Africa’s overreliance on pharmaceutical imports presents a continued obstacle to improving the health of its populations. The COVID-19 pandemic shone a light on this problem, as supply-chain disruptions led to stockouts of many essential medicines, the impact going beyond the direct effect of the pandemic itself. Since then, many African countries have underscored their intention to move towards greater self-sufficiency in the production of quality medicines and other therapies.

The production of quality-assured malaria drugs in Africa, the continent that accounts for 95% of global cases and deaths, falls short of demand. As a result, the continent is heavily reliant on importation of these essential medicines. In line with its mission to promote equitable access to malaria medicines, Medicines for Malaria Venture (MMV) has been working in partnership with African manufacturers to support them to meet the World Health Organization’s (WHO) quality standards. Most recently, MMV has been working with 3 African pharmaceutical manufacturers towards WHO Prequalification, with one manufacturer in Kenya successfully prequalifying 2 antimalarials.

MMV is a Product Development Partnership (PDP) that works to ensure the discovery, development, and accessibility of new and existing malaria interventions to those most at risk. These interventions include child-friendly antimalarials, seasonal malaria chemoprevention (SMC), and therapies for use during pregnancy. To this end, MMV has established a large and growing partnership network that includes hundreds of national malaria control programmes, pharmaceutical companies, and other science and policy experts. MMV has a track record of collaboration with pharmaceutical manufacturers in malaria-endemic countries to strengthen their capacity to produce quality medicines. These efforts have helped address a range of issues related to cost, packaging, distribution, continuity of supply, regional supply chain autonomy, training of healthcare workers and sustainability in many malaria-endemic countries. MMV also works with international procurement and funding agencies to support the entry of these drugs into the market. This, in turn, has improved access to vital, quality-assured antimalarial therapies.

Key takeaways

95% of malaria cases and deaths occur in Africa, and efforts to control the disease are stalling.

Africa imports up to 61% of the packaged medicines and up to 80% of the pharmaceuticals it uses.

Producing quality medicines closer to patients who need them most will save lives and accelerate progress.

The disruptions to global supply chains during the COVID-19 pandemic highlighted the need for a regionally sourced, quality-assured supply of antimalarials on the continent.

MMV has over 18 years of experience in supporting manufacturers to meet the World Health Organization’s (WHO) quality standards. Most recently, MMV has been working with 3 African pharmaceutical manufacturers towards WHO Prequalification, with one manufacturer in Kenya successfully prequalifying 2 antimalarials.

Defeating malaria together

MMV is an international partnership that develops new and affordable drugs to treat malaria. Their goal is to improve access to innovative and quality-assured antimalarial therapies.
The urgency to strengthen African production of therapies used to treat and prevent malaria

Fast access to malaria treatment is crucial to reduce the impact of this disease that can kill in a matter of hours. Artemisinin-based combination therapies (ACTs) are the mainstay of malaria treatment against the deadliest form of the parasite. A locally available, reliable source of ACTs, close to the patients who need them most, will save lives; this can also help displace products of substandard or unknown quality, which are known to contribute to resistance.

Malaria chemoprevention, whereby medicines are used to prevent malaria infection and its consequences, is a powerful way to reduce the toll of this disease. Malaria chemoprevention involves administering antimalarial medicines to populations at heightened risk if infected. An important example of a medicine used for malaria prevention is sulfadoxine-pyrimethamine (SP). SP is a well-tolerated, efficacious, and affordable medicine used alone or in combination with other drugs to prevent malaria in infants, children, and pregnant women.

Over the past decade, the use of SP-based chemoprevention strategies has grown. In June 2022, WHO expanded its guidance to support the administration of SP-based chemoprevention interventions to broader groups of people living in malaria-endemic areas in Africa: eligible populations now include infants aged 0-24 months, school-aged children, and increasing numbers of pregnant women. Demand for this medicine is therefore expected to grow even more in the years to come.

