

## **PRESS RELEASE**

# **First Nigerian manufacturer obtains WHO prequalification for key malaria prevention drug**

*Swiss Pharma Nigeria Limited (Swipha), with support from MMV and Unitaid, becomes the first Nigerian manufacturer of WHO-prequalified sulfadoxine-pyrimethamine, used for preventing malaria in those most at-risk – children and pregnant women*

- Milestone part of a broader effort to strengthen regional manufacturing capacity and expand the availability of quality-assured medications to combat malaria across Africa, where most malaria deaths occur.
- Nigeria records the highest number of malaria cases of any country in the world and relies solely on domestically manufactured sulfadoxine-pyrimethamine.
- Swipha undertook a detailed process to submit a comprehensive set of data about the quality, safety and efficacy of the product to WHO, with technical support from MMV and financial support from Unitaid.

**Geneva, Switzerland and Lagos, Nigeria 21 August 2024.** Swipha, a Nigerian pharmaceutical manufacturer, has received prequalification from the World Health Organization (WHO) for their sulfadoxine-pyrimethamine (SP), an effective medication for preventing malaria infection in pregnant women.<sup>1</sup>

Swipha undertook a detailed process to submit a prequalification dossier to WHO for their SP 500/25mg tablet, starting with extensive research and development for product formulation followed by a bioequivalence study to assess efficacy and safety. This accomplishment was realized with the technical and dossier support of Medicines for Malaria Venture (MMV) and with funding from Unitaid. This joint effort was part of a broader initiative to increase quality, sustainable supplies of malaria medicines globally.

WHO's [prequalification](#) programme ensures that medicines adhere to global standards of quality, safety and efficacy. Swipha's prequalification adds to efforts to bolster regional medicine production and reduce overdependence on imported medicines, highlighted when the COVID-19 pandemic disrupted global supply chains.

"We are honoured by the WHO prequalification of our sulfadoxine-pyrimethamine drug, a testament to Swipha's dedication to improving public health. This achievement reflects our commitment to producing high-quality medicines and contributing to the ongoing fight against malaria," said Abbas Sambo, Business Development & Licensing Director of Swipha.

Malaria poses a significant health challenge in Nigeria, where one in four cases and one in three deaths from malaria occur, the highest rates of any country. Fighting malaria is a national health priority in Nigeria. The scarcity of African-manufactured, WHO-prequalified medicines

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<sup>1</sup>By itself, SP is used to prevent malaria infection in pregnant women and in infants. When combined with amodiaquine, it is used in seasonal malaria chemoprevention, an intervention which prevents malaria in children in areas where the disease is highly seasonal.



has been a significant impediment in the fight against malaria, particularly in Nigeria, where programmes rely solely on domestically manufactured SP.

"The Nigerian National Malaria Elimination Programme is elated about Swipha's attainment of WHO prequalification for the production of quality assured sulfadoxine-pyrimethamine with support from global health organizations MMV and Unitaid. This is a major milestone that Nigeria has been striving to achieve. It promises to have a tremendous impact on the Nigerian health system by increasing availability of quality-assured medicines and building national capacity for sustainable manufacturing and monitoring of quality medicines as well as positioning Nigeria as a global competitor in the pharmaceutical sector," said Dr Godwin Ntadom, Coordinator of the Nigerian National Malaria Elimination Programme.

"Unitaid is proud to support efforts to increase high-quality production of a vital antimalarial medicine in Nigeria, the epicentre of the malaria crisis. Growing manufacturing capacity for malaria drugs in Africa, where nearly all malaria infections occur, is critical to building stronger health systems and ensuring countries are equipped to respond to the diseases that pose the greatest threat to their populations," stated Dr Philippe Duneton, Executive Director of Unitaid.

Swipha is the second manufacturer in Africa to receive prequalification for SP as part of a larger effort to increase quality supplies of regionally produced antimalarial medicines led by MMV and Unitaid. A third African manufacturer is expected to secure WHO prequalification for SP shortly, also in Nigeria.

"Swipha's achievement of WHO prequalification for sulfadoxine-pyrimethamine is a significant stride in the global fight against malaria. The collaborative efforts between Swipha, Unitaid, and MMV underscore the power of equitable partnership and local leadership in creating impactful solutions to combat diseases that disproportionately affect vulnerable populations," said George Jagoe, Executive Vice President of Access and Product Management at MMV.

This achievement reaffirms the critical role of partnerships between pharmaceutical entities, global health organizations and governments in the collective journey towards eliminating malaria.

## NOTES FOR EDITORS

### Background on the malaria burden

The African Region shouldered about 95% of malaria cases and 96% of deaths globally in 2022. Children under the age of 5 accounted for nearly 80% of all malaria deaths in the region.

In 2022, four countries in the African Region – Nigeria (26.8%), the Democratic Republic of the Congo (12.3%), Uganda (5.1%) and Mozambique (4.2%) – accounted for just over half of all malaria cases globally.

