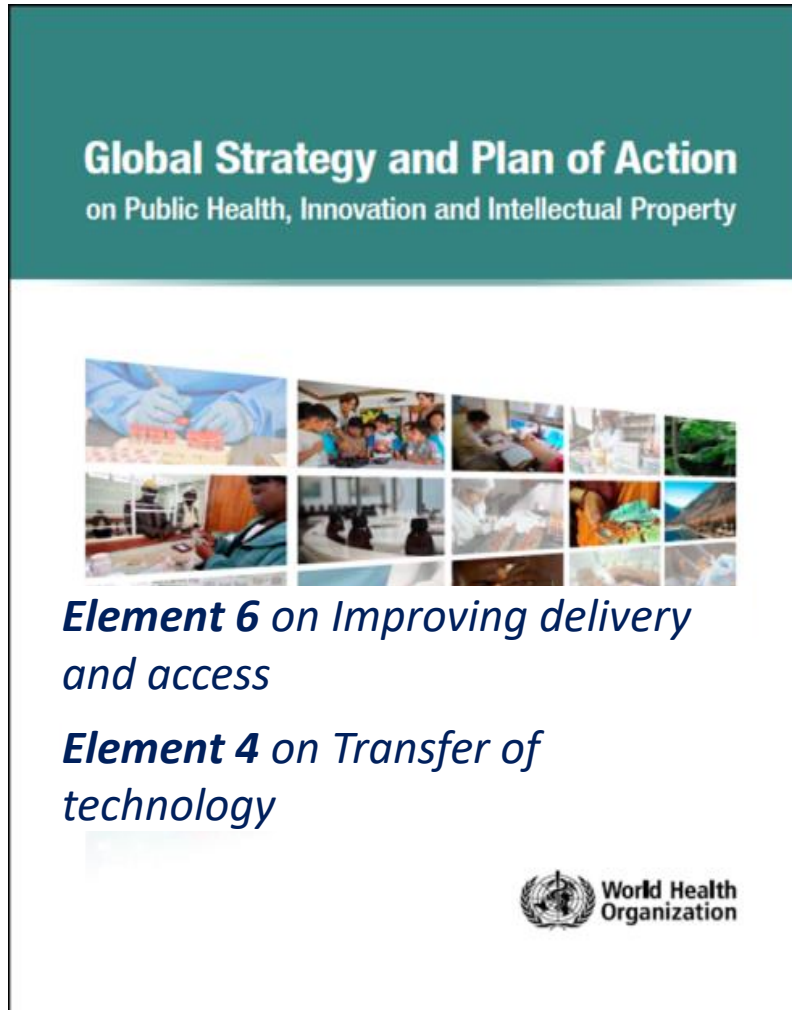


World Health
Organization

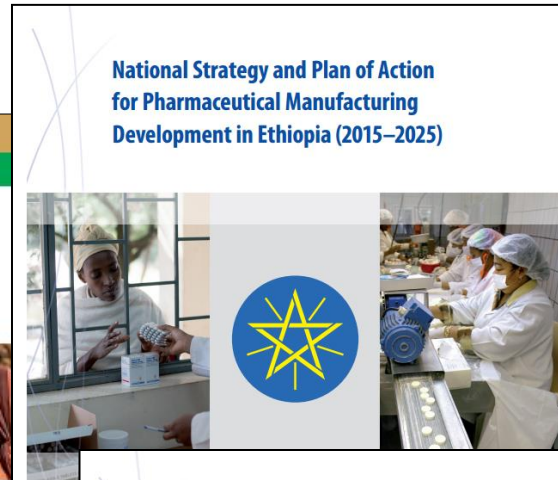
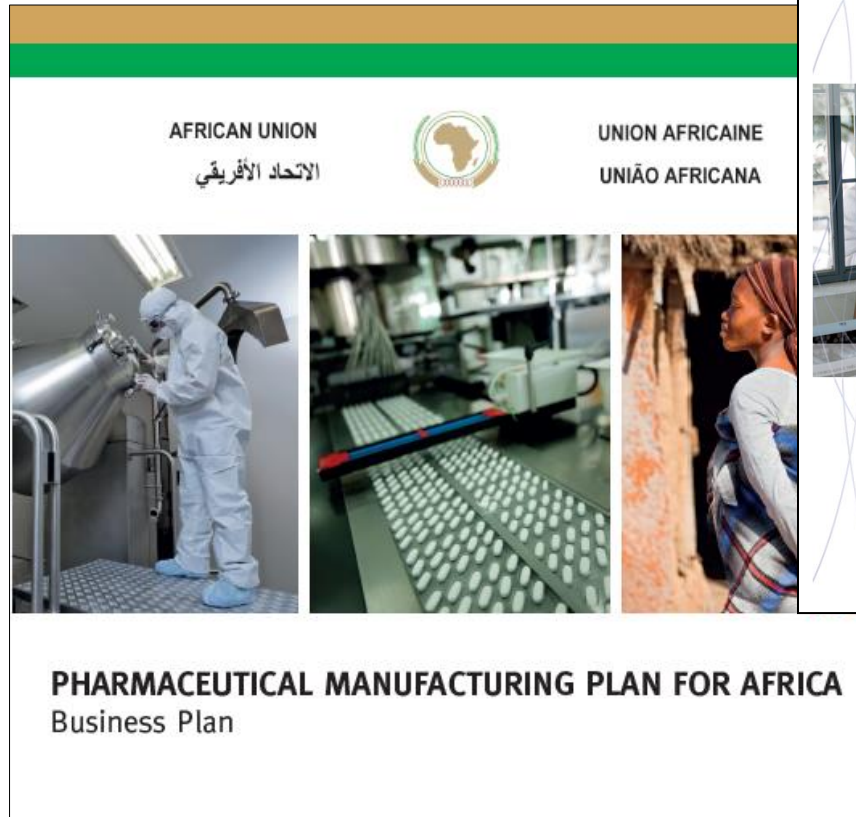


Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI)

- Strategy to promote new thinking on local production & technology transfer, innovation and access
- WHO launched an initiative to promote local production in developing countries with funding from EC



Supporting implementation of AU Pharmaceutical Manufacturing Plan for Africa (PMPA)



Launch of Ethiopian National Strategy and Plan of Action for Pharmaceutical Manufacturing Development and Improving Access

14 July 2015



- Ethiopia's National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (NSPA-Pharma) is the first national translation of the PMPA
- Significant progress has been achieved in Ethiopia under NSPA-Pharma

Interagency statement on promoting local production of medicines and other health technologies

Launch of the first interagency statement on promoting local production by the 6 signatory organizations at the 72nd World Health Assembly



<https://www.who.int/publications/m/item/interagency-statement-on-promoting-local-production-of-medicines-and-other-health-technologies>



INTERAGENCY STATEMENT ON PROMOTING LOCAL PRODUCTION OF MEDICINES AND OTHER HEALTH TECHNOLOGIES

Low- and middle-income countries (LMICs) are becoming increasingly interested in developing the local production of quality-assured medicines and other health technologies. This is due to its potential to assist LMICs in improving access to quality-assured medicines and other health technologies, achieving universal health coverage (UHC), and reaching the health-related targets and broader developmental objectives of the Sustainable Development Goals.

The term "Local Production" can be defined in various ways. For the purposes of this statement, "local" refers to the geographical location, i.e. occurring in the country or region, and "production" – in regard to pharmaceuticals for example – refers to all activities along the pharmaceutical manufacturing value chain. Within the context of the public health agenda, promoting local production requires a holistic approach that considers policy coherence, regulatory systems strengthening, access to finance for sustainable production, a careful assessment of the business case, development of skilled human resources, access to technology for production and needs-based innovation, creation of investment incentives and other factors, to enable manufacturers to comply with international quality standards, be competitive and engage in sustainable manufacturing.


The Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property, adopted at the 61st World Health Assembly (WHA) in 2008, cites local production and related transfer of technology as one of the elements to promote innovation, build capacity and improve access. More recently, at the 71st WHA in May 2018, Member States highlighted the importance of local production in the context of the global shortage of, and access to, medicines and vaccines.


A number of international organizations have also expressed their desire to source quality-assured medical products closer to the point of use. The pull effect of significant market opportunities can be a major factor in driving progress, particularly when aligned with partnerships in supporting the development of the industry and health workforce.


Strengthening local production is a cross-cutting endeavour. Sustainable local production requires effective multisectoral collaboration in order to promote enabling investment, legal and technical environments. In many LMICs, the capacity of both local manufacturers to produce and supply quality medical products and the national regulatory authority to ensure quality, efficacy and safety is insufficient. Any supply of medical products – both through local production and imports – should go hand in hand with the strengthening of regulatory capacities in order to achieve compliance with international GxP¹ and other quality standards. Close partnership between the international community and LMICs is essential to support countries and regions to build the capacities, institutions and industries that can sustain the progress made.


With the globalization of the pharmaceutical industry and the variety of country contexts, there is no "one-size fits-all" approach in promoting local production of quality-assured medicines and other health technologies. However, in recognition of the important role local production can play in improving access to quality-assured medical products and achieving UHC, the undersigned organizations aim to work in a collaborative, strategic and holistic manner in partnership with governments and other relevant stakeholders to strengthen local production. We are committed to contribute based on our respective organizations' expertise and mandate.


