

# **WORLD LOCAL PRODUCTION FORUM**

Enhancing access to medicines and other health technologies

Report of the First WLPF  
21-25 June 2021





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# Abbreviations

AI: artificial intelligence

COVID-19: 2019 coronavirus disease

DFIs: development finance institutions

EUA: Emergency Use Authorization

GMP: good manufacturing practices

LMICs: low- and middle-income countries

NRA: National Regulatory Authority

PPE: personal protective equipment

R&D: Research and Development

WHA: World Health Assembly

WLPF: World Local Production Forum

# Introduction

The *World Local Production Forum: Enhancing access to medicines and other health technologies* (WLPF) brings the global community – foremost government leaders, industry associations, technology experts and innovators, civil society, the international community, and other stakeholders – together under the auspices of WHO to shape the development of local production and highlight the challenges and opportunities for the sector for public health impact.

For over two decades, there has been an increasing emphasis on the importance of local production and related technology transfer in the context of promoting equitable access to medicines and other health technologies. Many countries, particularly low- and middle-income countries (LMICs), are viewing local production as a strategy to improve timely access and safeguard health security; however, existing challenges remain, and new challenges have emerged. In the face of the current COVID-19 pandemic, global manufacturing capacity has been shown to be insufficient to meet global health needs, and diversifying manufacturing of health products geographically to complement existing production chains could contribute to addressing this issue.

This report summarizes the first World Local Production Forum which was held virtually from 21-25 June 2021. The Forum brought together over 70 speakers and panellists and was attended by delegates from over 100 countries, industry associations, finance providers, civil society groups, UN agencies and international partners. Topics that are key in promoting sustainable local production in the current COVID-19 situation and beyond were explored and discussed more deeply in the Forum: partnerships and cooperation business ecosystem, regulatory systems, licensing and technology transfer, financing, vaccines, and innovation, artificial intelligence (AI) and the digital revolution. The agenda of the first WLPF is available on the World Local Production Forum website.<sup>1</sup>

Looking ahead, the WLPF will provide an ongoing platform to drive efforts to support and strengthen local production of health products in low- and middle-income countries, with support from the Local Production and Assistance Unit, WHO, as the WLPF Secretariat.

On the closing day of the first World Local Production Forum, it was announced that The Netherlands would be the hosting country of the next Forum. This secures it as a long-term mechanism to promote dialogue and decision-making to strengthen local manufacturing capacity and move towards the shared goal of universal access to health technologies.

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<sup>1</sup> The WLPF website URL is: <https://www.who.int/initiatives/world-local-production-forum>.

# Opening remarks, and Plenary Session: Accelerating local production through partnerships and cooperation

## Key messages

- World leaders and heads of agencies resonated the local production agenda and the timely World Local Production Forum, especially in light of the current COVID-19 pandemic
- Collaboration and sustained collective actions supported by an effective governance mechanism are required to generate a synergized and coordinated approach in strengthening local production to improve access
- Regional approaches (e.g. regional manufacturing hub, pooled procurement) to address regulation, financing, skills development, infrastructure, scientific collaboration, fragmented local markets, the resilience of supply chain, etc. are important in the context of local production
- Sufficient resources need to be mobilized and allocated in promoting local production

The World Local Production Forum (WLPF) is a new WHO initiative focused on improving access to quality, safe and effective medicines. Benefits include strengthening health security as well as socioeconomic development through job creation, market development and boosting of research and development. Alongside this, there is an understanding that Member States must meet standards of quality, safety and effectiveness and that the local production capacity that is created and supported needs to be sustainable.

The COVID-19 pandemic has exposed the dangers of concentrating production capacity in just a few countries or regions and is a contributory factor in the uneven roll out of vaccines, personal protective equipment (PPE) and other essential medicines and health products during the current pandemic. Currently, ten countries are accountable for COVID-19 vaccine production – an example of the centralized of production capacity that exists today.

It was noted that a defining mark of the pandemic is the general lack of sharing of data and information, vaccines, PPE and other life-saving tools, with inequality fuelling a two-track

pandemic and the consequences of a fragile global supply system becoming clear. Those countries dependent on imports for the majority of their health products were particularly exposed – a factor which has heightened the pressing need to build and diversify local production capacity geographically.

Numerous speakers recognized that the WLPF has come at a timely moment, helping to strengthen production capacity where it exists and building it where it is lacking. It is understood that this process requires long term commitment from all stakeholders, leadership from governments, and collaboration across countries, companies, finance institutions and industrial development.

Political will and a change in mindset are required, with the landmark resolution on strengthening local production being adopted at the Seventy-fourth World Health Assembly, with co-sponsorship by over 100 countries, a sign that this is becoming ever more widely recognized and supported.

Regional hubs and the importance of the regional perspective were highlighted by a number of speakers, with the advantages brought by, for example, defragmenting markets and potentially generating economies of scale. It



is also important to remove trading restrictions and facilitate global flow of trade, which benefits supply chains and facilitates better market access for local manufacturers. The importance of collaboration was also brought to the attention of the G7 summit a few weeks ago, with countries encouraged to share technology and know-how.

