

Antimalarial manufacturing in Africa: A call for regional action

1. Executive summary

Strengthening pharmaceutical manufacturing in Africa is critical to meet the health-related Sustainable Development Goals (SDGs), support climate targets by reducing transport costs and carbon emissions, and ensure sustainable access to affordable, context-specific, quality-assured, climate-smart health products. Strengthening regional manufacturing also generates quality job opportunities and contributes to socioeconomic development. However, with the majority of the world's health products produced in just a few high-income countries, most low- and middle-income countries do not produce the affordable and accessible tests, treatments and tools they need. This leaves countries vulnerable to price volatility, supply chain disruptions, or unavailability of essential health products, particularly during periods of supply scarcity in the face of surges in regional or global demand or after climate-related shocks or extreme weather events.

Unitaid, a global health organization with a unique role of identifying and investing in new health products and approaches in low- and middle-income countries, has identified a priority set of health product categories that could contribute to regional sustainability and preparedness if made at the regional level. For each of these product categories, Unitaid has researched the feasibility, cost-effectiveness, and potential partners required to strengthen regional manufacturing. The first of these reports is on the production of new malaria treatments in Africa.

According to data from the World Health Organization (WHO), 608,000 people died from malaria worldwide in 2022 – 95% of those were in sub-Saharan Africa, and 78% of those were children under 5. But despite shouldering the largest global burden, Africa produces very few antimalarial treatments – the simple, cost-effective cure for the disease. Most artemisinin-based combination therapies (ACTs) are procured from China and India. Although malaria case incidence has reduced dramatically since 2000, progress has stalled and urgent threats like antimicrobial resistance and climate change are emerging. The main WHO-recommended antimalarial treatment – artemisinin-based combination therapy – is losing its effectiveness as the malaria parasite develops resistance. Scientific modelling suggests that diversification of available treatments is one of the effective approaches to stay ahead of the resistance.

Recent calls to action, such as the “Declaration for accelerated malaria mortality reduction in Africa”¹ and the “Lusaka Agenda: Conclusions of the Future of Global Health Initiatives process”² have been unequivocal on the need for urgent action for a speedy and coordinated approach to accelerating regional manufacturing as an enabler to equitable access. Similarly, the decision by the African Union for the Africa Centres for Disease Control and Prevention (Africa CDC) to broaden the mandate of the Partnerships for African Vaccine Manufacturing to encompass therapeutics and diagnostics and the African Union's appointment of Kenyan President William Ruto as a local manufacturing champion underscore the strong political commitment on the continent to strengthen regional manufacturing. Furthermore, the establishment of the African Medicines Agency and the regulatory harmonization initiatives by the African Union Development Agency-NEPAD illustrate the collective efforts at a continental level to address industry challenges and implement strategies outlined in the business plan for the Pharmaceutical Manufacturing Plan for Africa adopted in 2012.

By strengthening regional manufacturing capacity to produce new antimalarials, including non-artemisinin-based treatments, and helping to diversify the use of recommended treatments, we can help

¹ “Declaration for accelerated malaria mortality reduction in Africa: Commitment that ‘No one shall die from malaria’”, Issued by the Ministers of Health of High Burden High Impact countries in Africa, accessed 18 April 2024, <https://minsante.cm/site/sites/default/files/Yaounde%20Declaration%20on%20Malaria.pdf>

² “The Lusaka Agenda: Conclusions of the Future of Global Health Initiatives process”, Future of Global Health Initiatives co-chairs, accessed 18 April 2024, <https://d2nhv1us8wflpq.cloudfront.net/prod/uploads/2023/12/Lusaka-Agenda.pdf>

fight drug resistance and strengthen health security for millions of people at risk of malaria in Africa. To date, support has been limited for strengthening regional manufacturing of pharmaceuticals in Africa due to key challenges such as limited infrastructure, limited access to affordable financing, a shortage of relevant skills, limited avenues for technology transfer, high cost of production, the cost and difficulty of securing WHO prequalification, and weak regulatory and quality assurance systems. Unitaid has identified opportunities for interventions that address these barriers to achieve scaled, cost-effective, sustainable and commercially viable manufacturing of new antimalarials in Africa.