Launched in Geneva on 24 May 2019.



Dr. Tedros Adhanom Ghebreyesus
Director-General, WHO


Ms. Gunilla Carlsson
Executive Director, a.i., UNAIDS


Mr. Li Yong
Director-General, UNIDO


Ms. Henrietta H. Fore
Executive Director, UNICEF

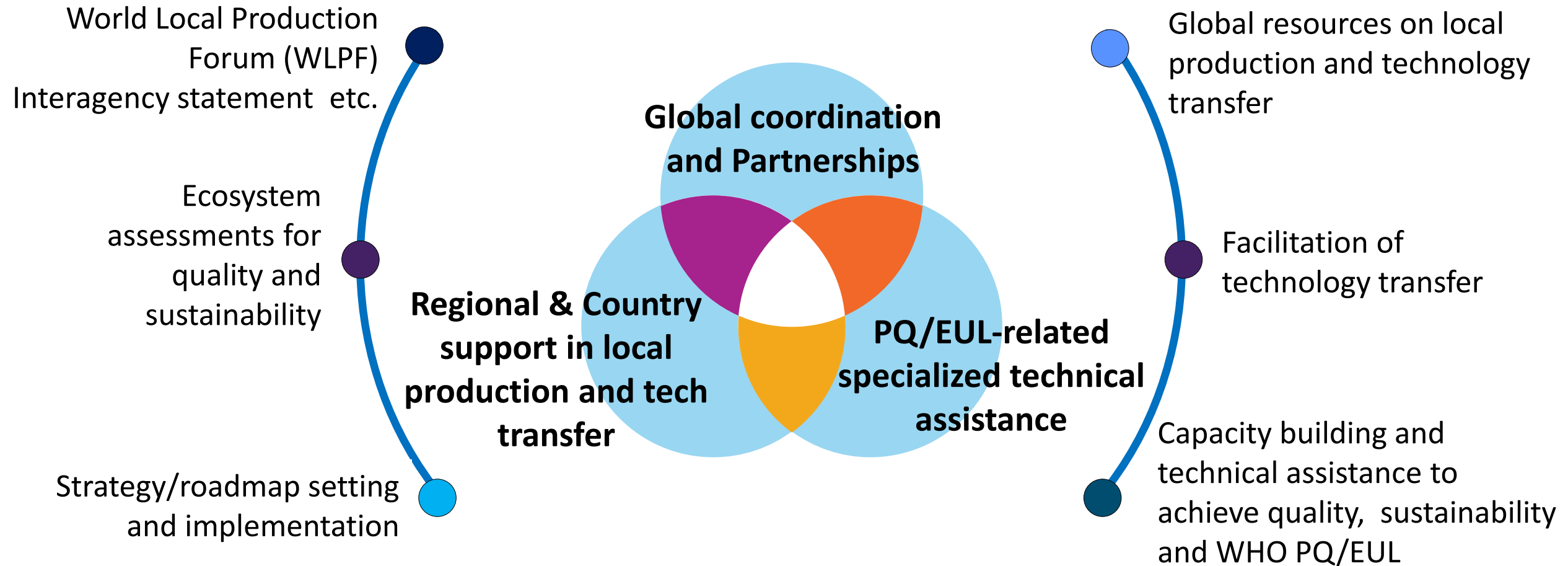

Dr. Mukhisa Kituyi
Secretary-General, UNCTAD


Mr. Peter Sands
Executive Director, The Global Fund

¹ Good manufacturing practices, good clinical practices, etc.

LPA Unit's mandates in strengthening quality and sustainable local production to improve access

Further strengthened by Resolution WHA74.6:



Resolution WHA74.6 on Strengthening local production of medicines and other health technologies to improve access

Adopted at the 74th World Health Assembly (2021) with >100 co-sponsoring Member States

Signals the important role of local production as a strategy to increase timely access and strengthen health security during pandemics and in peacetime

Urges Member States and WHO to continue efforts in a holistic, strategic and collaborative manner



World Local Production Forum: Enhancing access to medicines and other health technologies



New WHO initiative to foster global coordination, synergies and partnerships

Sustainable platform for the global community of Member States, industry, experts, academia, UN agencies, international organizations, etc.

