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## Advance the African Medicines Agency to benefit health and economic development

The African Medicines Agency can enable African people to live the healthier lives they deserve while boosting continental trade and economic development, write **Michel Sidibé and colleagues**

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Many African lives were cut short by the covid-19 pandemic. We will likely never know the true magnitude of the pandemic in Africa owing to the lack of testing kits or infrastructure to monitor the pandemic. Although the virus did not cause the millions of deaths that were predicted, it exposed the continent's vulnerabilities in ensuring access to vital drugs, vaccines, and health technologies. The African continent was sidelined in the global rush for vaccines in 2021 and 2022—and currently fewer than half of the African population has been fully vaccinated.<sup>1</sup>

This represents a gross failure of global empathy and solidarity, as well as a lack of African solutions and infrastructure. Drugs sold in Africa are the most expensive in the world, as long pharmaceutical supply chains, with multiple intermediaries, increase the prices. Moreover, 42% of all the substandard and falsified medicines reported to the World Health Organization between 2013 and 2017 came from the African region.<sup>2</sup> In sub-Saharan Africa, as many as 436 000 deaths annually are linked to falsified and substandard antimalarial medicines and antibiotics used to treat pneumonia in children.<sup>3</sup> This is preventable. One solution is the African Medicines Agency (AMA), but it needs wider support and investment for it to be operationalised with urgency.

The idea of an African organisation like this has been around for at least a decade and is strongly supported by the New Partnership for Africa's Development—the African Union's development agency. A treaty to establish an African medicines agency was endorsed by the African Union in 2019 and came into force in late 2021. The aim is to improve access to safe, effective, affordable, and quality medical products across African countries by creating and enabling regulatory environment.<sup>4</sup> By developing common standards and regulations, coordinating reviews of clinical trial applications, coordinating the evaluation of medical products and pharmaceutical ingredient manufacturing sites, and sharing information about products authorised for marketing, it will foster the growth of domestic production and facilitate trade across the continent. There are hopes that the entry of new products into the healthcare system can be accelerated, the costs of medicines can be decreased, access to medicines will be increased, and that fake, substandard, and harmful products will be crowded out. In short, the AMA has a key role in improving the health and wellbeing of Africans. It provides an opportunity to design and implement a continental regulatory system, for African people, by African

people, and leveraging African capabilities and talent.

The pandemic illustrated the importance of African self-reliance when it comes to health related products. One estimate suggests that Africa imports 70% of its pharmaceutical products.<sup>5</sup> This situation has been attributed to, among other things, weak or absent drug regulatory systems with unclear policies and incomplete or inconsistent legal and regulatory frameworks. A stronger, harmonised drug regulatory environment, including cooperative commercial authorisation of medicines developed by African pharmaceutical companies, as envisioned by the AMA, is an integral part of a well functioning ecosystem for health—it is vital to health security, universal health coverage, and healthy populations.

The AMA is positioned to work closely with the Africa Centres for Disease Control and Prevention, and other platforms such as the African Vaccine Regulatory Forum, to enhance Africa's contribution to clinical research and innovation and improve diversity in clinical trials—for example, tackling the dramatic imbalance in global genomic data. The continent with the most genetically diverse population in the world must not be left behind in regulation of genetic technology and data. It is unacceptable that Africa, which is home to 17% of the global population and carries 25% of the global disease burden, accounts for less than 2% of genomic data used in medical innovation and less than 3% of clinical trials.<sup>6</sup>

The theme of the African Union summit this year is accelerating implementation of the African Continental Free Trade Area. This will integrate a market of 1.3 billion people and potentially 2.2 billion people by 2050. The African pharmaceutical sector, which was worth \$28bn in 2017, is expected to grow to \$56-70bn in 2030, with the potential to create over 16 million jobs by then.<sup>7</sup> There is international interest in investing in the pharmaceutical sector in Africa, but it is looking for confidence in the regulatory environment. The AMA and the free trade area are mutually reinforcing. The economies of scale offered by the trade area will mean that market size is no longer an obstacle to pharmaceutical manufacturers engaging in local production of medicines and vaccines. The trade area will also streamline border procedures and lower costs. Meanwhile, AMA aims to foster local production, including for export.

The leaders of 55 African countries have made development of the pharmaceutical industry a key priority, as enshrined in the African Union's Vision 2063: "The Africa We Want."<sup>8</sup> As leaders assemble

at the African Union summit and make commitments to boost continental trade, we commend them for the progress made in establishing AMA. But the job is far from done. We encourage African Union member states to ratify the AMA and believe that doing so will inspire global confidence in African made products and enhance the reputation and growth of African pharmaceutical manufacturers, enabling them to become net exporters.

The AMA can help grow Africa into a resilient manufacturing powerhouse bringing African solutions to problems to help all Africans. This will boost the African free trade area. And all African countries will benefit from a single market approach. This is something that is in line with Nelson Mandela's belief that "in a globalised world, we are the keepers of our brothers and sisters, especially in the arena of health."

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