

## »» Vaccines ‘Made in Africa’: Considerations on building local vaccine production capacity

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Only around 1% of vaccines administered in Africa are produced locally. During the pandemic, the absence of a local industry has led to serious bottlenecks in supplying vaccines (not just COVID-19 vaccines) to the African population, some 1.2 billion people, causing a range of health issues and various forms of social harm. Vulnerable groups of the population (some 40% of the African population) such as children and pregnant women have suffered most from the supply bottlenecks. In order to eliminate them and prepare for future health crises, the African Union aims to have 60% of vaccines used in Africa manufactured on the continent by 2040. Whether this goal is achievable depends on the development of the industrial basis and demand conditions. This Focus discusses both aspects against the backdrop of the historic and political conditions on the continent and the donor situation.

Unlike other regions of the world, Africa manufactures only around 1% of the vaccines that are administered locally. The lack of local vaccine manufacturers makes the continent particularly vulnerable to disruptions to international value chains, as we have witnessed during the peak periods of the pandemic and continue to observe today. The aim of developing a local vaccine industry is to make the continent more resilient against disruptions in supply chains for vaccines while strengthening Africa's industrial basis and innovative capacity. At the same time, a local vaccine industry makes an important contribution to strengthening the health of the population. Improved specialist knowledge of the epidemiological particularities and studies with the local population enable the local vaccine industry (including R&D) to respond to those particularities and, in this way, develop suitable highly effective vaccines. Having an own vaccine industry will enable the continent to respond to future epidemics and pandemics.

The goal of the African Union (AU) is to have 60% of vaccines used in Africa manufactured on the continent by 2040. As an international organisation, the AU is responsible for coordinating the activities of the nation states. The African Centre for Disease Control, for example, which was in charge of handling the coronavirus pandemic, is under its supervision.

The topic is receiving much attention at national level as well. Many African nations see themselves as the ideal location for the development of an African vaccine industry. Some of them do not have or only have a small pharmaceutical industry to date. The aim of this publication is to take a brief look at the pharmaceutical landscape and discuss which states and locations are suitable for the development of a vaccine

industry. The study also discusses the further (demand-side) factors that influence the success of such a project.

### Africa's dependence on the global vaccine market

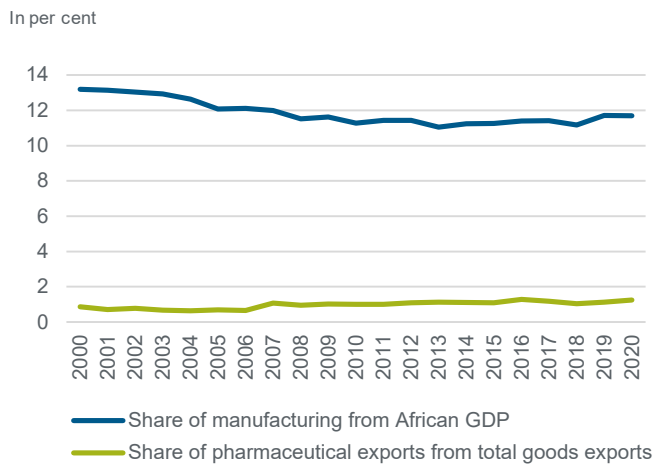
The debate on the development of local vaccine production picks up on the broader debate about the industrialisation of the continent which has gathered momentum in recent years.<sup>1</sup> Africa's share of manufacturing is small compared with other regions of the world. Manufacturing generates only around 11.2% of the continent's GDP (Figure 1). Over the past years, Africa's development was rather characterised by de-industrialisation. Furthermore, the share of manufacturing is divided extremely unevenly across the African countries. Industrial production is geographically concentrated in northern and southern Africa. Recently, South Africa in particular succeeded in increasing the proportion of manufacturing in GDP. Along with other political initiatives, the debate around the development of a vaccine industry is an attempt to reverse the deindustrialisation trend and establish an industry that directly serves the needs of the continent and its population. In this, Africa is not pursuing the goal of China or Asian countries to produce low-cost products for the global market but of manufacturing high technology for a growing local market.

The basic foundation for developing vaccine production, which always includes local vaccine research and development, is the pharmaceutical sector. But as illustrated by export figures, that sector is very small (Figure 1). This segment of the manufacturing sector accounts for only around 1.2% of total goods exports. Africa is a net importer of pharmaceutical goods (including vaccines), which means the continent imports more than it exports. In the year 2020, exports outstripped imports by a 14-to-1 ratio; in other words, Africa imported 14 times as many pharmaceutical products as it exported.

Around 75% of pharmaceuticals administered in Africa are imported from China, Europe and India (See Figure 2).