There was also wide appreciation of the clear and crucial requirement for effective coordination and collaboration across multiple elements related to strengthening of the health products industry, especially when considering the challenges and needs in LMIC. Therefore, holistic and collaborative solutions need to be developed, with the goal of ensuring that sustainable local production is successfully developed. Key areas of focus include access to

affordable finance and transfer of technology and know-how, whilst at the national level, public health and industrial policies need to be harmonized.

It is also important to synergize efforts and avoid unnecessary duplication, whilst at the national level, effective government leadership includes development of dedicated and effective coordination mechanisms, given the wide number of stakeholders involved. Other recognized elements are the need to invest in skills development, strengthen regulatory frameworks and capacities, and provide financial incentives to stimulate and encourage investment in the sector. The role of civil society was also recognized, in particular concerning distribution and safe use of products.

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## Session Speakers

### Chairs

- **Mariângela Simão**, Assistant Director General, Access to Medicines and Health Products, WHO
- **Soumya Swaminathan**, Chief Scientist, WHO

### Speakers (in speaking order)

- **Tedros Adhanom Ghebreyesus**, Director General, WHO
- **Ngozi Okonjo-Iweala**, Director General, WTO
- **Li Yong**, Director General, UNIDO
- **H.E. Lia Tadesse**, Minister of Health, Ethiopia
- **Jutta Urpilainen**, Commissioner for International Partnerships, European Commission
- **Henrietta Fore**, Executive Director, UNICEF
- **Sandile Buthelezi**, Director General of National Department of Health, South Africa
- **H.E. Budi Gunadi Sadikin**, Minister of Health, Indonesia (represented by Dante Saksono Harbuwono)
- **Isabelle Durant**, Acting Secretary General, UNCTAD
- **H.E. Marco Pontes**, Minister of Science and Technology, Brazil
- **H.E. Hala Zayed**, Minister for Health and Population, Egypt

# Session 1: Building the business eco-system for local production

## Key messages

- Long-term government commitment and support for local production are critical to ensure sustained human capital development, financing, regulatory system strengthening and compliance with international quality standards, among others
- With public health as the driver, policies among different ministries should be coherent with shared goals to promote local production and benefit public health needs
- A concerted effort based on multi-stakeholder collaboration, with government support, is critical for market information to be available and accessible for sustainable local production

It is widely recognized that a number of factors need to be addressed in parallel in order to develop a business ecosystem for local production. Without this, weak ecosystems result in many barriers facing manufacturers wishing to produce quality assured products, which results in loss of quality and competitiveness over the long term. These factors include, but are not limited to:

- Policy coherence among ministries
- A robust regulatory system
- Affordable financing
- A range of time-limited incentives
- Availability of a skilled workforce
- Market access

The start point to developing an enabling environment is provision of long term government commitment and support. Alongside this, coherent policies need to be developed across different ministries, recognizing that these ministries may have different policy goals.

Examples within LMICs can be found where there was a clear long-term government strategy to prioritize the sector, with policies issued and courses of action taken which led to the generation of a strong manufacturing base. These steps were often taken well in advance of the COVID-19 pandemic, but the current

situation can be viewed as a wakeup call to address the challenges facing health product manufacturers in other LMICs and develop a diversified manufacturing base geographically.

Demonstrable, long-term government commitment also encourages investors as it indicates the prioritization of the sector and can reduce investors' risk perception. Examples of such commitment which have been employed in LMICs include setting in place the right regulatory framework, continued budget allocation and support for research and development, as well as public sector participation in basic research, financing and infrastructure development.

Continuous improvement and reform is also necessary, given the need to ensure that government policies remain relevant over the long term and adapt to changing environments and requirements.

Also of importance is consideration of developing strong and harmonized regional markets, which offer market sizes supporting development of sustainable production capacity. This is especially important where countries do not have individual market sizes large enough to support a diverse and sustained local manufacturing base when looking at a territory-by-territory basis. In order to achieve these

regional markets, harmonization of the regulatory and political framework is a key consideration. This also leads to increased opportunities for pooled procurement, offering the potential for smaller economies to secure better pricing for their health products and offering attractive markets for locally based manufacturers.

Market access and shaping is another key facet of a supportive business ecosystem. Incentives, such as volume guarantees, can support the development of strong business cases and in so doing, support the investment case for expansion of manufacturing capacity and upgrading projects. In this way, companies are better positioned to attract the capital required to invest in long-term development projects. Therefore, demonstration of concrete demand and market assurance can be seen as a foundation for the local production case. This

supports development of well-organized and well-coordinated arrangements with local stakeholders – both public and private – which collectively represent the local level ecosystem.

