

# Malaria Treatment

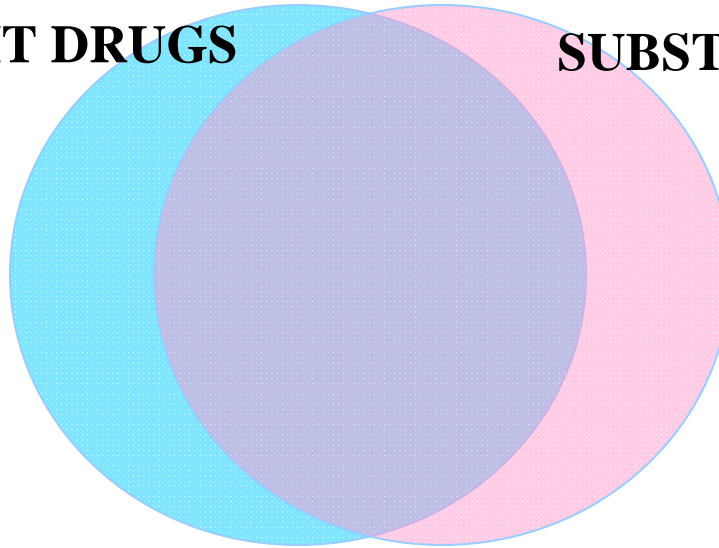
Improving access to effective malaria treatment

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# Counterfeit vs. Substandard drugs

## COUNTERFEIT DRUGS

*Willfully  
mislabeled  
as to  
identity or  
source*



## SUBSTANDARD DRUGS

*Low quality  
(insufficient  
ingredients,  
incorrect ratio of  
ingredients, wrong  
ingredients, old or  
otherwise degraded  
ingredients)*

# Unreliable Estimates: The Global Size of Substandard Medicines

COUNTRY/ REGION	WHO/IMPACT ESTIMATE
United States	<1%
Europe	<1%
United Kingdom	<1%

COUNTRY/ REGION	WHO/IMPACT ESTIMATE
Russia	10%
CIS	20%
China	8%
Indonesia	25%
India	20%
Nigeria	16%
Kenya	30%
Lebanon	35%
Cambodia	13%

# Why is there an increase in poor quality drugs?

- Low marginal cost, high marginal returns
  - Weak rules preventing fakes; poor enforcement of extant rules on good quality production.
  - Low penalties for producers and traffickers
  - Product high demand means high prices
- Enabled by:
  - Complex supply chains in West and opaque ones in poorer nations
  - Corruption, low risk of capture and limited punishment
  - Ignorance of many in supply chain

# Six Country Study

- Anti-malarial drugs collected in major cities, Accra, Nairobi, Lagos, Kigali, Dar es-Salaam, Kampala;
- TLC & Dissolution tests conducted;
- GPHF Minilab used – suitable for field testing & deployed across many African countries including many of above cities;
- Results published PLoS ONE May 7 '08

**Table 1: Testing results by formulation\* and country purchased for TLC and dissolution**  
(total failed either dissolution or TLC/total treatments tested)

	Ghana	Kenya	Nigeria	Rwanda	Tanzania	Uganda	Total
SP	50% (3/6)	38% (6/16)	50% (1/2)	50% (3/6)	27% (3/11)	33% (3/9)	<b>38% (19/50)</b>
AQ	33% (2/6)	50% (4/8)	25% (1/4)	-	100% (2/2)	56% (5/9)	<b>48% (14/29)</b>
Mefloquine	0% (0/1)	-	50% (1/2)	-	0% (0/3)	27% (3/11)	<b>24% (4/17)</b>
Artesunate	38% (3/8)	0% (0/4)	33% (2/6)	-	31 (4/13)	33% (6/18)	<b>31% (15/49)</b>
Artemether	0% (0/3)	100% (1/1)	-	-	-	29% (2/7)	<b>27% (3/11)</b>
DHA	40% (2/5)	56% (5/9)	100% (1/1)	-	50% (2/4)	67% (2/3)	<b>55% (12/22)</b>
Artemether-lumefantrine fixed-dose combination	38% (3/8)	0% (0/4)	14% (1/7)	0% (0/3)	0% (0/1)	22% (2/9)	<b>19% (6/32)</b>
<b>Total</b>	<b>35% (13/37)</b>	<b>38% (16/42)</b>	<b>32% (7/22)</b>	<b>33% (3/9)</b>	<b>32% (11/34)</b>	<b>35% (23/66)</b>	<b>35% (73/210)</b>

\*Co-packaged ACTs are listed as individual monotherapies

SOURCE: Roger Bate, Philip Coticelli, Richard Tren, Amir Attaran, "Antimalarial drug quality in the most severely malarious parts of Africa – a six country study," PLOS One.

# Artesunate monotherapies



Table 2: Testing results by alleged region of manufacture  
(\*manufacturer information not available for 3 tested samples)

Region of manufacture	Total Samples Failing TLC or Dissolution	Total Samples Tested	Percent Failed
Africa	30	63	48%
Asia	29	90	32%
Europe	12	50	24%
U.S.	0	4	0%

- Collectively, Africa and Asia are responsible for 83% (59/71) of the failed drugs observed in the study.

SOURCE: Roger Bate, Philip Coticelli, Richard Tren, Amir Attaran, "Antimalarial drug quality in the most severely malarious parts of Africa – a six country study," PLOS One



# What can be done?

- Identify the problem: lack of GMP, poor transportation, poor final storage, counterfeits, old drugs repackaged;
- Correct the problem: GMP or storage – education, counterfeiting or old drugs – police regulatory authorities;
- Nigeria is leading the way on quality  
2002 > 50% substandards, 2007 < 16%.