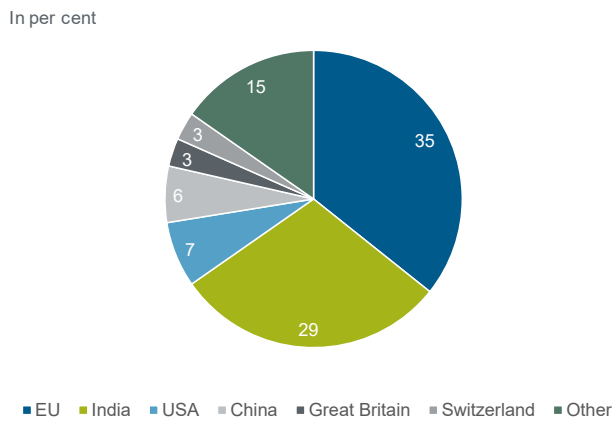
Africa's dependence on vaccine imports is even greater. Only 1% (approx. 12 million doses) of global vaccine production takes place in Africa.<sup>2</sup> The continent is particularly dependent on vaccine imports from India, its main supplier, which manufactures around 60% of vaccines administered in Africa. At the same time, however, the African continent represents 25% of global vaccine demand.

Figure 1: Manufacturing sector in Africa and pharmaceutical exports



Source: World Development Indicators, UNCTAD

Figure 2: Origin of pharmaceuticals



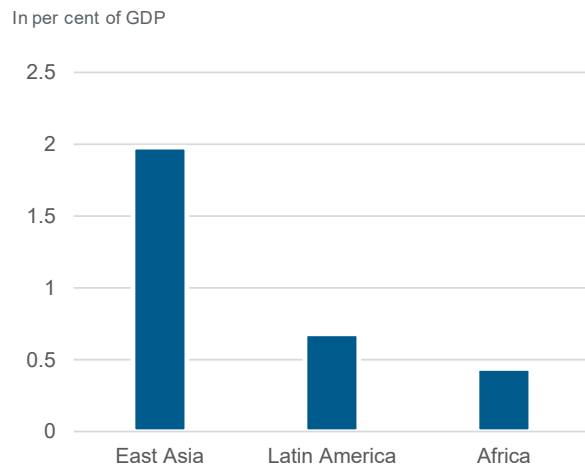
Source: UNCTAD, 2020

**Reasons for the absence of a vaccine industry**

According to Ekström et al. (2021), reasons for the high dependence on imports and the lack of a local industry include insufficient investment, especially in research and development (Figure 3), poor transfer of knowledge and brain drain to Europe and the US in particular. Besides these demand-side factors, however, local demand for vaccines also plays an important role.

In acquiring vaccines, the majority of African countries is supported by international donors such as Gavi and the Bill and Melinda Gates Foundation. These organisations purchase vaccines from international pharmaceutical companies. The high demands on quality and quantity meant that African manufacturers did not have a chance. Another facet of this unequal competitive situation was the opening of markets as part of various WTO rounds. For many richer countries such as South Africa, the removal of trade barriers and tariffs meant that it suddenly became cheaper to import vaccines than to manufacture them locally.

Figure 3: Overall expenditure on research and development by region (developing and emerging economies)



Source: World Development Indicators, 2020 (Africa=20-year average across 30 countries including Egypt and South Africa)

In the past, this import dependence was unproblematic because supply difficulties were very rare and lasted for very short periods of time. That picture has changed in the coronavirus pandemic. It revealed significant supply bottlenecks. India halted the export of coronavirus vaccines in order to combat its own pandemic. However, that also affected exports of other vaccines. Africa was cut off from the supply of high-quality and affordable vaccines, particularly as vaccine suppliers such as the US and Europe prioritised the use of the relatively expensive vaccines to meet the demand in their domestic markets.

This risk of supply chain constraints will remain even after the pandemic comes to an end. Owing to China's zero-COVID policy, the problems and delays within the global value chain are currently continuing. The global vaccine production chain is suffering from supply bottlenecks and the resulting increases in shipping and air freight rates. The increased transport costs as well as the heightened vulnerability of supply chains to disruptions bolster the arguments in favour of building local vaccine production in Africa. Against the backdrop of the global situation, re-shoring the manufacture of critical goods is being debated all over the world.

The African union (AU) is therefore calling for the development of local vaccine production in Africa – in addition to strengthening public healthcare systems. The aim of the AU is to increase production capacity (including fill and finish) in the continent over the coming years. To this end, the Partnership for African Vaccine Manufacturing (PAVM) was established with the aim of coordinating national and international policies. The aim of building African vaccine production is also being supported by the G7 and its member states under the Building Back World Initiative adopted in 2021. Individual African states are also receiving support in the framework of bilateral development cooperation.