To strengthen regional manufacturing in Africa for new antimalarials and other tests, treatments, and tools, Unitaid will leverage its role as pathfinder, investor and influencer to: regionalize the production of active pharmaceutical ingredients (APIs) as well as securing, in the nearer term, more affordable sourcing options for APIs produced outside of the continent; strengthen bioequivalence³ and bioanalytical capabilities⁴; and strengthen formulation development and manufacturing capabilities. Unitaid's interventions will focus on affected communities in low- and middle-income countries. Unitaid will collaborate with governments and other relevant stakeholders to promote prioritization of the right products in procurement and regulatory interventions, promote procurement with a purpose, and deploy appropriate market shaping tools. These will contribute to the delivery of affordable, context-specific, quality-assured health products, which are crucial for the success and sustainability of public health programs and universal health coverage.

2. The importance of regional manufacturing of health products

While Africa shoulders 25% of the world's disease burden – including major infectious diseases like HIV, tuberculosis and malaria – more than 95% of the active pharmaceutical ingredients and 70% of the pharmaceuticals consumed on the continent are imported. This leaves countries vulnerable to price volatility, supply chain disruptions or unavailability of essential health products, particularly during periods of supply scarcity in the face of surges in regional or global demand or after climate-related shocks or extreme weather events. This vulnerability was brought into stark relief during the COVID-19 pandemic, when global lockdowns, increased demand and interruptions to supply meant countries without local manufacturing capabilities did not have access not only to COVID-19 tools, but routine medical supplies as well.

Taking a smart approach to making tests, treatments and health tools available in Africa by strengthening regional manufacturing on the continent will enhance health security, increase sustainable access to affordable health solutions and provide tailored solutions for regional needs. This will also contribute significantly to the health-related SDGs and support achievement of climate targets by reducing transport costs and carbon emissions.

There are several key challenges that must be overcome, including the cost and complexity of achieving quality and regulatory compliance, poor access to finance, suboptimal infrastructure, and unpredictable public sector demand. Strengthening regional manufacturing will therefore take a coordinated effort across a range of partners, including regional manufacturers well-placed to expand; manufacturers able to provide technology transfer; national governments and regional blocs facilitating trade and creating regional markets; pooled procurement platforms; and partners that buy the products.

³ Bioequivalence refers specifically to the similarity in the rate and extent of absorption of the active pharmaceutical ingredient from a pharmaceutical product compared to a reference product when administered at the same dose under similar conditions.

⁴ Bioanalytical capabilities are the procedures for collecting, processing, storing, and analyzing a biological matrix with the purpose of detecting and quantifying a specific chemical compound.



Africa has ~600 health care production sites for 1.1 billion people

India has ~10,000 for 1.4 billion people

China has ~5,000 for 1.4 billion people

Unitaid saves lives by making new health products available, adapted, and affordable for people in low- and middle-income countries. Unitaid identifies challenges that are slowing progress towards global health goals, finds and invests in innovative products and solutions, then works with countries and partners to take them to scale so people everywhere can benefit.

Unitaid's Regional Manufacturing for Equitable Access approach draws on its proven track record of identifying and accelerating access to new health products, deep experience in market shaping and extensive network of partners – from manufacturers and product development partners to scale funders, procurers, nongovernmental organizations, civil society and governments. Unitaid is initiating its interventions in Africa, where countries rely the most on imported health products and where increased regional capacity would greatly improve sustainability and access to products that address regional needs. The goal is to contribute to the evolution of a sustainable African manufacturing industry that delivers a range of health products at scale, meeting the required quality standards and priced competitively. Unitaid will, in parallel, seek to identify opportunities for impact in Latin America and other underserved regions of the world.

