

UNCTAD-WHO Global Webinar

Investment in quality local production to address supply bottlenecks related to the pandemic

23 April 2020

Meeting Report

UNCTAD and WHO on 23 April 2020 organized a webinar on investment in quality local production to address supply bottlenecks related to the Covid-19 pandemic and beyond. The event, which was attended by 127 participants online, was opened by James Zhan, Director of UNCTAD's Investment and Enterprise Division, and Emer Cooke, Director of WHO's Regulation and Prequalification Department. Both emphasized the importance and potential of local pharmaceutical production to respond to Covid-19-related supply bottlenecks through effective partnerships between low income country-based producers, foreign investors, host country governments and development partners.

Mr. Zhan outlined three challenges for the pharmaceutical sector, and more broadly for public health system:

- Tackling the vulnerability of the international production and supply chains;
- Mobilizing enough productive capacity to satisfy global demand for large volumes of urgently needed novel treatments, diagnostics and vaccines; and
- Improving the accessibility and affordability of badly needed medicines and equipment by poor people in low-income countries.

Mr. Zhan voiced the concern that in case of insufficient global manufacturing capacity for Covid-19-related products, low income countries could be left behind in the supply of essential treatments and vaccines. Investment in local production capacity can therefore enhance health security in these countries, as well as contribute to global manufacturing capacity. Mr. Zhan in this context emphasized the importance of partnerships for the upgrading of local capacity to ensure availability and affordability of Covid-19-related products for the poor.

Ms. Emer Cooke stated that Covid-19 is putting the spotlight on the role of local production of medical products, particularly Covid-19 related products, as a strategy to address shortages and ensure access. Creating an enabling business environment through coherent policies, regulatory system strengthening, building knowledge, skills and capacity, needs-based innovation and other factors are critical to ensure sustainable quality local production. Partnerships are essential in promoting local production and in combatting this pandemic. Covid-19 is giving a unique opportunity for all to come together as one against a common threat and to change the path for this and future pandemics and for sustainable health systems.

The webinar benefitted from the interventions by six experts from the pharmaceutical and vaccine industries, developing country policymakers and development partners (see Annex to this report). The discussants shared their views on the following interrelated questions:

1. What are domestic capacities of low-income country producers in respect of current Covid-19 candidates and vaccine production?
2. What kind of measures are necessary to scale up investment in domestic capacity to ensure quality and sustainability of production?
3. What is the role of development partners?

All discussants in their analyses agreed on the vulnerability of international supply chains and the importance of investment and partnerships to assist local producers in meeting WHO standards of quality, efficacy and safety. The **main points** highlighted during the discussion were the following:

- Despite past experience, policymakers have not learned certain lessons. During the last pandemics, the world had experienced similar supply side constraints and many governments had pledged to improve local capacity for the supply of vaccines. Yet Africa finds itself in the same situation now.
- Countries like Thailand have some important domestic capacity, but due to limited resources, they need to choose where to invest in quality upgrading: in active pharmaceutical ingredients, vaccines, or others. In the area of vaccines, local capacity is significant in Asian developing countries, but only minimal in Africa. In East Africa, there is local production capacity of essential medicines in oral solid, semi-solid, and liquid dosage forms. This can be extended to new Covid-19 candidate products under clinical studies. Local producers are open to strategic partnerships for related voluntary technology transfer, know-how and management of related intellectual property (IP). There are ongoing efforts in the East African Community (EAC) to address the gap in vaccine manufacturing capacity through public-private partnerships.
- The sustainability of existing business models to supply medicines needs to be re-examined considering the implication of concentration of suppliers in a few countries and the failure to build capacity where the need is.
- Disruption of supply is significant not only in the area of ready-to use health commodities but also concerns active pharmaceutical ingredients (APIs), which are necessary for local production. Even where supplies of APIs remain open, increased demand in Covid-19-related APIs have resulted in excessive prices that make related

production unsustainable. Moreover, there is also significant disruption of transportation and customs clearance of imported raw materials. Because of these developments, East African manufacturers are now utilising less than 50% of their capacity.

- There are remarkable efforts in regional harmonisation in the East African Community and ongoing work on harmonisation at the African continental level. The East African Community has taken a regional approach to investment and partnerships in production and supply. Many countries have reformed their laws, but effective incentives are still missing for producers to upgrade their capacity to meet quality standards. In this context, the regional industry association calls *inter alia* for preferential procurement, tax exemptions on all excipients and packaging material, and improved links between research and production.
- Manufacturers, such as in Africa and Asia, are committed to quality and are keen to advance their GMP and quality assurance standards toward adoption of international standards with support from WHO and partners.
- The national regulatory system also plays an important role in ensuring quality. Strengthening the regulatory system should be concurrent with strengthening manufacturing capacity.
- The global pharmaceutical industry has responded rapidly to the Covid-19 crisis. There is an unprecedented global joint effort of R&D, sharing of scientific knowledge and technological resources.

On the **way forward**, discussants emphasized the following needs:

- International organizations like UNCTAD and WHO should engage further in match making between technology providers and potential recipients, in facilitating technology partnerships, and in building capacity in licensing of intellectual property rights.
- Partnerships with WHO to assist holistically in strengthening manufacturing and regulatory capacities and in procuring locally produced essential products, and to join in the global Covid-19 response efforts.
- International cooperation needs to be forward looking and focusing on building strategic production and supply capacity of quality-assured products in different regions.
- Governments should re-examine the effectiveness of existing incentives. They should consider increased domestic production capacity as an insurance for the next pandemic. Advance purchase commitments could be useful to kick-start manufacturing new products, such as vaccines, where the market is unattractive and companies need guaranteed markets. Sustainability of local production could be achieved by governments supporting procurement from local producers who achieve and maintain production and supply of quality-assured vaccines and other products. Such procurement policies should aim at a time span of five to ten years and can include foreign investors that assist in local production. Development partners and international organizations should support these efforts.

In their closing remarks, the moderators Jicui Dong, who leads WHO's Local Production & Assistance Unit, and Christoph Spennemann, in charge of UNCTAD's Intellectual Property Unit, emphasized further cooperation with stakeholders. WHO and UNCTAD will intensify their joint efforts to promote quality local production in low income countries, aiming at improving the accessibility and affordability of essential medical products for the poor.

Annex: Webinar Discussants

- Skhumbuzo Ngozwana, Board Member, Federation of African Pharmaceutical Manufacturers Association (FAPMA)
- Morena Makhoana on behalf of the Developing Countries Vaccine Manufacturers Network (DCVMN)
- Jennifer Gache, Industrial Development Advisor, Industrial Development Department, East African Community, Secretariat
- Chutima Akaleephan, Senior Pharmacist and Senior Researcher, International Health Policy Program, Ministry of Public Health, Thailand
- Karim Bendhaou, Chair of International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Africa Engagement Committee
- Jude Nwokike, Promoting the Quality of Medicines (PQM+) Program Director, US Pharmacopeia