### Supply structures: Africa's pharmaceutical and vaccine industry

Africa's pharmaceutical industry is composed of around 600 companies and is mostly spread out over eight countries. Around 22 African countries do not have any pharmaceutical industry at all. Most companies sell their products only locally, that is, within national boundaries. Around 25% of the local pharmaceutical industry is owned by multinational corporations. Foreign companies also constitute the cradle of Africa's modern pharmaceutical industry. From around 1920, production locations were increasingly established by international companies in different countries including Kenya (1920) and South Africa (1925)<sup>3</sup> in order to supply settlers and, increasingly, the local population with modern medicines.

The development of a local vaccine industry can draw on existing technical infrastructure in the form of sterile premises and bioreactors at these locations. Manufacturing pharmaceutical products – such as vaccines – involves a high degree of complexity, particularly with regard to the operation and maintenance of facilities. With a view to this industrial basis, the broad literature describes an African production that lacks human capital and is technically not very sophisticated. However, it must be said that this description is inaccurate, at least for a small number of production locations. The availability of this pool of specialists along with a manufacturing and logistics infrastructure was an important factor that prompted the US pharmaceutical firm Johnson & Johnson to establish a manufacturing plant for coronavirus vaccines in South Africa in 2020<sup>4</sup>. This production facility was intended to supply the African market and, in part, the global market with modern vaccines. But the oversupply of coronavirus vaccines from 2021 and the lack of local demand led to the decision to shut down production prematurely. Nevertheless, the venture demonstrated that it was possible to produce highly modern vaccines in Africa. The knowledge gained from production is not lost either but strengthens South Africa as a pharmaceutical location.

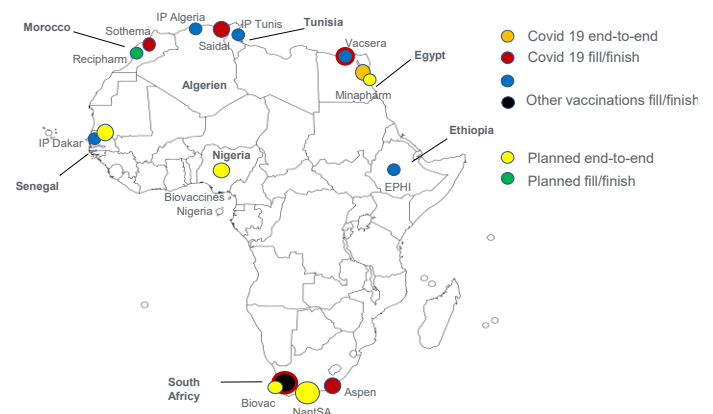
#### Excursus: Vaccine development projects of German Financial Cooperation

German Financial Cooperation (FC) with Africa is supporting the development of an infrastructure for vaccine research, development and production in a number of projects. The geographical focus is on Ghana, Senegal and South Africa. The projects aim to provide academic and non-academic education and training for experts, enhance research, improve linkages between basic research, practical research and production and strengthen and digitalise the regulatory authorities. In addition, there are plans to set up pilot facilities for the manufacture of vaccine candidates based on mRNA and non-mRNA technology in South Africa. DEG is also supporting commercial vaccine producers in South Africa such as Aspen Pharmacare. At pan African level, German FC is supporting Afreximbank with a loan of EUR 250 million to support local production capacities.

According to an estimate by McKinsey, in addition to the South African firm Aspen there are around 25 companies concerned with the production and distribution of vaccines in a very broad sense. Like the pharmaceutical industry, these firms are geographically concentrated in the north of the continent, in South Africa and Nigeria. This African vaccine

industry can be divided into three groups. The first group, around 10 of the firms involved in vaccine production in Africa, operates primarily in the downstream segment, which means they are concerned with the import, distribution and packaging of vaccines manufactured in Asia, Europe or the US. The second group of vaccine manufacturers provides fill and finish services on the continent for the production of vaccines under licence for international corporations such as Johnson & Johnson, GSK, Sanofi and Sinopharm. This group includes around 10 companies<sup>5</sup>. The third group of just three or four companies is involved in vaccine research. They include BioVac and Afrigen in South Africa and Innovative Biotech in Nigeria.

