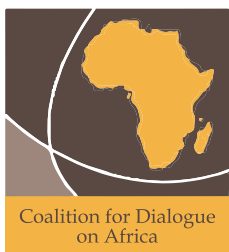


Advocacy for

# Vaccine Research, Development and Manufacturing in Africa

*ADVOCACY BRIEFS*





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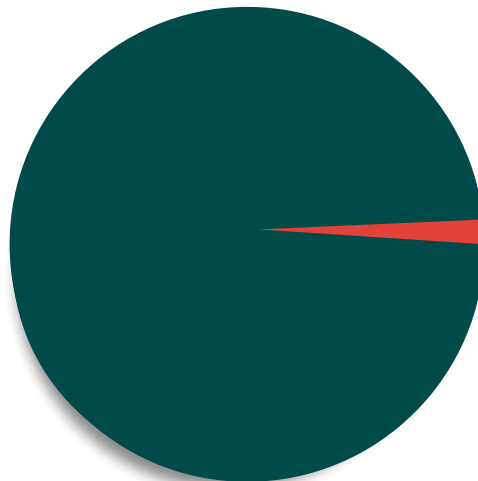
Africa has an annual demand of 1.3 billion doses of vaccines, and it manufactures only about 1% of its vaccine requirements – 12 million doses – while the remaining 99% is imported (Figure 1). As of 30 September 2021, with COVID-19 raging, only 5% of the African population was fully vaccinated and 90% had not received their first dose. By contrast, in most of the countries in the global north, over 90% of vulnerable groups had been fully vaccinated while some of these nations are hoarding vaccine doses six times their national requirements. The United States and Europe are considering giving booster shots to their citizens – beyond full vaccination – while some Africans are waiting in vain for a first dose of the vaccine.

**FIGURE 1:** VACCINE MANUFACTURING IN AFRICA: THE STATE OF PLAY<sup>1</sup>

### VACCINE MANUFACTURING SUPPLY CAPACITY IN AFRICA

**99%**

of doses are  
imported



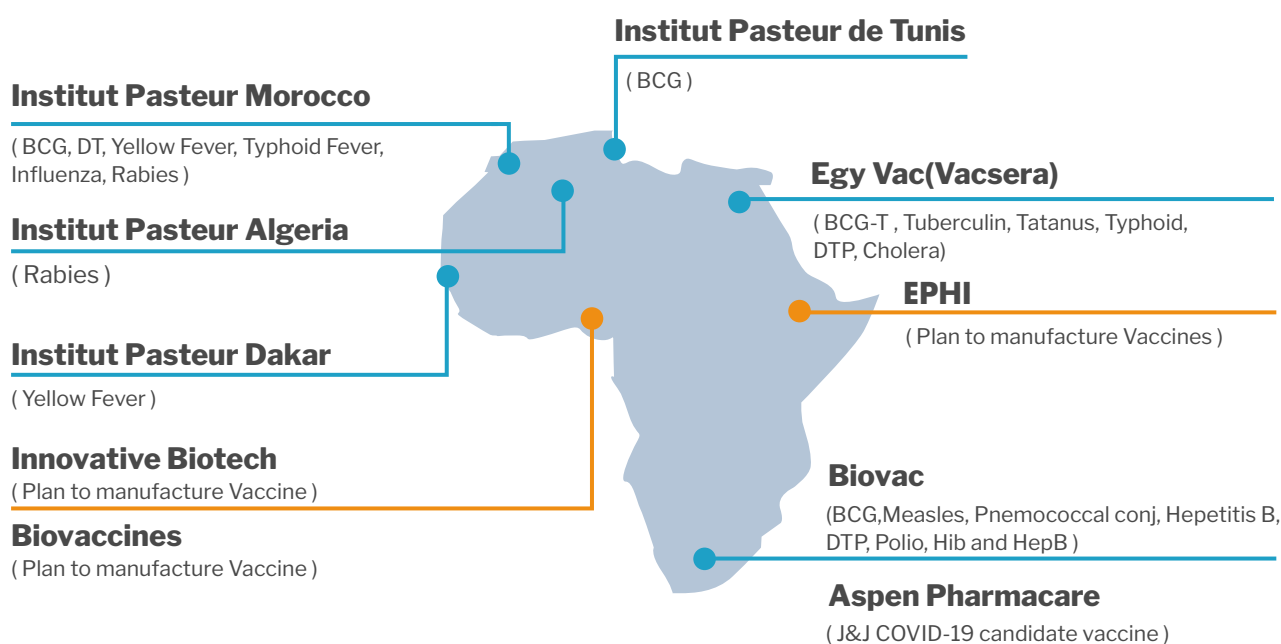
**1%**  
12 million doses  
are manufactured  
in Africa

These circumstances are unacceptable and unsustainable. Africa cannot depend on these nations for its salvation from the COVID-19 scourge and from future pandemics. How can 55 African governments, 1.3 billion Africans (17% of the world population), with a collective GDP of US\$2.5 trillion, the entire African diaspora, African businesses, universities, entrepreneurs, intellectuals, and scientists fail to develop a single COVID-19 vaccine internally?

Whilst there are vaccines from Pfizer, Moderna, Johnson & Johnson, Oxford-AstraZeneca, and the Russians (e.g. Sputnik V) and Chinese (e.g. Sinovac and Sinopharm), there is none from Africa.<sup>1,2,3</sup>