Galvanize collective action and sustain momentum in overcoming the challenges, harnessing opportunities and shaping strategies and the direction of local production globally

First World Local Production Forum (Jun 2021)



Some key takeaways:

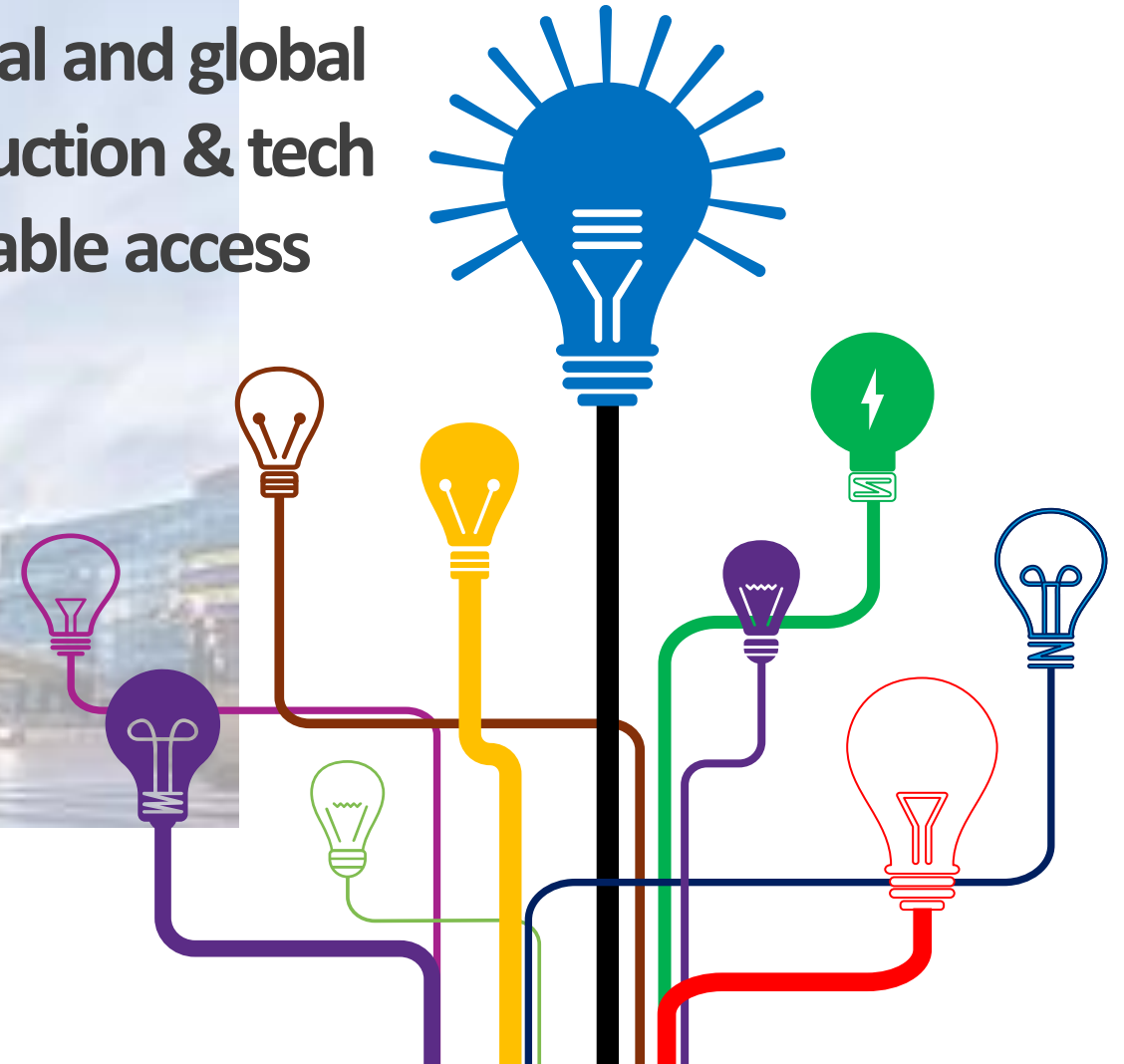
- Critical components include partnerships & cooperation and consideration of sustainability
- Diversification in technology, products and locations are key for pandemic preparedness

- **Tedros Adhanom Ghebreyesus**, Director General, WHO
- **Ngozi Okonjo-Iweala**, Director General, WTO
- **Li Yong**, Director General, UNIDO
- **Henrietta Fore**, Executive Director, UNICEF
- **Isabelle Durant**, Acting Secretary General, UNCTAD
- **Jutta Urpilainen**, Commissioner for International Partnerships, European Commission
- **Lia Tadesse**, Minister of Health, Ethiopia
- **Sandile Buthelezi**, Director General of National Department of Health, South Africa
- **Budi Gunadi Sadikin**, Minister of Health, Indonesia
- **Marco Pontes**, Minister of Science and Technology, Brazil
- **Hala Zayed**, Minister for Health and Population, Egypt
- **Erika Martinez Lievano**, Minister, Mission of Mexico to the UN in Geneva
- **Stéphanie Seydoux**, Ambassador for Global Health, France
- Etc.