In the first phase of implementation, Unitaid has identified a priority set of health product categories that could contribute to regional sustainability and preparedness if made at the regional level. Unitaid's prioritization was based on five key criteria: resilient and equitable public health opportunity; transformative potential of technology platform(s); Unitaid's historical investment and level of effort; synergy with Unitaid's unique positioning; and product ecosystem and market readiness. Based on this analysis, Unitaid identified five priority products from therapeutics, diagnostics and medical devices groups:

1. New malaria treatments, including non-artemisinin-based drugs.
2. HIV treatments, including HIV medicines for children.
3. Better medicines for prevention and treatment of postpartum hemorrhage.
4. Rapid diagnostics tests for HIV and hepatitis C.
5. Next-generation long-lasting insecticide-treated nets for malaria.

For each of these products, Unitaid has researched the feasibility, cost-effectiveness, and potential partners required to strengthen regional manufacturing.

Unitaid's definition of manufacturing of health products

Manufacturing of health products can be defined as all activities, including some or all value-added manufacturing operations, leading to the production of the respective health products. These include the synthesis of active pharmaceutical ingredients (APIs), antigens or antibodies and other constituents of in-vitro diagnostics, and final formulation of finished pharmaceutical and diagnostics products.

3. Regional manufacturing for climate-smart health products

Unitaid's definition of climate-smart health products are that they have a strong public health value, are relevant for affected communities, support Unitaid's objectives for mitigation and adaptation, and are more sustainable than current products and interventions. Unitaid's strategic emphasis and dual focus on promoting climate-smart health products and strengthening supply chain resilience through regional manufacturing initiatives create a compelling case for advancing synergistic collaboration and cooperative approaches. By aligning efforts in these areas, Unitaid aims to drive equitable access to health innovations while simultaneously ensuring environmental sustainability. By aligning efforts in these key areas, Unitaid can unlock dual benefits. For example:

- By integrating climate-smart practices into health product manufacturing at the outset of regionalization projects, and ultimately leapfrogging, Unitaid can effectively work and invest towards advancing low-carbon manufacturing methods and mitigate various environmental impacts throughout the product lifecycle.
- Regional onshoring of manufacturing not only enhances market proximity but also reduces reliance on distant suppliers and centralized supply chains, thus reducing vulnerabilities to disruptions in global trade, or those linked to climate change-related crises and extreme weather events. By integrating climate-proofing measures such as more resilient production infrastructures and diversified supply chains, regional manufacturing has the potential to bolster resilience of access to lifesaving products.
- Investment in climate-smart supply chains and technologies, coupled with regional manufacturing capabilities, facilitates adaptation to evolving environmental conditions and propels sustainable innovation in both product design, production processes and delivery models.

Unitaid acknowledges the potential economic, technological, and regulatory challenges associated with balancing climate-smart strategies with regional manufacturing initiatives. Leveraging its unique position and market shaping role within the global health architecture, however, Unitaid identifies a significant strategic opportunity to address barriers for regional manufacturing of climate-smart health products cohesively and make well-informed tradeoff decisions. Through collaborative efforts, strategic partnerships, and holistic approaches, Unitaid aims to identify synergies and proactively mitigate tensions from the outset. With partners, Unitaid will explore potential initiatives that include incorporating new criteria into procurement tenders with partner agencies, creating market incentives for suppliers and adopting collaborative approaches that have complementary investment models. Ultimately, Unitaid is committed to optimizing outcomes that prioritize equitable access to life saving products while simultaneously promoting environmental sustainability. This comprehensive approach underscores Unitaid's dedication to driving positive change and nurturing sustainable solutions within the global health landscape.

4. Malaria in Africa

Malaria, a preventable, curable disease transmitted by the Anopheles mosquito, is endemic in Africa; 30 countries have moderate and high transmission. Although malaria case incidence has reduced dramatically since 2000, since 2015 progress has plateaued and as a result the world is not on track to achieve global malaria targets. Funding has stalled, and new threats like antimicrobial resistance and climate change are emerging. Malaria parasites and the mosquitoes that transmit them are developing resistance to WHO-recommended antimalarial medicines, artemisinin-based combination therapy, threatening one of our strongest lines of defense. Climate change is pushing malaria-carrying mosquitos to new regions and higher altitudes as temperatures rise and rainfall patterns shift, putting more people at risk. The transmission season is getting longer, putting more people at risk for longer periods of time, and extreme weather events like flooding and storms increase the breeding grounds for mosquitoes.

