

Why it is important to attach conditions to investments in regional production of health products

Dem Ausschuss ist das vorliegende Dokument in nicht barrierefreier Form zugeleitet worden.

Introduction

Wemos is a Dutch-based public health organization that advocates structural change to achieve global health justice. Our main themes are access to medicines and finance for health.¹ Wemos' team has been closely following the developments around regional manufacturing during and following the Covid-19 pandemic.

It is our conviction that supporting regional production should improve access to medicines, vaccines and medical tools in Africa, by African manufacturers, for African populations. To move in that direction, it is key that the German (and other) government(s) set conditions to the public funding allocated to it.

Sustainable regional production of health products in Africa should lead to equity

Currently, African manufacturing supplies only around 1% of the total continental demand. Enhancing regional production of health products in Africa is vital if the continent is to meet its own needs. Wemos supports global and concerted efforts to strengthen local and regional production capacity in Africa in a way that fosters health equity, sovereignty² and self-reliance³ for the African continent.

The assumption behind strengthening regional production is that it would enable low- and middle-income countries to research, develop, manufacture and roll-out health products for and by themselves. This will improve their access, help to address their specific health needs and make them less dependent on high-income countries. Regional production is expected to lead to health equity and countries' sovereignty and self-reliance. To achieve these objectives, well-defined strategies and firm commitments are needed, as well as more transparency and accountability. Moreover, it is key that governments investing in regional

¹ www.wemos.org/en

² We defined sovereignty as autonomous determination of priorities in R&D, on pricing and on allocation of manufactured products.

³ We defined self-reliance as sufficient supplies to meet medical needs in the region and reduced dependency on external factors.

production attach conditions to their public funding that guarantee progress towards health equity, sovereignty and self-reliance.

Ambitions for regional manufacturing in Africa

The African Union set a bold target for African countries to produce and supply more than 60% of the continent's vaccine requirements by 2040. This means developing the manufacturing capacity to produce at least 1.5 billion vaccine doses per year by 2040.⁴ Nowadays, companies that are actively involved in vaccine production initiatives are concentrated in only 5 African countries.⁵ There is very limited research & development (R&D) and upstream production (growing larger volumes from the main substance). Most local companies are only engaging in packaging and labelling, and occasionally in filling and finishing steps.⁶ This illustrates the long way ahead to develop an end-to-end vaccine manufacturing capacity to supply the whole continent.

Today, the initiatives supporting vaccine manufacturing on the African continent are mostly led by three main actors:

- 1** The African Union, mainly through the Partnerships for African Vaccine Manufacturing (PAVM),
- 2** The World Health Organization (WHO), via the mRNA vaccine technology transfer hub, and
- 3** The private sector, especially in the form of subsidiary companies, mainly from the Global North.

Wemos' case study on BioNTech Africa

To gain more insight into regional production, Wemos worked with African partner organizations⁷ on a case study of BioNTech. This German biotechnology company is setting up an mRNA facility for vaccine manufacturing in Rwanda.⁸ The case study analyses to what extent and how the BioNTech facility - and satellite production sites in general - can contribute to sustainable regional production in order to achieve health equity, sovereignty and self-reliance on the local, regional and continental level.

The manufacturing facility of BioNTech in Rwanda consists of modular factories in shipping containers, so-called BioNTainers. It constitutes a concrete response to the lack of production of vaccines in Africa. In the short-term, the facility could increase the production of and access to mRNA Covid-19 vaccines in Rwanda, East Africa and the continent. Besides, it could strengthen the regulatory system in Rwanda and support the production of Active Pharmaceutical Ingredients (APIs) in Africa.

⁴ <https://africacdc.org/news-item/africa-cdc-hosts-lead-partners-of-the-pavm-to-review-the-broader-vaccine-manufacturing-ecosystem-in-africa/>

⁵ South Africa, Morocco, Tunisia, Egypt, and Senegal

⁶ <https://www.afro.who.int/news/what-africas-vaccine-production-capacity>

⁷ With Afya na Haki (Ahaki), the Great Lakes Initiative for Human Rights and Development (GLIHD) and Health Development Initiative (HDI).

⁸ To be published soon.