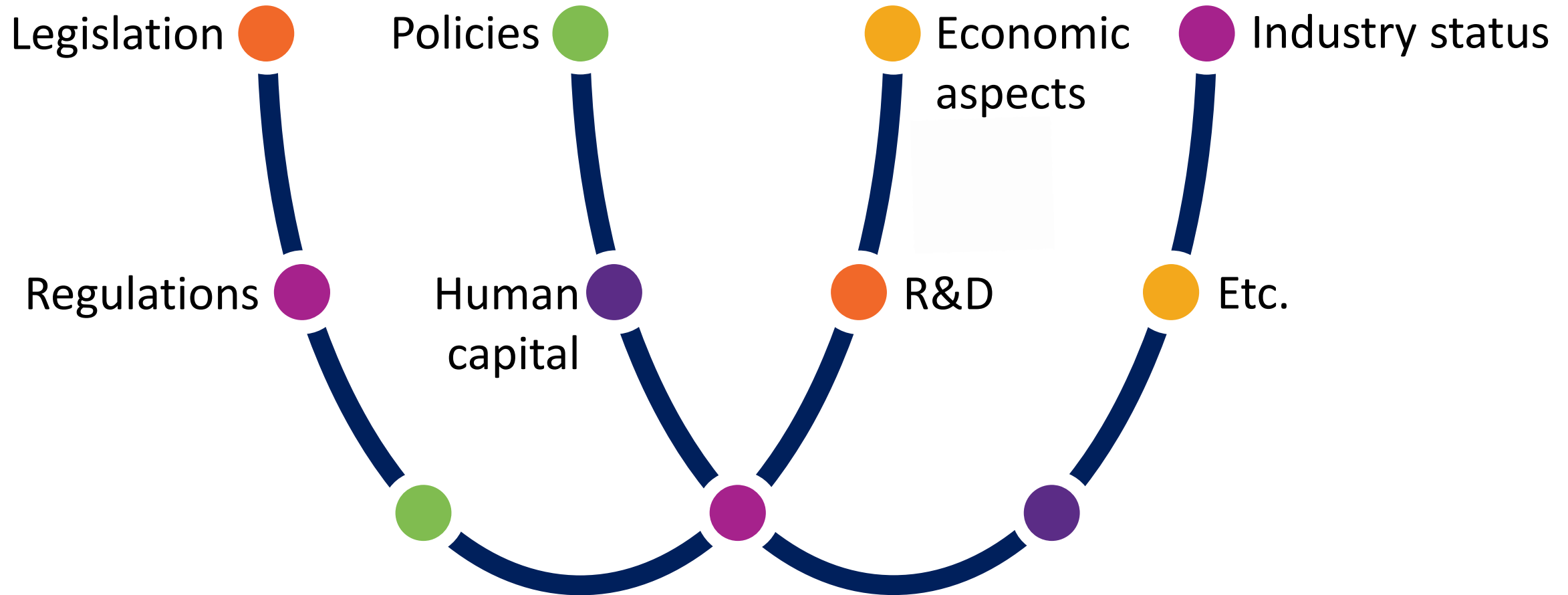
Second World Local Production Forum at The Hague, Netherlands

Date: 6-8 November 2023

Focus on leveraging regional and global partnerships for local production & tech transfer for timely, equitable access