**FIGURE 2:** AFRICA'S LIMITED VACCINE MANUFACTURING CAPACITY<sup>1</sup>

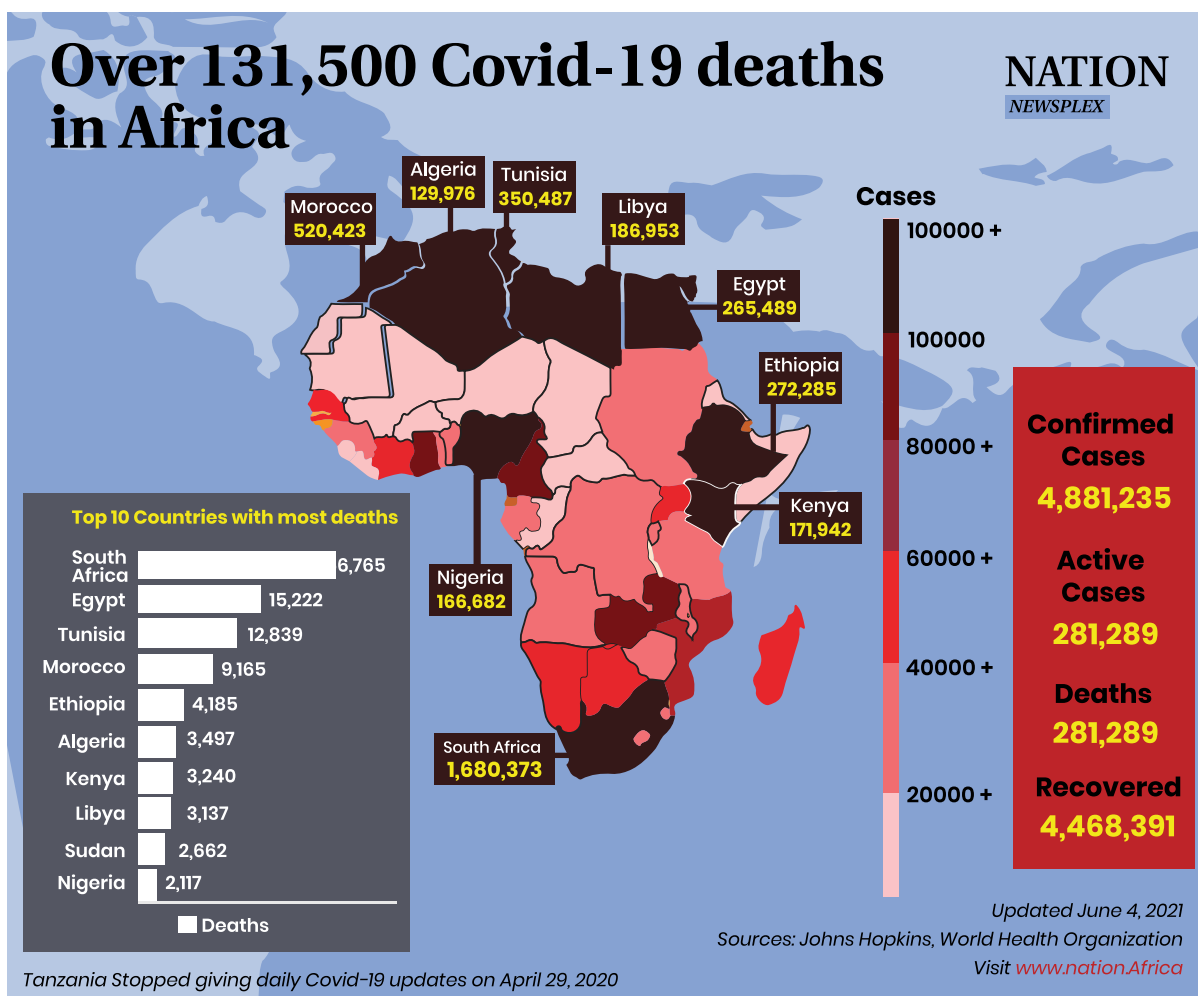
## VACCINE MANUFACTURING SITES IN AFRICA



## LIMITED VACCINE MANUFACTURING CAPACITY

The continent is overdependent on vaccine imports, leaving Africans exposed to supply chain and public health risks. This matter has been made abundantly clear by Africa's current struggle to access COVID-19 vaccines. There is limited manufacturing capacity (Figure 2) in only a handful of countries such as Morocco, Senegal, South Africa, Egypt, Algeria, and Tunisia. Only seven African countries have companies operating in the vaccine manufacturing value chain. More significantly, of these nations, only one – Senegal – exports a WHO pre-qualified vaccine; the rest do not export. The uneven global distribution of manufacturing capacity, inequitable access to finance, and poor healthcare infrastructure have led to the absence of equitable and universal access to COVID-19 vaccines and vaccination. Overreliance on vaccine imports is causing needless loss of lives and livelihoods on the continent due to the unavailability of vaccines, delays and uncertainty in delivery, and inefficient vaccine rollouts. Figure 3 shows the devastation of the COVID-19 pandemic on the continent.<sup>9</sup>

**FIGURE 3:** THE DEVASTATING IMPACT OF COVID-19 ON AFRICA [JOHNS HOPKINS, WHO]



It is one thing to have access to vaccines and another thing to conduct effective vaccination. The latter depends on national vaccine absorptive capacity – the country’s ability to use all available vaccines effectively and in time. Africa is characterised by poorly developed distribution networks (road, rail, and air), which hamper the efficient transportation of vaccines to the communities. This situation is compounded by inadequate healthcare infrastructure (storage, refrigeration, hospitals, and clinics) and poor supply chain management. Inefficient and poorly developed procurement systems negatively impact vaccination efforts just as the scarce or insufficient vaccination skills.<sup>16</sup>

The COVID-19 pandemic has been an eye-opener and a learning opportunity for the continent. It has exposed Africa’s fragile healthcare infrastructure and its debilitating over-reliance on external vaccine value chains. The continent’s health security is totally dependent on the benevolence and goodwill of other nations. Never again should Africa find itself in this situation. Work must start now to ensure equitable and universal access to vaccines and vaccination on the continent. It may become too late to intervene effectively concerning COVID-19; hence the concentration must be on current health challenges and future pandemics.<sup>14</sup>

## **1.1 WHY ARE VACCINE RESEARCH, DEVELOPMENT AND MANUFACTURING CAPABILITIES LIMITED IN AFRICA?**

To develop an effective Africa-led vaccine and vaccination system, it is instructive to review the history of the challenges. There are many reasons for the limited vaccine research, development and manufacturing on the continent. Countries and leaders have focused on national strategies and not regional efforts, therefore, there is no continental approach to the issue. Without the pooling of resources regionally and continentally, vaccine research, development, and manufacturing would be a tough proposition. Whilst national efforts in the seven countries mentioned earlier are commendable, they have been uncoordinated. As a result, there is no link to – or synergies unlocked within – the respective regional economic commissions (RECs) or the continent.