Figure 4: Africa's current and future vaccine manufacturers



Source: McKinsey (end-to-end refers to the entire vaccine manufacturing process. Fill and finish refers to the bottling and packaging of finished vaccines into vials)

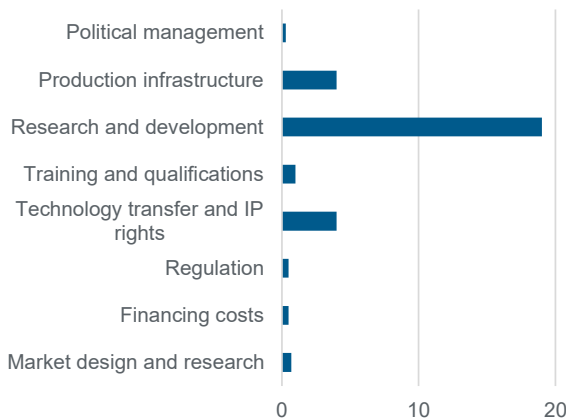
Figure 4 provides an overview of the landscape of existing vaccine manufacturers and planned factories described above. Thus, building an African vaccine industry is about investing in existing locations and manufacturers and enabling them to manufacture vaccines to a high international standard and export them too.

Because of the weak industrial structure of Africa's vaccine industry, however, research and development remains the area with the largest deficits. Commercial research is relatively small. Promoting locally researched and developed vaccines is important for Africa in particular. For one thing, locally researched and developed vaccines are said to be more effective because they are particularly well adapted to the needs and disease profiles of the local population. For another, Africa suffers from specific diseases such as tuberculosis, HIV and malaria for which international pharmaceutical companies have not yet developed any vaccines, among other things because of lack of global demand.

As described, only a very small number of pharmaceuticals companies conduct vaccine research and development. Egypt and South Africa are important research and development locations (AU 2009). Both countries have a relatively broad research landscape, especially in the academic domain. Also, both spend the highest amounts on research and development on the African continent. But researchers often work in laboratories and research facilities that do not meet prescribed international standards. These standards must be met for the commercial manufacture and exportation of vaccines. National regulatory authorities are an important element for ensuring

that international standards are followed because they certify compliance. In order to be able to carry out this certification, the national regulatory authorities themselves must meet international requirements (WHO standards). National African regulatory authorities have deficits in the area of WHO certification compared with their peers. This deficit and the lack of qualifications of national regulatory authorities are also a result of the absence of local vaccine production and the fact that they have merely had to monitor imports. However, it will take some time for the national authorities to have the capacity to implement WHO requirements and standards. The level of development of national regulatory authorities differs widely from one African country to another. According to a study commissioned by the AU, the cost of developing and expanding Africa's vaccine industry will amount to approx. USD 30 billion over 20 years. The largest cost item in this model calculation is vaccine research and development (see Figure 4). By contrast, the cost of patents, a factor on which a large portion of the political debate is focused, is estimated to be low.

Figure 5: Estimated costs of building an Africa-wide vaccine industry (in USD billion)



Source: PAVM, AU 2021

In its study on the development of vaccine production, McKinsey estimates that standard vaccines (e.g. against rotaviruses) manufactured in Africa will be 3 to 16% more expensive than vaccines from Indian competitors. According to the study, manufacturing costs vary very widely as a function of the selected vaccine technology (vector, mRNA, etc.), the production location and its conditions (e.g. infrastructure, productivity and talent pool). The key question that will play a role in deciding on the success of the African vaccine industry is whether the African states and the international donor community are willing to pay this premium for vaccines Made in Africa if attempts to reduce vaccine manufacturing costs remain unsuccessful.

**Demand situation: Africa's market for vaccines**

Contrary to current reports in the German and international media about insufficient sales of coronavirus vaccines, overall demand for vaccines in Africa is high. There are many different reasons for the lack of sales of coronavirus vaccines. Its rapid population growth, in particular, makes Africa one of the world's largest vaccine markets. Around 25% of vaccines manufactured around the world are administered there. Imports are clearly growing by double-digit rates. The continuing

high population growth rate is further driving demand, especially for vaccines that treat standard diseases, referred to as legacy vaccines. In addition, there are a number of diseases for which no vaccines exist yet, such as HIV, tuberculosis and malaria. These diseases are a particular burden for the already weak healthcare systems and there is an urgent need to develop vaccines for them. Africa could seek to meet this demand itself by building vaccine research and development capacities of its own.

Figure 5: Support situation in Africa, as at 2020



Source: Gavi, McKinsey

Most of the vaccine campaigns in Africa are financed by the GAVI vaccine alliance (Figure 5), covering around 90% of vaccine demand. Only 10 African countries procure vaccines on their own. Interestingly, these 10 countries also have the best chances of building local vaccine production capacity. This imbalance between buyers and suppliers could stand in the way of the pan-African goal of building a local industry with R&D, as their interests could diverge.

