**Definitions**

Differentiating the different types of poor quality medications is important because causes and remedies differ.

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Falsified</strong></td>
<td>A medicine deliberately and fraudulently mislabelled with respect to identity or source</td>
</tr>
<tr>
<td><strong>Substandard</strong></td>
<td>Genuine drug products which do not meet the required quality specifications</td>
</tr>
<tr>
<td><strong>Degraded</strong></td>
<td>Drugs that have deteriorated after production due to inadequate storage</td>
</tr>
</tbody>
</table>

**Join the WWARN project**

- [www.wwarn.org/drug-quality](http://www.wwarn.org/drug-quality)
- email info@wwarn.org
- facebook.com/AntimalarialResistance
- @WWARN or visit twitter.com/WWARN

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**Drug quality and the fight against infectious diseases**

[www.wwarn.org/drug-quality](http://www.wwarn.org/drug-quality)
Preserving a Vital Resource

The global community is making significant progress to combat malaria. Widespread adoption of artemisinin combination therapies (ACTs) is helping to decrease morbidity and mortality. However, the emergence and spread of artemisinin resistance in Southeast Asia threatens the progress of recent years. The public health community must continue efforts to increase access to preventative measures and to ensure supplies of safe, effective medicines.

Poor quality medicines - both falsified and substandard - of commonly used antimalarials are frequently found. The consequences include prolonged sickness, treatment failure, side effects, loss of income, increased healthcare costs and death. These medicines may contain sub-therapeutic amounts of artemisinin derivates, such as artesunate, but usually contain no malaria medication at all. Inadequate dosing is serious not only for antimalarial resistance, but also antimicrobial resistance.

“It is widely believed that falsified and substandard medicines are contributing to the spread and emergence of malaria drug resistance in Southeast Asia and potentially further afield,” says Prof Paul Newton, Head of WWARN’s Antimalarial Quality Group.

The WWARN Network

The Worldwide Antimalarial Resistance Network (WWARN) serves the global malaria community through the provision of high quality data resources, a collection of practical research tools and a global forum for exchange of scientific and public health information on antimalarial drug resistance.

For this reason, WWARN believes that a better understanding of the prevalence and public health burden of poor quality medicines is necessary to ensure that all patients receive good quality treatment. The network works with collaborators to survey the situation in different countries and to:

- Collate and map published antimalarial medicine quality literature to allow national malaria control programmes and medicine regulatory authorities to have easy access to this information
- Increase awareness to improve the quality of medicines that patients actually take
- Support statistically valid field sampling and evaluate new analytical methodologies
- Encourage discussion of poor quality medicine epidemiology and the health implications
- Amend guidelines to ensure that the quality of medicines used in clinical trials is good
- Advocate for more investment in national and international regulation of medicine distribution

With no new antimalarials expected for some years, we must do everything possible to preserve the efficacy of these important medicines. Unless action is taken quickly, falsified and substandard drug use will increase, creating the conditions for ACT-resistant malaria parasites to spread, threatening millions of lives.

A Changing Climate

Lack of information results in limited consensus on sampling methodology, the most appropriate chemical analyses, or the prevalence of poor quality drugs. Research from the WWARN AQ Group has found that up to 30 per cent of antimalarial samples tested, mostly in the private sector, since 1946 were either falsified or substandard, increasing the health risks to patients and the risk of drug-resistant malaria.

There are signs that the public health climate is changing:

- More emphasis is now placed on public health impact
- There is more scientific research
- More collaboration between governments, countries, international organisations, the pharmaceutical industry, public and academic partners.

The Antimalarial Quality (AQ) Surveyor

WWARN’s Antimalarial Quality Surveyor is an online tool that maps and summarises published reports about the quality of antimalarial medicines. It identifies and brings together disparate information by summarising antimalarial quality reports, describing the quality of malaria medicines, techniques, assays and sampling – over time and by location.

Discover this open access, independent, global repository and map in English and French:

Visit [www.wwarn.org/aqsurveyor](http://www.wwarn.org/aqsurveyor)

External Quality Assurance

The WWARN External Quality Assurance team are working closely with laboratories to improve the analysis of treatments during clinical trials, and in turn, enhance the overall quality of research data captured.

The team are working with laboratories in two key ways:

- **Reference Materials Programme** - provides validated, antimalarial drug reference material to minimise bias arising from poor quality standards and enable data comparison.
- **Proficiency Testing** - helps laboratories assess their ability to carry out drug analysis, resolve any potential problem areas and improve their results, and in doing so improve the quality of pharmacokinetic data published.

New Initiatives

**Medicine Sampling Procedures** - we are working with the WHO to support the development of new guidelines on sampling procedures and reporting of medicine quality surveys to help improve the monitoring and post-market surveillance of medicine quality.

**Medicine Quality Legal Surveyor** - this Surveyor aims to map and summarise individual country legislation, including the definitions of poor quality medicines used, and highlight potential opportunities to strengthen national and international legislation.