African governments and the African private sector have not invested adequately in public health. It is a heavily underfunded sector that has not received enough prioritization and attention by governments but has rather depended on non-strategic donor and external budget support.

The educational system on the continent, from primary school, through secondary, to tertiary education, has not emphasised research, entrepreneurship, knowledge generation, innovation, and creativity. Consequently, the products of African universities and research centres are medical doctors, pharmacists, scientists and experts who lack confidence, capacity and competence with respect to vaccine research, development and manufacturing. The role of these professionals has been to dispense vaccines and provide basic medical services and maintenance of externally designed and developed value chains. Among these elites, there is neither competence nor confidence with respect to research, development and manufacturing.

There has been a failure to leverage partnerships within the continent as one entity and with countries/companies in the global north and south. Any such partnerships have been bilateral and at the country level. The Aspen partnership with Johnson & Johnson in South Africa is a classic example. Economies of scale, impact and better deals are often extracted in partnerships driven at the African Union level or (at a minimum) on a regional platform such as the Southern African Development Community (SADC).<sup>11</sup>

Africans have failed to understand that vaccine research, development and manufacturing constitute a major commercial enterprise with huge profit margins. Thus, whilst vaccines assist in achieving health security, they also present a business opportunity for Africans to participate and benefit from.

Of course, everything falls and rises on leadership. There is need for a more visionary and technocratic African leadership in the public and private sectors to be able to drive the research, development and manufacturing of vaccines on the continent.

There are several fundamental and foundational requirements for vaccine research, development and manufacturing to take place in Africa. These include an enabling policy framework, resources (financial, physical and intellectual), relevant skills, expertise and training, enabling infrastructure, appropriate managerial capacity, and appropriate levels of investment together with effective financing mechanisms. There must be vaccine development and acquisition strategies such as in situ, concurrent with manufacturing and use of centres of excellence.

It is essential to investigate what needs to be done to build Africa's vaccine research and development capacity and to identify the issues, challenges and opportunities? Of course, emphasis must be placed on the role of the private sector, technology transfer, expertise, government policy framework, vaccine ecosystem, partnerships, and continental integration. Indeed, private-public partnership models are critical to the discourse.

These matters must be addressed to develop a new continental vaccine and vaccination strategy. However, in doing so, it is unproductive to reinvent the wheel. There is a need to leverage existing initiatives and institutions such as (a) the upcoming Africa Medicines Agency (AMA) – a specialised agency of the African Union dedicated to improving access to quality, safe and efficacious medical products in Africa, (b) African Medicines Regulatory Harmonization (AMRH) – another programme of the African Union implemented as part of (c) the Pharmaceutical Manufacturing Plan for Africa (PMPA). AMRH's objective is to ensure that African people have access to essential medical products and technologies. At the same time, PMPA addresses the African pharmaceutical industry across the 55 Member States to strengthen capacity to produce high-quality, affordable pharmaceuticals across all essential medicines. Continental integration and political unity will be at the centre of the vaccines and vaccinations strategy; hence the African Continental Free Trade Area (AfCFTA) becomes a critical framework and a dynamic driver of the ambition.<sup>4,9</sup>

## **2.1 POLICY RATIONALE AND COHERENCE**

It is essential to understand the difference between getting access to vaccines and rolling out vaccination, and to review and identify the different but complementary challenges involved. Only after such an evaluation can the meaning and attainment of equitable and universal access be fully envisaged. Without equitable and universal access to vaccines and vaccination, there is no national health security, and without health security, there is no national security. Hence, it is an existential matter for Africa to move from being just a vaccine market – an inactive recipient of donated medicines – to a producer and, ultimately, a net exporter of vaccines. In addition to carrying out research, developing and producing its own vaccines, the policy framework must allow the assembling of externally developed vaccines.

This means ‘fill and finish’ operations on the continent must be facilitated while understanding the limitations and trade-offs of such a strategy, given the long-term African ambition for vaccine sovereignty anchored entirely by locally developed and manufactured vaccines.

Central to the African vaccine policy is understanding the limitation of national vaccine strategies of small and fragmented states. The thrust should be regional and continental approaches that leverage economies of scale and are more efficacious than nationally inspired ones. National efforts must only be pursued as part of an agreed regional or continental plan, cascaded from the African Union to individual countries.

Global vaccine diplomacy and nationalism are best addressed and negotiated through the African Union platform and vaccine policy must be promotive of monitoring, evaluation and transparency.

## **2.2 CAPACITY BUILDING AND KNOWLEDGE ACQUISITION**

To achieve equitable and universal access to essential vaccines and vaccination, there is a need to facilitate the requisite capacity building and knowledge acquisition. The starting point is focusing on assessing and strengthening existing relevant African institutions, systems and instruments such as AMA, AMRH, PMPA, AfCFTA, African IPR institutions and arbitration centres.

The current capacities of these institutions must be assessed to improve and strengthen them. There is a need for independent evaluation of the institutions that are involved in this process, with emphasis on building capacity for vaccines and vaccinations, including human capacity and vaccination promotion. The location of the relevant African Union instruments or institutions must be based on the capacity of countries to host them, for example, how much resources and capital a country is prepared to invest in the instrument’s establishment and operations. Experiences and lessons from the location of previous entities such as AfCFTA, Space Agency and AfDB, must be considered.

It is prudent to note that capacity building falls into two categories: vaccines research, development and manufacturing, and the actual vaccination exercise (procurement, distribution, supply chains, and skills). All these areas will require capacity development and training.<sup>9,10</sup>

In addition to capacity building, there is a need for relevant knowledge acquisition. Mastery of the following would be fortuitous: vaccine technology literacy, vaccination requirements knowledge, vaccine and vaccination policy best practices, vaccine intellectual property rights (IPR) literacy, including clarity on The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the World Trade Organisation (WTO) frameworks. A solid understating of the regional and continental integration imperatives is essential, while best practices for harvesting vaccine logistics and supply chain management should be pursued.

