

Satellite sites for regional production: the way to health equity?

Report of Wemos' side event at the World Local Production Forum on 6 November 2023

To what extent do satellite production sites of large pharmaceutical companies from the Global North contribute to health equity, sovereignty and self-reliance for low- and middle-income countries? Wemos convened a side event on this topic at the 2nd World Local Production Forum, which took place in The Hague from 6 to 8 November 2023.

The forum was organized by the World Health Organization (WHO) together with the Dutch government to foster exchange and collaboration on regional manufacturing of health products, including medicines and vaccines. In current initiatives to strengthen regional production, satellite production sites of large pharmaceutical and biotechnology companies play a central role. For our side event, we invited key public health experts to discuss whether these satellite production sites truly contribute to equitable access to health products.

Key takeaways from the panel discussion

- Satellite production sites may be a valid short-term solution.
- Satellite production sites are not seen as a long-term solution to achieve sovereignty and selfreliance for low- and middle-income countries.
- Without addressing intellectual property barriers, satellite production sites cannot achieve equitable access.
- Regulatory strengthening is required to allow satellite production sites to foster local manufacturing.
- Trust towards vaccines and governments must be restored for satellite production sites to achieve access.

Stick to health equity

Wemos believes that health equity and countries' sovereignty and self-reliance must be and remain the core objectives of strengthening regional production of health products. Wemos looks at what is needed to sustainably strengthen regional production and ensure this fully benefits the region concerned. In this



context, we examine whether satellite production sites are the right way to go. To shed light on this, Wemos is also conducting a case study, gathering information on the BioNTech mRNA facility in Rwanda.

Panel of experts at the side event

Moderator

Dr Ellen 't Hoen - Director of Medicines Law & Policy

Panellists

- Charles Gore Executive director of the <u>Medicines Patent Pool</u>
- Jens Pedersen Senior advisor for <u>Africa CDC</u>
- Dr Marta Fernández Suárez Chief technology officer at <u>FIND</u>
- Dr Moses Mulumba Director general of <u>Afya na Haki</u>



From left to right: Antonio Perrelli (Wemos), Charles Gore, Dr Moses Mulumba, Jens Pedersen, Dr Marta Fernández Suárez, Dr Ellen 't Hoen.

Highlights of the panel discussion

What is the role of the Global North in achieving local production, and what should countries of the Global South do to achieve greater self-reliance and sovereignty?

Our panellists highlighted the need to strengthen the regulatory environment. Jens Pedersen, senior advisor of the Africa CDC, stressed the importance of supporting both National Regulatory Authorities (NRAs) and the African Medicines Agency (AMA) as a long-term goal, while the short-term objective would be to support faster regulatory approval of African products, for example through the WHO prequalification. Dr Moses Mulumba, director general of Afya na Haki (Ahaki), observed that it will be very difficult to achieve local production without taking into account the regional level. It was also noted that in many African countries taxes on medicinal products are extremely low, while taxes on raw materials remain high. This results in significant imports of drug substance and a proliferation of fill-and-finish initiatives. A paradigm shift is therefore needed.



How useful can satellite production sites be, and how do they fit in the plans of the African Union to foster local manufacturing?

Most speakers agreed on the short-term benefits of satellite production sites. They also acknowledged that this production model could nurture the ecosystem, build capacity and contribute to local skills, through a 'learning by doing' model. On the other hand, the panellists highlighted the shortcomings of satellite production sites, especially on long-term goals such as sovereignty and self-reliance of low- and middle-income countries. The panellists emphasized that without proper technology transfer and a fully-fledged handover towards local manufacturers, satellite production sites' ambition to deliver better access may not succeed. Vaccine nationalism was identified as another prominent issue for satellite production sites. "What happens if BioNTech's main production facility in Germany breaks down during a pandemic? Would the Rwandan facility be shipped back to Germany?" Charles Gore, executive director of the Medicines Patent Pool, asked.

What is the role of civil society organizations from the African continent in the field of local manufacturing?

Dr Moses Mulumba insisted on the need to build trust. New initiatives to strengthen regional production are received with mistrust, by both beneficiaries and policymakers. The Covid-19 pandemic reinforced this conception, due to vaccine hoarding carried out by high-income countries. If this major bottleneck is not properly addressed, satellite production sites (and regional manufacturing in general) will be affected.

What lessons can we learn from the field of diagnostics to promote more equitable vaccine manufacturing?

Panellists acknowledged that vaccines and diagnostics share many similarities. Challenges regarding the ecosystem are similar, as we can see for procurement and regulatory hurdles. "One peculiar aspect concerning diagnostics is the way intellectual property is addressed," Dr Marta Fernández Suárez, chief technology officer at FIND, noted. She explained that for diagnostics, most of the intellectual property comes in the form of know-how, without the involvement of patents. This allows to shift the focus towards technology transfer. For vaccines, both patents and know-how represent substantial barriers. According to the speakers, satellite production sites could constitute a possible way forward, as long as they focus on meaningful technology transfer, or sharing of intellectual property and know-how.

Intellectual property is identified as a major barrier in achieving sustainable regional manufacturing. How can we address this with regard to satellite production sites?

The panellists acknowledged the importance of empowering local manufacturers in Africa as a potential strategy to overcome intellectual property barriers. The mRNA vaccine technology transfer programme, for example, is creating an end-to-end vaccine manufacturing platform, that would go from research and development (R&D) to governments in Africa buying their own products. The relevance of technology and knowledge transfer was reiterated by the speakers. They also stressed the role of a clear timeline for the handover of satellite production sites towards local manufacturers.



Quotes



Jens Pedersen

"Equal opportunity does not mean equal outcome. If you are serious about supporting African production, you will have to help build capacity and scales."



Dr Moses Mulumba

"When it comes to regional production of health products, we need to talk about trust. Trust in the products, trust in the companies, trust in the government. The role of civil society organizations will be key to do so."



Dr Marta Fernández Suárez

"Technology transfer of fully owned entities in the region is a priority. It's not just the product, but also the revenue that must stay in the region."



Charles Gore

"You don't want someone outside Africa deciding what Africa needs. Companies within Africa need to respond to that."



More information

Would you like to know more about strengthening regional production and what is needed to achieve health equity, sovereignty and self-reliance? Read our <u>position paper 'Eyes on the prize: regional production</u> <u>of medicines to achieve health equity, sovereignty and self-reliance'</u> and keep an eye out for the publication of our case study on the BioNTech mRNA facility in Rwanda (planned for January 2024).

