



BioNTech Africa: in the region, but also for and by the region?

A case study with recommendations for sustainable
regional production of health products

This report is a publication of:

Wemos

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Abbreviations and acronyms

ABI	African Biomanufacturing Institute
ACT-A	Access to Covid-19 Tools Accelerator
AfCFTA	African Continental Free Trade Area
Africa CDC	Africa Centres for Disease Control and Prevention
AMA	African Medicines Agency
AMC	Advance Market Commitments
APIs	Active Pharmaceutical Ingredients
APTF	African Pharmaceutical Technology Foundation
AU	African Union
AVAT	African Vaccine Acquisition Trust
AVMA	African Vaccine Manufacturing Accelerator
AVMI	African Vaccine Manufacturing Initiative
BioNTech	Biopharmaceutical New Technologies
CHAI	Clinton Health Access Initiative
Covid-19	Coronavirus Disease 2019
EAC	East African Community
Enabel	Belgian Development Agency
EU	European Union
FTE	Full-time equivalent
GBT	Global Benchmarking Tool
GIZ	German Development Cooperation
GMP	Good Manufacturing Practices
ICT	Information and communications technology
IFC	International Finance Corporation
IP	Intellectual property
IT	Information technology
KfW	German Development Bank
MAV+	Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies
mRNA	Messenger Ribonucleic Acid
NEML	National Essential Medicines List

NRAs	National Regulatory Authorities
PAVM	Partnerships for African Vaccine Manufacturing
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PPP	Public-private partnership
QA	Quality assurance
QC	Quality control
R&D	Research and development
RCE-VIHSCM	Regional Center of Excellence for Vaccines, Immunization, and Health Supply Chain Management
Rwanda FDA	Rwanda Food and Drugs Authority
SDGs	Sustainable Development Goals
SMEs	Small- and medium-sized enterprises
STEM	Science, Technology, Engineering and Mathematics
TB	Tuberculosis
TVET	Technical and vocational education and training
UNICEF	The United Nations Children's Fund
UR-CMHS	University of Rwanda, College of Medicine and Health Sciences
WHO	World Health Organization

Executive summary

Introduction

The Covid-19 pandemic painfully exposed unequal global access to medical products. While high-income countries were vaccinating their population multiple times, low- and middle-income countries experienced dire vaccine shortages. In response to this disparity, both public and private institutions started setting up initiatives in the Global South to strengthen regional production of vaccines and other health products. In Africa, only 1% of the vaccines administered are produced locally. Nonetheless, the burden of many infectious diseases remains consistently high.

Strengthening regional production should enable low- and middle-income countries to research, develop, manufacture and roll out health products for and by themselves. This improves their access, helps to address their specific health needs and makes them less dependent on high-income countries. Regional production should lead to health equity and countries' sovereignty and self-reliance regarding access to health products.

Health equity:

- Everyone has a fair and just opportunity to attain their highest level of health.
- Low- and middle-income countries have access to health products to the same degree as high-income countries.
- Governments ensure access for everyone, leaving no one behind.

Sovereignty:

- Autonomous determination of priorities in research & development.
- Autonomous decisions on pricing of manufactured products.
- Autonomous decisions on allocation of manufactured products.

Self-reliance:

- Sufficient supplies to meet medical needs in the region.
- Reduced dependency on external factors.

Objective of the case study

In several current initiatives to strengthen regional production in the Global South, satellite production sites of large pharmaceutical and biotechnology companies from the Global North play a pivotal role. For example, BioNTech is setting up an mRNA facility for vaccine manufacturing in Kigali (Rwanda) and Moderna had moved towards doing the same in Nairobi (Kenya).ⁱ Therefore, it is relevant to ask ourselves whether these new satellite production sites will boost regional production in a way that fosters health equity, sovereignty and self-reliance.

Wemos, together with Afya na Haki (Ahaki), Health Development Initiative (HDI) and Great Lakes Initiative for Human Rights and Development (GLIHD), conducted a case study of regional production in Africa, with a specific focus on the BioNTech facility for mRNA vaccines in Rwanda. The main objective was to analyze 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.

Methodology

The research took place between August and December 2023. Qualitative research methods were employed, through document review, semi-structured interviews with 21 representatives from 20 different entities and a side event organized during the 2nd World Local Production Forum with the participation of a panel of experts in the field of regional manufacturing of health products. The identified groups of stakeholders for the interviews entailed private biotechnology and pharmaceutical industry players, national and supranational institutions, development agencies and civil society organizations. The research data was captured using coding techniques.

Key findings

The manufacturing facility of BioNTech in Rwanda – in the form of modular factories in shipping containers, so-called BioNTainers – 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. Furthermore, it could strengthen the regulatory system in Rwanda and support the production of Active Pharmaceutical Ingredients (APIs) in Africa.

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, remains doubtful. It currently lacks policies and strategies – or public information about these policies and strategies – 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.

Conclusions

The BioNTech Africa facility as well as other – current and future – initiatives for regional production of health products require clear plans and commitments to not only ensure access to health products in the short-term, but also to 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.

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 – also in the case of indirect funding of manufacturing facilities, such as financial support to create an enabling environment for these facilities to thrive. An essential condition would be that Northern-based pharmaceutical companies should transfer the required technology and know-how to African manufacturers.

Background of the study

Vaccine nationalism and inequity

In the aftermath of the Covid-19 pandemic, we took stock of the devastating impact of a virus that has resulted in over 7 million deaths globally,ⁱⁱ destroyed livelihoods and arrested progress on various Sustainable Development Goals (SDGs). Despite breakthrough medical innovations to prevent, detect and treat Covid-19, the rollout did not ensure equal and just allocation of health products across countries. While high-income countries bought up vaccine stocks for steep prices, pharmaceutical companies mostly refused to share their technology and know-how to expand production and increase access to these products. Governments – and other public financiers of research and development (R&D) linked to Covid-19 innovations – did not attach conditions to their funding to ensure affordability, availability and technology transfer for vaccines,ⁱⁱⁱ or support temporary waivers of intellectual property rights. This is particularly concerning considering the substantial amount of public funds that were allocated. While high-income countries hoarded available doses, low- and middle-income countries had to rely on charity models, which failed to deliver reliable, timely and equitable access to much-needed vaccines, treatments and diagnostics. Due to stringent intellectual property (IP) policies,^{iv} the concentration of vaccines and other medical products is located in a handful of countries, most of which are high-income, with up to 90% of the global vaccine market shared by only 4 companies in 2021.^v In the wake of the Covid-19 pandemic, it was already clear that over-reliance on a small group of vaccine manufacturers was detrimental to global, equitable access.^{vi} The initial months following the development of the first Covid-19 vaccine painted a grim picture of delivery on the African continent.^{vii} By April 2021, 1 billion doses of Covid-19 vaccines had been administered globally. Of these, three quarters had been administered in only ten countries.^{viii} Africa, as a continent, had at this point received 37 million Covid-19 vaccine doses, of which about 23.6 million were successfully administered.^{ix} Other estimations provide an even lower figure of about 18 million administered doses, a paltry 2% of all doses delivered globally, corresponding to 1.4% of the total population of Africa.^x This inequitable scramble persisted for months: Anna Mia Ekström, a professor at Karolinska Institute, reported that in November 2021, one year after the first Covid-19 vaccine had been introduced, only 35 million vaccines had been administered in low- and middle-income countries,^{xi} the bulk of which were located on the African continent.^{xii} At this point, up to 7 billion doses of Covid-19 vaccines had been administered globally.^{xiii}

While high-income countries executed bilateral agreements with vaccine manufacturers, the African continent's expectations were firmly pegged to collaborative initiatives such as the Access to Covid-19 Tools Accelerator (ACT-A) and its pooled procurement and distribution mechanism COVAX.^{xiv} Vaccine nationalism, mostly perpetuated by countries from the Global North, had a detrimental impact on the African continent, leading the President of South Africa, Cyril Ramaphosa and the World Health Organization (WHO) Director-General, Dr Tedros Adhanom Ghebreyesus,^{xv} to describe this process as “vaccine apartheid”^{xvi} characterized by delayed economic recovery as well as an increased number of preventable deaths.^{xvii} This predicament has been experienced before with the AIDS epidemic,^{xviii} but also with Ebola and H1N1 vaccines.^{xix}

Challenges in increasing regional production to address global health equity

Increasing regional manufacturing seems to be the logical antidote to global health inequities for governments from both the Global South and North. Yet whilst the idea of producing locally can be seen as a positive move towards self-reliance for low- and middle-income countries when compared to charity models and dependency on imported products, financially sustainable manufacturing and equitable distribution are not inherently guaranteed by regional production of medical products. Scientific literature indicates numerous challenges^{xxi} in the production of medical countermeasures in Africa, including insufficient transfer of know-how, shortage of a trained workforce, insufficient regulatory frameworks and policy environment, patents and other IP rights, restricted capacity for R&D, and weak supply chains for inputs and ingredients. Such bottlenecks not only represent a barrier for actors considering investing in local manufacturing, but they also increase the costs and decrease the output of local manufacturing investments. While opting for local manufacturing over importing at the lowest possible prices on international markets offers advantages in terms of availability and accessibility, it may also lead to locally manufactured drugs being outpriced by imported health products, rendering local manufacturing financially unsustainable.

Vaccine manufacturing initiatives on the continent

Initiatives focused on local manufacturing in Africa have been a longstanding endeavour, pre-dating the emergence of the Covid-19 pandemic. Before the pandemic, vaccine manufacturing initiatives were concentrated in five African countries: Egypt, Senegal, Tunisia, Ethiopia and South Africa. All initiatives (except one) primarily focused on the fill & finish of vaccines. Fill & finish is the process of filling vials with a vaccine substance and packaging the products for distribution. Only the Institut Pasteur de Dakar in Senegal was involved in the production of a WHO-prequalified vaccine for yellow fever.^{xxii}

According to a WHO landscaping of Covid-19 vaccine development, a total of 277 candidates were under development worldwide as of April 2021.^{xxiii} Of these, just five were credited to the African continent, four being tested at the National Research Centre in Egypt,^{xxiv} and the other at a private Nigerian firm.^{xxv} At this point, all five vaccine candidates were merely at the preclinical evaluation stage,^{xxvi} and none of them went past this phase.

Today, initiatives supporting vaccine manufacturing on the African continent are mainly led by three actors: the African Union, the World Health Organization (WHO), and the private sector, especially in the form of satellite production sites, mainly from the Global North.^{xxvii}

African Union initiatives

The Partnerships for African Vaccine Manufacturing (PAVM) was established by the African Union and the Africa Centre for Diseases Control in April 2021 to complement the mandate of the African Vaccine Manufacturing Initiative^{xxxviii} and the Pharmaceutical Manufacturing Plan for Africa. The main objective of this partnership is to “bolster vaccine manufacturing, financial partnerships, regulatory systems and technology transfer.”^{xxxix} PAVM’s Framework for Action set the ambitious goal of locally producing 60% of vaccines required for the African continent by 2040.^{xxx} PAVM also focuses on enabling African universities to become vaccine research and manufacturing hubs for the continent.^{xxxi} The African Union established the African Medicines Agency as the continent’s medicine regulatory body.^{xxxii} However, until the requisite ratifications, its functions will be carried out by the Africa Regulatory Taskforce.^{xxxiii} The Africa Regulatory Taskforce established a centralized framework enabling member states of the African Union to expedite emergency marketing authorizations of new vaccines.^{xxxiv}

The African Union has also launched bilateral initiatives, such as the agreement for formulation filling, finishing and packaging of approximately 300 million Johnson & Johnson doses of vaccine per annum^{xxxv} for distribution to the African market.^{xxxvi} The Algerian state-owned group Sidal, a leading producer of generic medicines in the country, made an agreement with the Russian government to supply Algeria with the Sputnik V Covid-19 vaccine.^{xxxvii} Similarly, Egypt entered into an agreement with the Chinese government, pertaining to the fill & finish process of the Sinovac Biotech vaccine at the Egyptian Holding Company for Biological Products and Vaccines (VACSERA).^{xxxviii} The Biovac Institute in South Africa made an agreement with ImmunityBio, a US-based vaccine manufacturing institute, for the manufacture of Covid-19 vaccines.^{xxxix} Morocco’s agreement with Recipharm, a Swedish company, is a similar development. Senegal entered into an agreement with the European Union, the United States and other EU countries such as France, Germany and Belgium to finance the Institut Pasteur de Dakar.^{xl}

Activities led by the African Union have been carried out in close coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+).

World Health Organization’s mRNA vaccine technology transfer hub

The WHO’s mRNA vaccine technology transfer hub was set up in 2021 in South Africa as result of Workstream III of the COVAX Manufacturing Task Force.^{xli} The aim of this hub is to enhance capabilities in low- and middle-income nations for the production of mRNA vaccines via a centre for excellence and training, known as the mRNA vaccine technology hub. The hub is located at Afrigen Biologics and Vaccines in Cape Town, South Africa, and it collaborates with a series of technology beneficiaries, defined as “spokes”, in low- and middle-income countries. The WHO and its partners share know-how, quality control and necessary licenses with a centralized entity with the aim of facilitating a “broad and rapid technology transfer to multiple recipients” (spokes).^{xlii} The WHO is working with a consortium of partners, including Biovac, Afrigen Biologics and Vaccines, the South African Medical Research Council, the Africa Centres for Disease Control and Prevention (CDC) as well as a network of universities. Each of these actors occupy a different role in the mRNA vaccine technology transfer hub project.^{xliii} Six African institutions were already part of the hub by 2021:^{xliiv} Biovaccines Nigeria Ltd in Nigeria, Institut Pasteur de Dakar in Senegal,

BioGeneric Pharma S.A.E in Egypt, Institut Pasteur de Tunis in Tunisia, Afrigen in South Africa and another institute in Kenya that still had to be defined.^{xlv}

Private sector's satellite production sites

Pharmaceutical and biotechnology companies, mainly from the Global North, have seized the opportunity of a growing African market to expand their output capacity. In October 2021, Moderna announced plans to spend up to 500 million dollars on establishing a vaccine manufacturing facility in Africa to build and grow its global network of vaccine manufacturing initiatives, and in 2022 Kenya was chosen to host the new facility.^{xlvi} Once set up, this facility should be able to produce about 500 million doses of vaccines annually.^{xlvii} BioNTech also announced plans to establish Africa's first mRNA vaccine facilities in Senegal and Rwanda by 2022,^{xlviii} to produce up to 500 million doses of vaccines annually.^{xlix}

Moderna's and BioNTech's facilities are concrete examples of what we might call satellite production sites,ⁱ namely manufacturing facilities of pharmaceutical and biotechnology companies that are established in a different location than the primary country of production. To date, not much is known about such facilities. What is already in the public domain is that BioNTech has shipped compact modules to Rwanda with the aim of bringing mRNA production from Europe to East Africa.ⁱⁱ As reported by the Telegraph,ⁱⁱⁱ the German biotechnology company has fine-tuned these portable units in Marburg, Germany. A first unit, intended for drug substance production, has already been shipped to Rwanda, while a second unit, designated for the final drug product, should follow in 2024.