However, it remains doubtful whether the initiative can also enhance the sovereignty and self-reliance of the country, region and continent in the long-term, when it comes to access to health products. It currently lacks policies and strategies – at least public information about these – to ensure that the region can fully develop, produce and market mRNA vaccines and other health products for and by themselves in the future, based on the local, regional and continental epidemiological needs. For example, it is unknown whether BioNTech will transfer the technologies and know-how required for production to the Rwandan government and/or local manufacturers.

The BioNTech Africa facility, as well as other – current and future – initiatives for regional production of health products, requires clear plans and commitments to not only ensure access to health products in the short-term, but to also contribute to national sovereignty and self-reliance in the long-term. Moreover, as these initiatives concern public health, they should be transparent about their plans and commitments.

Our study concludes that governments, multilateral organizations and global health funds can enforce transparency and attach conditions to public funding designated for regional manufacturing initiatives to ensure that they contribute to health equity, sovereignty and self-reliance. This also applies to indirect funding of manufacturing facilities, such as financial support to create an enabling environment for these facilities to thrive (e.g. infrastructure, regulatory frameworks, skilled workforce). An essential condition would be that Northern-based pharmaceutical companies must transfer the required technology and know-how to African manufacturers.

Recommendations to EU governments

European governments, such as the German government, finance regional manufacturing in Africa mainly through the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+).⁹ They also financially and technically support specific countries and their enabling environment where private companies, such as BioNTech, have decided to invest directly. In Rwanda, for example, Germany invested 43,75 million euro through the wider investment package of 94 million euro that MAV+ invested in the country.¹⁰

Considering the large amount of public investment (direct or indirect) that enable private companies in high-income countries to thrive, there is a risk that well-intentioned donor investment reinforces market dynamics that favour a handful of large international producers over local efforts.¹¹ Therefore, conditions should be attached to ensure that funding is aligned with public health needs on the African continent. Such conditions should include:

⁹ https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa_en

¹⁰ Rwanda - boosting African healthcare from within - European Commission (europa.eu)

¹¹ <https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0003147>

- a. Safeguards that the initiative meets public health priorities (i.e., the definition of epidemiological targets should be based on local, regional and continental needs);
- b. Insurance that priority is given to fully-fledged transfer of technology, knowledge and know-how to local manufacturers;
- c. The inclusion of local, regional and continental entities in the decision-making process around manufacturing sites (e.g. on which vaccines to produce and who to sell to).

On Gavi's African Vaccine Manufacturing Accelerator (AVMA)

The new Gavi's financial instrument, the African Vaccine Manufacturing Accelerator (AVMA), aims to provide financial incentives to African-based manufacturers. Based on its current eligibility criteria and financial incentives, we wonder if AVMA will reach the right producers. Moreover, it only intervenes at a late stage of the development chain, while it is important that it supports all steps of the vaccine manufacturing value chain (R&D, clinical trials, production, packaging, distribution, etc.)

Eligibility

Since all companies located on the African continent are eligible, any multinational company establishing a subsidiary on the African continent has access to AVMA's financial incentives. Given that most biotechnology and pharmaceutical multinationals have substantial capital and the ability to present a product to WHO prequalification, they have an important advantage over African-based producers. This raises the question whether African-based producers should be favoured over biotechnology and pharmaceutical multinationals.

To build capacity for regional manufacturing on the African continent aimed at progressing health equity, we believe that the definition of regional production should include African producers who hold ownership and who are involved in the decision-making process regarding which vaccines to produce and who to sell them to.

Financial incentives

There are different types of financial incentives. Pull funding focuses on creating favourable market conditions for a product that is being put on the market. Push funding, in contrast, aims at supporting a recipient to develop a product before it reaches the market.

The AVMA mechanism includes two competitive market pull incentives: 1) a milestone payment when the WHO prequalification is obtained, and 2) a price subsidy, delivered when winning competitive Gavi-UNICEF tenders.

- 1 The milestone payment for WHO prequalification ignores the fact that only larger, established (international) producers can obtain such prequalification, because they have sufficient capital to pre-invest in product development and regulatory dossiers. The only WHO prequalified vaccine that is

currently produced on the African continent is for yellow fever, by the Institut Pasteur in Dakar. Any new local producer will have to attract significant upfront funding, which is not readily available to new or emerging producers in Africa.

- 2 Rewarding competition through a price subsidy linked to successfully winning Gavi-UNICEF tenders ignores the market's unequal power dynamics, with a few international manufacturers dominating the market. It reinforces market logic, which assumes that companies compete on an equal footing.

