Substandard Medicines: WHO's inadequate response

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In response to peer-reviewed data that manufacturers sold substandard medicines,[1,2] the World Health Organization (WHO) asked the alleged manufacturers to test their own products. Self-regulation is not likely to give an honest answer, and it is astounding that WHO embraces it.

Our data highlighted that products approved by stringent regulatory authorities (SRAs) and the WHO pre-qualification program (WHO PQP) performed roughly 4 to 5 times better than non-approved products. But some problems were found with WHO-approved products. Prior to publication of our first article a confidential memo detailing the findings was sent to WHO PQP.

We had endeavored to be collegial to WHO by sending them details of the suspect batches for further investigation prior to our public discussion of the overall results. As stated elsewhere, we do not find fault with WHO's approach, given that WHO is not a drug regulatory agency, and does not have the resources to perform substantial oversight of manufacturers and their products. WHO PQP has helped improve the overall quality of drugs in the market and has probably driven younger manufacturers to strive to meet international quality standards.

However, more than 5 months after publication of our first article, WHO has publicly responded in a report[3] that contains several inaccuracies and implicit sleights:

1. WHO PQP did not request batch details of products, we provided them before they were even aware there was a problem. Similarly, we volunteered to send samples of the remaining products prior to being asked for them.
2. Testing was conducted by the laboratory at the London School of Hygiene and Tropical Medicine, which is part of the ACT Consortium that is backed by WHO. Indeed some of these scientists would have been authors on the first article but pressure from WHO malaria team members via the ACT Consortium as a result of the findings caused them to withdraw.[4]
3. As AFM acknowledged back in August,[5] USP informed us that no quality problems were found with some of the same batches they tested.

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[1] Bate R, Hess K, Tren R, Mooney L, Cudjoe F, Ayodele T, Attaran A: Subsidizing artemisinin-based combination therapies: a preliminary investigation of the Affordable Medicines Facility – malaria. *Research and Reports in Tropical Medicine.* 2012, 2012(3):63-8.

[2] Bate R, Hess K: The role of pre-shipment batch testing in ensuring good medicine quality. *MalariaWorld Journal*. 2012, 3(12).

[3] World Health Organization Prequalification of Medicines Programme. Investigation into compliance with quality specifications of artemisinin-based combination products procured during the pilot phase of the Affordable Medicines Facility – malaria. December 2012. Available at http://apps.who.int/prequal/info_press/documents/AMFm_medicines_testing.pdf. Accessed December 27, 2012.

[4] Bate R: Substandard drugs are an even greater danger than fakes. *AEIdeas*. July 13, 2012. Available at http://www.aei-ideas.org/2012/07/substandard-drugs-are-an-even-greater-danger-than-fakes/. Accessed December 27, 2012.

[5] Africa Fighting Malaria. AFM update on recent drug quality studies. August 2012. Available at http://www.fightingmalaria.org/article.aspx?id=1839. Accessed December 27, 2012.

One has to wonder why, after over 5 months, WHO has still not tested the two dozen tablets we supplied, but has released a report about the broader issues we raised. Perhaps most concerning however is why WHO is relying on authentication by the manufacturers of their own products. It is startling that WHO, an organization so worried that it not be seen as being too close to the pharmaceutical industry, would simply take industry's word that their products meet international quality standards.

We suspect the reason that WHO put out this report in an apparently rushed fashion was because the Global Fund is annoyed that substandard drug policy issues were discussed on Capitol Hill last week; Congressman Meeks (D-NY) and Congresswoman Bass (D-CA) hosted an event, which discussed the issue of substandard drugs, and included our research.[6]

The US President's Malaria Initiative (PMI) tests every batch of drug it procures and has occasionally found problems with approved products.[7] As a result, we suggested implementing a policy that all batches of donated products should be subject to pre-shipment testing, and manufacturers found repeatedly failing should not be allowed to tender. WHO has said such screening would not be "an effective use of donor funds". Yet there are quick, sensitive and inexpensive ways of authenticating known products, notably with the use of handheld spectrometers.

According to WHO's report, the Global Fund tests only 5% of batches and this is considered "sufficient for quality assurance purposes." We are doubtful malaria patients would agree.

We are now also doubtful that if WHO ever gets around to testing the tablets we sent that we will get an honest accounting of what they find. After all, WHO's largely uninformative report in support of business as usual at WHO and Global Fund is just another indication that WHO and Global Fund are incapable of actually addressing problems.

[6] Capitol Hill Briefing. Dangerous Medicine: Substandard Copies in the Developing World. December 2012. Available at https://groups.google.com/forum/?fromgroups=#!topic/tb-roundtable/SCFlhu-QRAA. Accessed December 27, 2012.

[7] Bate R: Medicine that is more placebo than cure. *The Washington Post*. July 12, 2012. Available at http://www.washingtonpost.com/opinions/makers-of-shoddy-medicines-should-be-put-on-notice/2012/07/12/gJQAxVyPgW_story.html. Accessed December 27, 2012.