PRESS RELEASE

First African-manufactured combination therapy for seasonal malaria chemoprevention receives WHO prequalification

- Universal Corporation Ltd (UCL), a Strides Pharma Science Limited (Strides) enterprise, with support from MMV, becomes the first African manufacturer to gain WHO prequalification for their sulfadoxine-pyrimethamine + amodiaquine product.

- Sulfadoxine-pyrimethamine + amodiaquine (SPAQ) is a combination drug used to prevent malaria in children living in areas of seasonal malaria transmission.
- The combination therapy is employed in seasonal malaria chemoprevention (SMC) programmes and is designed to protect children by clearing existing infections and preventing new malaria infections during the season of greatest risk.
- An African manufacturer of WHO-prequalified SPAQ can boost SMC programmes, improve access to quality medicines, support malaria prevention, reduce morbidity and mortality, strengthen global supply chains, and promote local economic development.

Geneva, Switzerland and Kiambu, Kenya, 6th November 2023 – UCL, a leading Kenya-based pharmaceutical manufacturer, supported by Medicines for Malaria Venture (MMV), has received prequalification from the World Health Organization (WHO) for its product, SPAQ. This historic achievement makes UCL the first Africa-based manufacturer to attain WHO prequalification for this life-saving malaria treatment.

Prequalification is a WHO programme established to apply standards of quality, safety and efficacy of medicinal products. This recognition demonstrates UCL’s commitment to maintaining the highest quality standards in the production of antimalarial drugs. Furthermore, the accomplishment is a welcome step, boosting regional production capabilities and providing greater access to essential medicines within the African continent, where about 95% of all malaria cases and 96% of deaths from malaria occur.

“Universal Corporation Ltd is committed to advancing the fight against malaria and improving the health and well-being of communities across Africa. The WHO prequalification of our SPAQ production is a significant step forward in achieving these goals”, said Perviz Dhanani, Founder and Managing Director of UCL.

SPAQ is a vital component in the fight against malaria, particularly through SMC programmes. Timely delivery of SPAQ is critical, considering its administration must sync with the seasonal period of peak malaria transmission (typically 4-5 months) and involves the distribution of millions of doses to multiple African countries. The logistical complexity of SMC delivery campaigns is amplified by the large number of children requiring this preventive medicine.

"Local manufacturing plays a pivotal role in improving public health in Africa, and the WHO prequalification of Universal Corporation Ltd’s SPAQ production is a notable accomplishment. This milestone not only demonstrates the continent's resolve to strengthen the self-sufficiency of its public health systems but also boosts confidence in locally manufactured products aligning with the African Union Agenda 2063 ambitions,” said Dr Jean Kaseya, Director General of the Africa Centres for Disease Control and Prevention (Africa CDC). “
Recent studies also show that offering SPAQ in combination with RTS,S or R21, the two malaria vaccines recommended by WHO, increases protection among children under 5 compared to either intervention alone.

UCL’s new status as a manufacturer of prequalified SPAQ has the potential to ensure that more children will be protected during the rainy season. Until recently, WHO recommended SMC only for children from 3 months to 5 years old. However, in June 2022, WHO updated its guidance to recommend this intervention for any child at high risk of severe malaria in areas of seasonal malaria transmission. This expansion resulted in more than 48 million children being protected from malaria, significantly reducing the burden of this deadly disease.

David Reddy, CEO of Medicines for Malaria Venture, expressed his enthusiasm for this milestone stating, “the WHO prequalification of UCL’s SPAQ is a significant achievement in our efforts to combat malaria in Africa. By expanding the availability of high-quality, locally manufactured anti-malarial drugs, we can strengthen SMC programmes and ensure that any child at high risk of malaria in areas of seasonal transmission is protected from the devastating impact of this disease. This achievement is a testament to the dedication and expertise of UCL and the ongoing collaboration between MMV and African manufacturers.”

The prequalification of UCL’s SPAQ could contribute to the expansion of SMC programmes across Africa. With increased access to WHO-prequalified drugs, more children will receive the necessary protection against malaria during the high transmission season, leading to a significant reduction in malaria-related illnesses and deaths.

NOTES FOR EDITORS

Background on the malaria burden

According to the latest WHO World Malaria Report released on December 8, 2022, there were an estimated 619,000 malaria deaths globally in 2021 compared to 625,000 in the first year of the pandemic. In 2019, before the pandemic struck, the number of deaths stood at 568,000.