Objectives and research questions

In light of the abundance of new financial investments in satellite production sites, Wemos and Ahaki, in collaboration with HDI and GLIHD, conducted a case study on the BioNTech Africa project, which seeks to build mRNA manufacturing capacity for Covid-19 and other health products. By studying such initiatives, and placing them in the broader context of vaccine manufacturing on the continent, our aim is to investigate and describe the extent to which the approach of satellite production sites in general,^{liii} and more specifically the one offered by BioNTech Africa in Rwanda, is likely to contribute to sustainable health equity, sovereignty and self-reliance for low- and middle-income countries regarding access to health products.

Research questions:

- 1** What are the characteristics of the BioNTech Africa facility in Rwanda?
- 2** To what extent does the BioNTech Africa facility contribute to supporting sustainable health equity, sovereignty and self-reliance regarding access to health products at the local, regional and continental level?

- 3 What policy recommendations can be formulated to overcome bottlenecks and contribute to sustainable health equity, sovereignty and self-reliance regarding access to health products at the local, regional and continental level?

Methodology

Methods of data collection and sampling procedures

Data collection methods included:

- Document review:
 - Document review based on (but not limited to) the African Union's goals, good practices, lessons learnt, bottlenecks, recommendations and other relevant sources for local manufacturing in the region. The review included government and intergovernmental body policies, peer-reviewed articles, official documents, grey literature, press releases and technical reports retrieved from online research and, where possible, through outreach to the actors involved.
- Exploratory interviews with key informants to identify the main themes and research questions.
- In-depth, semi-structured interviews with key stakeholders using a pre-defined set of questions. Key informants were selected according to relevance and following snowball sampling, a method by which new respondents are identified through interviews. The selection of interviewees was carried out on the basis of key stakeholders' involvement, directly or indirectly, in the BioNTech Africa project, or, alternatively, according to their experience in the field of vaccine manufacturing in Rwanda, East Africa, or at the continental/international level. The research took place between August and December 2023 with 21 representatives from 20 different entities. Key informants from in-depth, semi-structured interviews comprise:
 - Policymakers and other relevant stakeholders from the recipient country, the East African region, the African continent and the Global South (11 respondents out of 21 invited stakeholders).
 - Policymakers and other relevant stakeholders from EU-based actors and international organizations (9 respondents out of 15 invited stakeholders).
 - Technical staff from the company involved (1 respondent out of 1 invited stakeholder).
- A side event organized during the 2nd World Local Production Forum with the participation of a panel of experts in the field of regional manufacturing of health products.

Questions were adapted to each key informant, depending on their background and affiliation with the represented organization. Not all identified stakeholders responded to our interview invitation or were able to participate in interviews. The perspective of several relevant actors involved in the implementation of the

project is therefore missing. This might have generated a bias, as the perspective of decision-makers from the local, regional and continental sphere is partially missing.

Ethical clearance

All organizations involved in data capturing obtained ethical clearance from the Rwanda National Ethics Committee (RNEC) in August 2023, approval notice n.258 / RNEC / 2023. Participation in the interview was voluntary, with the possibility of withdrawing at any time. The information stemming from the interviews has been anonymized. Participants had the opportunity to review their remarks after the interview, before the publication of this report.

Findings

Characteristics of the BioNTech Africa production site

BioNTech Africa's timeline

BioNTech's collaboration with the African Union started in August 2021, when both Rwanda and Senegal were identified as potential target countries, following a meeting in Berlin between President Paul Kagame of Rwanda, President Macky Sall of Senegal, President Ursula von der Leyen of the European Commission and Uğur Şahin, BioNTech's CEO and co-founder.^{lv} In October 2021, BioNTech signed a Memorandum of Understanding with the Rwandan government and the Institut Pasteur de Dakar, confirming plans to kick-start construction of the mRNA manufacturing facility in mid-2022.^{lv} A few months later, in February 2022, BioNTech presented its first modular mRNA manufacturing facility, consisting of two modules of six containers each, known as BioNTainers. The first module is dedicated to drug substance, while the second module delivers the final drug product. Performing drug product formulation includes production of Active Pharmaceutical Ingredients (APIs), a process which is currently limited within the African continent.^{lvi} One of the main innovations of the BioNTech facility in Rwanda would therefore be constituted by the production of APIs. Construction of the first BioNTainer unit (for drug substance) ended in December 2022, and it was swiftly shipped to Kigali in March 2023.^{lvii} In December 2023 the official inauguration of the BioNTech site took place.^{lviii} In the coming years, BioNTech is expected to ship the second BioNTainer unit (first quarter of 2024), complete the construction of all buildings on site, including warehouses, offices and laboratories for quality control, and train specialized personnel to operate the facility. Setting up production lines will require 3 to 6 months, plus 6 additional months for operationalization. Operationalization will require significant amounts of test samples. Only after operationalization, a first batch will be produced, without being sold. The first mRNA-based vaccine batches, required for process validation, are expected for 2025.^{lix}

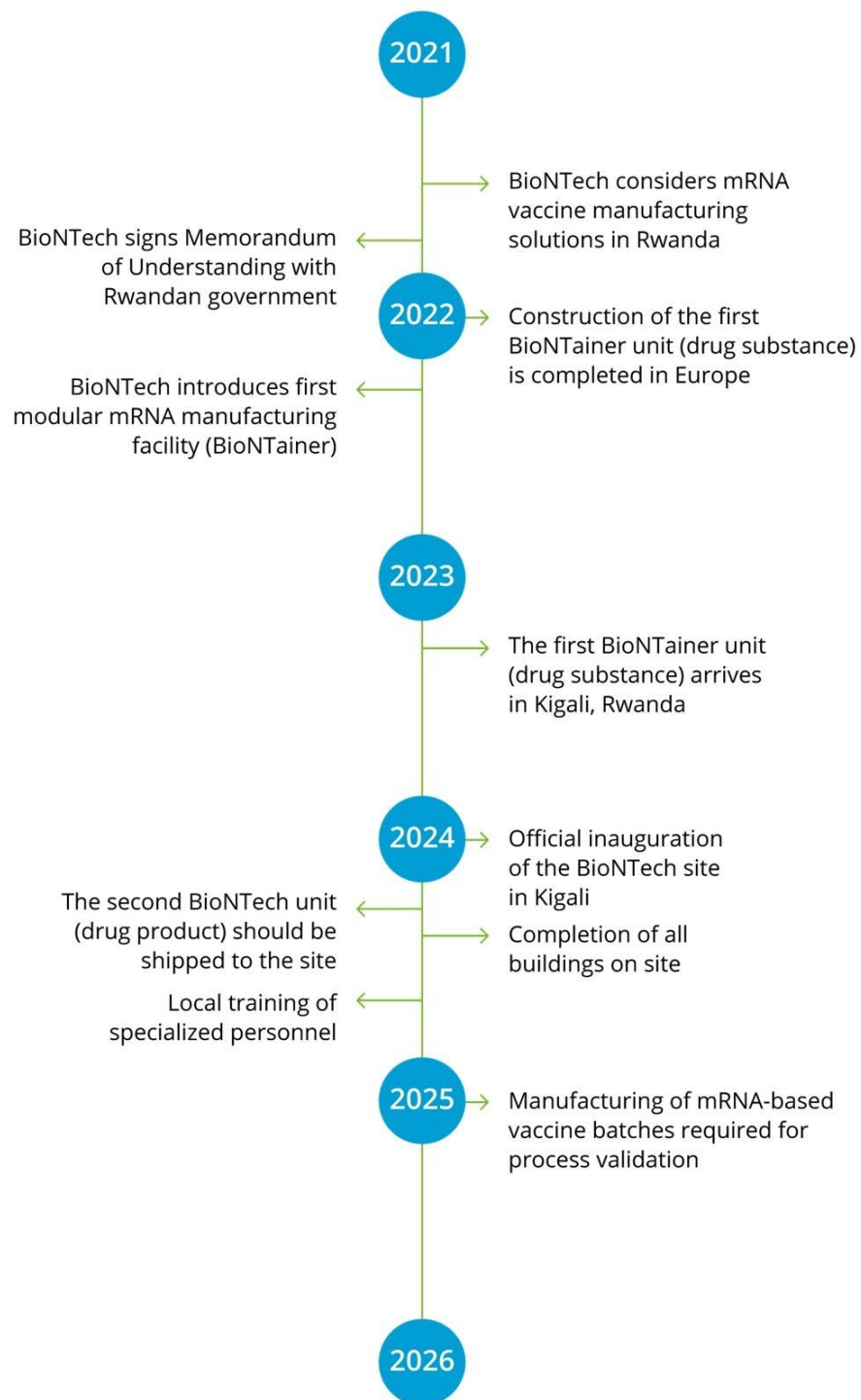


Figure 1: Timeline of BioNTech Africa facility in Rwanda

An essential characteristic of BioNTainers is their ability to deliver not only in a short period of time, but also without a previously developed ecosystem. As modular factories housed in shipping containers, these manufacturing facilities are somewhat isolated from the surrounding environment.

Business case for the BioNTainers

One of the first aspects discussed with respondents was the business case for the facility, and more specifically choosing Rwanda to host it. According to one respondent, it all comes down to BioNTech not being a fully-fledged vaccine producer, but a developer. Another respondent pointed out that the focus of the company has stayed on R&D for years, so it is important to understand how the shift towards manufacturing has occurred. If BioNTech's research into mRNA vaccines continues, the company will be pressured to either give up patents, or to produce themselves. With this in mind, BioNTainers should be considered not only as manufacturing facilities but as a product themselves. For now, BioNTainers need to show that they can work as a standalone solution, and profit-making will not be essential for this phase concerning product development (where the BioNTainers themselves are the product).

"The BioNTainer is the new 'product' from BioNTech, not just a solution for producing vaccines. They are selling the BioNTainers." - Anonymous interviewee

Geographical scope of BioNTech Africa

For now, Rwanda is the only African country hosting BioNTainers, but the intention is to expand the reach beyond the country, as also confirmed by a recent press release^x from BioNTech itself, observing that "Upon successful validation, the Kigali facility will serve as a lighthouse project for subsequent mRNA-based vaccine manufacturing facilities of smaller or larger scale to support clinical development or commercial-scale production in line with local or regional demand", adding that "additional sites could be designed as larger facilities providing increased commercial-scale manufacturing capacities in Africa, or they could be smaller and specialized in the manufacture of batches for the clinical evaluation of product candidates."

Rationale for choosing Rwanda to host BioNTainers

The decision to select Rwanda as the host country is supported by a strong political commitment from the country to become a hub for the African Union, not only for the region, and lead the continent towards an increased capacity for the production of treatments, vaccines and diagnostics. A respondent highlighted that the Rwanda government has demonstrated its ability to develop a strong Information Technology (IT) and Information and Communications Technology (ICT) industry in a considerably short period of time and aims to replicate the same success with policy reforms accelerating vaccine manufacturing.

What are the risks of an automated manufacturing approach?

According to another respondent, doubts have emerged about the BioNTainers manufacturing model, defined as a potential "black box", alluding to a completely automated process that could prevent a clear view of the manufacturing process and other related areas within the value chain landscape.

"It is not clear to what extent the container model is going to be a black box, as well as a completely automated process." - Anonymous interviewee

The financial basis of BioNTech Africa

New initiatives like the one from BioNTech need long-term financial support. Beyond supporting the establishment of the manufacturing facility itself, funds are also crucial for bringing down barriers (on both the supply and demand side) and therefore creating a supportive and enabling environment for local manufacturing.

Financial resources allocated by BioNTech

Financial sustainability has been identified by respondents as a key element of the BioNTech Africa project. Funds for the manufacturing facility in Rwanda have been integrally provided by BioNTech. The investment amounts to a total of around 150 million US dollars. It was stressed that BioNTech has not acquired complementary funds from development institutions or governments specifically and directly for the BioNTech Africa facility. Other key players, such as MAV+ (the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa) have financially contributed to the overall enabling environment, facilitating the establishment of the BioNTech Africa facility.

Indirect financial and technical support

Beyond the direct support dispensed by BioNTech, actors from the EU and the AU have been indirectly involved in supporting the enabling environment in Rwanda and at the African Union level. This will eventually allow BioNTech Africa to access the market and overcome potential bottlenecks connected to newly established facilities on the African continent. These investments demonstrate the crucial role of public funds in the field of access to medicines.

“Team Europe is not financing BioNTech directly but is supporting the Rwandan ambition to become a production hub in the health sector.” - Anonymous interviewee

Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+)

Team Europe has financially and technically supported, albeit indirectly, the BioNTech project. This has happened through the MAV+ initiative, one of the flagship projects of the Global Gateway, with the allocation of an overall sum of 93.75 million euros.^{lxii} Team Europe is composed of different key actors, such as the European Union, EU member states and their implementing agencies and public development banks, the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD). Team Europe was originally conceived as a coordinated response from EU member states and the EU to the Covid-19 pandemic. Global Gateway is an EU investment strategy, and MAV+ is a Team Europe Initiative through which Global Gateway invests in manufacturing and access to vaccines, medicines and health technologies. MAV+ stands for Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa, and it is part of the five regional Team Europe Initiatives focused on health.^{lxiii} MAV+ is composed of the European Commission (DG INTPA), EU member states, development

agencies and other institutions (e.g. European Medicine Agency) that aim to support manufacturing and access to vaccines, medicines and health technologies in Africa.^{lxiii} As highlighted by one respondent, Team Europe funds may not exclusively originate from the EU budget. Funds could come from, for example, Belgium’s development agency Enabel, the German Agency for International Cooperation (GIZ), or the European Investment Bank. According to a factsheet^{lxiv} issued by the European Commission, Team Europe’s contribution of 93.75 million euros can be broken down into three main financial streams, as indicated below.