## **2.3 COMMUNICATION AND ADVOCACY**

To effectively achieve equitable and universal access to vaccines and vaccinations in Africa, there is a need to create general awareness of all pertinent issues across the entire vaccine ecosystem. This should include policy recommendations to governments and the private sector, education of the general population, and engagement of academia and media, with active involvement of influencers such as celebrities, artists and grassroots activists. There must be engagement of the civil society, religious and traditional leadership, and academic institutions. Policy dialogues must be conducted to enhance vaccines and vaccinations awareness.

African leaders, the private sector, and every citizen must understand that vaccines and vaccinations constitute a major commercial enterprise beyond achieving health security. Africans must benefit from the business side of vaccines, use the commercial opportunities to drive their economies and improve shared economic prosperity on the continent. The ambition is that global players such as Gavi, Global Fund, WHO and the “Big Pharma” must buy and distribute drugs and medicines developed and manufactured in Africa by African companies.

It is instructive to note that “Big Pharma” and the vaccine producer countries of the global north and south – United States, Europe, China, Russia, and India – may be the most likely to be disinterested in an African continent that develops and produces vaccines that satisfy 100% of its requirements. It is not in their business or financial interest, hence, the ambition to achieve equitable and universal access to vaccines and vaccinations in Africa will be achieved despite them. Africans are on their own on this critical journey and this must be unequivocally clear to African leaders, their governments, the private sector, and civil society organisations. The generality of the African people must be mobilised to have confidence in the vaccines developed and manufactured – that these vaccines are as good, if not better, than those developed externally.

## **2.4 DATABASE MANAGEMENT**

As people get vaccinated, it is essential to keep records carefully to keep track of the vaccination process and effectively manage it, thus guaranteeing efficiency and universal access. Such database management of citizens post-vaccination must be developed and operationalised at the national level, but regionally coordinated and feeding into the continental vaccine uptake monitoring and evaluation system. There is a need for a continental travel database to track and monitor infections across the continent, thus mitigating the impact of infectious diseases.

Africa must create its own continent-wide regulatory and certification processes for vaccines while strengthening existing national frameworks. This must be done after a comprehensive review of current global and national certification processes. The African Union must guide the establishment of the regulatory framework and enabling legislation for private sector participation and these efforts must be aligned with the work of the AMRH. In fact, AMA must be nurtured and resourced so it can effectively help with continental harmonisation.<sup>1,6</sup>

The African Union must appraisal and help align the WHO vaccine approval processes to continental needs. For example, two Chinese COVID-19 vaccines were belatedly approved for emergency use by WHO (Sinopharm, 7 May 2021 and Sinovac, 1 June 2021). It is unusual to belatedly approve a product that has already been proven to be effective and has been used to effectively address the COVID-19 pandemic in China and some other countries? The Russian Sputnik V has been arguably the most efficacious and safest of all the COVID-19 vaccines on the market, but this has not yet been approved by the WHO.

Of course, the Chinese and Russians are hesitant to submit all their intellectual property and industrial secrets to the WHO for the fear that it may end up in insecure and unsafe hands.

Should Africa wait for WHO approvals? South Africa is a prominent victim of this naivety of taking WHO approvals as gospel. They have ignored Chinese and Russian vaccines to the detriment of their COVID-19 vaccination programme.

Zimbabwe and other African countries were more strategic and obtained vaccines from China and Russia. However, some South Africans were, at some point, going to Zimbabwe to get vaccinated with these vaccines, yet South Africa is the most industrialised country on the continent. Africa CDC, the continent's primary institution for public health emergencies, has also not embraced the Russian and Chinese vaccines.

The African Union must urgently take a clear, shared and enforceable position on WHO approvals. In the long run, when there is an established African capacity to produce vaccines, it may be prudent to operate the way the Chinese and Russians have handled the COVID-19 situation. They have developed and manufactured their own vaccines, certified and approved them, and used them to secure the health of their populations without necessarily waiting for WHO approvals.

Some have argued that it is the Chinese themselves that delayed in submitting data for WHO approval. But we must ask why the Chinese delayed in submitting their data? What is the case with Sputnik? The Russians have also not submitted or have delayed in submitting? If so, why? Why are countries circumspect about submitting data to WHO? Where does this leave Africa? Should we not have our own certification and approval processes?

In the global north and the rest of the global south, countries do not wait for WHO approvals for emergency use of vaccines because they have national approval systems. For example, on 12 April 2021, India approved Sputnik V for emergency use against COVID-19, Turkey did the same on 30 April 2021. The European Union's European Medicines Agency is responsible for vaccine approvals for the bloc. AMA must be empowered and resourced to conduct approvals for the African continent when it is finally established. The kind of embarrassing situation where South Africa's vaccine rollout was in limbo (7 June 2021) because they were waiting for decisions on the Johnson and Johnson vaccine from the United States' Food and Drug Administration should be avoided.

The BRICS framework is another platform that Africa can leverage to increase access to vaccines. Given that three members – Russia, India and China – are prolific developers and producers of vaccines, there is scope to procure from them and partner with them in the research, development and manufacture of vaccines. A collective BRICS certification and approval system for vaccines can be established in partnership with the rest of the continent.

South Africa is a member of the BRICS and, unfortunately, it has not adopted any of the vaccines from the BRICS countries, that is, China (Sinopharm, Sinovac), Russia (Sputnik) and India (Covaxin); even after the two Chinese vaccines were belatedly approved by WHO. In February 2021, South Africa rejected a donation of 15 million doses of Sputnik V vaccines from Russia. Thus, it seems a free South Africa, the most industrialised economy on the continent, a product of revolutionary support from Russia and China, and a member of the BRICS, prefers Western vaccines – Pfizer, Oxford/AstraZeneca and Johnson & Johnson. Incidentally, these preferred vaccines have had a share of their own efficacy and safety challenges.