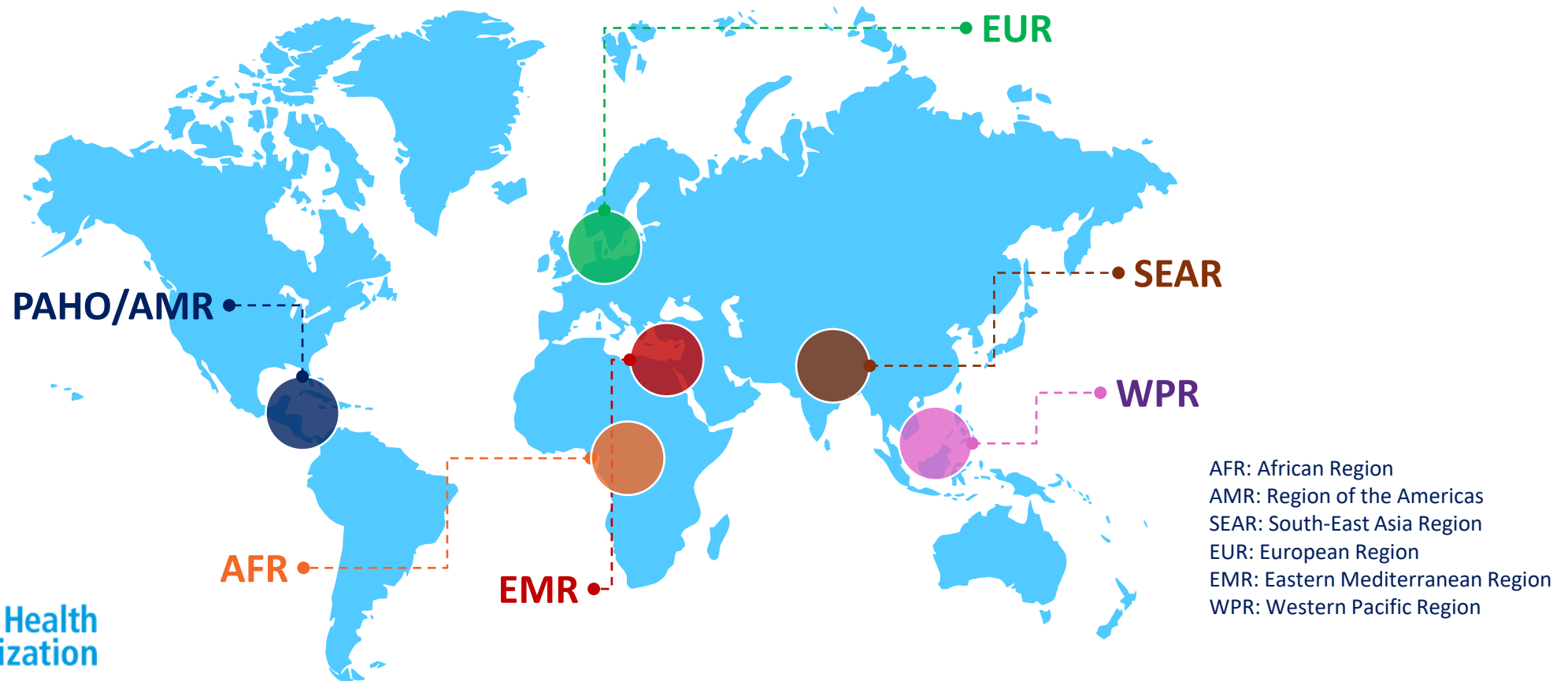


Ecosystem assessment for quality and sustainable local production



Increasing demand for capacity building from Member States

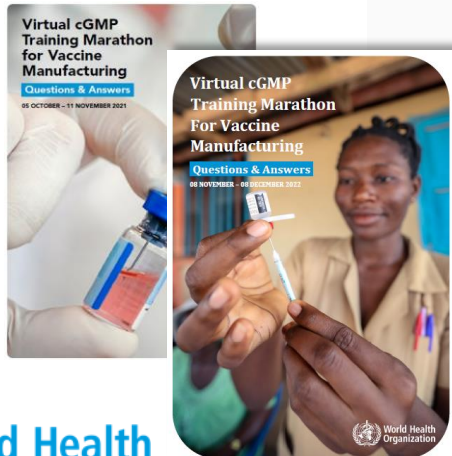
Since 2020, over 3,500 from manufacturers, regulators & government have been trained in **Virtual cGMP Training Marathons** with progressively in-depth and advanced GMP concepts and building the understanding of current GMP standards & requirements to ensure quality



Comprehensive approach toward capacity building to ensure quality

Virtual cGMP Training Marathon for Vaccine Manufacturing Q&A booklets

Over 500 questions from manufacturers & regulators around the world on key GMP topics for vaccine manufacturing



Q&A Booklets are published and available at LPA website



Virtual workshop on Vaccine CTD/CMC Requirements for WHO PQ/EUL (Jun 2022)

Poor quality vaccine dossiers delay the review processes and market entry
A global event to improve understanding of vaccine quality and dossier requirements and improve the quality of dossiers to facilitate the review and hasten attainment of PQ/EUL

Countries were increasing efforts to strengthen local production of IVDs, particularly for COVID-19



"The webinar was very informative and supportive for especially IVD manufacturers. I suggest doing more events on a similar topic."