Africa is disproportionately affected. According to WHO data, 608,000 people died from malaria worldwide in 2022 – 95% of those were in sub-Saharan Africa, and 78% of those were children under 5. Malaria also poses serious risks to pregnant women, causing one in 10 maternal deaths in regions where the disease is endemic and increasing health risks for the baby. But despite shouldering the largest global burden, Africa produces very few antimalarial treatments – the simple, cost-effective cure for the disease.

No single tool will stop malaria, which is why Unitaid and its partners are supporting a range of tools: new vector control products like insecticide-treated nets and spatial repellents to protect people indoors, the introduction of the world's first malaria vaccine for children under 5, and preventative treatments for pregnant women and children. To fight drug resistance, Unitaid is also helping countries deploy strategies that diversify antimalarial treatment use, as modelling suggests that this is one of the approaches that can help mitigate and stay ahead of parasite resistance. Most of these treatments, however, are currently produced outside of Africa – mainly in the pharmaceutical powerhouses of China and India. Building regional manufacturing capacity to manufacture effective malaria medicines in Africa can help enable sustainable access to diversified treatments on the continent.

5. The market for antimalarials in Africa

Driven by continued transmission and rapid population growth in high burden countries, the need for antimalarial treatment in Africa is projected to reach US\$1 billion with an expected demand of US\$764 million by 2030⁵. WHO recommends the use of six artemisinin-based combination therapies to treat most cases of malaria: artemether-lumefantrine (AL), artesunate-amodiaquine (ASAQ), artesunate-mefloquine (ASMQ), dihydroartemisinin-piperaquine (DHAP), artesunate+sulfadoxine-pyrimethamine (AS+SP), and artesunate-pyronaridine (ASPY).

Despite the existence of multiple recommended treatment options, the antimalarial market in Africa is dominated by a single ACT: artemether-lumefantrine (AL). This dominance is potentially driving resistance to artemisinin in Africa. Artemisinin partial resistance⁶ has been confirmed for the first time in Africa, specifically in Eritrea, Tanzania, Rwanda and Uganda, and experts believe the problem is likely even more widespread. With Africa's heavy reliance on ACTs, the threat of drug resistance, including partner drug resistance on the continent, must be urgently addressed to avert the potential escalation to widespread clinical treatment failures. While ACTs remain effective in Africa, scaling up appropriate access to quality products is still a top priority alongside efforts to mitigate resistance. A potential opportunity to address this looming challenge lies in the diversification of ACTs treatments, as highlighted in WHO's "Strategy to respond to antimalarial drug resistance in Africa"⁷.