Another component which supports the generation of a supportive environment for local manufacturing, and is often an issue, is the ability to access comprehensive market information. In some LMIC countries and regions this is a particular problem. The lack of a comprehensive and transparent set of market data has multiple negative consequences for local producers: they cannot take advantage of local market opportunities if comprehensive and reliable data is not available. Investors and potential product and technology partners can be dissuaded if they are not able to assess the regional and national health product needs and therefore understand the market growth opportunities that exist.

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## Session Speakers and Panellists

### Chairs

- **H.E. Xolelwa Mlumbi-Peter**, Ambassador to the WTO, Permanent Mission of South Africa to the United Nations Office at Geneva and other International Organizations in Switzerland
- **Hanne Bak Pedersen**, Deputy Director Supply Programme, UNICEF

### Setting the scene

- **Emmanuel Mujuru**, Chairperson, Federation of African Pharmaceutical Manufacturers Associations

### Panellists (in speaking order)

- **Julieta Loustau**, Undersecretary of Industry, Ministry of Productive Development, Argentina
- **Rafael Andres Díaz-Granados**, Executive Director, Latin American Federation of the Pharmaceutical Industry (FIFARMA)
- **Stephen Karingi**, Director, Regional Integration and Trade Division, UNECA
- **James Droop**, Senior Advisor, Foreign, Commonwealth & Development Office, United Kingdom of Great Britain and Northern Ireland
- **Rungpetch Sakulbumrungsil**, Dean, Faculty of Pharmaceutical Sciences, Chulalongkorn University, on behalf of the Government of Thailand
- **Jicui Dong**, Unit Head, Local Production and Assistance Unit, WHO

## Session 2: Getting regulatory systems pandemic ready

### Key messages

- A strong regulatory system is an important component of the business ecosystem of local production
- Strengthening local production should be in parallel with strengthening local regulatory capacity as local production without quality assurance does not deliver public health benefits
- Regulatory harmonization and reliance through collaboration and cooperation can help regulatory authorities use limited resources effectively and reduce duplicative regulatory processes
- Communication, information sharing and strengthening of networks are critical to agile regulatory systems and pandemic preparedness

One of the central themes to the discussion on getting regulatory systems ready for pandemics was the importance of collaboration and cooperation.

Building a regulatory system prepared for pandemic events requires strengthening and preparation before such situations arise, and benefits from a focus on three aspects: developing efficient processes, converging standards, and developing reliance on the regulatory process. During the pandemic itself, key efforts from WHO included streamlining the clinical development process and continued provision of scientific advice.

Panellists acknowledged the need for strong governance in order to develop and maintain strong regulatory systems and the benefit of reduced duplication through greater collaboration.

The COVID-19 pandemic revealed two types of problems associated with regulatory systems: on the clinical development side, the many small, non-informative trials taking place worldwide burdened the regulators; on the manufacturing side, a particular issue was caused by regulators working independently from each other, which slow down the approval of changes from manufacturers (due to the fact that a product or manufacturing change needs to be approved in

each country before wide implementation). This second issue again points towards the importance of regulatory cooperation and harmonization being an essential component to speeding up the process and avoiding the situation of multiple dossiers.

Panellists also described particular developments in their countries which facilitated the response to the COVID-19 pandemic. One example was the importance of developing a functioning Emergency Use Authorization (EUA) system, which can be leveraged upon declaration of a public health emergency. Again, such systems need to be developed outside of pandemic situations, so that they are ready and available when required.

Another requirement is to develop a proactive communication strategy, ensuring that clear, actionable and credible information can be efficiently distributed to national stakeholders and the general public, which builds confidence amongst the population regarding treatments and also vaccination policy.

Additionally, one approach to ensuring collaboration when travel is severely restricted is to develop and utilise a strong virtual collaboration network amongst regulators and other bodies including WHO – this has been built up during the pandemic and proven effective.

An approach to encourage research and development of new medicines and vaccines, in countries with a substantial pharmaceutical industry presence, is to ensure that the NRA quickly issues guidance concerning technical information and the regulatory pathway. In this way, the National Regulatory Authority (NRA) facilitates new product development, and this can be used alongside an expedited review and approval process for products already approved and marketed in other countries, to ensure that medicines and vaccines can be efficiently brought to market with minimal time delays.

The COVID-19 pandemic has shown that regulatory systems can support agility, cooperation and preparedness, providing a firm base to further strengthen the processes and networks, and improve the necessary systems ahead of future events. In this regard, increased information sharing is a key aspect to enhance. One area which came under particular pressure, and where further work is necessary, is the

global supply chain. It was understood that this can only be strengthened through strong regulatory systems.

The link between the regulator and policymakers was also highlighted. An important point in this regard is that Government leaders and other policymakers need to recognise and welcome the fact that strong regulatory systems benefit public health. A strong regulator is a fundamental component of assuring access to quality medical products for the public and also benefits local manufacturers by facilitating access to foreign markets and international procurement tenders. Equally, without adequate regulatory systems, there is not the strong, supportive local manufacturing ecosystem for local medicines producers. This also means that the National Regulatory Authority needs to be well-resourced from multiple standpoints: financial, scientific and administrative, as well as having a strong legal framework and effective enforcement powers.