EU	Belgium	Germany	Total
49.5 million euros	0.5 million euros	43.75 million euros	93.75 million euros

No further information on the type of employed financial instrument (loans, grants, conditional loans) was made available. MAV+ has not directly financed BioNTech, but has proactively supported Rwanda’s ambition to become a production hub in the biotechnology sector, as also attested by the presence of the President of the EU Commission, Ursula von der Leyen, during the inauguration ceremony of BioNTech Africa in December 2023. Out of the MAV+ 93.75 million-euros investments in Rwanda, 40 million euros has been recently deployed to develop the country’s pharmaceutical sector, notably focusing on higher education, technical and vocational education and training (TVET), research and development (R&D), entrepreneurship (supporting the start-up ecosystem and providing business support, and possibly deploying seed funding for start-ups to increase the ecosystems capacity), and stronger supply chains. In summary, MAV+ support in Rwanda can be divided in five main areas, as shown in the table below and indicated on a factsheet^{lxv} from the EU Commission website on the MAV+ approach in Rwanda:

Area	EU member states leading the intervention
Support to SMTs and Startups	Germany
Support to Higher Education and R&D	Belgium, France, Germany, Sweden
Support to Technical and Vocational Education and Training (TVET)	France, Germany, EU
Support to Supply Chain/Logistics	Belgium
Support to Regulatory Oversight	Austria, Belgium, France, Germany, Lithuania, Sweden, EU

For more information on MAV+, please see the appendix.

The role of the International Finance Corporation

The World Bank’s International Finance Corporation (IFC) initially announced it would be supporting Rwanda’s “association with BioNTech”, “to explore establishing end-to-end manufacturing capability for mRNA vaccines”, as explained in a press release from September 2021.^{lxvi} However, at the time of writing, the announcement has not been followed by any investment, at least according to the IFC investment database.^{lxvii}

BioNTech Africa and a skilled local workforce

Establishment of a skilled local workforce

Despite being highly automated facilities, the BioNTainers need a properly functioning workforce. It was noted that Rwanda was not meeting human resources requirements^{lxviii} to serve the emerging industry with a sufficient skilled workforce. BioNTech needs staff across the whole value chain, including electricians, engineers and construction workers. To facilitate the growth of such a workforce, it will be vital for BioNTech Africa to also support technical and vocational education and training (TVET). One respondent suggested that academic institutions should establish specialized programmes and facilitate partnerships with manufacturers, both in Rwanda and other African countries. This includes joint research, internships, apprenticeships and eventually job opportunities for students and graduates. This would help foster technical expertise in host countries and pave the way for technology transfer to happen at a later stage. Another respondent suggested that in order to establish a skilled workforce in Rwanda, transitional measures, including outsourcing, must be taken into account at the outset of BioNTech Africa's production. To attain identified key performance indicators by 2040, Africa CDC/PAVM framework for action^{lxix} shows that 12,500 full-time equivalent (FTE) special skills in vaccine manufacturing will be needed on the continent by 2030. The same respondent reported that BioNTech alone would need about 100 FTE to kick-start the plant in Rwanda, and the number will grow to 500 by 2030 when the plant is operating at full capacity. Therefore, the needs for skilled personnel are significant.

An estimation of BioNTech Africa facility's employment needs

According to one interviewee, the BioNTainers should execute mRNA vaccine production in bulk (mRNA manufacturing and formulation), while fill & finish activities should be performed by partners. The overall number of employees needed to operate the facility is still unclear and fluctuates between 100 (as reported by BioNTech in a recent press release) and 200 people, according to one respondent. If the targeted product is the Pfizer-BioNTech Covid-19 vaccine, the BioNTainers in Kigali could aim for an estimated initial annual capacity up to 50 million doses, with the possibility of scaling up to 100 million doses at a later stage. According to one respondent, about half of the employees will be academics carrying out quality control (e.g. shift supervisors), technical roles such as maintenance and cleaning and support staff. The other half will be composed of workers with a higher educational background. The specific tasks of these highly specialized workers have not been further clarified.

Composition of skilled local workforce

Retrieved information indicates that the facility will host staff from seven member states of the African Union. BioNTech is partnering with academic institutions to support skills and curriculum development with the goal of preparing recent graduates for work in the vaccine manufacturing industry. The major fields of study at bachelor's and master's levels to meet these needs include Bioprocess Technology, Industrial Biotechnology, Pharmaceutical Technology (including QA/QC), Chemistry, Biological Sciences, Biochemistry, Chemical Engineering, Mechanical Engineering and Industrial Engineering. The headcount currently includes a pan-African team from seven African nationalities. No details were provided regarding the proportion of the overall workforce that the pan-African team would represent. BioNTech also collaborates with the

African Biomanufacturing Institute (ABI) to facilitate the academic accreditation of professional experience gained working on site at the BioNTech Africa facility in Kigali. The ABI was formally established in June 2022 by the Government of Rwanda and operates as an institute of higher education with university status. It is under the oversight of the Ministry of Education and is managed in close coordination with the African Union. The institute's purpose is to meet the growing demand for highly skilled individuals and attract local talent in STEM (Science, Technology, Engineering and Mathematics). According to one of the respondents, BioNTech will oversee the manufacturing process performed by local actors and train the local workforce. Another respondent suggested that governments ought to better define expectations on what investors should comply with in terms of developing capacities for a national workforce and employability criteria and providing clarity on the positions and level of expertise required for employment, suggesting that both skilled and semi-skilled workers can benefit the industry. In the run-up to the launch of the production, BioNTech plans to work with its staff from Germany to accelerate the training of the local workforce, who will be responsible for running the production and for the associated laboratory and quality assurance tasks on site.

An end-to-end value chain for African vaccine manufacturing

Establishment of an end-to-end value chain to meet Africa's needs

mRNA vaccine manufacturing consists of three main steps: upstream production (mRNA production), downstream purification and concentration, and drug product formulation. Beyond the actual manufacturing process, other significant activities take place in the value chain of mRNA vaccines, such as R&D and fill & finish. In order to build a self-reliant, end-to-end value chain that can help fight pandemics and high-burden diseases such as malaria, HIV and tuberculosis (TB), all steps should take place on the continent. As highlighted by a recent briefing paper issued by the Africa Centres for Disease Control and Prevention (Africa CDC), Clinton Health Access Initiative (CHAI) and PATH,^{lxx} current and planned vaccine manufacturing initiatives on the African continent (including formulation and fill & finish) will be able to cover the production of about 2 billion doses, while current vaccine demand stops at 1.3 billion doses for the African continent. This figure includes the overall output of doses, but does not include the production of antigens, which would remain significantly low.^{lxxi} It was observed that there will also be a significant demand for local manufacturers, particularly small- and medium-sized enterprises (SMEs), to produce syringes and other related products, necessitating a substantial increase in financing.

BioNTech Africa's contribution to an end-to-end value chain in Africa

The BioNTech facility is meant to fill in Africa's gap for vaccine upstream production and downstream purification. According to a press release^{lxxii} from BioNTech, the facility in Rwanda is "a node in a decentralized and robust end-to-end manufacturing network in Africa."

The BioNTech Africa project, differently from other existing initiatives that have been implemented (or planned) in Africa, should handle the earlier phases of vaccine manufacturing, expanding a sector (drug substance production) that must grow in the coming years, going beyond just fill & finish. The BioNTainers should execute mRNA vaccine production in bulk (mRNA manufacturing^{lxxiii} and formulation), while fill &

finish activities will be undertaken by partners that still need to be identified and should be located in Africa.^{lxxiv} According to information available in 2022, fill & finish activities could take place in Ghana and South Africa. A respondent highlighted that antigen production and fill & finish will be initially outsourced, possibly to Germany and Ghana, respectively, meaning that the mRNA plant in Kigali would start with vaccine formulation. In this case, no antigen production would be carried out on site. The Rwandan facility is intended to serve as a manufacturing facility, so no R&D is expected to be performed. To this end, WHO's mRNA vaccine technology transfer hub emerged as a valid avenue for the future. Afrigen (leading the hub) collaborates with five countries in total but has not collaborated with BioNTech to date. As the hub activities progress, it will be easier to collaborate with other initiatives investing in mRNA production. Later steps of the value chain emerged, which are still under discussion. It is therefore difficult to assess to what extent these operations will be carried out at the local, regional or continental level. Rwanda needs a pharma park to surround and support new facilities. Once this park is set up, it will impact self-reliance and local production. This will only happen if the emerging industrial sector is not limited to the production of vaccines.

Intellectual property and transfer of technology, skills, knowledge and know-how

Transfer of technology involves the sharing of both tangible (e.g. machinery) and intangible (e.g. know-how, processes, methods) elements and has emerged as a pivotal aspect of the BioNTech Africa project. In the last decades, knowledge, know-how and skills have progressively emerged as subsets of the wider concept of technology transfer and constitute the so-called “soft” or intangible technologies, as opposed to “hard” or “tangible” technologies.^{lxxv} In order to successfully build capacity for future and long-term manufacturing, transferring both types of technology will be crucial for the industrial development of recipient countries from the Global South. Without a sound transfer of technology,^{lxxvi} countries hosting satellite production sites cannot reach sovereignty and self-reliance regarding access to vaccines. The same goes for the transfer of intellectual property: in this case, it is vital to transfer or assign patents to local entities.

BioNTech Africa and the transfer of technology

While all respondents concurred on the importance of technology transfer, divergent views emerged on the potential of the BioNTech Africa facility to be effectively carried out. It was also stressed that the Rwandan government has been actively involved in the overall project, but details remain scarce on the extent to which technology will be transferred to the government and/or local manufacturers from the country/region. According to one respondent, this might set the scene for future collaborations with local manufacturers from Rwanda. Another respondent highlighted that, at least in some cases, technology tends to be proprietary, and the holder (in this case BioNTech) may choose not to disclose it. BioNTech is allegedly working closely with partners at both local and international levels, as well as experts from research and academia, to facilitate technology transfer. As for the transfer of patents, no license agreement of BioNTech with a local entity is currently expected. BioNTech is also working closely with the German Agency for International Cooperation (GIZ) on capacity building, consulting the agency on needed inputs, structuring and conducting of training modules, establishing networks for trainings offered by GIZ to BioNTech. GIZ is

also interested in providing clean-room laundries (coats of the production site need to be cleaned and cannot be single use). These technical laundries do not exist yet in Rwanda. GIZ is working on how to address this topic, whether it is a business case to be supported in Rwanda, or a regional concern to be addressed in neighboring countries (Tanzania and Kenya have been suggested as potential implementing countries).

In the context of BioNTech Africa, a respondent highlighted that a sound transfer will need to entail all technologies related to manufacturing plants, quality control, proficiency testing for laboratories, as well as virtual reality- and artificial intelligence-assisted skills laboratories and physical laboratories, R&D, clinical trials capacity, good clinical practices, industrial processes (e.g. lyophilization, formulation, fill & finish), upstream transportation, robotics manipulation in downstream processes, dry ice and liquid nitrogen manufacturing, industries around cell line production, production of media fermentation processes, packaging, material industries etc. The transfer towards local manufacturers has also been highlighted as a good opportunity to tackle the issue of substandard and falsified products, as shorter supply chains can reduce dependence on imported products that might emerge as substandard or falsified.

“The technology transfer towards local and regional manufacturers is a good opportunity to solve the issue of substandard and falsified products in our markets.” - Anonymous interviewee

BioNTech Africa and the transfer of intellectual property rights

Together with technology, intellectual property should be transferred or assigned to local manufacturers in order to allow the production of the targeted products beyond BioNTech Africa’s facility. Patent sharing, for example, is essential to empower manufacturers from all over the continent, including WHO’s mRNA vaccine technology transfer hub. Licensing patents, which are part of intellectual property rights, is essential to allow other producers than the one holding IP rights to use, manufacture, sell or otherwise exploit the patented invention. The lack of a sound transfer of intellectual property rights, however, appears to be an inherent limitation of the BioNTech Africa initiative, as setting up isolated, compact and highly automated units to carry out production is not the best option, considering that over 100 manufacturers already had the potential to produce mRNA vaccines in 2021.^{lxxvii}

A handover for the benefit of local manufacturers

As for the transfer of hard technologies, a fully-fledged handover of the facility to the benefit of local manufacturers has been considered as an option according to both press articles^{lxxviii} and respondents. The latter were nonetheless divided on the possibility of handing the facility over to manufacturers operating at the local, regional or continental level. One respondent mentioned that there would be a plan to sell producing units to the Rwandan government in the future. According to this respondent, this is what everyone assumed in the space of the emerging sector of Rwandan vaccine manufacturing. The handover would take place after 3 to 5 years of production conducted under BioNTech, and it would be carried out to the benefit of the Rwandan government. Another respondent suggested that the cost of upgrading the

facility would be higher than the initial investment. If so, the Rwandan government would have no interest in taking over production. For this same respondent, the facility was allegedly offered to the government, but the costs for upgrading it through the years would have constituted a considerable barrier.

The role of the European Union in transferring technology

The EU is promoting technology transfer through one of the six workstreams of the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+). It is however essential to bear in mind that the support delivered by MAV+ is not impacting (at least not directly) the BioNTech Africa project and the associated transfer of technology. At the continental level, MAV+ is structured into three dimensions (supply, demand and enabling environment), further subdivided into six workstreams, namely 1) industrial development, supply chains and private sector, 2) market shaping, demand and trade facilitation, 3) regulatory strengthening, 4) technology transfer and intellectual property management, 5) access to finance, and 6) R&D, higher education and skills.^{lxxxix} Team Europe's contribution to vaccine manufacturing in Rwanda, accounting for 93.7 million euros, specifically focuses on three main areas, namely regulatory capacity strengthening, skilled workforce and technology transfer.^{lxxx} As for the latter two, three main initiatives have been identified as relevant. A first initiative promotes partnerships between the University of Rwanda and EU universities and aims, among other things, to inaugurate a master's programme to train a workforce in medical production. A second initiative, sponsored by the German government and funded by the German Development Bank (KfW), aims to sustain the Regional Center of Excellence for Vaccines, Immunization, and Health Supply Chain Management (RCE-VIHSCM). The College of Medicine and Health Sciences, as part of the University of Rwanda (UR-CMHS), also supports the RCE-VIHSCM, and has a central role to play in the social and economic development of the nation through the training of medical doctors and health professionals. Finally, a third initiative provides support to a local manufacturer of medicines (Akagera Medicines). At the continental level, MAV+ is also supporting technology transfer towards local manufacturers through WHO's mRNA vaccine technology transfer hub (and its associated network of recipients).