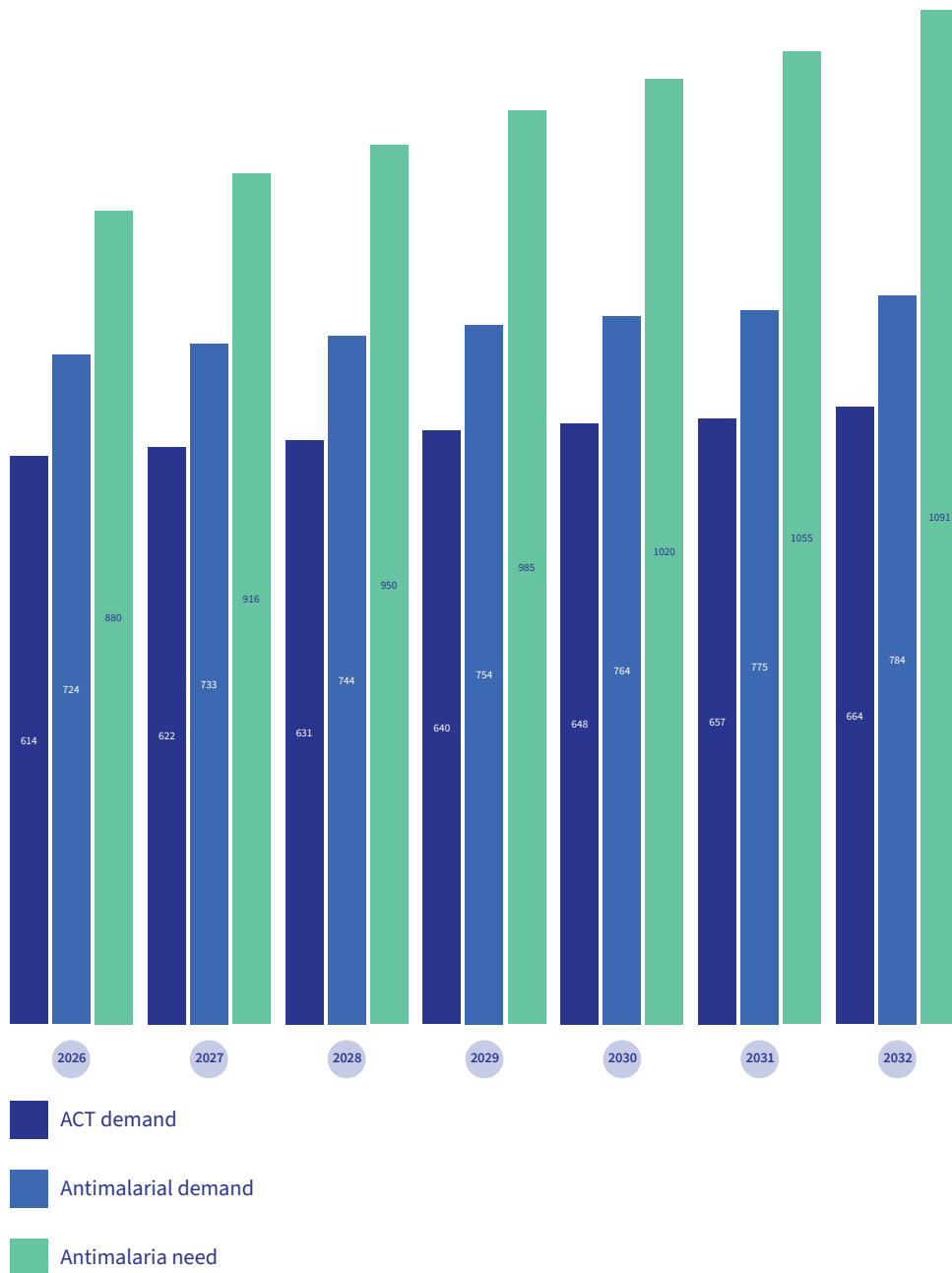
⁵ Antimalarial need is defined as the number of treatments that are required to treat all malaria febrile episodes, regardless of whether the febrile patients seek treatment, while antimalarial demand is defined as the volume of treatments likely to be consumed given national coverage constraints, based on extrapolation of current trends.

⁶ A delay in the clearance of malaria parasites from the bloodstream following treatment with an ACT. As a result, the artemisinin compound is less effective in clearing all parasites within a 3-day period among patients who are infected with artemisinin partially resistant strains of malaria.

⁷ "Strategy to respond to antimalarial drug resistance in Africa", WHO, accessed 18 April 2024, <https://www.who.int/publications/i/item/9789240060265>

Figure 1: Need and demand of ACTs and antimalarials in Africa

Treatments (millions)



6. Africa has an emerging antimalarial manufacturing value chain

Research conducted by Unitaid, together with results from ongoing work with partners and other stakeholders to strengthen pharmaceutical manufacturing, shows that there is significant improvement in manufacturing capabilities in Africa. The research acknowledges that there are still gaps and barriers to be addressed, but these are surmountable. Unitaid has identified opportunities for interventions that address these barriers to achieve scaled, cost-effective, sustainable, and commercially viable manufacturing of key antimalarials.

Oral solid dosage forms constitute one of the most dominant pharmaceutical formulation types currently manufactured in Africa. This points to existing capabilities, including platform technology, that can be leveraged to manufacture new antimalarial medicines and potentially other priority oral solid medicines that could be supported by Unitaid and other partners.