Unfortunately, a broad range of factors have impeded coverage with malaria prevention and treatment medicines in Africa. These include gaps in coordination, policy, regulations, human resources, and service delivery. Deficits in the supply and quality of malaria medicines have persisted due to the following factors:

- Few producers of quality-assured medicines: Africa imports up to 80% of its pharmaceutical needs. Of the 375 medicine producers in the region, only five manufacture drugs to WHO Prequalification standards. The rest are constrained by underinvestment, infrastructure limitations, and regulatory challenges. A diversified, locally sourced supply base will help prevent the risk of stockouts and save more lives.
- Procurement of quality-assured medicines is not prioritized: the supply of quality-assured drugs is often not guaranteed in malaria-endemic countries. It is important for governments to prioritize procurement of quality-assured antimalarials.

Supporting African pharmaceutical manufacturers to meet quality standards is therefore critical to safeguard the supply of quality antimalarial medicines in the region. This in turn, can boost uptake of lifesaving tools, meet the needs of Africa’s rapidly growing population, and displace products of unstandard or unknown quality. The production of quality-assured medicines in Africa will also help diversify sources of global medicine production.

MMV’s track record in support of African manufacture of antimalarials

Over the last 18 years, MMV has built a successful track record of helping pharmaceutical partners in Asia, North America, and Europe achieve regulatory approval or WHO Prequalification for their antimalarial products. MMV has more recently been supporting African manufacturers to produce quality-assured antimalarial therapies and to increase the supply of active pharmaceutical ingredients (API) for critical antimalarials. So far, MMV’s work has focused on the following two countries:

1. Kenya. MMV, with support from Unitaid, has been working with Kenyan manufacturer Universal Corporation Ltd (UCL) to produce WHO Prequalified SP for IPTp and SPAQ for SM. In July 2022, UCL became the first African manufacturer to gain WHO Prequalification for SP to prevent malaria in pregnant women. In October 2023, UCL received prequalification from WHO for SPAQ. UCL’s new status as a manufacturer of prequalified SP for IPTp and SPAQ has the potential to ensure that more African children and pregnant women will be protected from malaria. UCL is one of only five manufacturers in Africa to have received this quality certification for a medical product.

2. Nigeria. In 2020, with funding from Unitaid, MMV started work with two pharmaceutical companies in Nigeria, Emazor and Swipha, to develop a quality-assured child-friendly, dispersible formulation of SP to protect women, children and infants from malaria. Swipha is expected to receive WHO pre-qualification for this product by the end of 2023.
Drivers of change: collaboration, technical support, and an enabling environment

The primary focus of MMV’s effort is in the areas of collaboration and technical support. MMV will support up to five drug manufacturers to produce WHO prequalified malaria active pharmaceutical ingredients (API) or finished medicines, thereby doubling the continent’s ability to produce quality-assured medicines. Governments, regulators, funders, and procurement agencies can support the creation of an enabling environment to accelerate impact.

Collaboration

Building an African pharmaceutical manufacturing sector that meets international quality standards will require pan-African and international collaboration and leadership bolstered by political will and far-sighted investors. It will also require guidance and commitment from normative bodies as well as private-sector cooperation.

Technical support

MMV has worked with African manufacturers to meet GMP standards by providing market information and supporting them to prepare dossiers and develop packaging and training materials. MMV’s support to manufacturers helps improve the overall quality of their total portfolio.

An enabling environment

Funders, governments, regional bodies, procurement agencies and health regulators have also shown commitment to Africa’s drive to make its own medicines. This is key for progress. For example, health regulators in Africa are working towards the regional harmonization of drug development and pre-qualification. In addition, Africa’s Continental Free Trade Area (AfCFTA) will create a large free trade area, develop regional value chains, and is expected to alleviate Africa’s reliance on external economies.

Conclusion: The rising tide lifts all boats

Achieving progress towards Universal Health Coverage is heavily dependent on access to affordable and high-quality essential medicines, vaccines, and diagnostics. Local production should therefore be integrated as a key component of functional health systems. The regional manufacture and equitable distribution of antimalarial therapies and interventions will speed progress towards the elimination of malaria. As the capacity and skills of drug manufacturers grow, they will be able to leverage their experience with malaria medicines and expand into products for other diseases with increased collaboration from pan-African policymakers. The implementation and financing of these strategies are worthy of full global support.