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## Session Speakers and Panellists

### Chairs

- **Mojisola Adeyeye**, Director General, National Agency for Food and Drug Administration, Nigeria
- **Murray Lumpkin**, Deputy Director, Bill and Melinda Gates Foundation

### Setting the scene

- **Rogério Gaspar**, Director, Regulation and Prequalification Department, WHO

### Panellists (in speaking order)

- **Emer Cooke**, Executive Director, European Medicines Agency and Chair, International Coalition of Medicines Regulatory Authorities
- **H.E. Kim Ganglip**, Minister, Ministry of Food and Drug Safety, Republic of Korea
- **Janet Woodcock**, Acting Commissioner, US Food and Drug Administration
- **Delese Mimi Darko**, Chief Executive Officer, Ghana Food and Drug Administration
- **Rubina Bose**, Deputy Drugs Controller, Central Drugs Standard Control Organization, India
- **Margareth Ndomondo-Sigonda**, Head, African Union Development Agency-New Partnership For Africa's Development

## Session 3: Unlocking global manufacturing potential through licensing and technology transfer

### Key messages

- Sharing of intellectual property, know-how, trade secrets, etc. and voluntary licensing and effective technology transfer are essential to facilitate rapid scale-up of production capacity
- An enabling environment for technology transfer includes good governance, skilled workforce, access to market information and viable national/regional markets, among others
- The capacity to receive and absorb the transferred technology should be assessed to produce quality-assured products and to support a sound business plan

The COVID-19 pandemic has highlighted the need to scale and diversify manufacture of key products, especially those in short supply, across the globe.

In this way, access can be improved especially for LMIC populations - as is the urgent need now for COVID-19 vaccines. The current crisis clearly shows that relying on supply from just a few companies only provides limited access of products to LMICs, in particular. This means that technology transfer and licensing are of prime importance in the move to towards equitable access to essential health products.

Technology transfer involves not only access to technology but also access to essential know-how, data, processes, intellectual property, trade secrets and development of capabilities to successfully absorb the technology and product in the recipient manufacturer. Private and public collaborations are often central to the facilitation of technology transfer.

Provision of nonexclusive licenses can be an important strategy as, by maintaining a range of generics manufacturers, there is competition which ensures that prices are driven down, thus improving affordability and access to these products. Regulatory and technical support should also be provided to the technology recipients.

When considering licensing of products and technology, a number of factors are important in the development of an environment conducive to technology transfer. These include:

- Political stability and transparent governments
- Appropriate structural and capital infrastructure
- Good access to market information
- Adherence to high regulatory standards
- Provision of skilled human capital
- Clear economic development priorities
- Viable local and/or regional markets
- Access to trusted partners

Capacity building is clearly a vital element in the development of recipients capable of absorbing a product, process or technology. Providing training in the area of production processes also help as they indicate the level of commitment required within a potential recipient, in terms of both training and technology requirements.

One particular challenge highlighted was the need to objectively assess local production facilities in low resource environments, and it was indicated that assistance is often still required to assist a potential recipient with its needs assessment. This includes a market analysis and comprehensive understanding of the particular production process. This is

especially important in the area of vaccines and biologics technology transfer.

Development of production capability in entities focused on facilitating technology transfer can be very useful, where this accelerates the translation of innovations through product development. Importantly, by investing and developing this capability and expertise during non-pandemic times it can be quickly applied when pandemics occur. So, this again points towards the need to invest in developing capacity – in this case supporting technology transfer and translation of innovation – during ‘normal’ times which can then be quickly applied during pandemics and other health emergencies.

When considering sustainability of manufacturing capacity, it is valuable if technology transfer is viewed as a sustained element and not just a one-off event. Therefore, if recipients can build long term relationships with providers this supports successful LMIC manufacturing and there is a holistic and ongoing relationship between provider and recipient, with sustained technology transfer and support over a number of years.

When considering the generation of viable markets, it was again noted there is a need to consider the regional and not just the national dimension. This supports sustainable business models and often offers a more attractive proposition to the technology or product provider, improving the potential that it will look favourably on licensing opportunities to local manufacturers within the region concerned.

Concluding elements to bear in mind are that technology transfer and licensing should be considered across the range of health products areas: there may be a focus now on vaccines given the COVID-19 pandemic but in the longer term, diagnostics and therapeutics should remain firmly on the agenda. There is also a clear importance on the multilateral systems and partnerships with many international entities playing a role in supporting and enhancing technology transfer. Equally, governments need to commit to supporting technology transfer by providing a conducive environment and developing a broad range of supporting strategies, adapted to country contexts.