The antimalarial manufacturing value chain is already being nurtured in Africa, with significant historical investments delivering impact. There are several manufacturers of ACTs and other malaria medicines in Africa, notably in Nigeria, Kenya, Ghana, and Uganda. While many of these are of unknown quality status, efforts of governments and multiple stakeholders to collaborate with these manufacturers have yielded some positive results, including the following:

- Universal Corporation Limited (UCL) Kenya is the first African manufacturer to gain WHO prequalification for SP to prevent malaria in pregnant women with support from Malaria Medicines Ventures (MMV) and Unitaid. In October 2023, UCL received WHO prequalification for SPAQ.
- Cipla Quality Chemical Industries Ltd (QCIL) Uganda is listed as a manufacturing site for Cipla’s WHO-prequalified AL 20/120mg finished pharmaceutical product.
- Swiss Pharma Nigeria Limited (Swipha) and Emzor Pharmaceutical Industries Limited in Nigeria, with support from MMV and Unitaid, are developing a quality-assured, child-friendly, dispersible formulation of SP to protect women, children and infants from malaria. Swipha is expected to receive WHO prequalification for this product soon.

African developers and manufacturers have ongoing activities along the entire value chain for antimalarials



Product development

Nascent capabilities: Chemical Process Technologies Pharma (CPT Pharma) and H3D Foundation (South Africa), Emzor (Nigeria)



Formulation development

Multiple manufacturers in at least four countries



Quality assurance

UCL (Kenya) and QCIL (Uganda) with WHO prequalification; Swipha and Emzor (Nigeria) in process

New API manufacturing capacities emerging in Africa

- In technical collaboration with Mangalam Drugs & Organics Ltd. (India), Emzor (Nigeria) is developing the first API manufacturing facility in West Africa for production of five antimalarials: artemether (A), dihydroartemisinin (DHA), lumefantrine (L), sulfadoxine (S) and pyrimethamine (P).
- Advanced laboratory-scale synthesis of multiple APIs, including amodiaquine, by CPT Pharma (South Africa)
- H3D Foundation and CPT Pharma (South Africa) partnership to pilot promising products and new synthesis pathways.

On APIs, manufacturing capacities are emerging on the continent, with Mangalam Drugs & Organics Ltd., a pharmaceutical and API manufacturer in India, having entered into a technology transfer agreement with Emzor to support the production of five antimalarials: artemether, dihydroartemisinin, lumefantrine, sulfadoxine, and pyrimethamine. The API manufacturing facility is expected to start functioning in 2025 with a projected annual capacity of 400 metric tonnes.

7. A pathway for operationalizing regional manufacturing of antimalarials

To unlock the considerable potential for manufacturing of antimalarials in Africa, some key challenges would need to be addressed. Unitaid has charted a course that responds to these challenges, to catalyze on-continent manufacturing of this emerging product opportunity.

	Secure supply of cost-optimized API	Development & scale-up of generic formulation	Regulatory approval	Market shaping
Key activities	Long term agreement with appropriate market shaping interventions	Support accelerated development of generic formulations	Small & uncertain volume does not support significant product-specific investment; support quality assurance for generic formulations	Market creation advocacy, volume guarantees, procurement criteria
	Further API cost optimization	Establish bioequivalence		
Unitaid's role	Facilitate supply contracts with quality assured API suppliers	Engage contract development & manufacturing organizations (CDMOs) to develop formulations, pursue bioequivalence studies & technology transfer to African manufacturing site(s)	Provide technical & financial support for quality assurance	Engage with procurement and market shaping partners to defray market risk & enable market participation
	Design and facilitate partnerships for innovative API cost optimization			
Relevant actors to support Unitaid on implementation (non-exhaustive list)	API manufacturers	International CDMOs, African manufacturers	WHO, African Medicines Agency, regional regulatory harmonization initiatives	The Global Fund, governments, private sector companies, PMI, host governments, development finance institutions
Activity initiation timeline & activity duration	Initiate along with formulation development	Initiate immediately	After technology transfer to African site (12 months)	Simultaneously with regulatory approval

Building on the capabilities that currently exist on the continent, Unitaid would support viable African pharmaceutical manufacturers to nurture the manufacturing of cost-competitive, quality-assured antimalarials, focusing on the new antimalarials aimed at improving diversification and mitigating antimalarial drug resistance. This support, however, will be in exchange for contractual access terms⁸ that will ensure that the overall objective of equitable access is not compromised.