In 2022, more than 12.7 million pregnant women in Africa contracted malaria, mainly in the WHO sub-regions of West and Central Africa. The consequences of malaria in pregnancy can be catastrophic. A mother's immunity to the parasite is reduced by the biological and physiological changes of pregnancy, increasing her susceptibility to infection and her risk of severe illness and death. Furthermore, the accumulation of parasites in the placenta can lead to adverse outcomes for the child. *Plasmodium falciparum* malaria is associated with one in ten maternal deaths in malaria-endemic countries, as well as a three- to fourfold increase in the risk of miscarriage. Malaria in pregnancy can also result in low birthweight and premature birth, which increases the risk of neonatal mortality and can have lasting developmental consequences for the growing child.

### African efforts to create favourable market manufactured drugs

The quality approval of Swipha's SP follows a decision made at the African Union's Assembly of Heads of States in February 2024, at which Africa CDC was given a mandate to establish a pooled procurement mechanism for medical products by African manufacturers. This initiative aims to create predictable demand for African medicine suppliers, an initiative which also complements the African Union's ambition to produce 60% of the continent's vaccine and medical needs in Africa by 2040. The Africa CDC mandate will also provide greater access to essential medicines within the African continent, where about [95% of all malaria cases and 96% of deaths from malaria occur](#).

### Background on strengthening local production of medicines and other health technologies to improve access

Attaining the highest standard of health is a fundamental right for all. Access to quality-assured, well-tolerated, effective and affordable medicines, and other health technologies for all is a specific component of the Sustainable Development Goals Target 3.8.1 and in achieving universal health coverage.

There is an increasing need to manufacture essential medicines in the developing world. Africa's disproportionate reliance on imported medicines and the disparity in the supply of quality medicines and vaccines for Africa came into stark view during the COVID-19 pandemic. The continent has approximately 375 drug makers, serving a population of over 1.2 billion people. Yet, as of now, only six African pharma manufacturers have obtained WHO prequalification for a medical product.

### Background on seasonal malaria chemoprevention, perennial malaria chemoprevention and intermittent preventive treatment in pregnancy



WHO has revised the guidelines for three crucial malaria prevention strategies: seasonal malaria chemoprevention (SMC), perennial malaria chemoprevention (PMC, formerly known as intermittent preventive treatment in infants, or IPTi), and intermittent preventive treatment during pregnancy (IPTp). These strategies involve administering SP-containing preventive chemotherapy to young children and pregnant women, who are highly susceptible to malaria. This approach has demonstrated its safety, efficacy, and cost-effectiveness in reducing the impact of the disease and preserving lives.

For more information, visit [https://apps.who.int/gb/ebwha/pdf\\_files/WHA74/A74\\_ACONF1-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_ACONF1-en.pdf)

## **About the partners**

### **About Swipha**

Swipha is a pioneering pharmaceutical company based in Nigeria, committed to delivering high-quality healthcare solutions to address pressing medical needs in Africa and beyond. With a relentless dedication to innovation, Swipha leverages cutting-edge research and development to produce a range of essential pharmaceutical products that contribute to improving public health outcomes.

As a socially responsible company, Swipha's mission is to make a meaningful impact by ensuring access to safe, effective, and affordable medicines for communities in need. Through strategic partnerships, rigorous quality standards, and a strong commitment to ethical practices, Swipha is shaping the future of healthcare in Africa and working towards a healthier, more resilient continent. For more information, visit [www.swiphanigeria.com](http://www.swiphanigeria.com).

### **About Unitaid**

Unitaid is a global health agency engaged in finding innovative solutions to prevent, diagnose, and treat diseases more quickly, cheaply, and effectively, in low- and middle-income countries. Its work includes funding initiatives to address major diseases such as HIV/AIDS, malaria, and tuberculosis, as well as HIV co-infections and co-morbidities such as cervical cancer and hepatitis C, and cross-cutting areas, such as fever management. Unitaid is now applying its expertise to address challenges in advancing new therapies and diagnostics for the COVID-19 pandemic, serving as a key member of the Access to COVID-19 Tools (ACT) Accelerator. Unitaid is hosted by the World Health Organization. For more information, visit <http://www.unitaid.org>.

### **About MMV**

MMV is a Swiss-based not-for-profit organization working to deliver a portfolio of accessible medicines with the power to treat, prevent and eliminate malaria. Born in 1999, out of a need for greater health equity, we close critical gaps in research, development and access – working “end-to-end” to expand the use of existing antimalarials and innovate new compounds to protect public health.

MMV has over 18 years' experience in supporting local manufacturing that meets WHO's quality standards, working with pharmaceutical manufacturers in malaria-endemic countries to reinforce 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. MMV also works with international procurement and funding agencies to support the entry of these drugs into the market.

For more information, visit <http://www.mmv.org>.

### **Media contacts**

Chinedu Anokwulu, Market Access Manager, Swipha

Mobile: +234 913 936 8646

Email: [chinedu.anokwulu@swiphanigeria.com](mailto:chinedu.anokwulu@swiphanigeria.com)

Doreen Akiyo Yomoah, Communications Manager, MMV

Mobile: +41 79 238 60 74

Email: [yomoahd@mmv.org](mailto:yomoahd@mmv.org)

Kyle Wilkinson, Communications Officer, Unitaid

Mobile: +41 79 445 17 45

Email: [wilkinsonk@unitaid.who.int](mailto:wilkinsonk@unitaid.who.int)

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