

## FOUR FACTORS BLOCKING MEDICINES BEING MANUFACTURED IN AFRICA

[Francis Aboagye-Nyame](#)



Setting up a continent-wide medicine regulator could be crucial to getting Africa's people the treatments and Covid vaccines they need. Here's why more countries need to put their weight behind it

As [Covid-19](#) began to spread around the globe in March 2020, drug supplies — ironically — shrank, because of the pandemic's effect on global supply chains.

Chinese factories, which produce about [70% of the active pharmaceutical ingredients \(APIs\) that Indian drug manufacturers use](#), were shuttered during China's severe lockdown early last year. Much of the world relies on India's exports of [26 key generic drugs](#) and drug ingredients, but without raw ingredients, India was [forced to restrict](#) its pharmaceutical exports, which account for [one fifth \(in volume\) of the world's exports of generics](#).

The Chinese and Indian supply and export contractions exposed sub-Saharan Africa's vulnerability to variation in the supply of medical products because of the dependence of these countries on imports (which make up [70% to 90% of their medicines](#)).

The severe repercussions of pharmaceutical-supply shocks reach beyond what is needed to combat Covid-19: A [UN Aids analysis](#) in June projected that the pandemic could lead to stock-outs and increased costs for the antiretrovirals needed to treat HIV, potentially leading to 500 000 additional Aids-related deaths in sub-Saharan Africa alone.

But the pandemic has also highlighted long-standing weaknesses in the pharmaceutical systems of African countries: A shortage of manufacturing capacity (only [three facilities](#) in Africa are capable of producing any of the active pharmaceutical ingredients needed to create drugs from scratch), weak regulatory systems for products produced or imported, and poor accessibility of products both within countries and across the region.

Along with gaps in the overall health systems of African countries, these problems help to explain why about [half of the continent's people](#) lack access to essential medicines and [nearly 50%](#) of children in sub-Saharan Africa die of vaccine-preventable diseases each year.

The [AU](#) has called for the continent to conduct more of its own manufacturing to help to ensure a sustainable supply of medicines. But to make that a reality, and ensure that the medicines produced in Africa are safe and effective, four interrelated systems need to be in place.

### 1. We need better systems to regulate medicines

Africa needs stronger medicine regulatory systems that can manage the introduction of treatments for both locally manufactured and imported medications — the better the system, the higher the chances that only safe and effective medicines will enter a country.

Pharmaceutical manufacturers in Africa face special [hurdles](#), such as fragmented and inefficient product registration systems, weak communication networks and a lack of ability to gather and share information. Moreover, the reluctance of global pharmaceuticals to share sensitive product information, for fear of compromising intellectual property rights, is an obstacle.

The [World Health Organisation \(WHO\) estimates](#) that [one in 10 medicines](#) circulating in low, or middle-income countries is substandard or falsified. But that's just the tip of the iceberg: for each fake product spotted, there are many more lurking, the WHO says.

The AU Development Agency – the New Partnership for Africa's Development (Auda-Nepad) is leading the work of the [African Medicines Regulatory Harmonisation](#) initiative, a project that helps member states to co-ordinate their policies and regulatory practices. The idea is to standardise processes, such as the registration of medicines registration, across countries, so that companies could use a standard application for registration that will reduce the costs and time it will take to get medicines approved.

The AU is in the process of creating the [African Medicines Agency](#) (AMA) to facilitate continent-wide co-operation on medicine regulation. The decision to establish the AMA was endorsed by member states in 2019, but it needs 15 countries to sign and ratify the agreement. Nineteen have signed, but so far, only six countries have ratified it. At the [April 12-13 AU conference on vaccine manufacturing](#), the Africa Centres for Disease Control director, John Nkengasong, said the AMA was “critical” for continent-wide regulation and harmonisation.

Other countries must heed [the call by the International Alliance of Patent Organisations](#), endorsed by 40 countries, to follow suit.

### 2. We need to become better at producing raw materials

Africa [lacks critical raw materials for pharmaceuticals, even common additives like corn starch and cellulose derivatives](#) are mostly imported. Countries need these materials to be able to ramp up safe, global-standard manufacturing capabilities. For this, technical knowledge — partly in the form of [technology transfer](#) within partnerships — will be critical. [South Africa](#) and Egypt have begun taking steps to manufacture “active pharmaceutical ingredients” or APIs (one example of an API is [recombinant DNA used to make synthetic human insulin](#)), and Ethiopia has a five-year [action plan](#) for building a native industry that includes making APIs. To promote more efforts like these, governments could provide tax incentives, subsidies, free land leases and legal protection against counterfeiting.

### 3. Countries need to work together because it will make medicines more accessible

Countries should promote manufacturing based on regional needs rather than their individual requirements, and also make it easier to sell medical products across borders by removing regulatory and trade bottlenecks. This will make it easier for medicines to reach people — both within and across countries.

Medical products should, therefore, be a priority sector for the [African Continental Free Trade Area](#), which can be implemented and tapped to open markets, enforce common standards, and support investments in the fledgling pharmaceutical industry.

Free-trade zones, otherwise known as free ports, are “special economic areas that benefit from tax and duties exemptions. While located geographically within a country, they essentially exist outside its borders for tax purposes,” [according to the US think-tank, Global Financial Integrity](#). Countries make use of such facilities to promote regional collaboration on manufacture and procurement of medicines. It would, however, be crucial for checks and balances to be in place [to prevent counterfeit products from entering markets](#).

Regional collaboration could also leverage pooled procurement mechanisms, speeding up purchasing and distribution, and enabling smaller markets in Africa to have easier, cheaper access to more products.

We’ve recently seen how this could work: the AU’s [Africa Medical Supply Platform](#) offers personal protective equipment, rapid-test kits, ventilators and other Covid-related medical products, some locally made. The platform aggregates demand and allows participants to negotiate prices.

Similarly, the continent also needs a mechanism that can support the local pharmaceutical industry to meet the standards of global buyers such as the Global Fund, Pefpar and UN children’s agency Unicef, to rally support for building Africa’s nascent pharmaceutical manufacturing industry.

### 4. We need universal access to healthcare systems that make medicine affordable

When medicines do reach individuals, they must be affordable. Most countries lack adequate health-insurance schemes, so families are saddled with [large out-of-pocket payments](#) for medicines. In Kenya, a week’s worth of antibiotics could [cost a month’s wages](#). This is an issue for poorer households in all low- and middle-income countries; 9.5% of their expenditure [goes toward medicines](#). But it’s a fixable problem: [Rwanda instituted a community-based health-insurance programme in 2011](#) that now covers more than 90% of its people and has reduced out-of-pocket spending [from 28% to 12%](#) of total health expenditure. With some organisation and public spending, governments can ensure that medical care — including pharmaceutical products made in Africa — is affordable and accessible to their people.

#### [Francis Aboagye-Nyame](#)

Francis Aboagye-Nyame is the programme director of the USAID-funded medicines, technologies, and pharmaceutical services project at the US-based health organisation, Management Sciences for Health.