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## Session Speakers and Panellists

### Chairs

- **Erika Martínez Liévano**, Minister, Permanent Mission of Mexico to the United Nations Office and other International Organizations at Geneva
- **Mandeep Dhaliwal**, Director, HIV, Health and Development Group, UNDP

### Setting the scene

- **Mariângela Simão**, Assistant Director General, Access to Medicines and Health Products, WHO
- **Charles Gore**, Executive Director, Medicines Patent Pool

### Panellists (in speaking order)

- **Greg Perry**, Assistant Director General, International Federation of Pharmaceutical Manufacturers and Associations
- **Lawrence Banks**, Director General, International Centre for Genetic Engineering and Biotechnology
- **Sidney Yee**, Chief Executive Officer, Diagnostics Development Hub, A\*STAR, Singapore
- **Nevin Bradford**, Chief Executive Officer, Cipla Quality Chemical Industries Limited, Uganda
- **Roger Kampf**, Counsellor, World Trade Organization

## Session 4: Expanding access to affordable capital

### Key messages

- Governments need to elevate the importance of the public health agenda and public health security to enable supportive policies to promote a conducive financial environment
- Strong, viable and bankable business cases, which offer long-term commercial sustainability and address local/regional health needs, are crucial to attract financing and investment
- Cooperation and coordination among development banks, donors and other finance providers are essential to share risks

Access to finance has long been an ongoing challenge facing LMIC manufacturers, in particular in Africa.

Perspectives amongst key development finance institutions (DFIs) however are that the pandemic has brought a new focus and understanding on the need to address the issue comprehensively, above and beyond efforts over the last few decades which, arguably, have not led to the required improvements in access to capital. In effect, this current focus on ensuring provision of affordable capital can be viewed as an opportunity, given the wide awareness at present of the need to develop local production capacity, as well as understanding of the need to localize financial institutions to support projects and greater willingness of international donors to facilitate financial support.

Over the past 18 months, there has been clear realization of the unsustainable concentration of global supply chains in medicines, vaccines and other health products. Another key highlighted trend is government support in various forms including investment finance, provision of grants and market interventions such as advance purchase commitments – whilst these interventions have often been in developed countries they demonstrate potential routes to follow for LMICs. Collectively, these trends indicate that blended finance and government support are two important aspects impacting on an improvement in finance provision for LMIC manufacturers.

The spotlight is very much falling on key DFIs who can play a larger role. In parallel, there is greater understanding of the need for public and private sectors to engage in greater and more effective collaboration – and in this regard DFIs have a key role to play given to their mandates and ability to balance public and private interests. Of note, the fact that DFI's are familiar with the particular challenges faced in LMICs means that they are well placed to support other development aspects such as capacity building and project management.

The unprecedented level of collaboration which has developed to tackle the pandemic – involving a wide variety of bodies from the public and private sector and including governments, health and finance institutions – can be further leveraged to develop access to capital solutions. There does however, need to be an ongoing focus on expanding production in a commercially viable and sustainable way and strong business cases must be developed. A multifocal approach is required with due consideration on areas including the legal and regulatory frameworks, technology transfer capacity and market shaping.

Concessionary finance is recognized as playing a key role in production scale-up, in combination with government and private sector involvement and with development of innovative financial instruments. This also requires a reshaping of risk appetite.



The wider benefits of local production need to be born in mind when developing solutions, including security and reliability of supply, improving affordability and also the economic and social benefits including job creation, as well as improving the balance of payments of LMICs.

DFI's on the panel indicated their willingness to take greater and more active roles in financing the sector – both directly and through support of financial instruments – but it was also noted that until recently, there was a lack of consensus regarding the value of local production and relatively speaking a low level of actual financing being provided by development banks into actual manufacturers. Historically speaking, there was a degree of focus on financing procurement rather than production.

Taking all of these dynamics and factors into account, the panel reiterated the importance of developing sustainable business models that represent attractive investment opportunities, and the need for greater public-private collaboration to drive meaningful change and improve access to capital.

A key concluding message is that governments should take responsibility for their role in the creation of a conducive investment environment, including in particular shifting priorities such that public health is elevated in importance, and recognizing that health security is in many ways as important as defence security. By doing this, policy changes can be made which support the investment landscape, with aspects such as subsidization, price preferences and advance purchase commitment representing some of the potential government-driven measures to attract investment.

The opportunity to generate an improved financing environment therefore exists, especially given the spotlight shone on local production by COVID-19. By continued collaboration involving industry and the private sector, UN bodies and other agencies, DFIs and other finance institutions, national, regional and continental bodies and other stakeholders, the objectives can be met.