There is a need to unshackle Africa's health policies from the undue influence of donors, "Big Pharma" and Western institutions such as the United States CDC. There must be a drastic shift of African health policies from a curative healthcare system to a preventative one – from disease management to wellness. Deliberate efforts must be made to identify areas that must be transformed to pursue this dramatic shift in healthcare philosophy and practice.

Of course, the strong regulatory and certification processes must take clear cognisance of the limitation of fragmented and small nation-states and the power of an integrated and united African approach. All these must be executed in alignment with the mandates of NEPAD and AMA. These solid and effective certification processes on the continent should challenge donor-funded and influenced health policies. Africa must not always accept the supremacy of the WHO certification process. Donors do not fund the Chinese, Russian and Indian healthcare systems. Africans must be the main funders of their healthcare systems to have total control and influence.

Clearly, vaccines certification and approval are later issues after we have developed our own vaccines, however, the thinking and design must be part of the conversation to establish immediate strategy to strengthen Africa's vaccine regulatory framework.<sup>1,2</sup>

### **3.1 POLICY HARMONISATION**

It is essential to assess national vaccines and vaccination policies to ensure in-country cohesion and align them with the regional and continental frameworks. The different national efforts must be studied to identify and facilitate mutual learning of national best practices and sharing among African countries. There must be harmonisation within each of the five regions – ECOWAS, SADC, EAC, Maghreb and Central Africa. The needs and capabilities of each region must be assessed, and the outcome used to inform the content of strategic efforts. Continental harmonisation of vaccine and vaccination policies must be further enhanced by promoting and supporting two critical institutions – AMA and AMRH.

Beyond the continent, it is essential to identify and leverage vaccine and vaccination policy global best practices while adapting them to Africa's needs, conditions and aspirations.

### **3.2 INTELLECTUAL PROPERTY RIGHTS**

As Africa embarks on the ambitious journey of research, development and manufacturing of vaccines, it is essential to review the relevant trade-related issues such as IPR, patents, TRIPS, and the WTO framework. There is a need to identify and understand the challenges and opportunities relating to IPR. Implications of recent developments such as the announcement on 21 May 2021 that South Africa and India requested global waiving of the IPR for vaccines – a proposal supported by 120 countries, including the United States. The US President, Joe Biden, has emphatically spoken in favour of this suggested IPR dispensation. However, four months later (30 September 2021), there has not been any meaningful movement on this important commitment.<sup>17</sup>

The implied possibilities for the continent must be evaluated and implemented. For example, external global companies that have developed vaccines can manufacture them in Africa on their own. Alternatively, they can partner with local African players to manufacture vaccines on the continent. Another possibility is that African countries independently manufacturing vaccines belong to external companies under the proposed waiver of vaccine IPR. However, all the possibilities should not be ad-hock but guided by a clearly articulated Africa-wide strategy.

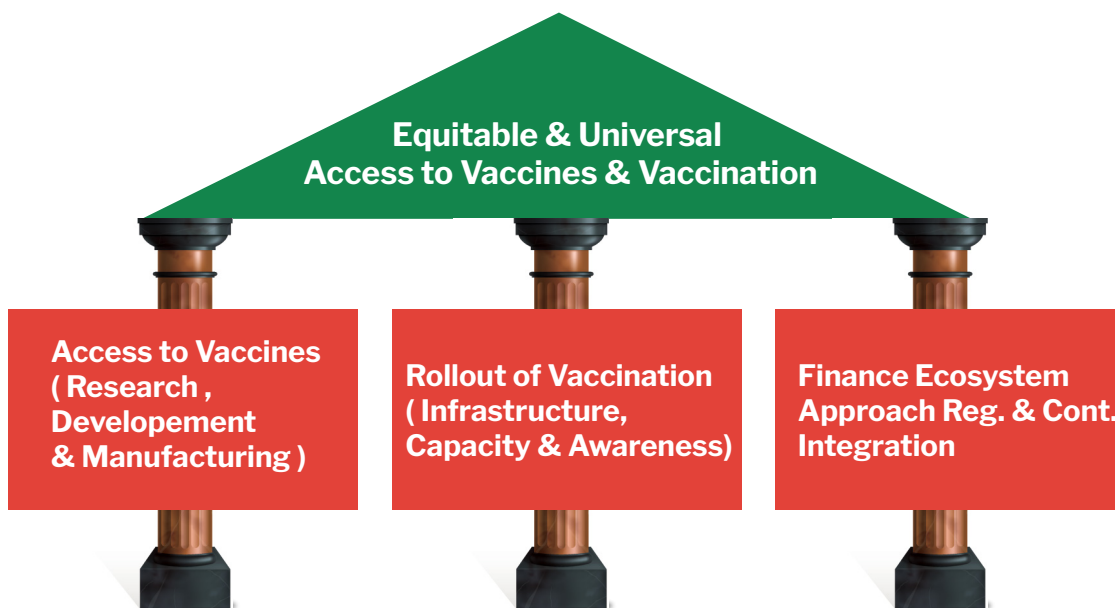
Once Africa has developed its own vaccines, it is vital to protect the local vaccine IPR while encouraging partnerships between developers and manufacturers across the continent. All these activities will require the establishment of a well-developed African Union vaccine IPR policy. There is a need to strengthen and deepen independent African national and regional IPR agencies, supported by the formation of sound and effective dispute and conflict resolution mechanisms for the continent. In fact, all IPR arbitration must be conducted on the continent.

In developing vaccines locally, producing the Active Pharmaceutical Ingredient (API) is complex and expensive, however, vaccine raw material is cheap. The development of the African petrochemical industry will make the development of API more achievable. Of course, the cart must not be put before the horse. African IPR issues – with respect to vaccines developed on the continent – will become more critical after such achievement. However, in the short-run, Africa would also be reliant on technology transfer platforms and external APIs that would rely heavily on IPR negotiations. As a case in point, the discussions with China, Russia and Egypt included IPR issues upfront. Hence, IPR conversations must take place from the beginning of the journey to vaccine sovereignty. It must also be appreciated that IPR is an international issue. Hence due process must be followed in dealing with the matter.