If AVMA's aim is to develop production capacity in Africa, for Africa and by Africa, financial incentives should be specifically targeted at local and regional manufacturers.

Shaping a sustainable ecosystem for manufacturing of health products

Since the early 2000s, the dominant strategy within the global health field has been to fix or shape the market, with a strong focus on better matching supply with demand and using donor funds to optimize markets as a way to increase access to health products in low- and middle-income countries. This approach considers the market as a given reality, assuming healthy competition, transparency and market powers. However, these are notoriously absent in the pharmaceutical market, with extensive monopolies, a lack of price transparency and regulatory barriers. An economic-based approach will not promote a sustainable manufacturing market and help increase health equity.¹² Instead of trying to overcome perceived failures, governments and international funders using public funds, such as Gavi, should act ex-ante and change the design of the market at its core to foster an ecosystem that ensures health for all.¹³

This ecosystem should go beyond the focus on low-cost production and economies of scale, and instead stimulate the emergence of a more diverse set of small-and-medium scale producers, or a local innovation ecosystem, that could address the local or regional health needs in Africa. Governments from low- and middle-income countries will need to play an active role and shape a conducive policy environment. This also requires political leadership and (financial) support, from both African and European countries.

Focus on early-stage development and innovation

AVMA takes inspiration from the Advanced Market Commitment, a pull incentive also used by Gavi. It commits to purchase a fixed number of doses if manufacturers reach a pre-determined target within a certain timeframe. The financial mechanism focuses on the last stages in the value chain: it offers committed funding to support the purchase and roll-out of vaccines in countries that are otherwise unable to purchase at high prices. However, it does not support early-stage vaccine development and innovation.

¹² <https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0003147>

¹³ https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/who-council-eh4a_casestudy-mrnahub.pdf

Early-stage development includes discovery research and early development, typically performed in academic or other research institutions and funded through public funding, as well as pre-clinical and clinical trials. These are all crucial steps in the R&D value chain that require financial support. That is why the PAVM Framework for Action¹⁴ calls for increasing R&D activities to include pre-clinical and clinical trials, particularly for diseases with high impact on the continent.

Finally, it should be noted that AVMA comes from the remaining funds of COVAX, a mechanism that was created to address global access inequities during the Covid-19 pandemic. The resulting investments should therefore specifically focus on preventing future inequities and effectively support African manufacturers so that they can step up and produce for themselves.

Conclusion: conditions to ensure regional production increases equitable access

We consider regional production of health products is an important way to improve access to medicines, vaccines and medical tools for African populations, provided that it fosters health equity, sovereignty and self-reliance for the African continent. To progress on this ambition, a 'business-as-usual' approach will not be enough.

It is essential that governments attach the right conditions to the public funding they allocate to regional manufacturing. Such conditions should include safeguards to a) meeting public health priorities, b) the transfer of technology, knowledge and know-how to local manufacturers, and c) the inclusion of local, regional and continental entities in decision-making.

Furthermore, Africa should establish a favorable ecosystem attracting investments for African producers that cover the whole manufacturing value chain.

Only then, we can ensure that equitable access to lifesaving medical products becomes a reality worldwide. As members of parliament, you have the opportunity to contribute to a system of regional production that increases the independence of the African continent and can improve and save millions of lives, now and in the future. The momentum is now.

¹⁴ <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>

Background information:

Webinar: Regional production for equitable access to medicines: do's and don'ts - 17 May 2023

How can regional production of medicines and other health technologies be strengthened in a way that it truly ensures equitable access and countries' self-reliance and sovereignty? This question was central to our webinar in the run-up to the 76th World Health Assembly.

<https://www.youtube.com/watch?v=cTBNeJzXPV8>

Eyes on the prize: regional production of medicines to achieve health equity, sovereignty and self-reliance (position paper, May 2023)

Health equity and countries' sovereignty and self-reliance must be and remain the core objectives of strengthening regional production of medicines and other health technologies.

<https://www.wemos.org/wp-content/uploads/2023/05/Position-paper-regional-production-May-2023.pdf>

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

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

<https://www.wemos.org/wp-content/uploads/2023/11/Report-Wemos-side-event-World-Local-Production-Forum-2023.pdf>

Contact:

- Aliénor Devalière, senior global health advocate: alienor.devaliere@wemos.org
- Antonio Perrelli, global health advocate: antonio.perrelli@wemos.org