Regional and continental distribution

Vaccine doses, once produced, need to reach a specifically targeted market. Without a well-coordinated plan for both continental and regional distribution, doses may reach a market that is not suitable for the quality and quantity of the product. As for BioNTech Africa, production capacity will depend on the final product and its dosage. If used to produce the Pfizer-BioNTech Covid-19 vaccine, the first set of BioNTainers could produce an estimated initial annual capacity of up to 50 million doses.

Targeted market for BioNTech Africa's products

Vaccines manufactured by BioNTech are expected to support supply within the African Union, including domestic use within Rwanda.

If the BioNTainers initially produced 50 million doses per year (with the possibility of scaling up to 100 million per year^{lxxxix}), the Rwandan population (approximately 13 million people) would be an overly

constricted target market. It was indeed suggested that the whole region, if not the African continent, should benefit from the product. A respondent suggested that most vaccines are moved by air, making distribution relatively agile. Nonetheless, the cost of shipping from Rwanda to another African country could be even higher than importing from large-scale manufacturers, namely from India. This means that moving vaccines can be agile in terms of logistics, but not cost-efficient if compared to imported vaccines. Premiums were highlighted as a possible solution, but determining the terms by which they should be implemented was reported as a major challenge. Premiums are means of supplementary compensation awarded to regional producers to foster competitive capabilities while they are setting up their manufacturing operations. In conclusion, when premiums are set, national and international procurers are willing to pay a higher price for vaccines produced by regional manufacturers compared to those made by foreign manufacturers.

Trade barriers and distribution of vaccines

Surmounting tariff and non-tariff trade barriers has also been identified as a key aspect for the implementation of the BioNTech Africa project. The continent is far from operationalizing free trade zones and agreements. Barriers need to be lowered, requirements harmonized, and licensing restrictions reduced, among other critical actions. According to a respondent, Rwanda is a small market that has already done well in supporting the free movement of people, but much work still needs to be done in the field of goods and services.

The involvement of other countries as recipients of BioNTech Africa vaccines will be vital for the financial sustainability of the project. “The survival of this project hinges on the existence of an African market, which is currently non-existent”, highlighted a respondent, also observing that Kenya, for example, would not have any interest in buying a product made in Rwanda over an equivalent product shipped from India at a cheaper price. This could change if the value chain is distributed over the continent, and multiple countries control a segment of the value chain (e.g. a first country performs R&D, a second one produces drug substance and drug product, and a third carries out fill & finish). In light of this, operationalization of the African Continental Free Trade Area (AfCFTA) would be crucial for the circulation of both manufactured goods and raw materials. AfCFTA has the potential to accelerate the smooth flow of products, removing tariff and non-tariff barriers, thus promoting the distribution of goods and augmenting access to medical countermeasures, especially in pandemic times.

Other actions needed to ensure equitable distribution of vaccines

Further information was gathered on effective strategies that can be put in place to ensure equitable distribution. Respondents emphasized the importance of establishing essential infrastructure, including research centers, roads, logistics (e.g. transportation and storage facilities) and regulation, to facilitate the seamless distribution of vaccines across the continent from Rwanda to recipient countries. The importance of a robust regulatory framework was highlighted as one of the most crucial aspects. This suggests that a well-connected and regulated system is essential to ensure that vaccines reach all corners of Africa, contributing to equitable health outcomes.

Market access, procurement strategies and price determination

Market access is a crucial element for newly set vaccine manufacturers. In order to stay competitive and be financially sustainable, new manufacturers must indeed obtain access to the market, and this can only happen through an effective procurement strategy. Procurement is strongly linked to the market price of vaccine doses, which constitutes another key element of market access.

Current demand and challenges around market access

According to some respondents, the demand for products that will be manufactured by BioNTech Africa is still to be fully assessed. It was indicated that the Rwandan market is limited, so the reach must necessarily expand to the regional and/or continental level. Other respondents highlighted the importance of setting up organized planning processes for vaccine production. This includes forecasting and aligning production with actual demand to avoid overproduction or shortages. The impact of the product on the market of local manufacturers based in Rwanda therefore remains uncertain.

Capacity of the African continent to accommodate mRNA vaccine manufacturers

Concerns about sustainability, which requires commercial success, also emerged during the interviews. For more than twenty years, low-cost vaccines flying in from India prevailed, jeopardizing local production from African companies. mRNA vaccines could transform this dynamic, considering that they are mostly cheaper and easier to manufacture.^{lxxxii} According to one respondent, the African market should be able to incorporate five mRNA vaccine manufacturers. In this case, BioNTech's focus should stay on one entity, without fragmenting production over too many facilities.

Procurement plans for BioNTech Africa

As for the BioNTech Africa project, procurement strategies are not defined yet. Respondents were not aware of plans from the international vaccine alliance Gavi^{lxxxiii} or any African government and concluded that it was too early to say anything about the progress of the overall project. In the absence of a clear procurement strategy for the products of the BioNTech Africa facility, respondents focused on the necessary conditions for the project to prosper and compete at a global level. These conditions might offer valuable avenues for the procurement of vaccine doses produced by BioNTech Africa.

Firstly, Africa will need medical products to aim at the entire African market of 1.4 billion people. When asked about potential purchasers for the final product, respondents made a distinction between different options that appear to be currently under discussion among policymakers at the African and international level:

- If the Covid-19 vaccine is the target product of BioNTech Africa, African countries will likely secure doses for a small segment of their high-risk populations.
- For malaria, medical products are usually purchased through Gavi and the Global Fund, with a wider market reach. mRNA vaccines against malaria from BioNTech Africa could be directly acquired by African Union member states.

- The mRNA malaria vaccine under development within BioNTech's pipeline would be a product targeting eradication, therefore not limited to disease control. As explained by one of the respondents, because of this factor alone, manufacturing such antimalarial vaccines would not necessarily make a great business case.

The role of Gavi in procuring vaccines from BioNTech Africa

It was noted that in the past Gavi collaborated with only five manufacturers. Today their reach has expanded to 19 manufacturers, mostly in high-income countries, and with only one manufacturer from the African continent (i.e. Institut Pasteur de Dakar, Senegal). This could change with Gavi's new initiative, the African Vaccine Manufacturing Accelerator (AVMA). AVMA takes inspiration from Advance Market Commitments (AMC) and constitutes a long-term financial mechanism to ensure that Gavi will purchase a fixed number of doses if manufacturers reach a pre-determined target within a certain timeframe.^{lxxxiv} Gavi is not specifically involved in the BioNTech Africa project. In more general terms, they do not provide grants or loans directly to manufacturers. Setting up AVMA could foster collaboration and resource optimization across the continent. AVMA constitutes a mechanism based on pull incentives. Pull incentives are granted upon the achievement of a pre-determined outcome (e.g. WHO prequalification). As for the possibility of using AVMA to confer pull incentives to BioNTech Africa, there is no indication or guarantee that this will happen in the future. Beyond Gavi, respondents also suggested that the African Vaccine Acquisition Trust (AVAT) could be involved in the future for the procurement of vaccine doses. AVAT's main goal is to carry out centralized purchase of vaccines on behalf of African Union (AU) member states. AVAT was established in response to the Covid-19 pandemic and represents a joint effort among the African Export-Import Bank (Afreximbank), the Africa Centres for Disease Control and Prevention (Africa CDC) and the World Bank.

Pricing criteria of BioNTech Africa

Little to no information was disclosed by respondents regarding the pricing criteria for their manufactured products. There was consensus among the respondents that BioNTech will sell doses of Covid-19 vaccines at a non-for-profit price and will exclusively target African countries. According to one interviewee, the price will be approximately determined on the basis of production costs, following a not-for-profit criterion. Low- and middle-income countries should also have affordable access to the doses of potential vaccines against malaria, HIV and TB, if successfully developed and approved. Interviewees were uncertain about the impact that BioNTech Africa could have on the existing ecosystem of local and regional manufacturers, considering that their launch price might be much lower than the market price for locally and regionally established manufacturers.

“What happened in Africa for 20 years is that very low-cost vaccines coming from India killed local production.” - Anonymous interviewee

Regulatory framework for locally produced vaccines

The impact of BioNTech Africa on the regulatory framework in Rwanda and Africa

Complying with strict international quality standards is crucial to prevent falsified and substandard medical countermeasures from being introduced into the African market. Especially at the country level, regulatory hurdles have frequently been highlighted as prominent roadblocks to the establishment of an enabling environment for local manufacturers to thrive. Not only the lack of reliable National Regulatory Authorities (NRAs), but also the profound fragmentation of the overall continental framework has been pointed out as a major issue. According to one respondent, BioNTech's investment, alongside other factors, contributes to strengthening regulatory capacities in Rwanda. Such improvements can provide better quality medicines and help Rwandan manufacturers to be competitive vis-à-vis the industrial hegemony of the Global North. It was stressed that the existence of strong regulatory measures serves as a cornerstone for ensuring that the processes involved in vaccine manufacturing strictly adhere to quality and safety standards. This will eventually result in more confidence within both domestic and international markets, contributing to promoting trust in the safety of vaccines produced within the local, regional and continental regulatory framework.

Strengthening the regulatory system in Rwanda

Respondents highlighted that one of the cornerstones of the regulatory strengthening accompanying the BioNTech Africa project will be the obtainment of maturity level III at the Rwanda Food and Drug Authority (Rwanda FDA). Maturity level III is the prerequisite set by the WHO Global Benchmarking Tool for countries to apply for vaccine prequalification. A regulatory authority with maturity level III indicates a stable, well-functioning and integrated regulatory system, while level 4 indicates a regulatory system operating at an advanced level of performance and continuous improvement. As of October 2023, 14 countries have achieved WHO maturity levels 3 or 4 through their national medicines regulatory authorities (NRAs). Within this group, there are five African countries, namely Egypt, Ghana, Nigeria, South Africa and Tanzania.^{lxxxv}

Once a product successfully obtains prequalification, it becomes part of the list of WHO prequalified products, indicating that the product is suitable for procurement by United Nations agencies such as UNICEF, the Global Fund, and other international procurement agencies. A first benchmarking took place in December 2022, and 50 recommendations were issued to the Rwanda FDA to be further implemented, whereas in April 2023 the Rwanda FDA received 'only' 23. Another benchmarking was scheduled for mid-September 2023, while the last benchmarking was carried out in late February 2024. During the last benchmarking, Rwanda FDA did not achieve maturity level III, and 9 outstanding recommendations were suggested by the WHO. The main roadblocks are to be found in the recruitment and training of additional staff, and the clearance of the list of authorized medicines, considering that those products were directly approved by the Ministry of Health before the Rwanda FDA was operational.

Team Europe is supporting the Rwanda FDA to reach maturity level III benchmark through the "twinning" between EU and Rwandan authorities (FDA).^{lxxxvi} As for implementing partners, GIZ is supporting the Rwanda FDA to regulate BioNTech in the future, especially in the field of Good Manufacturing Practices

(GMP) inspections. Collaboration between the Rwanda FDA and other African national regulatory authorities has also been highlighted as an important element, as evidenced by the memorandum of understanding (MoU) jointly signed by the Rwanda FDA and Ghana FDA in June 2022. As reported by an update^{lxxxvii} issued by the Rwandan government, the MoU “will allow both National Regulatory Authorities to collaborate in areas of mutual interest, especially in the processes and procedures of the World Health Organization (WHO) Global Benchmarking Tool (GBT) and technical assistance related to the regulation of medicines and vaccines.”

Current capacity for Good Manufacturing Practices (GMP) inspections

According to one of the respondents, the Rwanda FDA reaching maturity level III would be irrelevant for the BioNTech mRNA facility, as the benchmark is required in the same country where fill & finish activities will take place – and fill & finish, as highlighted by respondents and documental sources, will not be performed in Rwanda. However, all respondents agreed that there would only be advantages in increasing regulation in Rwanda, as strengthening regulatory authorities will increase the capacity of the country to successfully ensure that medical products meet quality, safety and efficacy standards.

One respondent stressed that the sums committed to regulatory development could have been spent differently, referring to all sums dispensed prior to the disbursement of the additional 40 million euros deployed by MAV+. According to the received information, the capacity of the Rwanda FDA for GMP inspections was not prioritized, with all focus being invested into maturity level III benchmarking. Respondents reported that this came as a surprise, since it is mandatory that production sites are GMP approved in order to sell active ingredients. Considering the commitment made by the German government to support the establishment of a new Quality Control Laboratory for Rwanda FDA, GIZ has conducted an assessment mission in Rwanda in 2023. The quality control laboratories have been funded through GIZ and will take three years to be fully operational (2026). The respondent highlighted that the Rwanda FDA would have been ready to operate by now if a lead GMP inspector had been in place. Another respondent highlighted that with the imminent operationalization of the African Medicines Agency (AMA), there will be an increase of capacity in joint inspection programmes. These will occur following the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Another respondent affirmed that reaching maturity level III would only be required for the export of the final product, and it should not be a requirement for carrying out fill & finish per se, as indicated by another respondent.

It was also indicated that building regulatory frameworks would need continual efforts. For instance, bodies such as Rwanda's National Quality Infrastructure will play a crucial role and must be considered, as they ensure that vaccine manufacturing consistently meets rigorous quality and safety standards, allowing the market to possibly be extended beyond the African continent.

What are the institutions involved in regulatory strengthening in Africa?

