Large market share for non-quality-assured malaria medicines in Africa

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A new study of malaria medicine quality in 8 sub-Saharan African

countries has found a large and potentially growing market for non-quality-assured (QA) malaria treatments—medicines not pre-approved by global health organisations - as much as 20% of the private-sector market in Kenya, and 42% in the Democratic Republic of Congo (DRC). As one of the most comprehensive recent studies relating to medicine quality in the region, the findings provide new insights for patients, researchers, policy makers and malaria control programmes because QA status is often linked to the quality of medicines - which can impact patient health and safety, malaria control efforts and artemisinin drug efficacy.

The study, conducted in the private and public sectors of Benin, DRC, Kenya, Madagascar, Nigeria, Tanzania, Uganda and Zambia, was published today in a *Malaria Journal* article titled 'Do anti-malarials in Africa meet quality standards? The market penetration of non-quality assured artemisinin combination therapy in eight African countries'. Researchers measured the availability and market share of medicines not pre-approved under World Health Organization (WHO), Global Fund or European Medicines Agency (EMA) quality assurance programmes.

Researchers collected data from 29 malaria medicine outlet surveys and audited more than 330,000 artemisinin-based combination therapies (ACTs) between 2009 and 2015. Based on samples from randomly selected clusters in the 8 countries, in 2014-15, non-QA medicines represented 42% and 27% of the private-sector market in Kinshasa and Katanga, respectively, 20% in Kenya, 19% in Uganda and Benin, 12% in Nigeria, 8% in Zambia and 5% in Tanzania. Moreover, non-QA medicines were available in 48% of private outlets in Nigeria, 38% in Uganda, 21% in Tanzania, 17% in Zambia and 83% and 53% in the Kinshasa and Katanga provinces of the DRC, respectively. In contrast with the private sector, the public-sector market share of non-QA medicines in 2014-15 was generally smaller - 6% in Nigeria, 5% in Kenya, and about 1% in Benin, Madagascar, Tanzania and Uganda.

Due to limited regulatory capacities in many malaria-endemic countries, public health officials look to pre-approval status to help ensure medicine quality. Although approval status alone does not guarantee the safety of a medicine - in fact, non-QA treatments can be safe and effective in some cases - it does provide a strong, evidence-based indication of quality, the article states. Poor quality antimalarials include falsified medicines - or those produced fraudulently - and substandard medicines, which were improperly manufactured or have degraded over time.

"These findings really improve our ability to understand the complex problem of medicine quality in Africa", said co-author Dr Megan Littrell, Principal Investigator at the ACTwatch project, which led the research collaboration. 'Although the data focus on quality-assurance status, it's hugely beneficial to know where non-QA antimalarials are most prevalent, particularly in countries with the highest malaria burdens, so that appropriate interventions can be considered alongside other efforts to tackle poor quality medicines".

In addition to showing substantial market penetration and availability of non-QA antimalarials, the study states that most countries showed an increase in the private-sector market share of non-QA medicines between 2009 and 2015. The greatest increase occurred in Kenya and Kinshasa, where the market share approximately doubled, from 19% and 11% in 2009 to 42% and 20% in 2014-15, respectively. The public-sector non-QA market share mostly decreased during this time, except in Kenya, Kinshasa (DRC) and Zambia where the non-QA market share shifted from 1%, 1% and less than 1% in 2009, respectively, to 5%, 18% and 32% in 2014-15.

"Non-QA antimalarials clearly have a strong market penetration across Africa, and these findings should help inform policy responses", said Professor Paul Newton, a co-author of the article and Head of the

Medicine Quality Group at the Infectious Diseases Data Observatory (IDDO). "However, we have also found numerous differences on the ground, so we must tailor our strategies for removing these medicines accordingly, by improving regulation, aligning national registration medicine lists with global standards, enhancing access to QA antimalarials and providing more support for manufacturers to ensure that their products are all quality assured. Frequent monitoring of the available antimalarials should be conducted to understand what patients are taking and the quality of the medications".

The article, which included co-authors from the London School of Hygiene and Tropical Medicine, also found that diverse generics and formulations were available, but typically imported and distributed in urban areas at either pharmacies or drug stores. In countries such as Nigeria, over 90 unique manufacturers were found to be supplying non-QA medicines. In most cases, the private sector is the most common source of treatments, at for-profit health facilities, pharmacies, drug stores, general retailers, and mobile providers. However, patients also receive medicines from public-sector outlets, such as hospitals, clinics and other facilities.

Provided by Infectious Diseases Data Observatory