At present, the procurement of vaccines is organised by international aid organisations at global level and takes place where they have their head office, for example in Geneva. The fact that the global procurement of vaccines is dominated by the large aid organisations has prompted the African Union and individual states to demand an Africa quota in the procurement of vaccines as a way of supporting the development of local vaccine production. The aim is for Africa to manufacture around 30% of coronavirus vaccines procured by Gavi<sup>6</sup>. It is unclear why this quota should apply only to coronavirus vaccines. South Africa stopped manufacturing these vaccines in early June 2022 for lack of demand. At this stage, Africa does not have a Gavi-licensed manufacturer anymore. Nevertheless, it is reasonable to have a debate about a regional sales quota. Such a quota could secure some of the demand for African vaccines and thereby provide an incentive for private investors to invest in building vaccine production capacity.

African vaccine manufacturers must have a WHO licence to be able to participate in tenders of the global aid organisations and the local medical regulatory authority that monitors the development and manufacturing process must possess at least WHO Maturity Level 4 status. The WHO standard for the manufacture and export of vaccines has four maturity levels. None of the African medical regulators currently meet this quality criterion, so they can neither export vaccines nor sell them to the international aid organisations. In order to meet the necessary standards, the various African countries intend to invest massively in their local regulatory authorities, including with international support.

International donor support is based on a country's income level. In the coming years, many African nations will be losing international donor support, including Nigeria, the largest market in Africa. This will open up the opportunity for affected African countries to buy vaccines on their own and, in this way, to support the development of the vaccine industry. One consideration here is whether the African Union might act as a central buyer for these countries. The AU has already acted as a pan-African buyer of vaccines in the fight against the coronavirus pandemic, which enabled it to secure lower prices. The pooling of procurement could strengthen the bargaining position of individual countries towards international pharmaceutical companies, and on that basis an attempt could also be made to tie the purchase of vaccines to conditions such as investments in local manufacturing infrastructure.

### Conclusion: Vaccines 'Made in Africa' are possible

The pandemic has demonstrated how vulnerable Africa is to global value chain disruptions. This vulnerability is particularly pronounced in the area of vaccine production. Thus, 99% of vaccines used in Africa must be imported, most of them from India, which makes it particularly susceptible to supply chain disruptions. Africa has relied for too long on the possibility of importing affordable vaccines from around the world, as have other places in the world. As a result of the pandemic, ongoing

value chain disruptions and increased transports, decision-makers are now rethinking this approach.

Not only is there a political will to build vaccine manufacturing capacity. In some African countries – particularly Egypt and South Africa – the conditions for it are not bad either. These countries have a pool of qualified workers who are already experienced in the manufacture of pharmaceutical products and vaccines. There is no question that building vaccine production capacity will require very high investment volumes. McKinsey estimates that around USD 30 billion in public and private sector funds will be needed. Whereas the public sector will have to focus mainly on the areas of public infrastructure, i.e. basic research, training and qualification of skilled workers and investment in national regulators, the private sector is called upon primarily to expand commercial R&D and manufacturing capacities. In order to ensure that private investors actually make the necessary investments, African governments must also send out the right signals. Demanding a quota for the purchase of vaccines 'Made in Africa' from international donors is an important step towards developing a vaccine market. However, the 10 nations that are not receiving any support from international donors must also commit and be willing to pay any higher prices for vaccines that are researched and manufactured locally. How much African ministers of finance and health will be willing to pay for locally manufactured vaccines will therefore be crucial for the successful development of an African vaccine industry.

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<sup>1</sup> Africa Growth Initiative by Brookings 2018. Source: <https://www.brookings.edu/wp-content/uploads/2018/09/Manufacturing-and-Industrialization-in-Africa-Signe-20180921.pdf> (accessed on 8 June 2022)

<sup>2</sup> Ekström et al 2021: Addressing production gaps for vaccines in African countries. Bulletin World Health Organisation, 99, 910–912.

<sup>3</sup> Banda et al 2016: Making Medicines in Africa: An Historical Political Economy. Springer Berlin.

<sup>4</sup> Aspen Pharmacare, Source: <https://www.aspenpharma.com/2020/11/02/aspen-announces-agreement-with-johnson-johnson-to-manufacture-investigational-covid-19-vaccine-candidate/> (accessed on the 8 June 2022)

<sup>5</sup> Ekström et al 2021: Addressing production gaps for vaccines in African countries. Bulletin World Health Organisation, 99, 910–912.

<sup>6</sup> Barnes 2022: African leaders urge global vaccine body to buy locally made Covid jabs. Financial Times, 17 May.