As for entities sustaining regulatory strengthening, many actors are (and will be) at stake. For PAVM and the Africa CDC, the long-term goal will happen at the national and regional level, supporting both NRAs and the African Medicines Agency (AMA). The short-term goal will be to facilitate and support quicker regulatory

approval of African products, for example through WHO prequalification. Another crucial aspect that was highlighted by interviewees regards the harmonization that the AMA could provide between national regulatory authorities, once fully operative. Interviewees highlighted that AMA should take the lead on advanced products, including complex molecules like mRNA vaccines, so the Rwanda FDA will be able to rely on AMA at the continental level. Collaboration and cross fertilization are therefore expected to happen soon between the Rwanda FDA and AMA.

Coherence with local, regional and continental epidemiological needs

Local production does not automatically translate to fulfilment of local needs. In order for local manufacturing to result in the production of medical countermeasures that are beneficial for the local, regional and continental population, it is crucial to target diseases that have a high burden in Rwanda, East Africa and the African continent.

According to a respondent, the concept behind the BioNTainer solution is setting up a “flexible container solution in a comparatively short timeframe, granting access to modern mRNA vaccine production tailored to local needs.” In order to evaluate the consonance between BioNTech’s pipeline and epidemiological needs from the local, regional and continental level, current options for vaccines to be produced by BioNTech Africa must be analyzed.

Current target diseases for vaccines produced by BioNTech Africa

BioNTech will likely kick off its production with Covid-19 vaccines, notably through “an RNA process similar to that of the Pfizer-BioNTech Covid-19 Vaccine.”^{lxxxviii} In the future, BioNTech could consider producing prophylactic mRNA vaccines for malaria, HIV and TB that the company is currently developing. According to one respondent, this process could be lengthy, requiring at least 8 years.

It is important to remember that BioNTech only has a single product marketed, the Covid-19 vaccine. Producing Covid-19 vaccines is useful to test the production and the surrounding regulatory and distribution system. Such a product would likely constitute a proof-of-concept case, since there is no epidemiological rationale justifying the sole production of Covid-19 vaccines in Rwanda, East Africa and the African continent right now, especially if compared with other infectious diseases that have a massive continental burden.

According to one respondent, the most anticipated good that could be produced through BioNTainers is the prophylactic malaria vaccine, which is undergoing clinical trials (it is in phase 1, but the respondent asserted that the development phase should be swift). Oncology and TB cases would also be part of BioNTech plans, according to the same respondent. Respondents also highlighted that focusing on mRNA vaccine technology might be a good strategy to help the continent meet self-reliance and sovereignty ambitions.

Another example of a product that may respond to local epidemiological needs is a rabies vaccine. This is estimated to be simple to produce, and effective, and it has the potential of landing a vast user base. Other respondents included other prevalent diseases on the continent as a target for products. Ebola, cholera, hepatitis and monkeypox were identified as top priorities, highlighting the need to address diseases with a

significant regional burden. Such prioritization aligns with the goal of tailoring vaccine production to the specific health needs of African nations.

Coordination with other initiatives

As previously mentioned, many initiatives targeting vaccine manufacturing have been (or are expected to be) launched on the African continent. Considering previous market failures and a stark tendency of individual vaccine markets to incentivize monopolistic and oligopolistic behaviours, it will be crucial to coordinate existing initiatives to reduce avoidable gaps and overlaps. All existing efforts on the continent should be aligned based on public health needs and priorities.

The interaction between BioNTech Africa and other manufacturing initiatives

BioNTech is bringing an established, proven mRNA platform – unlike other initiatives that need to be built from scratch. A major downside of bringing a new manufacturing site, such as the one from BioNTech, to the African continent is that production might result in a monopoly situation, through patenting and other strategies concerning intellectual property and know-how. This would reduce the benefit for the continent, financially and health-wise. Some companies (notably from Australia and South Korea) have been identified as likely to collaborate in joint ventures with initiatives such as WHO's mRNA vaccine technology transfer hub in South Africa. BioNTech appears more reluctant to collaborate on joint initiatives, only showing interest in fully-fledged collaborations in the field of fill & finish. According to one respondent, small biotechnology companies are more likely to participate in joint ventures and collaborations in general. mRNA production is expected to allow companies to perpetuate monopolies for some time. The mRNA vaccine technology transfer hub in South Africa has been highlighted as a valuable structural solution challenging the current model of the biotechnology industry, but their products are not expected to be developed as soon as BioNTech vaccines. A monopoly would not be beneficial for public health needs, one respondent observed. The same respondent also pointed out that companies from the private sector of the Global North will benefit from positive effects from the emerging enabling environment in Rwanda, both in the short and long term (expertise of Rwanda FDA, presence of a well-developed infrastructure, etc.) In Rwanda, vaccine manufacturing has been described as a young but rapidly developing sector. UNIZIMA (Belgium) and Akagera Medicines (US-based but with Rwandan shareholders) are the main examples of existing pharmaceutical manufacturers in the country. Their activities are mostly focused on R&D, according to one of the respondents, and a scale-up of manufacturing has not been indicated as imminent. Africa CDC and PAVM emerged as the main entities in charge of fostering such collaborations. Meetings involving these manufacturers have been reported to happen on a regular basis.

Current coordination of vaccine manufacturing initiatives in Africa

Harmonized policies, including mutual recognition, standardized procedures, market authorization, product registration/licensing, inspection, post-market surveillance (PMS) and pharmacovigilance, will be critical to craft a healthy pharma market based on collaboration between different initiatives. This is why the AMA, the African Continental Free Trade Area (AfCTA),^{lxxxix} the African Pharmaceutical Technology Foundation (APTF) and the African Biomanufacturing Institute (ABI) will be critical in sustaining the long-term goals for vaccine

manufacturing established by PAVM. Many of these initiatives have been or will be, once fully operationalized, located in Rwanda. Setting up most of these initiatives in a timeframe of one year has made a case for the rapidly expanding role of Rwanda in the field of pharmaceutical and vaccine manufacturing in Africa. The establishment of like-minded structures for accelerating technology transfer was also mentioned as crucial in the future.

It was stressed that coordination between existing initiatives will be vital for the diversification of vaccine production in Africa. Considering the shortcomings of the international pooled procurement and distribution mechanism COVAX linked to vaccine nationalism and bilateral agreements breaches by countries from the Global North, enhanced collaboration on the African continent can proactively deploy unified actions in anticipation of future emergencies. For this purpose, negotiations around the Pandemic Treaty and amendments to the International Health Regulations might help pave the way for future collaboration.

“Coordination is essential. We’ve seen a plethora of investments in vaccine manufacturing. We need to understand the interplay between different vaccines at the continental level. If done with nationalistic interests, this is not going to work.” - Anonymous interviewee

Organizations working in the space of local production of vaccines (and other relevant areas) that are based in Kigali, Rwanda

Name of the organization	Function
African Pharmaceutical Technology Foundation (APTF)	The APTF was launched by the African Development Bank in 2022 to foster innovative approaches and incentive partnerships, intellectual property and domestic capacity-building for sustainable pharmaceutical manufacturing on the African continent.
African Biomanufacturing Institute (ABI)	ABI aims to facilitate the academic accreditation of professional experience gained working on site at the BioNTech Africa facility in Kigali. ABI was formally established in June 2022 by the Rwandan government and operates as an institute of higher education with university status under the oversight of the Ministry of Education. It is managed in close coordination with the African Union.
African Medicines Agency (AMA)	Specialized agency of the African Union dedicated to improving the quality, safety and efficacy of medical products in Africa.
Rwanda Food and Drugs Authority (Rwanda FDA)	Rwandan National Regulatory Authority (NRA).

Examples of existing coordination between initiatives

Considering the wide range of initiatives proliferating on the African continent after 2021, we can ask ourselves whether all these efforts are converging in the same direction and are therefore well coordinated. Some actors are already taking care of coordinating the rising pharmaceutical and vaccine manufacturing sector in Africa. The Africa CDC was identified as the leading actor, probably followed by the WHO (also through the WHO Regional Office for Africa). A respondent highlighted that coordination between the pharma and biotechnology sector and Africa CDC has been fruitful in the past, and that Africa CDC still plays a crucial role in empowering the whole network. The same respondent underscored that the WHO and the Africa CDC do not share the same vision on desirable outcomes of vaccine manufacturing within the African continent, without providing any further detail. The African Vaccine Manufacturing Initiative (AVMI) was also indicated as a focal point for continental coordination.

The importance of coordination

Coordination of vaccine manufacturing in Africa was also stressed by one of the respondents as an opportunity to reform the organization of the supply chain in Africa. Pandemic preparedness and response would be achievable by attaining shorter and more resilient supply chains. Local manufacturing was therefore referred to as the biggest solution in the jigsaw puzzle. This is also the rationale behind institutions like the Global Fund moving procurement and supply towards the Global South. Coordination between ongoing initiatives was also highlighted as a necessary tool to bolster coherence between produced goods and local, regional and continental epidemiological needs.

A broader picture of satellite production sites and their potential

Depending on the success of the BioNTainers model, satellite production sites might become an appealing solution for Global North-based biotechnology and pharmaceutical companies to expand production to the Global South. It is therefore crucial to better understand the inherent qualities and limitations of satellite production sites. Compared to other initiatives, such as the ones sustained by the AU and the WHO, the roll-out of satellite production sites, especially the one from BioNTech, has been relatively swift.

The role of trust in the pharmaceutical and biotechnology industry

A first aspect that was put under scrutiny regards the lack of trust towards the pharmaceutical and biotechnology industry. According to one respondent, satellite production sites will have to face this dire lack of trust. It was stressed that profit motives often prevail over public health reasoning, and African citizens are disheartened by this. New initiatives targeting vaccine manufacturing are often received with mistrust from both beneficiaries and policymakers. According to one of the respondents, the role of civil society organizations will be crucial in surmounting the issue, building trust in the product and in the producer, but public health needs must be prioritized first.

The impact on health equity, sovereignty and self-reliance

Another respondent observed that satellite production sites might be a viable solution to foster health equity, especially in the short-term. Taking the products to African regions that are lacking capacity is often a challenge, but the agile structure of satellite production sites does not require a fully developed pharmaceutical park. While health equity could be upheld as long as produced goods remain in the region, there are outcomes that cannot be attainable through satellite production sites, especially long-term goals such as sovereignty and self-reliance of countries from the Global South. For this to happen, technology transfer towards locally owned entities in the region must take place. According to a respondent it is not just the product, but also the revenue that should stay in the region. Joint ventures, for example, may be a valuable solution to share profit, especially in the short-term, between Northern- and Southern-based manufacturers.

The difference between regional manufacturing and satellite production sites

A structural issue emerged from the answers provided by respondents: should we consider satellite production sites as equivalent to African manufacturers, or should we see them as manufacturing facilities owned by companies from the Global North offshoring part of their production? Depending on the answer, these facilities might benefit from incentives, premiums and other sorts of advantages aiming to facilitate the establishment of regional manufacturing. It should be noted that it is not only a matter of where production is set, but also of ownership of intellectual property rights such as patents, machinery, know-how and knowledge, as well as a matter of where the profits stay (in the region, or in the country where headquarters are located). As rightly observed by one of the respondents, if manufacturing is carried out in the region, revenues should stay in the region for it to be defined as “regional manufacturing”. This does not seem to be the case for the BioNTech Africa facility. For now, the manufacturing facility in Rwanda will sell

for a not-for-profit price, but this might change in the future. Clarifying such aspects in advance is key to ensuring that health equity, sovereignty and self-reliance are put at the heart of regional manufacturing.

Control over production

Another respondent highlighted that facilities such as satellite production sites might respond to the needs of the base factory (located in the main country of production), especially in pandemic times. “What happens if the main production site breaks down during a pandemic? Would the Rwandan facility be shipped back to Germany? It’s about who has control over things”, declared one of the experts joining our side event during the 2nd World Local Production Forum, pointing out that difficulties may arise in the long-term. The importance of a clear timeline for the handover of satellite production sites towards local manufacturers was also stressed.

The socio-economic impact of satellite production sites

Respondents emphasized the creation of employment and the generation of revenue as significant economic benefits. Other key advantages included a reduction in the overall cost of public health due to decreased reliance on imports, fostering a healthier workforce by mitigating disease prevalence, and diminishing dependence on imported medicines. If successful, all mentioned benefits will result in an amelioration of the overall well-being of the population, at least based on economic criteria.

Overview key findings

On health equity

- Satellite production sites in the form of modular factories in shipping containers offer a rapidly deployable and transportable response to increase local and regional manufacturing of vaccines, regardless of the eco-system in which they are located.
- Coordination with other existing initiatives for vaccine manufacturing in Africa has emerged as a crucial instrument to avoid gaps and overlaps.
- Satellite production sites in general – and the BioNTech Africa facility in particular – can contribute to health equity by increasing access to health products on the local, regional and continental level.

On sovereignty

- Little to no information is currently available on distribution strategies for the final manufactured products, but these are likely to stay on the African continent. The same applies to procurement strategies.
- The BioNTech Africa facility will manufacture mRNA Covid-19 vaccines first. After this phase, it is likely to consider producing mRNA vaccines against malaria, HIV and tuberculosis (TB).
- BioNTech Africa is likely to determine the price for their Covid-19 vaccines on a not-for-profit basis. BioNTech Africa is also expected to provide “affordable access” to doses of potential vaccines against malaria, HIV and TB – if successfully developed and approved. No further clarification has been provided about what “affordable access” entails.
- It remains doubtful whether satellite production sites in general – and the BioNTech Africa facility in particular – can and are aiming to contribute to countries’ sovereignty.

On self-reliance

- The BioNTech Africa initiative is bringing production of Active Pharmaceutical Ingredients (APIs) to the African continent. This should contribute to the long-term regional development of a sustainable, quality-focused drug manufacturing industry that is less dependent on supplies of APIs from outside the continent.
- It remains unclear where and when other phases of the value chain, such as research & development and fill & finish, will take place in the future. An end-to-end pharmaceutical value chain located in Africa is critical for regional manufacturing to stay sustainable.
- The BioNTech Africa facility has been integrally financed by BioNTech itself, but the enabling environment, including the regulatory system, has been massively sustained by public funding from Team Europe and the government of Rwanda.
- The establishment of the BioNTech Africa facility has stimulated the strengthening of the regulatory system in Rwanda, allowing it to market safe, effective and quality-assured medical products.
- It is not yet known whether, how and when BioNTech Africa will (fully) hand over the facility to the Rwandan government and/or local manufacturers.