The malaria portfolio offers the most promising opportunity for optimizing API manufacturing costs in African production. To secure an uninterrupted supply of cost-optimized API for identified African manufacturers, Unitaid could forge long-term supply contracts with quality-assured API suppliers. In addition, Unitaid could lead the design and facilitate partnerships for innovative approaches for further cost optimization of APIs.

⁸ Contractual access terms set the balance between the manufacturer's commercial interests and Unitaid's main goal for equitable access with the public health goal of making essential medicines affordable and available, especially in developing countries. The agreements typically cover pricing, distribution, licensing, and intellectual property rights.

Formulation development support would be key for African manufacturers through the creation of funded partnerships with contract development and manufacturing organizations⁹ (CDMOs) that could develop optimal formulations, conduct bioequivalence studies, and eventually transfer technology to African manufacturers. The opportunity for shared product development projects should be explored for cost optimization with one formulation developed by a CDMO being transferred to more than one manufacturer across different regions. Also, this opportunity would be leveraged for capacity building of manufacturers, by shadowing, and to nurture a CDMO ecosystem in Africa.

Unitaid would leverage existing and new partnerships with the WHO Department of Regulation and Prequalification, African Medicines Regulatory Harmonization program, the African Medicines Agency, national regulators, and other relevant stakeholders to support manufacturers on quality assurance.

African manufacturer's most pertinent request is access to markets, and to fulfill this request, Unitaid should also design and/or facilitate market-shaping initiatives for accelerated market entry of the finished quality-assured products by leveraging partnerships with governments, the Global Fund, International Finance Corporation, U.S. President's Malaria Initiative (PMI), the World Bank, regional development banks, and other stakeholders.

Regional manufacturing of quality-assured ACTs also offers a chance to advance climate-smart product manufacturing. This entails integrating lower carbon API production routes to curtail carbon emissions, which currently account for approximately 78% of product emissions¹⁰; improving heat stability of ACTs; and potentially exploring use of semi-synthetic artemisinin as a critical alternative to natural artemisinin, which is susceptible to heat and drought during cultivation.

8. Antimalarial manufacturing in Africa: A call for regional action

Malaria remains a significant public health threat, particularly in sub-Saharan Africa. It heavily burdens communities and health care systems, hindering their development and well-being. To effectively control and ultimately eliminate malaria, a multi-pronged approach is crucial. One key element is establishing a reliable and secure supply of effective, quality-assured antimalarial treatments. This should leverage the existing political will and lessons learned from the COVID-19 pandemic and be expanded to cover other essential medicines for universal health coverage.

This call to action outlines a two-pronged approach: the “ABCs of regional value chain strengthening” and the “triple Ps for supply security”.

The “ABCs of regional value chain strengthening”:

- **API regionalization:** African governments and partners should work in a coordinated manner to strengthen supply security by supporting end-to-end manufacturing across the antimalarial value chain. Active pharmaceutical ingredients (API) manufacturing on the continent is nascent, and it is crucial to provide technical assistance, human capacity development, and low-cost financing for existing and new projects.
- **Bioavailability/bioequivalence (BA/BE) capabilities enhanced, including bioanalytical and clinical trials:** As regulatory systems and networks in Africa advance, bioavailability/bioequivalence (BA/BE) studies will become a standard requirement for regulatory approval processes, where applicable. Good Clinical Practices (GCP) compliant clinical trials are a key requirement for both the product development pathway and regulatory bioequivalence requirement for medicines. Currently, the

⁹ Contract development and manufacturing organizations provide drug development and manufacturing services to pharmaceutical companies.