## BUILDING AFRICA'S BROAD VACCINE RESEARCH AND DEVELOPMENT CAPACITY

There is a need for clarity regarding the key steps in the journey to build Africa's broad vaccine research and development capacity. The issues, challenges and opportunities must be explored adequately. The emphasis should be on the role of the private sector, technology transfer, expertise, an enabling policy framework, a vaccine ecosystem, partnerships, and continental integration. Primacy must be placed on private-public partnership models. Figure 4 demonstrates the key pillars that will drive equitable access to essential vaccines and vaccinations on the continent.

**FIGURE 4:** THE KEY DRIVERS OF ACCESS TO VACCINES AND VACCINATION



The task is to grow and expand Africa's capabilities and capacities to carry out vaccine research and development. The starting point is the mapping and SWOT analysis of current national level pharmaceutical and biotechnology research and development capabilities across the continent, particularly in the seven countries: South Africa, Senegal, Morocco, Algeria, Rwanda, Nigeria, and Egypt. Thereafter, it is essential to identify best practices, lessons and gaps.

The objective should be to develop a continental strategy through regional research and development centres of excellence located in the five African RECs. These facilities will serve the entire regional bloc where they are located and the rest of the continent when necessary. The regional research hubs must attract African talent from across the continent and the diaspora – African experts working in the global north and south and any skilled professionals of African descent from all over the world.

There is a need to identify potential research and development partnerships nationally, regionally, continentally, and globally. Specifically, African Union-driven collaborations with China and India must be pursued. More significantly, lessons must be drawn from these global south key players in vaccine research and development. Joint research and development partnerships must be sought with global pharmaceutical giants such as Pfizer, Johnson & Johnson and Moderna. However, these collaborations must be initiated and engineered at the African Union level – and strictly not at the national level – on African terms.

Vaccine research and development must leverage the fourth industrial revolution (4IR) technologies, local research institutes and the African private sector. There must be clarity on the specific roles of the African private sector, academic institutions, research centres, and philanthropists funding research and development on the continent.

Attention must be given to potential local and traditional vaccines. Investigations and clinical trials on these indigenous remedies must be conducted to demonstrate drug safety, efficacy and side effects. The clinical trials must formally establish the impact and limitations of developed local vaccines producing technical guidelines for the interventions, in addition to certification of dosages and packaging.

There should be an assessment to facilitate the development of the capacity to carry out extensive clinical trials on the continent, and to establish the efficacy and safety of vaccines. There is a need for national, regional and continental facilities and capabilities to conduct such trials. Every vaccine to be administered must have been tested by Africans first. There must be an African position on the efficacy and safety of every vaccine available to the continent's people. Specifically, there is a need to develop laboratory capacity to test the safety, efficacy and side effects of all the COVID-19 vaccines and other vaccines. Without exception – all vaccines being brought into the continent must be independently tested by African institutions and experts before the adoption. Currently, across the continent, US-FDA approval of drugs is the gold standard. Through embracing (ratification by all 55 Member States), resourcing and capacitating AMA, Africans must challenge this hegemony and take full control of their public health.

An additional requirement is pharmacovigilance – the practice of monitoring the effects of medicines after they have been licensed for use. The objective is to identify and evaluate previously unreported adverse reactions. Again, this is essential on the continent.

As a long-term strategy, as vaccine development ramps up on the continent, there must be professional clinical trials for locally developed and manufactured vaccines. This requires building national, regional and continental testing capacity, buttressed by world-class infrastructure, skills, systems, and standards for clinical trials. Finally, there is a need to empower, strengthen and harmonise standards associations across the continent.

Having built vaccine research and development capacity on the continent, the next hurdle is to escalate vaccine manufacturing efforts, which can be achieved by reviewing vaccine manufacturing global best practices, addressing Africa-specific issues, challenges and opportunities. Emphasis must be placed on the role of the private sector, technology transfer, training for sustainability, expertise, policy framework, vaccine ecosystem, partnerships, and continental integration. The second CoDA paper by Dr Philip Onyebujoh – *Vaccine Research and Development in Africa* – extensively covers the technical aspects of the journey for vaccine R&D to vaccine manufacturing.

The ambition is to develop Africa's capability and capacity to manufacture vaccines, including those developed on the continent and those originating externally. There must be mapping and SWOT analysis of current national level pharmaceutical and bio-technological manufacturing capacity as a starting point. In this way, identification of best practices, lessons and gaps is accomplished. Again, of particular interest will be South Africa, Senegal, Morocco, Algeria, Rwanda, Nigeria, and Egypt. Next is identifying potential national, regional, continental, and global manufacturing partnerships, guided by an African Union strategic plan.

Manufacturing planning and execution will be enhanced by supporting and strengthening AMA and AMRH while leveraging ideas from the PMPA. Just as the case for research and development, the thrust should be to establish five manufacturing hubs in the continent's five regions. Efforts to develop vaccines on the continent will take time. Hence, in the penultimate, fill and finish should also be part of Africa's manufacturing strategy. This must be clearly understood as a short-term solution as there is an obvious tension between developing and manufacturing our own vaccines and assembling externally developed vaccines.<sup>10,16</sup>

The regional manufacturing centres must seek to attract African experts and professionals from across the continent without discrimination. The plants must proactively attract outstanding African talent working outside Africa in the global north and south. Of particular importance will be to leverage the broader African diaspora vaccine manufacturing skills and resources in the United States, Europe, West Indies, and elsewhere.

The continent must embrace and encourage the culture of start-ups and learn from global and instructive cases such as Moderna (mRNA). However, more significantly, Africa must learn and adapt to its conditions and needs, manufacturing best practices from China (e.g. Sinopharm and Sinovac) and India (e.g. India Serum Institute). Beyond picking up lessons, the continent must seek manufacturing partnerships with these manufacturing giants of the global south.