- A skilled workforce from the African continent will operate the BioNTech Africa facility, but no details about the ratio of local workers to European workers has been made available, and little to no information has been disclosed about the roles of the involved workers.
- The transfer of technology, knowledge, know-how and data is mostly happening within BioNTech. The transfer of technology towards Rwanda is mostly limited to knowledge transfer and will likely happen via the academic sector. No license agreement is expected between BioNTech and local/regional entities.
- It remains doubtful whether satellite production sites in general – and the BioNTech Africa facility in particular – can and are aiming to contribute to countries' self-reliance.

Discussion

The discussion has been organized following a division in three categories: health equity, self-reliance and sovereignty. These categories correspond to the three parameters that have been used in our study to measure the short- and long-term impact of the BioNTech Africa initiative on the local, regional and continental levels.

BioNTech Africa's impact on health equity

How fast is fast enough?

As already observed, the BioNTech Africa facility represents one of the most rapid responses to the longstanding challenge of vaccine manufacturer in Africa. But while satellite production sites are characterized by readiness and swiftness, BioNTech's efforts to bring regional manufacturing to Africa have not translated into the production of Covid-19 vaccines nor indeed any other vaccine (Malaria, TB, HIV) yet. Over 100 manufacturers in low- and middle-income countries are considered suitable for the production of mRNA vaccines, but technology and know-how need to be shared for them to start production. Eight of these manufacturers are located on the African continent. While it took years to craft BioNTainers and operationalize production for Covid-19 vaccines, BioNTech could have transferred technology to African manufacturers and start vaccine production within 6-9 months,^{xc} thus increasing access to vaccines. It is also important to observe that the narrative around BioNTainers, often depicted as fast and scalable solutions, should not be used to avoid providing information about the manufacturing process happening inside, including the know-how, as also stressed during interviews.

Coordination among existing initiatives

In order to increase access to medical products and overcome unjust disparities with the Global North, more than just one initiative will be needed on the African continent. This is why it will be crucial to pursue a fruitful coordination between the BioNTech Africa facility and other initiatives on the African continent. This topic emerged as a crucial issue during interviews, especially considering that BioNTech will gain a relatively unripe market for vaccine manufacturing in Rwanda and will benefit from a lack of competitors. Competition at the local, regional and continental level must therefore be preserved through the fruitful coordination of all existing initiatives. More coordination is specifically recommended with the WHO's mRNA vaccine technology transfer hub in South Africa, considering that BioNTech's contribution to R&D activities carried out would be essential. BioNTech, alongside Pfizer and Moderna, have already declined WHO requests to share their technology and expertise with the hub in the past. Since coordination will be a key element to reach health equity, it is essential that IP rights, but also technology, knowledge and know-how are shared with the mRNA vaccine technology transfer hub and all relevant initiatives that contribute to regional vaccine manufacturing.

BioNTech Africa's impact on sovereignty

Pricing criteria

Information on price determination was limited. The price of Covid-19 vaccines will be based on production costs only, following a not-for-profit logic, while low- and middle-income countries will be given "affordable access" to doses of potential vaccines against malaria, HIV and TB, if successfully developed and approved. The definition of "affordable access" is too vague and should be clarified by BioNTech so that the actual affordability of manufactured doses can be assessed. It should be highlighted that the impact on pricing policies is not limited to sovereignty, but also to health equity, especially in light of the issue of the affordability of produced vaccines. Considering the lack of information about production costs and the uncertainty about the final target product, it is still hard to determine the adequateness of the overall pricing policies for the years to come. Also, it is important to note that while affordability seems to be taken into account, locally based manufacturers might suffer from a well-established competitor producing at a cheap price, having to bear limited costs compared to local producers. The following example is useful to fully understand the impact of low prices on local and regional manufacturers.

The case of the Prevenar/PCV13 tender in South Africa

An example of cheap priced drugs wiping out locally based manufacturers can be drawn from the Prevenar/PCV13 tender in South Africa. In 2023, the South African government announced that the tender for the pneumococcal vaccine Prevenar/PCV13 had been awarded to the Serum Institute of India, while everyone was expecting Biovac, a bio-pharmaceutical company based in Cape Town, to successfully secure the tender. The Biovac Institute is a public-private partnership (PPP) between the Biovac Consortium and the South African National Department of Health. While South Africa had strongly advocated for local manufacturing in the past, the Prevenar/PCV13 tender demonstrates, once again, that if someone is producing for a cheaper price, it will be hard for local manufacturers to thrive, considering that they have to reach economies of scale first. While BioNTech Africa formally appears as focused on local manufacturing, it operates as a subsidiary branch of BioNTech SE (Germany). Other manufacturers that are not only producing locally but that are also local companies might therefore suffer the competition of cheaply priced medicines produced through such initiatives.

Procurement strategies

Gavi emerged as a relevant international procurer, but it was not possible to obtain more details about specific procurement strategies regarding BioNTech Africa mRNA Covid-19 vaccines. Gavi's new accelerator, AVMA, is based on pull incentives, while push incentives such as grant funding would be a more equitable instrument. Considering that emerging African countries face difficulties in securing financing to introduce pharmaceuticals to the market, push incentives have emerged as a more appropriate tool to achieve this goal.^{xci} The same goes for details regarding other products that might be manufactured in the future.

Without a clearer view of procurement strategies (and therefore of the demand for manufactured products) it will be impossible to assess the ability of the BioNTech facility to contribute to sovereignty, but also to health equity.

Alignment with epidemiological needs

Epidemiological needs appeared to still be unclear, with Covid-19 vaccines being kept as a target product for initial production tests. No respondent highlighted the necessity of coordinating the production of satellite production sites with National Essential Medicines Lists (NEMLS). A recent study proved that companies operating in different East African countries such as Kenya, Uganda and Tanzania often do not align their production with Essential Medicines (EM) needs. After completing Covid-19 test batches, BioNTech should therefore align with priorities determined by the NEML of Rwanda and other countries involved in the distribution of doses.

Distribution of the final product

While it was made clear that BioNTech intends to keep the distribution of the final product within the African region, the implementation of distribution, especially to other African countries beyond Rwanda, was identified as a complex task. The AfCFTA, working towards the elimination of tariff and non-tariff barriers, plays a crucial role in the facilitation of local, regional and continental distribution, so its operationalization must proceed.

BioNTech Africa's impact on self-reliance

The importance of a meaningful transfer of technology

In order for Africa to achieve self-reliance and self-determine its own public health priorities, technology, know-how and knowledge must be made available to local manufacturers and academia from Rwanda, East Africa and the continent. Setting a facility on the African continent should not be leveraged by BioNTech as a reason to deny the transfer or assignment of patents by affirming that mRNA production already takes place in Africa.

The transfer of technology could encompass the handover of the facility to the Rwandan government and/or local manufacturers from the region. In preparation for the transfer of technology, knowledge and know-how must be transferred by BioNTech, to avoid that a future handover is accompanied by difficulties in operating the facility due to a lack of a skilled workforce.

The MAV+ initiative is helping to pave the way for technology transfer, setting synergies between, for example, the University of Rwanda and EU universities. While education and basic knowledge channeled through academia set the scene for future technological development, technology transfer primarily occurs via private markets.^{xcii} Educating future generations about biotechnology does not automatically translate into a transfer of know-how regarding the manufacturing process of a specific facility, technology and product. This is why BioNTech is also training a skilled local workforce who will be responsible for running the production on site. Nonetheless, such transfer mainly occurs within BioNTech and it brings no direct

benefit to African manufacturers. More efforts will need to be made to stimulate the transfer of technology, knowledge and know-how not only among academic institutions, but also within the private sector and to the benefit of African manufacturers, with satellite production sites being potential means of not only of production but also dissemination.

Attaching public health conditions to financial support

The lack of direct public funding for the establishment of the BioNTech Africa facility means all involved parts cannot be held directly accountable. Nonetheless, public funds have been extensively used to support BioNTech's R&D for Covid-19 mRNA vaccines, the same product (and the same technology) that will be manufactured in the BioNTainers. These funds include 375 million euros from the German Federal Ministry of Education and Research (BMBF)^{xciii} and 100 million euros from the European Investment Bank (EIB)^{xciv}. Moreover, funds have been mobilized through Team Europe Initiative, MAV+. These funds have set the conditions for BioNTech to thrive and initiate vaccine manufacturing in an appealing and well-established business environment and regulatory framework. Such public funds are, indirectly, laying the foundations for the growing sector of vaccine manufacturing, and should come with conditions attached. Public investors such as Team Europe and national governments should set conditions to ensure that not only private investors from the EU, but also recipient countries and their companies can fully benefit from public investments and thrive in a self-reliant production model.

Conditions should entail:

- prioritization of fully-fledged transfer of technology, knowledge and know-how to the Rwandan government and/or to local manufacturers;
- a guarantee that in the event of a pandemic, distribution of doses will be focused on the local, regional and continental level;
- setting epidemiological targets that are based on local, regional and continental needs established by the African Union or local/regional bodies;
- inclusion of local, regional and continental entities (e.g. African Union, East African Community, the Rwandan government and African manufacturers) in the decision-making process regarding regional manufacturing sites; and
- a commitment to locate the whole value chain, from R&D to fill & finish, on the African continent.

Regulatory Strengthening

The creation of a market for the mRNA vaccines has facilitated the growth of the overall “enabling environment”, surrounding the emergent sector of vaccine manufacturing, especially in the field of drug regulation. While the WHO maturity level III benchmark should be obtained by the Rwanda FDA soon, more work seems to be needed to ensure that Good Manufacturing Practices (GMP) inspections can be performed. Interpreting the information received from respondents, the focus on regulatory strengthening has been the biggest priority in the implementation of the MAV+ initiative to support the manufacturing of health products in Africa, while other areas, such as GMP inspections, have been neglected and are only now being addressed. An extensive focus on all areas of regulatory compliance will therefore be needed to create a road-tested system that can anticipate future challenges.

A pan-African local workforce

As for the development of a skilled local workforce, it was reported that this will include a pan-African team from seven African countries, but details on the roles and the exact composition were not disclosed by BioNTech Africa at this stage. When commercial strategies are defined in more detail, this information should be made available to the public to comprehend to what extent the company is willing to integrate the job market of skilled African professionals.

An African end-to-end value chain for vaccine production

It was not possible to retrieve geographical and technical details about those segments of the value chain that will be located outside of the BioNTainers, such as R&D and fill & finish. One positive aspect linked to BioNTech Africa is the fact that it brings the production of Active Pharmaceutical Ingredients (APIs) to African soil. APIs production on the continent is notably insufficient, and BioNTainers can help bridge the gap. Moreover, 80% of existing manufacturers of packaged medicines on the African continent are concentrated in eight countries, with North Africa being the densest area.^{xv}

The establishment of R&D priorities for target mRNA products should be jointly ruled by Rwandan, East African Community (EAC) and African Union authorities together with BioNTech, not by the German company alone. With the aim of incentivizing more African countries to purchase the products in the future, the value chain should be spread over multiple countries, as also suggested by one of the respondents.

Conclusions

The analysis and interpretation of many aspects surrounding the BioNTech Africa facility contribute to a better understanding of to what extent and how the BioNTainers – and satellite production sites in general – can contribute to sustainable regional production in order to achieve health equity and countries' sovereignty and self-reliance in the context of local, regional and continental access to affordable health products. While advancing health equity seems to be more easily attainable in the short-term, achieving sovereignty and self-reliance for low- and middle-income countries requires long-term, structural commitments. Also, the degree of access to the vaccines produced by the facility may vary greatly at the local, regional and continental level.

To conclude, the BioNTech Africa facility constitutes a concrete response to the concern expressed by the African Union in 2021 about the scarcity of local manufacturing initiatives on the continent. While some elements, such as regulatory strengthening and the focus on manufacturing Active Pharmaceutical Ingredients (APIs), are positive, much remains to be done and more information must be made publicly available by the company on many relevant aspects, such as the internal process, effective technology transfer, management of intellectual property rights, and employment of a local workforce. Shipping the BioNTainers without addressing these bottlenecks will not effectively foster the development of regional manufacturing capacity in Africa over time. Also, transparency is a key factor in building trust in and acceptance of these private initiatives on the African continent. The coming years will prove whether the

model of satellite production sites can be sustained over time and bring a constructive approach to local, regional and continental manufacturing in Africa, and beyond.

Key message and recommendations

Key message

The BioNTech Africa facility as well as other – current and future – initiatives for regional production of health products require well-defined strategies and firm commitments in order to ensure short-term access to health products, but also to bolster long-term national sovereignty and self-reliance.

As these initiatives concern public health, manufacturers should be transparent about their plans and commitments. Governments, multilateral organizations and global health funds can enforce transparency and attach conditions to public funding and technical support designated for regional manufacturing initiatives. Conditions can also be attached in the case of indirect funding of manufacturing facilities, such as financial support to create an enabling environment for these facilities to thrive. An essential condition would be that Northern-based pharmaceutical companies should transfer the required technology and know-how to African manufacturers.

General recommendations

Recommendation to public investors

- **Financial and technical support for regional manufacturing in the African region should come with conditions attached.**

Financial and technical support to sustain supply, create demand and to build an enabling environment for regional manufacturing of health products (e.g. support for regulatory strengthening) creates an attractive environment for private companies. In addition, BioNTech benefited from 475 million euros of public investments to support research and development of mRNA Covid-19 vaccines, the same technology now used in Rwanda. Such support is dispensed by Team Europe Initiative MAV+, the European Investment Bank and individual member states, like Germany, the Netherlands and Belgium. Public investors should therefore attach conditions to the allocation of public investments in order to ensure that health equity, sovereignty and self-reliance are prioritized over the commercial interests of private companies.

Recommendation to private investors

- **BioNTech, like any other company seeking to manufacture health products on the African continent, should comply with the same conditions identified for public investors, and prioritize public health interests.**

Private pharmaceutical and biotechnology companies should comply with conditions (e.g. the transfer of technology, knowledge and know-how and the inclusion of local, regional and continental entities in decision-making process regarding regional manufacturing sites) to guarantee that health equity, sovereignty and self-reliance are at the heart of regional manufacturing of health products. If private investors benefit from public investments supporting their research and development activities, as well as the enabling environment for regional manufacturing, conditions must be established and met.