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## Session Speakers and Panellists

### Chairs

- **James Zhan**, Director, Investment and Enterprise, UNCTAD
- **Jaime Atienza Azcona**, Chief, Health Financing, UNAIDS

### Setting the scene

- **Tomasz Telma**, Senior Director and Head of Manufacturing, Agriculture and Services Department, International Finance Corporation, World Bank

### Panellists (in speaking order)

- **Birgit Pickel**, Deputy Director General Global Health, Pandemic Prevention and One Health, Federal Ministry for Economic Cooperation and Development (BMZ), Germany
- **Abdu Mukhtar**, Director, African Development Bank
- **Patrick Osewe**, Director, Asian Development Bank
- **Maria Shaw-Barragan**, Director, European Investment Bank
- **Ammar Abdo Ahmed**, Lead Global Health Specialist, Islamic Development Bank
- **Fred Abbott**, Edward Ball Eminent Scholar Professor, Florida State University

## Session 5: Building capacity to enhance access to vaccines and biologics for COVID-19 and beyond

### Key messages

- Diversification in technology, product and location is important for pandemic preparedness and sustainability; the hub and spoke model could deliver high impact to the diversification with efficiency and address manufacturers' training needs and skills development
- Development of skilled human capital is a vital component. Skills and capacity building for manufacturers and regulators are needed to ensure quality and timely market entry. Training in particular areas includes technology transfer, GMP, process development, etc.
- Innovative technologies could potentially reduce the time and cost for establishing vaccine manufacturing. It could also generate production flexibility across vaccines and biologics and support long term commercial viability and sustained capacity

The COVID-19 pandemic has highlighted the need to ensure equitable access to vaccines as well as other health products. A key opening point was that innovation without equitable access reinforces inequality and does not ensure collective progress.

It is also important to recognize the response of the vaccine industry to date, with close to 2.8bn doses of COVID-19 vaccines generated in under 5 months from an industry with a global capacity of 5.5bn annual doses. This has been made possible through unprecedented collaboration and cooperation.

Manufacturing hubs are recognized as a key strategy to build vaccine manufacturing capacity in LMICs, with the aim being that groups can learn the processes and understand the technologies housed in the hub, then take this knowledge back to their countries. Use of the hub for other vaccines between pandemics contributes to sustainability.

Work is currently being conducted to map current manufacturing capacity and capability in several regions, especially looking at LMICs.

The COVAX manufacturing taskforce is recognized as a key collaboration between a number of partners including CEPI, WHO, GAVI, UNICEF and the Bill and Melinda Gates

Foundation. Its core objective is to focus on COVID-19 vaccine manufacture and access, but will also mitigate unintended negative impacts on other vaccines and health products brought about by the COVID-19 vaccine manufacturing scale-up. Its deliverables include facilitating a global trade process for free movement of materials, creating critical partnerships and matchmaking, supporting the establishment and upgrading of manufacturing facilities (in LMICs in particular), as well as stimulating public and private sector investment and collaborations. Key challenges to be addressed include policy requirements, building regulatory capacity, developing sustained and resilient regional supply chains and the critical need to ensure a capable workforce is created, including upskilling and enlarging the current HR pool.

The critical importance of partnerships and collaborations was repeatedly highlighted, including not just technology providers and recipients but also funders, government, regulatory bodies and other key stakeholders.

Experiences of LMIC manufacturers are important to bear in mind and it was noted that the technical capacity to absorb technology is proportional to R&D know-how and skills, so this should not be ignored. It is important to

ensure a diversified approach within a continent in terms of both processes and technologies, whilst also considering on a regional basis both specific vaccines required as well as routine vaccination needs. Building trust and confidence is seen as being key to developing and sustaining the partnerships which are a central component to progress, building sustainable long-term manufacturing capacity, including ensuring successful technology transfer. Trust is built up through consistently delivering over time, and long-term commitment is necessary from the political through to the operational level.

The role of academia was also noted and again collaboration was a central theme, involving additional groups including industry and government as well as wider networks, with the potential for academia to support development of technologies that speed up process development and aim to lower cost as well as fostering long term collaborations supporting training programs.

When considering the importance of generating sustained capacity, it was noted that regional solutions are key as these generate viable economies of scale. Four overall factors which were noted are: a robust business plan, a large enough market for the vaccines to be manufactured, the right product mix to ensure sustainability beyond the current pandemic, and trained staff. Alongside this, capacity building of the national regulatory authorities is required.

New and innovative technologies can play a key role in the generation of sustained capacity, especially when they can reduce the facility footprint and consequently capital expenditure as well as reduce the manual processing steps required. A final area which was considered was that of biologics, which both benefit from the potential for new, flexible and automated manufacturing systems which can reduce their cost of manufacture, as well as contributing to sustainability of capacity if they can be produced within vaccine manufacturing facilities, given the common production processes involved.