However, all the collaborations must be at the continental level and not bilateral between individual African countries and China or India. All manufacturing partnerships must be initiated at the African Union level and then designated to regions and then countries. For example, the African Union can agree with China to partner in setting up a vaccine manufacturing plant. Using its continental strategic vaccine production plan, the African Union can decide that the plant will be in ECOWAS, and more specifically, Ghana or Nigeria, to produce vaccines for ECOWAS, with the excess being channelled to the rest of the continent as needed. The decision to set up a manufacturing partnership in Ghana, for example, should not be left to Ghana and China.

As already explained, such African Union-driven manufacturing plants must serve the region where they are located and the continent, and not just the country of location. The continent must have collective agency in all partnerships on the continent. It must not be reactive and uncoordinated in this matter. Germany's announcement on 21 May 2021 that it has chosen Ghana to set up a vaccine manufacturing plant is a classic example of what Africa must emphatically reject. The French President, Emmanuel Macron, made a similar unilateral pronouncement about Ghana on 29 May 2021. That is unacceptable.

There have also been reports about Algeria (7 April 2021) and Egypt (22 April 2021) being poised to manufacture the Russian vaccine – Sputnik V – without reference to a continental vaccine strategy. Again, on 22 June 2021, South African President, Cyril Ramaphosa, joined the WHO and French President, Emmanuel Macron, in announcing a new manufacturing hub for mRNA coronavirus vaccine technology in South Africa. In their pronouncements there is no reference to SADC vaccine production strategy much less a well-conceived and structured continental approach. These uncoordinated activities are detrimental to an effective strategy to achieve equitable and universal access to essential vaccines on the continent. They must be discouraged in favour of a continental vaccine research, development, manufacturing, and distribution approach.<sup>17,18,19</sup>

All potential global south and north partners to the continent must come through the African Union, guided by a well-thought-out continental R&D and manufacturing strategy. Yes to partnerships with rich nations and their big pharmaceutical companies, but only through continental institutions such as the African Union and AfCFTA. Platforms such as the Forum on China-Africa Cooperation (FOCAC) must be leveraged in designing vaccine manufacturing partnerships on vaccines with the Asian giant. Similar continentally driven platforms must be used to engage India, Brazil, United States, and European countries in pursuit of vaccine R&D and manufacturing partnerships.

Of course, in all these continentally driven R&D and manufacturing efforts, lessons must be drawn from current national R&D and manufacturing activities such as those in South Africa, Senegal, Morocco, and Egypt. As indicated earlier, India's Serum Institute is an instructive case study.

Ensuring the availability of vaccines on the continent is just the first step. The next challenge is getting the vaccines into citizens' arms. This second vital exercise will depend on national vaccine absorptive capacity – a country's ability to utilise all the available vaccines timeously and effectively.

## **6.1 LOGISTICS AND SUPPLY CHAIN MANAGEMENT (DISTRIBUTION AND INFRASTRUCTURE)**

There are key requirements for effective and universal vaccination, which include distribution strategy, refrigeration, storage, logistics, transportation, and skills. These elements and activities constitute the distribution and infrastructure part of the vaccine Logistics and Supply Chain Management (LSCM). It is vital to investigate national vaccination best practices and share lessons across the continent. The role of young people, traditional leaders and civil society in vaccination rollout must be carefully spelt out.

The potential and nature of the participation of the African private sector, government and civil society in vaccine rollout activities on the continent must be fleshed out. Creating the essential buy-in and ownership of vaccination strategy through an ecosystem approach to the challenges is essential. The vaccine distribution and infrastructure must be national, regional and continental.

The starting point is the use of the established methods – Expanded Programme on Immunization (EPI), which are donor-driven and free and mainly targets women and children. However, the EPI approach is not adequate and cannot be relied on alone. Governments should create space for the private sector to participate commercially to enhance vaccine distribution and vaccination. Private sector involvement can begin with current vaccines without waiting for new ones to be developed on the continent.

Cold chain facilities (storage and refrigeration) and transportation constitute a significant problem. The burning of expired COVID-19 vaccines in Malawi and South Sudan constitutes an extreme manifestation of these problems.<sup>7,14</sup>

Each African country's absorptive capacity for vaccines must be assessed, together with government and state readiness. It is essential to challenge global pharmaceutical reluctance to send vaccines to Africa on the claims of inability to deliver cold storage. The continent must creatively address the ultra-cold conditions through creative engineering solutions such as discarded shipping containers, fans, and solar panels. In any case, there is an opportunity to leverage and adapt cold chain technologies and systems from agriculture, more specifically horticulture. There is a need to develop adaptive, affordable, accessible, and scalable infrastructure solutions across the continent.

## **6.2 LOGISTICS AND SUPPLY CHAIN MANAGEMENT (PROCUREMENT AND VALUE CHAINS)**

The second part of LSCM addresses the issues around vaccine procurement and value chains, which requires understanding and strengthening of current national, regional and continental vaccine procurement systems. African procurement best practices must be shared, such as the South Africa Aspen, Senegal IPD and Egypt VACSERA.

For now, the continent must address issues regarding the procurement and value chains of vaccines developed outside the continent. Later, the procurement value chains for locally developed and manufactured vaccines should be pursued vigorously. There must be regional and continental collaboration in vaccine procurement. There is a need to identify vaccine procurement global best practices and adapt them to Africa's needs, conditions and aspirations.

There is currently very effective regional bulk procurement, using the Global Fund and Gavi, where drugs are rechannelled from areas of excess to those of shortage. This must be leveraged and enhanced. There is a need to document and accumulate lessons learned on this. Bulk procurement can be adapted across the continent, taking advantage of economies of scale. Lessons from bilateral procurement processes between individual countries and external source countries must be studied, for example, China and Zimbabwe or China and Ethiopia. There must be a scaling up of these ideas and value chains to the continental level.