Recommendation to civil society organizations

- **Civil society organizations should actively track and take part in initiatives aiming at establishing regional manufacturing of health products and demand that access conditions are established and met.**

Civil society organizations should be directly involved in monitoring and guiding the decision-making process before, during and after the establishment of initiatives enhancing regional manufacturing of health products. Civil society organizations have a key role to play in supporting a population's needs and prioritizing public health over commercial interests. Among other things, civil society organizations can effectively ask companies, such as BioNTech, to be more transparent and hold them accountable on most sensitive areas (e.g. coherence with local epidemiological needs, distribution of the final product, composition of the workforce, and procurement strategies).

Recommendations specific to the BioNTech Africa project

Recommendations to BioNTech

- **Transfer intellectual property rights, including technology, knowledge and know-how, to empower local manufacturers to autonomously produce medical countermeasures, also in the event of a pandemic.**

For now, the transfer of technology mainly occurs within BioNTech, from Germany to Rwanda. At the local level, the transfer of technology seems to entail the transfer of knowledge only, neglecting the transfer of hard technologies such as machinery, and other soft technologies such as know-how to the benefit of local manufacturers. The transfer of knowledge, flowing through university programmes, will be crucial to build the skilled workforce needed in the future, but is not sufficient to build industrial capacity for vaccine production.

- **Share technology and know-how for vaccines manufactured in the BioNTainers with the WHO's mRNA vaccine technology transfer hub.**

BioNTech, alongside Pfizer and Moderna, have already declined WHO requests to share their technology and expertise with the hub in the past. It is now crucial to share technology and know-how to scale up production and ensure an equitable geographical distribution and allocation of vaccines.

- **Clarify the type of products manufactured in the BioNTainers in order to establish procurement and distribution strategies.**

Without a clear understanding of what kind of products will be manufactured (Covid-19, HIV, Malaria or TB vaccines), it will be impossible to establish relevant strategies that directly depend on the nature of these products.

- **Establish a guarantee that in the event of a pandemic, the distribution of produced doses is focused on the local, regional and continental level.**

In 2021, when India suffered from a major Covid-19 wave, exports of doses were paralyzed for a long time, preventing the Serum Institute from supplying COVAX with the full 110 million doses aimed at low- and middle-income countries and preventing low- and middle-income countries from accessing medical countermeasures. A guarantee would ensure that doses reach target populations at the local, regional and continental level, especially in pandemic times.

- **Increase transparency by providing information on pricing policies as well as disclosing specifics on the employed workforce.**

Firstly, more information must be made available on the type(s) of vaccines that will be produced: Covid-19, malaria, HIV and TB. Secondly, pricing criteria have to be clarified: stating that there will be “affordable access” does not make it clear whether doses will be sold at a cost price, a fair price or a market price. Finally, more details are needed on the workforce, including the composition and allocated tasks, with the aim of ensuring that vaccine manufacturing is carried out by a skilled workforce from the local, regional and continental level.

Recommendations to BioNTech, the Rwandan government and the African Union

- **Ensure that the decision-making process for the whole value chain includes local, regional and continental entities (e.g. African Union, East African Community, the Rwandan government and African manufacturers).**

Relevant stakeholders at the local, regional and continental level should be put at the core of the decision-making model governing satellite production sites to guarantee that local health needs are prioritized.

- **Prioritize local, regional and continental epidemiological needs by engaging decision-makers from Rwanda, East Africa and the African continent.**

While the focus of BioNTech on diseases such as malaria, HIV and TB for the years to come is promising, it is not enough to ensure that decisions are aligned with the epidemiological needs of Rwanda, East Africa and the African continent. To incentivize coherence with local, regional and continental epidemiological needs, manufactured goods should be selected in accordance with WHO and National Essential Medicines Lists, through a joint decision-making process with local, regional and continental policymakers.

Recommendations to BioNTech, the Rwandan government and international procurers

- **Define procurement and distribution strategies to better shape the market and anticipate demand.**

Further information on procurement is needed to assess the adequacy of the policies currently being developed. Gavi’s accelerator (AVMA) should take into account push incentives, as they can foster access

to the market for emerging African manufacturers. Distribution strategies must also be defined in order to comprehend the geographical reach of manufactured vaccines.

Recommendations to Team Europe and other international investors

- **Invest more in initiatives that are locally owned and that are likely to bring more sovereignty and self-reliance for African countries, through structural solutions based on local health needs.**

While satellite production sites could constitute a short-term solution to ensure access to a few medical products, public investors should dedicate more resources and technical assistance to approaches that are tackling inequities from early stages of the value chain, as done by WHO's mRNA vaccine technology transfer hub in South Africa.

Appendix

Evolution of MAV+ in Rwanda

As reported by an interviewee, Team Europe's original support for regional manufacturing was predominantly focused on the regulatory sector, e.g. on twinning initiatives between National Regulatory Authorities and the Rwanda FDA, leaving a significant funding gap for workforce and logistics. This gap is supposed to be bridged through the allocation in December 2023 of an additional 40 million euros of MAV+ funds to further support vaccine production in Rwanda. The proposal for these additional disbursements was apparently discussed in July 2023 between various institutions, including the Rwandan government, the Rwandan Ministry of Health, the Rwandan Ministry of Education, the Rwanda Biomedical Center, and the Rwanda Food and Drug Authority. At the EU level, the operation involved Germany, Belgium, France, Lithuania, Sweden, Austria and the European Investment Bank. As of August, 4 EU countries were involved in the provision of 40 million euros of supplementary Global Gateway support to Rwanda. Sweden's funds are directed at higher education in biotechnology (PhD and master's degrees), considering the long-standing research collaborations between Sweden and Rwanda. France's contribution is also targeting higher education, in light of a large existing network spread across the continent, with existing fruitful collaboration such as the Pasteur Network. Germany and France are focused on technical and vocational education and training (TVET), and Germany is also supporting the Biotech accelerator and start-ups (as top-up solutions to provide seed grants). The Biotech accelerator has been established with the intention of de-risking both R&D and the overall business landscape: in summary, it will sustain emerging biotechnology ventures, and strengthen the local talent base.

Enabel was identified as an implementing agency to top up the equipment of quality control laboratories of the Rwanda FDA, as well as to support logistics and the supply chain. More details were also gathered on the first 20-million-euro contribution dispensed by MAV+, including a twinning programme between EU and Rwandan authorities (the Rwanda FDA), to provide for the transfer of regulatory competences. The twinning supports the Rwanda FDA in reaching maturity level III and sustains Rwandan authorities to strategically shape the supply side of local manufacturing through a programme called Kwigira, meaning "self-reliance" in Kinyarwanda, which works together with the Rwanda FDA on: workforce training, supporting the digitalization of the agency and other areas; the roll-out of partnerships between the University of Rwanda and EU universities (with the aim of launching a master's programme to train a workforce on medical production); a programme involving the German government and the Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management; and support to a local manufacturer of medicines (Akagera Medicines). The German Agency for International Cooperation (GIZ) also works as an implementing agency in the context of MAV+ and is heading the Biotech accelerator in Kigali. The abovementioned 40-million-euro fund from MAV+ is an add on to the Biotech accelerator, and will support, among other things, workforce, infrastructure, equipment for the Rwanda FDA quality control labs (GIZ funded) and other equipment.

MAV+ beyond Rwanda

The overall amount of funds disbursed for the African continent by MAV+ amounts to 1.3 billion euros.^{xvii}

The funds are divided into three main pillars: supply, demand and enabling environment. These pillars are further organized in the following workstreams:^{xviii}

- Industrial development, supply chains and the private sector
- Market shaping, demand and trade facilitation
- Regulatory strengthening
- Technology transfer and intellectual property management
- Access to finance
- R&D, higher education and skills

Annex

Stakeholder list from in-depth, semi-structured interviews and other data collection methods

- Afrigen Biologics and Vaccines
- Afya na Haki
- Akagera Medicines
- Apex Biotech Ltd.
- BioNTech
- Delegation of the European Union to Rwanda
- Embassy of Belgium in Rwanda
- Enabel
- FIND
- Gavi, the Vaccine Alliance
- German Agency for International Cooperation (GIZ)
- Igihe Ltd.
- kENUP foundation
- KT Press
- Medicines Patent Pool (MPP)
- Partnerships for African Vaccine Manufacturing (PAVM)
- PharmaLab Ltd.
- Quamed
- Rwanda Development Board (RDB)
- Rwanda Standards Board (RSB)
- The New Times
- Unitaid
- University of Rwanda
- US Pharmacopeia (USP)

References

- ⁱ Moderna. (2024, April 11). Statement on Kenya Manufacturing Facility. <https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2024/Statement-on-Kenya-Manufacturing-Facility/default.aspx>
- ⁱⁱ World Health Organization. (n.d.). COVID-19 deaths | WHO COVID-19 dashboard. <https://data.who.int/dashboards/covid19/deaths?n=c>
- ⁱⁱⁱ Wemos. (2022, November). Make pooling work to end pandemics: A qualitative analysis of the Covid-19 Technology Access Pool. https://www.wemos.org/wp-content/uploads/2023/04/Make-pooling-work-to-end-pandemics_Nov-2022.pdf
- ^{iv} Fernandes, G. et al. (2022). Building resilient health-care supply chains to manage pandemics in low- and middle-income countries. *Bulletin of the World Health Organization*, 100(2), 174–176. <https://doi.org/10.2471/BLT.21.287177>
- ^v Khan, M.I. et al. (2021). Vaccine manufacturing capacity in low- and middle-income countries. *Bulletin of the World Health Organization*, 99(7) 479–479A. <https://doi.org/10.2471/BLT.20.273375>
- ^{vi} Suri, R.K. et al. (2022). Vaccines: New challenges, new paradigms, new opportunities: Report of the 22nd DCVMN Annual General Meeting. *Vaccine*, 26, 3496-3497. <https://doi.org/10.1016/j.vaccine.2022.05.006>
- ^{vii} Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>
- ^{viii} Kreier, F., (2021, April 29) 'Unprecedented achievement': Who received the first billion Covid Vaccinations? *Nature* <https://doi.org/10.1038/d41586-021-01136-2>.
- ^{ix} Lamptey, E, et al. (2022). Covid-19 vaccines development in Africa: a review of current situation and existing challenges of vaccine production. *Clinical and Experimental Vaccine Research*, 11(1), 82-88. <https://doi.org/10.7774/cevr.2022.11.1.82>
- ^x Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>
- ^{xi} Ekström, A.M. et al., (2021). Addressing production gaps for vaccines in African countries. *Bulletin of the World Health Organization*, 99, 910-912. <https://doi.org/10.2471/BLT.21.287381>
- ^{xii} The World Bank, (n.d.) Low and Middle Income. <https://data.worldbank.org/country/XO>.
- ^{xiii} Ekström, A.M. et al., (2021). Addressing production gaps for vaccines in African countries. *Bulletin of the World Health Organization*, 99, 910-912. <https://doi.org/10.2471/BLT.21.287381>
- ^{xiv} Leach, M. et al. (2022). Vaccine anxieties, vaccine preparedness: Perspectives from Africa in a Covid-19 era. *Social Science & Medicine*, 298 . <https://doi.org/10.1016/j.socscimed.2022.114826>
- ^{xv} Bajaj, S. S., Maki, L., & Stanford, F. C. (2022). Vaccine apartheid: global cooperation and equity. *Lancet*, 399(10334), 1452–1453. [https://doi.org/10.1016/S0140-6736\(22\)00328-2](https://doi.org/10.1016/S0140-6736(22)00328-2)
- ^{xvi} Winning, A. (2021, May). South Africa warns of 'vaccine apartheid' if rich countries hog shots, Reuters. <https://www.reuters.com/world/africa/south-africa-warns-vaccine-apartheid-if-rich-countries-hog-shots-2021-05-10/>
- ^{xvii} Awosusi, A. (2022). Shaping market access for sustainable production of vaccines in Africa. *Journal of Global Health Economics and Policy*, 2. <https://doi.org/10.52872/001c.38054>
- ^{xviii} Hernández-Morales, A. (2020, April 20). *Politico* <https://www.politico.eu/article/coronavirus-lessons-from-aids-epidemic/>.
- ^{xix} Nkengasong J.N. et al. (2020). Covid-19 vaccines: how to ensure Africa has access. *Nature*, 586, 197–199. <https://doi.org/10.1038/d41586-020-02774-8>
- ^{xx} Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>