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## Session Speakers and Panellists

### Chairs

- **Stéphanie Seydoux**, Ambassador for Global Health, France
- **Rana Hajjeh**, Director, Programme Management, WHO EMRO

### Setting the scene

- **Soumya Swaminathan**, Chief Scientist, WHO
- **Matthew Downham**, Sustainable Manufacturing Lead, Coalition for Epidemic Preparedness Innovations

### Panellists (in speaking order)

- **John Nkengasong**, Director, Africa Centres for Disease Control and Prevention (represented by Nicaise Ndembi)
- **Rajinder Suri**, Chief Executive Officer, Developing Countries Vaccine Manufacturers Network
- **Patrick Tippoo**, Executive Director, African Vaccine Manufacturing Initiative
- **Hans Schikan**, Special Envoy, Vaccine Production and Procurement, The Netherlands
- **Martina Micheletti**, Director, Vax-Hub
- **David Robinson**, Deputy Director, Bill and Melinda Gates Foundation
- **Jose Castillo**, Chief Technology Officer, Univercells
- **Tiago Rocca**, Manager, Butantan
- **Weining Meng**, Vice President, Sinovac
- **Meng Li**, Director, Emerging Biopharmaceutical Manufacturers Network
- **Friso Smit**, Chairman, Utrecht Centre for Affordable Biotherapeutics

## Session 6: Leveraging innovation, AI and the digital revolution in the health products industry

### Key messages

- Innovation can take place in technology, product development, manufacturing processes and business models
- LMICs can leverage on innovation and the digital revolution to strengthen capacity and deliver significant impacts on the production and distribution of health products
- Innovations in AI and the digital revolution can address specific challenges faced by LMICs related to improving quality, reducing the risk and cost of drug development, data management, analysis and sharing, production, supply chains

Artificial intelligence (AI), alongside machine learning and the wider digital revolution, potentially offers innovative approaches to address noise and bias as well as to simply address the limits of human cognitive performance – for example in analysis and decision-making. When considering the transfer of technologies to LMIC-based manufacturers, there is the potential for these tools and approaches to address particular challenges there, including supply chain limitations, good quality and quality management systems gaps, and improve sustainability through offering innovative solutions to cost increases associated with decentralized lower production volumes (as compared to economies of scale from centralized higher production volumes). AI and the digital revolution may also help to address the complexity in production which can also be a particular challenge when transferring technology to LMICs.

Another area where innovation can play a big role is in reducing the negative consequences of either cutting costs or reducing risk and having to balance these two aspects of production. In this way, security of supply can be improved without negatively affecting product consistency and quality as production is shifted in to LMICs and consequently becomes more decentralized.

A current example of the use of digital technologies and driving innovation is the use of a digital data management system to track and better understand the COVID-19 pandemic within LMIC areas. In this case, by connecting surveillance with healthcare management, including the application of AI as well, improved healthcare solutions could be brought to bear. Additionally, automated processing of COVID-19 testing significantly increases throughout, whilst genomic surveillance allows better identification and tracking of emerging variants.

There are also opportunities to significantly improve diagnostic development, and again the COVID-19 pandemic has accelerated the application of innovative approaches to product development in this field, which are expected to positively impact on other diseases beyond the pandemic. Technology innovation is occurring at both the basic research level as well as product design and manufacturing.

Digital tools are also connecting data sources and facilitating early warning systems, providing solutions to improve surveillance. Additionally, mobile apps are expanding data access and importantly improving connections between patients and providers, which allows diagnostic information to better inform meaningful action and decision making.

Another aspect at the delivery end of the healthcare chain is the development and application of clinical decision support tools, which can be AI enabled. These can empower healthcare workers in decentralized settings and allow less skilled individuals to be involved in more complex tasks and processes.

Along these lines, further application of AI and big data can lead to 'democratizing expertise', whereby AI and digital health products can enable patient care in developing country settings where healthcare provision is much more challenging. AI offers the potential to increase the capacity of lower level, less specialized practitioners to offer services that typically rely on highly trained individuals. For example, use of algorithms to examine skin lesions can improve skin cancer screening provision without a directly proportional need for dermatologists to provide this capacity increase.

On the manufacturing side, one innovation of note is the transfer of scalable manufacturing

processes from the semiconductor industry to improve, for example, manufacture of disposable diagnostic cartridges which significantly reduces their cost. Along similar lines, innovations in design and development of molecular tests are leading to much smaller and more portable systems.

When considering the creation of an enabling environment to foster innovation, and the relationship between innovation systems and production, important factors to develop include access to intellectual and social skills, alongside provision of financial and political capital, the necessary scientific and technical services and support through the right control, standards and regulatory authorities. There is also a need to ensure flow of people and knowledge.

Further demonstration of the potential of innovation and the digital revolution to impact LMICs has been provided recently, where variant strains of COVID-19 were identified in various countries.

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## Session Speakers and Panellists

### Chairs

- **Bernardo Calzadilla-Sarmiento**, Managing Director, UNIDO
- **Jacinta Wasike**, Director Corporate Services, Pharmacy and Poisons Board, Kenya

### Setting the scene

- **David Kaslow**, Chief Scientific Officer, PATH

### Panellists (in speaking order)

- **Marco Aurélio Krieger**, Vice President, FIOCRUZ, Brazil
- **Marta Fernandez Suarez**, Director, FIND
- **Gerald Voss**, Scientific Director, TuBerculosis Vaccine Initiative
- **Nicholson Price**, University of Michigan
- **George Patrinos**, University of Patras
- **Michael Kahn**, University of Stellenbosch
- **Dave Berry**, Lead, UK Centre for Process Innovation

## Session 7: WLPF Outcomes, and Closing Addresses

The key messages from each session of the Forum, starting with the opening remarks and plenary session and concluding with Session 6, were presented in the WLPF Outcomes session.