Malaria cases continued to rise between 2020 and 2021, but at a slower rate than in the period 2019 to 2020. The global tally of malaria cases reached 247 million in 2021, compared to 245 million in 2020 and 232 million in 2019.

Despite successes, including an expansion of Seasonal malaria chemoprevention (SMC) and an increase of delivered Artemisinin-based combination therapies (ACTs), eradication efforts face many challenges, particularly in the African Region, which shouldered about 95% of cases and 96% of deaths globally in 2021. Children under the age of 5 accounted for nearly 80% of all malaria deaths in the region.

In 2021, four countries in the African Region – Nigeria (26.6%), the Democratic Republic of the Congo (12.3%), Uganda (5.1%) and Mozambique (4.1%) – accounted for nearly half of all malaria cases globally.

Background on Seasonal Malaria Chemoprevention therapy

Seasonal Malaria Chemoprevention (SMC) is a preventive strategy aimed at reducing the incidence of malaria in areas with a high burden of the disease and seasonal transmission,
particularly among children under five years old. It involves the administration of antimalarial drugs, typically sulfadoxine-pyrimethamine plus amodiaquine (SPAQ), to eligible children during the malaria transmission season.

SMC is usually implemented in areas with a seasonal pattern of malaria transmission, typically in the Sahel region of sub-Saharan Africa. The therapy is given monthly over a period of three to four months to provide protection during the peak transmission period. SMC has been shown to be highly effective in reducing the burden of malaria and preventing severe cases and deaths among children in endemic regions.

Since 2013, over 700 million doses of SMC have been distributed to young children in Africa’s Sahel region, safeguarding their lives. In 2022, over 48 million children were protected by SMC in 17 countries in Africa's Sahel region.

**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, safe, 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.

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 Universal Corporation Ltd (UCL)**

UCL is a Kenyan Pharmaceutical Manufacturing Company based in Kikuyu Township, Kiambu County in the Outskirts the capital city of Kenya, Nairobi.

The UCL manufacturing plant has been accredited with GMP certification by the local authorities (Pharmacy and Poisons Board of Kenya) and international quality compliance by various DRAs (Drug Regulatory Authorities). Currently, UCL manufactures over 100 formulations of Human medicines. This manufacturing capability is divided as per the dosage forms produced in each line & includes tablets, capsules, ointments, creams & powder (ORS).

The long-term plan of the company is to expand its specialty lines to cover all medical specialties. As quality is a priority, the manufacturing department is staffed by highly qualified and trained employees who undergo regular training on GMP procedures.

For more information, visit [http://ucl.co.ke](http://ucl.co.ke)

**About Strides**

Strides, a global pharmaceutical company headquartered in Bengaluru, India, is listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR). The Company mainly operates in the regulated markets and has an “in Africa for Africa” strategy along with an institutional business to service donor-funded markets. The Company’s global
manufacturing sites are located in India (Chennai, Puducherry, and two locations in Bengaluru), Singapore, Italy (Milan), Kenya (Nairobi), and the United States (New York). The Company focuses on “difficult to manufacture” products sold in over 100 countries.

For more information, visit https://www.strides.com/ http://www.unitaid.org/

About Medicines for Malaria Venture (MMV)

MMV is a leading product development partnership (PDP) in the field of antimalarial drug research and development. Its mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs.

MMV receives funding and support from government agencies, private foundations, international organizations, corporations, corporate foundations and private individuals. These funds are used to finance MMV’s portfolio of R&D projects, as well as specific, targeted access & product management (APM) interventions that aim to facilitate increased access to malaria medicines by vulnerable populations in disease-endemic countries and support their appropriate use.

Since its foundation in 1999, MMV and partners have built the largest portfolio of antimalarial R&D and access projects ever assembled, have brought forward 15 medicines that are treating patients. An estimated 13.6 million deaths have been averted by these MMV co-developed medicines. MMV’s success is based on its extensive partnership network of around 150 active partners including from the pharmaceutical industry, academia and endemic countries.

MMV’s vision is a world in which innovative medicines will cure and protect the vulnerable and under-served populations at risk of malaria and help to ultimately eradicate this terrible disease.

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

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