



PQP QUALITY MEDICINES FOR EVERYONE

PREQUALIFICATION OF
MEDICINES PROGRAMME
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World Health
Organization

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One-third of antimalarial medicines tested in six African countries fail to meet international quality standards

Almost 30% of anti-malarial medicines collected from Cameroon, Ethiopia, Ghana, Kenya, Nigeria and the United Republic of Tanzania failed to meet international quality standards, according to a new WHO report on a survey of the quality of antimalarials (the report is available on <http://www.who.int/prequal>).¹ Extreme deviations² — likely to be associated with direct, negative health effects — were found in 11.6% of the samples tested.

Why products failed

Product samples that failed to meet quality standards did so for a range of reasons, including insufficient active pharmaceutical ingredient (API), an excess level of degradation substances and poor dissolution. Two samples were found to totally lack one of the API(s).

Variation across countries

Survey results indicated that the quality of antimalarial medicines (for modern artemisinin-based combination therapy products (ACTs) and the more traditional sulfadoxine/pyrimethamine (SP) treatment) differs substantially across countries. In Kenya and Tanzania it appears to be reasonably well assured. In Ethiopia, no samples failed quality testing, but a high proportion represented products that had not been registered with the national medicines regularity authority (41%). This suggests that Ethiopia's pharmaceutical market may be vulnerable to penetration by products whose properties are unknown.

The highest incidence of samples that failed testing (64%) was found in Nigeria. This result implies that a patient in Nigeria is more likely to be treated with a substandard antimalarial medicine than with an antimalarial medicine that complies with international quality standards. Patients may fare better in Ghana and Cameroon, for which failure rates were 39% and 37%, respectively.

Failure rates were higher for countries where many products from many different manufacturers are sold. They were also higher for domestically-manufactured products than for imported products. They were noticeably low for imported products manufactured by well-established global manufacturers, and for WHO-prequalified products.³ *Less than 4% of samples of WHO-prequalified medicines collected failed testing; in each case the deviation observed was minor. WHO prequalification is clearly a highly effective mechanism for assessing and verifying medicines quality.*

The survey results were reviewed by WHO with medicines regulators from the participating countries and strategies agreed for strengthening medicines regulation, including supervision of manufacturers and improving their adherence to Good Manufacturing Practices (GMP) and extending post-marketing surveillance.⁴

Better regulation means better medicines

The better results of quality control testing noted in Kenya and the United Republic of Tanzania testify to the effectiveness of recent efforts made by these countries and partners, such as WHO, to improve their medicines regulatory processes. They are corroborated by a second, recent WHO report — *An*



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Assessment of Medicines Regulatory Systems in 26 Sub-Saharan African Countries. However, the report concludes that although each of the countries assessed has a legally designated national medicines regulatory authority, and although many of them are committed to regulating medicines effectively, that complex legislative frameworks and unclear delineation of regulatory responsibilities are impeding regulatory efforts. Lack of sustainable funding is another problem, as is a shortage of qualified staff and regulatory enforcement systems.

WHO is actively encouraging countries to use the tools that it has developed to enable them to regularly and systematically assess their regulatory systems, to improve market surveillance and to enhance the quality assurance systems of their pharmaceutical sectors. The Organization is ready to provide technical support in each of these areas.

Notes to editors:

- Half of the world's population is at risk from malaria. Each year almost 225 million cases occur, causing 781,000 deaths. Around 85% of these deaths are among children and mostly in Africa.
- Artemisinin-based combination therapies (ACTs) are the mainstay of treatment of uncomplicated falciparum malaria and thus a key component of malaria control strategies. They have been adopted as the first-line treatment for falciparum malaria in 80 malaria-endemic countries. Use of substandard ACTs, as well as of oral artemisinin-based monotherapies, contributes to the development of resistance to artemisinin and its derivatives.
- If resistance to artemisinin spreads beyond its current limited distribution and increases in prevalence, it will compromise the effectiveness of ACTs, leading to increased malaria morbidity and mortality.
- There are currently no antimalarial medicines in the development pipeline that could become an alternative to the artemisinin derivatives before 2017.

Both WHO reports mentioned in this information note can be also found on WHO web site at: <http://www.who.int/medicines/about/en/index.html>

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¹ The WHO "Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa" was conducted as part of a collaborative study with the United States Pharmacopeia (USP) Drug Quality and Information Programme, known as the "QAMSA Study". USP released results for three additional countries (Madagascar, Senegal and Uganda) in November 2009.

² Extreme deviations are defined in the report as a deviation by at least 20% from the content of one or more active pharmaceutical ingredients declared by the manufacturer, and/or a dissolved percentage of one or more active ingredients that is 25% less than the specified pharmacopoeial limit.

³ The WHO Prequalification of Medicines Programme evaluates priority medicines for treating HIV/AIDS, malaria, and tuberculosis. It also evaluates influenza-specific antiviral medicines, zinc for managing acute diarrhoea and products for reproductive health. Evaluation incorporates comprehensive review of the quality, safety and efficacy of the products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing site(s) (for active pharmaceutical ingredients as well as finished products. Products found to be acceptable are added to the WHO List of Prequalified Medicinal Products.

⁴ Post-marketing surveillance of a medicine starts once it has entered the general market. Post-marketing quality surveillance provides information on the sustainable quality of a product on the market whereas safety monitoring can provide additional information on the benefits and risks of a medicine.