This was followed by presentation of three WLPF Recommendations which emerged over the five days of the Forum.

The key messages and recommendations were well received. Reflections were provided by a panel.

The panellists commented in particular on the high value of the WLPF and the importance of the initiative, especially in the context of the current global health situation and the clear and widely recognized need to ensure that there is equitable provision of vaccines, medicines and other essential health products to fight the COVID-19 pandemic across all countries, leaving none behind.

The Forum was seen as a very timely intervention and panellists expressed a desire for additional stakeholders to be present at future events.

Panellists also supported further collaboration, recognizing the crucial role this is playing in addressing the COVID-19 pandemic. Diversifying manufacturing capacity and increased resilience of supply were noted as core outcomes of further efforts to strengthen local production, whilst ensuring that standards and quality are not compromised.

It is understood that a long-term approach is necessary to develop the health product industries, and the power of trade, public procurement and targeted investment needs to be brought to bear to move towards the joint objectives.

There was also acknowledgement that it is equally important to ensure there is a commitment to strengthening local production alongside strengthening the national regulatory authority. This considers the fact the equitable access to health products also requires access to products meeting international quality, safety, efficacy and manufacturing standards. This needs to be recognized by policymakers and government leaders, since access to substandard or falsified products, or those of unassured quality, does not benefit the public health provision within a country, nor does it benefit the political or economic health of that country. Quality manufacturing standards need to be ensured over the long term. With this in mind, it was noted that maintenance of high standards over time can be challenging and therefore investment in the sector should take this into consideration. This also takes account of the need to have solid strategies to maintain the standards as they develop and evolve.

Panellists also noted the importance of the regional dimension, with regional markets representing a key driver for sustainable local production and encouraging development of a manufacturing sector which can respond to the unmet needs in that region.

The WLPF concluded with closing statements. It was recognized that regional and local production sites are required across the globe. This requires a range of elements to be addressed, including greater access to technology and knowledge transfer.

By addressing the many components required to strengthen local production, including strengthening supply chains, addressing regulatory issues and streamlining the ability for

manufacturers to respond, providing the capital to allow investments in manufacturers and ensuring generation of sustainable capacity, the world can be better prepared for future pandemic events.

In the closing of the WLPF, it was announced that The Netherlands will be the hosting country for the next World Local Production Forum.

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## Session Speakers and Panellists

### Chair

- **Rogério Gaspar**, Director, Regulation and Prequalification Department, WHO

### Key messages presentation

- **Jicui Dong**, WLPF Secretariat and Unit Head of Local Production and Assistance Unit, WHO

### Panel reflections on the key messages (in speaking order)

- **Bernardo Calzadilla-Sarmiento**, UNIDO
- **Murray Lumpkin**, Bill and Melinda Gates Foundation
- **Jacinta Wasike**, Pharmacy and Poisons Board, Kenya
- **Akthem Fourati**, UNICEF
- **Ermias Biadgleng**, UNCTAD
- **Ran Wei**, UNAIDS
- **Cecilia Oh**, UNDP

### Closing address

- **H.E. Hugo de Jonge**, Deputy Prime Minister and Minister of Health, Welfare and Sport, The Netherlands
- **Mariângela Simão**, Assistant Director General, Access to Medicines and Health Products, WHO

## WLPF Recommendations

### *Recommendation #1*

WHA resolution WHA74.6 brought a renewed vigour in promoting local production to improve access. All actors (Member States, industry, partners etc.) should capitalize on this new momentum and continue strategic, collective efforts and commitment in strengthening local production through building the business ecosystem, multi-stakeholder collaborations, capacity building and training, regional/global approaches, etc.

### *Recommendation #2*

Manufacturers are a significant actor in promoting local production. A mechanism should be explored to stimulate industry engagement in the WLPF and provide a platform to strengthen collaborations with, and within, the industry and harness opportunities for the diffusion of priority technologies to LMICs.

### *Recommendation #3*

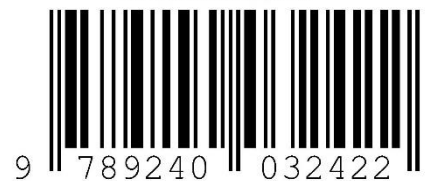
A strategic advisory group under the auspices of WHO and in collaboration with Member States and partners could be formed to address current and future global challenges and trends in local production and technology transfer.



**World Health  
Organization**

**Local Production & Assistance Unit  
Regulation and Prequalification Department  
Access to Medicines and Health Products Division**

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