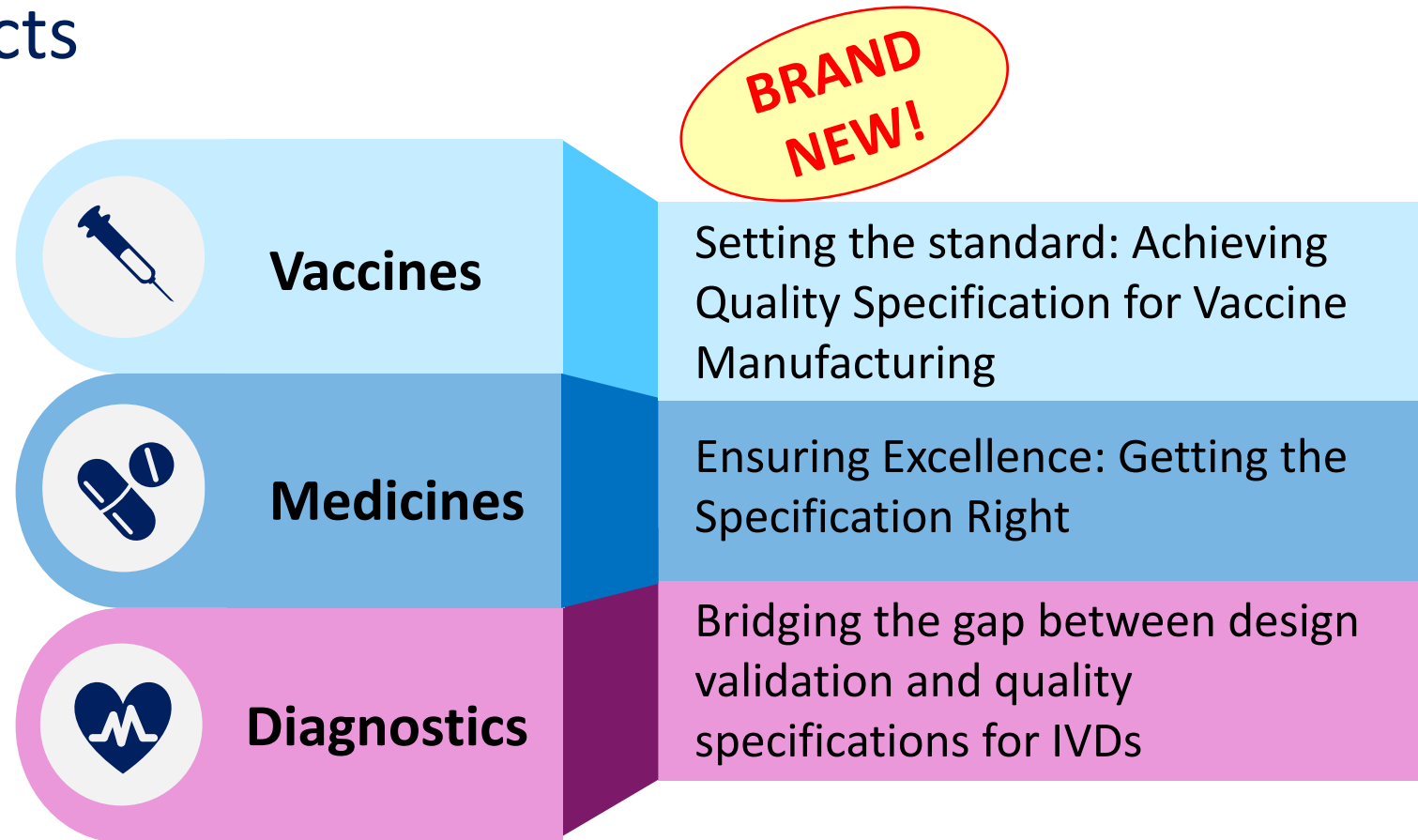
– IVD manufacturer, Turkey

Week of Quality: on the origin of specifications for strengthening the quality of health products

Week-long programme focused on establishing quality specifications

It brings forth quality requirements and expectations described in WHO/international guidelines to:

- build understanding of quality & specification
- improve compliance
- ensure quality



Week of Quality will be from 12-16 June 2023

Online pre-registration will be open soon for manufacturers and regulators with priority given to LMICs

PQ/EUL-related specialized technical assistance (TA) is another mechanism to build capacity to achieve quality and sustainability

Manufacturers

Facility:

- **QMS audit** and/or **mock GMP inspection** pre-WHO PQ
- Development of **CAPA** plan, including root cause analysis

Product:

- **Product-related** issues
- **Product dossier** to be submitted to WHO PQ
- Selection of appropriate products for WHO PQ

Training workshops to build capacity on specific topics requested by manufacturers, e.g. Virtual cGMP Training Marathon, on-site hands-on training

Contract Research Organizations

- **QMS audit** of facility
- Support for **GCP compliance**
- **Assistance with required documentation** for the FPP PQ dossier
- Review of **analytical methods** that would be used to generate data in the clinical/BE study
- **Audit of a completed study** by the CRO that is similar to the study to be done for the FPP being submitted to WHO PQ

PQ/EUL-related specialized TA for priority IVDs

Some examples of IVDs eligible for WHO PQ/EUL:

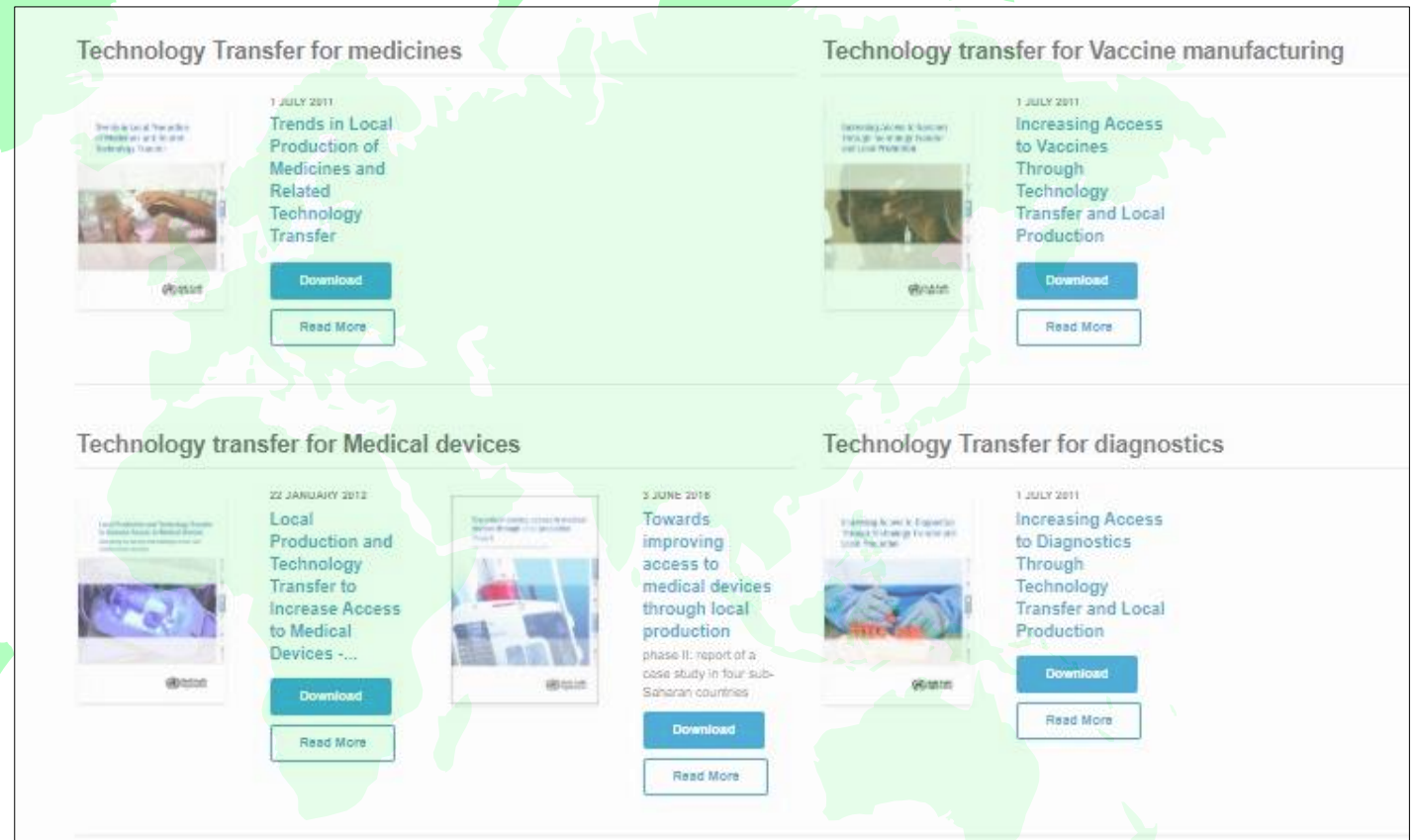
Technology	Disease
Rapid diagnostic test (RDT)	HIV-1/HIV-2 (diagnosis, self-testing), hepatitis B & C, malaria, cholera, syphilis
Nucleic acid test (NAT)	HIV-1/HIV-2 (diagnosis), hepatitis C, human papilloma virus (HPV), TB

Full list of eligible IVDs is here: <https://extranet.who.int/pqweb/vitro-diagnostics/eligibility>

Global resources and technical products on local production and technology transfer

Updated WHO Guidelines on Technology Transfer in Pharmaceutical Manufacturing

WHO Technical Report Series No. 1044 (2022)



Thank you

For more information and updates:

 localproduction@who.int

 [LPA_Worldwide](https://twitter.com/LPA_Worldwide)