-
- ^{xxi} Mulumba, M., & Machedmedze, R. (2015). Addressing bottlenecks to local production of medicines: Issues for international co-operation in East and Southern Africa. *Journal of Health Diplomacy*, 1(3). https://media.wix.com/ugd/35c673_88aa7a9ef7ed42c2be90955c17eda2ff.pdf
- ^{xxii} Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>
- ^{xxiii} Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>
- ^{xxiv} The vaccine platforms that were tested were; DNA based; Inactivated whole virus; Non replicating viral vector (Influenza A H1N1); and Protein Subunit S, N, M&S1 protein.
- ^{xxv} Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>
- ^{xxvi} Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>
- ^{xxvii} The list is not exhaustive, as also other initiatives have been taken.
- ^{xxviii} African Vaccine Manufacturing Initiative. (2017). Vaccine Manufacturing and Procurement in Africa. <https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf>
- ^{xxix} Ekström, A.M. et al., (2021). Addressing production gaps for vaccines in African countries. *Bulletin of the World Health Organization*, 99, 910-912. <https://doi.org/10.2471/BLT.21.287381>
- ^{xxx} Partnerships for African Vaccine Manufacturing (PAVM). (2022). Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action. <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>
- ^{xxxi} Partnerships for African Vaccine Manufacturing (PAVM). (2022). Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action. <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>
- ^{xxxii} Health Policy Watch. (n.d.). African Medicines Agency Countdown. <https://healthpolicy-watch.news/african-medicines-agency-countdown/>
- ^{xxxiii} The Africa Regulatory Taskforce is jointly established by the Africa Centre for Diseases Control, African Medicines Regulatory Harmonization (AMRH) Initiative, African Union Development Agency (AUDA-NEPAD) and the WHO African Vaccine Regulatory Forum (AVAREF)
- ^{xxxiv} Loembe, M.M., Nkengasong, J.N. (2021). Covid-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*, 54, 1353-1362. <https://doi.org/10.1016/j.immuni.2021.06.017>
- ^{xxxv} Indo-Asian News Service. (2020, November) Aspen inks Covid-19 vaccine manufacturing deal with J&J. *Economic Times (India Times)*. <https://health.economictimes.indiatimes.com/news/pharma/aspen-inks-covid-19-vaccine-manufacturing-deal-with-jj/79021314>
- ^{xxxvi} Lamptey, E, et al. (2022). Covid-19 vaccines development in Africa: a review of current situation and existing challenges of vaccine production. *Clinical and Experimental Vaccine Research*, 11(1), 82-88. <https://doi.org/10.7774/cevr.2022.11.1.82>
- ^{xxxvii} Algeria Press Services. (2021, April). Sputnik V vaccine to be produced in Algeria as from September. <https://www.aps.dz/en/health-science-technology/38794-sputnik-v-vaccine-to-be-produced-in-algeria-as-from-september>
- ^{xxxviii} Lamptey, E, et al. (2022). Covid-19 vaccines development in Africa: a review of current situation and existing challenges of vaccine production. *Clinical and Experimental Vaccine Research*, 11(1), 82-88. <https://doi.org/10.7774/cevr.2022.11.1.82>
- ^{xxxix} Lamptey, E, et al. (2022). Covid-19 vaccines development in Africa: a review of current situation and existing challenges of vaccine production. *Clinical and Experimental Vaccine Research*, 11(1), 82-88. <https://doi.org/10.7774/cevr.2022.11.1.82>
- ^{xl} Agence France-Presse. (2021). Senegal, EU and US sign deal for new vaccine-production plant. <https://www.wionews.com/world/senegal-eu-and-us-sign-deal-for-new-vaccine-production-plant-397115>
- ^{xli} Review of initiatives for access to Covid-19 innovations. (n.d.). <https://covid19response.org/>
- ^{xlii} World Health Organisation. (2021). WHO supporting South African consortium to establish first Covid mRNA vaccine technology transfer hub <https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub>
- ^{xliii} Bryce, E., & Ong, S. (2022). Covid-19 and mRNA technology are helping Africa fix its vaccine problems. *BMJ (Clinical research ed.)*, 377, <https://doi.org/10.1136/bmj.o1196>

^{xlv} Medicines Patent Pool. (2022, April). WHO and MPP announce names of 15 manufactures to receive training from mRNA technology transfer hub [Press release]. <https://medicinespatentpool.org/news-publications-post/who-and-mpp-announce-names-of-15-manufactures-to-receive-training-from-mrna-technology-transfer-hub>

^{xlvi} At the time of writing, Moderna's efforts have been paused as demand for Covid-19 vaccines wanes.

^{xlvii} Moderna. (2021, October). Moderna to build state-of-the-art mRNA facility in Africa to manufacture up to 500 million doses per year.

<https://investors.modernatx.com/news/news-details/2021/Moderna-to-Build-State-of-the-Art-mRNA-Facility-in-Africa-to-Manufacture-up-to-500-Million-Doses-Per-Year/default.aspx>

^{xlviii} BioNTech. (2021). BioNTech Plans to Initiate the Construction of an mRNA Vaccine Manufacturing Facility in Africa in mid-2022 [Press release]. <https://investors.biontech.de/news-releases/news-release-details/biontech-plans-initiate-construction-mrna-vaccine-manufacturing>

^{xlix} BioNTech. (2021). BioNTech Plans to Initiate the Construction of an mRNA Vaccine Manufacturing Facility in Africa in mid-2022 [Press release]. <https://investors.biontech.de/news-releases/news-release-details/biontech-plans-initiate-construction-mrna-vaccine-manufacturing>

^l Wemos identified the expression "satellite production site" in 2023 to describe initiatives such as the one from BioNTech Africa. <https://www.wemos.org/wp-content/uploads/2023/05/Position-paper-regional-production-May-2023.pdf>

^{li} Davies, M. (2022). Covid-19: WHO efforts to bring vaccine manufacturing to Africa are undermined by the drug industry, documents show. *BMJ (Clinical research ed.)*, 376.

<https://doi.org/10.1136/bmj.o304>

^{lii} Farmer, B. (2023). Africa eyes vaccine 'independence' as new pop-up factories make debut, Telegraph.

<https://www.telegraph.co.uk/global-health/science-and-disease/vaccine-biontech-africa-rwanda/>

^{liii} Satellite production sites are production sites of large pharmaceutical and biotechnology companies that are established in a **different location** than the primary country of production.

^{liv} BioNTech. (2021). Joint Communiqué: BioNTech Evaluates mRNA Vaccine Manufacturing Solutions in Rwanda and Senegal to Improve Long-Term Vaccine Supply [Press release].

<https://investors.biontech.de/news-releases/news-release-details/joint-communique-biontech-evaluates-mrna-vaccine-manufacturing/>

^{lv} BioNTech. (2021). BioNTech Plans to Initiate the Construction of an mRNA Vaccine Manufacturing Facility in Africa in mid-2022 [Press release]. <https://investors.biontech.de/news-releases/news-release-details/biontech-plans-initiate-construction-mrna-vaccine-manufacturing/>

^{lvi} Clinton Health Access Initiative. (2022). African vaccine manufacturing supply landscape and expansion: White paper.

<https://www.clintonhealthaccess.org/research/african-vaccine-manufacturing-supply-landscape-and-expansion-white-paper/>

^{lvii} BioNTech. (2023). Update on First BioNTainer for African-based mRNA Manufacturing Facility [Press release].

<https://investors.biontech.de/news-releases/news-release-details/update-first-biontainer-african-based-mrna-manufacturing-0/>

^{lviii} BioNTech. (2023). BioNTech Achieves Milestone at mRNA-based Vaccine Manufacturing Site in Rwanda. [Press release].

<https://investors.biontech.de/news-releases/news-release-details/biontech-achieves-milestone-mrna-based-vaccine-manufacturing-0/>

^{lix} BioNTech. (2023). BioNTech Achieves Milestone at mRNA-based Vaccine Manufacturing Site in Rwanda. [Press release].

<https://investors.biontech.de/news-releases/news-release-details/biontech-achieves-milestone-mrna-based-vaccine-manufacturing-0/>

^{lx} BioNTech. (2023). BioNTech Achieves Milestone at mRNA-based Vaccine Manufacturing Site in Rwanda. [Press release].

<https://investors.biontech.de/news-releases/news-release-details/biontech-achieves-milestone-mrna-based-vaccine-manufacturing-0/>

^{lxi} Funds from the Global Gateway Initiative are deployed to improve infrastructures and promote the connection of goods, people and services worldwide.

^{lxii} Global Health Advocates. (2024). Navigating the Team Europe approach in the EU-AU health partnership. Brief 1: How is Team Europe delivering on its health commitments? <https://www.ghadvocates.eu/app/uploads/2024-03-Brief-1-How-is-TE-delivering-on-its-health-commitments.pdf>

-
- ^{lxiii} Enabel. (2022). Team Europe Support Structure (TESS) for Manufacturing and Access to Vaccines, medicines and health technology products in Africa (MAV+) <https://open.enabel.be/en/p/2504/TESS+MAV%2B.html>
- ^{lxiv} European Commission. (2023). Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa – Rwanda https://international-partnerships.ec.europa.eu/document/download/6d87e8fc-6f8e-49bf-8c1e-fcfa7d772033_en
- ^{lxv} European Commission. (2023). Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa – Rwanda https://international-partnerships.ec.europa.eu/document/download/6d87e8fc-6f8e-49bf-8c1e-fcfa7d772033_en
- ^{lxvi} International Finance Corporation. (2021). IFC, Government of Rwanda Partner to Develop Vaccine Manufacturing Capacity in Rwanda. [Press release]. <https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=26615>
- ^{lxvii} International Finance Corporation. (n.d.). IFC Project Information and Data Portal – Rwanda <https://disclosures.ifc.org/enterprise-search-results-home/rwanda>
- ^{lxviii} Rwanda was not able to provide enough skilled workforce
- ^{lxix} Partnerships for African Vaccine Manufacturing (PAVM). (2022). Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action. <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>
- ^{lxx} Clinton Health Access Initiative. (2023, November). What will it take to develop a sustainable vaccine manufacturing ecosystem in Africa? <https://www.clintonhealthaccess.org/news/building-sustainable-vaccine-manufacturing-africa/>
- ^{lxxi} The production of doses would therefore rely on imported drug substance.
- ^{lxxii} BioNTech. (2023). Update on First BioNTainer for African-based mRNA Manufacturing Facility [Press release]. <https://investors.biontech.de/news-releases/news-release-details/update-first-biontainer-african-based-mrna-manufacturing-0/>
- ^{lxxiii} BioNTech Africa would produce Active Pharmaceutical Ingredients (APIs) within the African continent.
- ^{lxxiv} Despite growing, drug substance manufacturing represents a modest percentage of current initiatives, and a relatively small portion of future vaccine manufacturing projects on the African continent.
- ^{lxxv} Fox, D. M., (2019). Technology Transfer and the TRIPS Agreement Are Developed Countries Meeting Their End of the Bargain? *Hastings Sci. & Tech.* (10) https://repository.uchastings.edu/hastings_science_technology_law_journal/vol10/iss1/2
- ^{lxxvi} Technology transfer was one of the main bottlenecks impeding access to Covid-19 pandemic in low- and middle- income countries and it remains one of the key issues at stake in the negotiation of the Pandemic Accord.
- ^{lxxvii} Médecins Sans Frontières Access Campaign. (2021). Pharmaceutical firms across Asia, Africa and Latin America with potential to manufacture mRNA vaccines. <https://msfaccess.org/pharmaceutical-firms-across-asia-africa-and-latin-america-potential-manufacture-mrna-vaccines>
- ^{lxxviii} Warah, R. (2022, February). African countries push to produce vaccines locally. *One*. <https://www.one.org/africa/stories/africa-produce-covid19-vaccines-locally/>
- ^{lxxix} European Commission. (n.d.). Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa. https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa_en
- ^{lxxx} Considering the broader definition of technology transfer embraced in this work, it is advisable to include the “skilled workforce” pillar under our analysis of technology transfer.
- ^{lxxxi} As reported by two different interviewees.
- ^{lxxxii} Light, D. W., Lexchin, J. (2021). The costs of coronavirus vaccines and their pricing. *Journal of the Royal Society of Medicine*, 114. <https://doi.org/10.1177/01410768211053006>
- ^{lxxxiii} Gavi, the Vaccine Alliance, is a global entity established in 2000 to enhance the availability of new and underused vaccines for children (but also the general population) in the poorest nations worldwide. Gavi operates in collaboration with its core partners, the World Health Organization, UNICEF, the World Bank and the Bill & Melinda Gates Foundation.
- ^{lxxxv} Likuyani, B. (2024, February). WHO Maturity Levels 3 and 4 : How To Attract More African Countries. *African Pharmaceutical Review*.
- ^{lxxxvi} As already observed, Team Europe is working in many ways to improve current regulatory capacity. Twinning programmes and the Kwigira programme (workforce training, digitalization of the agency and general support for the Rwanda FDA) are in place.

-
- ^{lxxxvii} Rwanda FDA. (2022). Signing of Memorandum of Understanding between Rwanda Food and Drugs Authority (Rwanda FDA) and Ghana Food and Drugs Authority (Ghana FDA). <https://rwandafda.prod.risa.rw/news-details/signing-of-memorandum-of-understanding-between-rwanda-food-and-drugs-authority-rwanda-fda-and-ghana-food-and-drugs-authority-ghana-fda>
- ^{lxxxviii} BioNTech. (2023). BioNTech Achieves Milestone at mRNA-based Vaccine Manufacturing Site in Rwanda. [Press release]. <https://investors.biontech.de/news-releases/news-release-details/biontech-achieves-milestone-mrna-based-vaccine-manufacturing-0/>
- ^{lxxxix} Overcoming trade barriers was once again identified as a crucial aspect. The role of the African Union was also highlighted as pivotal in moving products regionally and continentally.
- ^{xc} Médecins Sans Frontières. (2022). German government must push BioNTech to urgently transfer mRNA vaccine technology. [Press release]. <https://www.msf.org.za/node/51578>
- ^{xcⁱ} Torreele, E., Sherwin, H. (2024, April) Health equity requires transformational change: Financial incentives based on worn-out market thinking will not deliver. *PLOS Global Public Health*. <https://doi.org/10.1371/journal.pgph.0003147>
- ^{xcⁱⁱ} Fox, D. M., (2019). Technology Transfer and the TRIPS Agreement Are Developed Countries Meeting Their End of the Bargain? *Hastings Sci. & Tech.* (10) https://repository.uchastings.edu/hastings_science_technology_law_journal/vol10/iss1/2
- ^{xcⁱⁱⁱ} BioNTech. (2020). BioNTech to Receive up to €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162. [Press release] <https://investors.biontech.de/news-releases/news-release-details/biontech-receive-eu375m-funding-german-federal-ministry/>
- ^{xc^{iv}} European Investment Bank. (2020). Germany: Investment Plan for Europe - EIB to provide BioNTech with up to €100 million in debt financing for COVID-19 vaccine development and manufacturing [Press release] <https://www.eib.org/en/press/all/2020-144-eib-to-provide-biontech-with-up-to-eur-100-million-in-debt-financing-for-covid-19-vaccine-development-and-manufacturing>
- ^{xc^v} World Economic Forum. (2023, March). Under AfCFTA, pharmaceutical investment means impact and profit. <https://www.weforum.org/agenda/2023/03/in-africa-s-free-trade-area-investment-in-pharmaceuticals-means-impact-and-profit/>
- ^{xc^{vi}} Global Health Advocates. (2024). Navigating the Team Europe approach in the EU-AU health partnership. Brief 1: How is Team Europe delivering on its health commitments? <https://www.ghadvocates.eu/app/uploads/2024-03-Brief-1-How-is-TE-delivering-on-its-health-commitments.pdf>
- ^{xc^{vii}} European Commission. (n.d.). Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa. https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa_en