¹⁰ “From Milligrams to Megatons: A climate and nature assessment of ten key health products”, Unitaid, accessed 18 April 2024, https://unitaid.org/assets/Report_From-milligrams-to-megatons_A-climate-and-nature-assessment-of-ten-key-health-products.pdf

- few BA/BE studies conducted by African manufacturers are done outside the continent. There is an urgent need for BA/BE capability strengthening in Africa to complement the drug development and manufacturing processes. Access to high-quality, cost-efficient BA/BE service providers will improve compliance of manufacturers and consequently enhance access to affordable, quality-assured regionally manufactured antimalarials. Furthermore, this will contribute to overall improvements in the quality of other essential medicines, regardless of the regulatory pathway chosen by manufacturers.
- **Capability strengthening and partnerships:** African governments and partners should support the development of generic formulations on the continent by facilitating technology transfer and building local technical capabilities in the long term to produce generic versions of essential malaria treatment drugs. This support entails providing technical assistance, training, and resources to enhance manufacturing capabilities and ensure quality. Additionally, governments and partners should prioritize promoting active investments in research and development to ensure Africa does much more in developing new medicines. In the meantime, there should be proactive engagement of originator companies to incentivize them to partner with African generic manufacturers through licensing partnerships and assisting generic manufacturers with the enablers for scaling up production to meet the demand for these treatments across affected regions.

The “triple Ps of supply security”:

- **People and promotion:** Prioritizing the well-being and needs of affected people and communities must be at the core of all the efforts in regional manufacturing in Africa or any other part of the world. A focus on people implies ensuring that equitable access to essential health products is prioritized, ensuring that the appropriate health technology is accessible (without any intellectual property barriers), quality-assured, affordable, available in the right quantities, and is being prescribed and delivered appropriately through the various health system contact points. Affected people and communities must be engaged at every step of the way to ensure the right fit. Furthermore, governments, partners, industry, and other relevant stakeholders should coordinate with affected communities to promote sustainable access through regional manufacturing. Unitaid sees an important role for global coordinating mechanisms, such as the RBM Partnership to End Malaria, to leverage their existing platforms to ensure a people-centric focus is included in the drive for regional manufacturing and access to medicines in general. This promotion should go beyond the health benefits of regional manufacturing to include other people benefits such as the creation of jobs and improvement of economies as well as the opportunities for climate-smart products and processes.
- **Procurement with a purpose:** Governments, donors and their procurement agencies should adopt innovative procurement processes that consider long-term factors beyond current ex-works price. Specifically, all economic and environmental implications of the manufacturing location of the finished product and APIs should be considered. The value and benefits of regional manufacturing of both the finished product and APIs would be better reflected in the decision-making process this way. This will help build climate-resilient supply chains and sustainable manufacturing ecosystems that are less vulnerable to disruptions caused by climate-related issues or any other disruptions that may impact global trade. To complement procurement, all stakeholders should embrace the added value of market shaping interventions (such as pooled procurement negotiations, volume guarantees, etc.) to regional manufacturing.
- **Payment schemes and financing mechanisms that are effective:** The addressable market for health commodities depends on the purchasing capacity of the end user. Governments and partners should promote access to health insurance and other financing mechanisms for access to health care to expand the addressable market and support regional manufacturing. Both established and innovative

- mechanisms to financing health care should be (re)designed to support regional manufacturers while maintaining their objectives of facilitating equitable access. Furthermore, where governments are major buyers of health products, prompt payment of suppliers should be ensured as standard practice.

The “ABCs of regional value chain strengthening” and the “triple Ps for supply security” are focused on some of the prioritized interventions for immediate action to strengthen regional manufacturing of antimalarials and other health products. However, the intention is not to undervalue the importance of other interventions such as intellectual property, trade tariffs, and removal of non-tariff barriers, infrastructure, regulatory strengthening, and access to foreign exchange. These also need speedy attention and there are several initiatives underway that will complement one another towards the achievement of the overall goals of access to medicines and to achieving universal health coverage.



About Unitaid:

We save lives by making new health products available and affordable for people in low- and middle-income countries. We work with partners to identify innovative treatments, tests and tools, help tackle the market barriers that are holding them back, and get them to the people who need them most – fast. Since we were created in 2006, we have unlocked access to more than 100 groundbreaking health products to help address the world’s biggest health challenges, including HIV, TB, and malaria; women’s and children’s health; and pandemic prevention, preparedness and response. Every year, more than 170 million people benefit from the products we’ve helped roll out.

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