What is ideal is the efficient and agile management of procurement based on multi-stakeholder partnerships. Furthermore, lessons can be drawn from the private sector regarding distribution, procurement and supply chain management. The Coca Cola system, which gets a coke bottle into every village, is an instructive source of lessons. Moreover, the company is a potential partner to assist with the cold chain distribution of vaccines. With buy-in from governments, the concept of advanced market commitments must be employed. Procurement lessons from current African vaccine operations such as Aspen in South Africa should be leveraged. There is no need to redesign or reinvent the proverbial wheel. Existing experiences must be solidified and leveraged.

It is vital that once Africa starts producing its own vaccines, there is an efficient logistics and supply chain management system to move vaccines from the African manufacturing plants to all the citizens of the continent.

Everything falls or rises on financial resources and resourcefulness. Equitable and universal access to essential vaccines and vaccinations in Africa requires both. The challenge is incentivising the private sector, philanthropists and governments to invest in the research and development of vaccines. There is a need to attract investment – private sector, governments, philanthropists and FDI – to research, develop and manufacture vaccines on the continent. These activities must be understood as profitable business opportunities, not just efforts to attain health security. Three major areas require significant investments and creative financing mechanisms: (a) vaccine R&D, (b) vaccine manufacturing, and (c) vaccination rollout logistics.

Research has shown that to develop and produce one vaccine from scratch requires US\$350-500 million. The cost drivers include initial genome identification research, infrastructure, human capital investment, technology transfer, and the R&D. A key determinant of the cost structure is the vaccine typology: (a) modular mRNA, (b) protein sub-units or (c) modified viral vaccine. All these factors will determine the levels of investment required for R&D&M on the continent.

Funding must be attained to roll out vaccination across the continent. It is imperative to sufficiently finance vaccine procurement and the associated value chains. The distribution of vaccines cannot be left to governments. The reasons for the private sector's lack of appetite for participation in the donor-funded value chain must be understood and addressed. Thus, the private sector must be commercially incentivised to participate in vaccine logistics and supply chain management. Financial support must be sought from national, regional, continental, and global financial institutions. The primary funding model for the Africa vaccines strategy must be characterised by pooling resources across the continent, unlocking economies of scale. Hence, AfCFTA, with a population of 1.3 billion people and a collective GDP of US\$2.5 trillion, becomes the best framework to finance and implement the vaccines strategy.<sup>2,5</sup>

African countries must spend 15% of their GDP on public health (Abuja Declaration) and there must be enhanced private sector participation in healthcare provision. Governments must create an enabling environment for private sector involvement. Yes, we must carry out R&D and manufacturing of medicines on the continent.

However, there must be clarity on and quantification of the return on investment (ROI) for Africa's R&D and manufacturing of medicines. We must leverage African economies of scale. Africans must be able to sell medicines (developed and manufactured on the continent) globally. There is a need to challenge the global public health political economy. African funding of public health gives Africans control of public health policy, e.g. emphasis on preventative medicine (wellness) instead of curative medicine (disease management).

Funding and resourcing are required for capacity building, knowledge acquisition, communication, and advocacy. Therefore, it is vital to do systematic budgeting of all necessary activities to achieve equitable and universal access to vaccines and vaccinations – establishing associated costs and sources of funding. Finance is the bedrock. Indeed, resources plus resourcefulness equal results.

It is important to understand that financing of vaccine work must be long-term, sustainable and projected beyond COVID-19; other diseases such as malaria and HIV must inform the financial imperatives.

The financing mechanisms required to achieve vaccine R&D&M and effective distribution on the continent can be summarised as follows: domestic government resources, private sector funding, multilateral institution investments (such as AfDB, Afreximbank and IFC), global investors (such as Wellcome, Mastercard, global entrepreneurs and multinational corporations), global and African philanthropists, and partnerships (national, continental and global). The funding could be through equity, loans, bonds, joint ventures, or grants. However, the key financial driver should be the African private sector (including African entrepreneurs), not for charity but for a handsome return. Vaccine R&D&M and distribution in Africa must be understood as a vibrant business and commercial opportunity.

The CoDA Independent Task Team on Development, Equitable and Universal Access to Essential Vaccines and Vaccinations in Africa aims to achieve equitable and universal access to essential vaccines and vaccinations on the continent. Several categories of enablers will increase Africa's capacity to develop and produce vaccines and, thereafter, get the vaccines into the arms of African people: strategic and continent-wide vaccine advocacy, review of existing R&D&M best practices in Africa, specific key requirements for vaccine R&D&M, strengthening and harmonisation regulatory capacities, understanding the technical issues involved in vaccine R&D, in particular, capacity for genome identification, identifying the building blocks for Africa's broad vaccine R&D strategy, and then moving from vaccine R&D to vaccine manufacturing.

It is crucial to develop African infrastructure for clinical trials to guarantee the safety and efficacy of the vaccines and develop the logistics and supply chain management to get vaccines into every African arm. Of course, resources equal results. The right levels of investment and efficacious financing mechanisms must be established.

Africa-wide partnerships, all-stakeholder collaborations, and establishing regional research, development and manufacturing hubs in the five African regions will increase Africa's capacity to develop, produce vaccines, and facilitate equitable vaccination across the continent. There is a need to nurture, encourage, leverage, and scale-up initiatives and partnerships such as that with Igbinedion University.

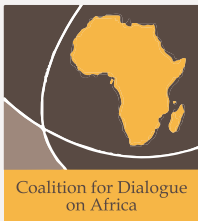
Research, development and manufacture of vaccines on the continent will only be possible if leaders and planners leverage the economies of scale unlocked by an integrated and politically united Africa. Embracing, strengthening and operationalising AfCFTA, AMA, PMPA, and AMRH will create an enabling foundation upon which the march towards vaccine continental sovereignty can be launched.

It is crucial to ensure that there is an African agency in all matters of public health, specifically, equitable and universal access to essential vaccines and vaccinations. Evidently, this can be achieved through a multi-stakeholder ecosystem approach. Lack of health security is a threat to national security, but more importantly, continental security. Unfortunately, Africa may have to achieve health security on its own, against all odds in the current political economy of global public health.

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