AFRICA FIGHTING MALARIA

COMMENTARY AND POLICY RECOMMENDATIONS ON COUNTERFEIT AND SUB-STANDARD MEDICINES. 20 JUNE 2007

Everybody's Business: Sounding the Alarm on Bad Medicines

Around the globe, the production and distribution of substandard and counterfeit drugs is a vast, increasing and largely underreported, problem. Adulterated medicines contain little or none of the active ingredients found in their branded equivalent, and often have adverse health effects.

A new paper[i] exposes the global threat of fake and substandard drugs and highlights many of the qualitative risks associated with counterfeit medicines. The authors also make a most disquieting observation—*global aid agencies are promoting the spread of substandard drugs because of a misguided belief in the efficacy of untested medicines.*

Researchers at the World Health Organization (WHO) estimate that the proportion of counterfeit drugs in the pharmaceutical market ranges from 1 to 50 percent, with estimates from other reputable researchers at 40, 30 and 17 percent.[ii] At country and regional levels, the numbers are just as striking:

- In a 2005 random survey by Kenyan drug officials, *30 percent* of the nation's drugs were found to be fake; some of the drugs were no more than chalk or water.[iii]
- During a 2002-2003 field survey in several Southeast Asian countries, *53 percent* of artemisinin-based antimalarials (the most effective antimalarial) that were purchased were shown to be counterfeit and contained incorrect levels of the active ingredient.[iv]
- In a quality-control study of antimalarial drugs in seven African countries, researchers found that the active ingredient content in at least *one of the three* formulations of the drug tested were below the recommended minimum levels.[v]

Counterfeiting pharmaceuticals has become a booming business in recent years. The Center for Medicine in the Public Interest predicts that counterfeit drug sales will reach $75 billion globally by 2010—an increase of more than 90 percent from 2005.[vi] This multi-billion dollar industry poses a serious risk to public health worldwide and creates numerous socio-economic problems:

- WHO estimates that 1 million deaths occur from malaria annually, and *200,000 of these deaths could be prevented* if fake drugs were absent from the market.[vii]
- *2,500 people died* as a result of fake vaccines administered during the Niger meningitis epidemic in 1995.
- In 2001, *39 of 104 antimalarial drugs* on sale in Southeast Asian pharmacies did not

1050 SEVENTEENTH STREET, NW, SUITE 520
WASHINGTON DC, 20036
TEL (202) 223 3298 FAX (202) 223 3646
www.fightingmalaria.org

contain any active ingredients and resulted in several preventable deaths.

- Scientists have documented resistant strains to previously effective treatments for HIV/AIDS and bird flu diseases; the International Federation of Pharmaceutical Manufacturers Association (IFPMA) notes that *drug resistance from fakes "…is among the key factors* contributing to the upsurge of major infectious diseases in developing countries."[viii]
- Counterfeit drugs undermine incentives to invest in further research and development and public confidence in health care providers and systems.
- Fake drugs place additional financial burdens on patients and governments, who must now pay for the devastation that toxic or substandard drugs cause.

With these chilling outcomes in mind, one would think that efforts to quell the spread of counterfeit drugs have been clear and decisive. Some countries mete out long prison sentences to deter counterfeit drug traders and manufacturers. But punitive sentencing alone has never been a fool-proof solution to any criminal activity, least of all one that deliberately and fraudulently deceives unsuspecting victims. Only increased monitoring activity by technically qualified laboratories and concerted policing will halt counterfeit drug activity. Global health organizations such as the WHO must step in to provide leadership and direction in stemming this threat. Unfortunately, WHO does not have the budget to undertake widespread activities.

Although WHO is doing its part, other agencies are actually encouraging the use of substandard drugs through the *promotion of unverified copy drugs*. The Global Fund to Fight AIDS, Tuberculosis and Malaria in particular has exacerbated the problem by *exempting as many as 93 percent of the drugs approved* on its antimalarial compliance list from registering bioequivalence data with a competent agency. While most drugs purchased by the Agency pass the bioequivalence test, nearly 20 percent of total purchases (well over 450 transactions) are for non-approved drugs—a policy that results in the wider acceptance of substandard drugs. Decision makers at the Global Fund enjoy a comfortable illusion: that securing cheaper generic drugs will save more lives, but this is not always true since not all copies are as good as their originals. Funding decisions must reflect the moral imperative to be as vigilant in the protection of poorer populations in recipient nations from potentially harmful drugs as we are towards the rich populations of the donor nations.

It is vital to remember that counterfeits are not everywhere, including the United States. Global health authorities have no business leaving this policy area unaddressed because of untenable illusions regarding the effectiveness of untested generic substitutes. From here onwards, they must move to strengthen and enforce international regulatory and detection systems.

Policy Recommendations

1. **All international donors** should require safety and bioequivalence data for all medicines they fund. And all donors should publish what drugs are bought by which country recipients with their donor funds, so international verification is possible.
2. **EU countries** should not allow double standards in drug approval. Drugs for export should comply with tough EU standards.
3. India and China should improve domestic testing standards for drugs, and like EU, prevent double standards for drugs for export.
4. **Global Fund** should immediately remove drugs from its compliance list which have no bioequivalence and safety data.
5. **FDA and WHO** should have increased funding to test for sub-standard drugs in the field.

6. **US Government** should reward whistleblowers at pharmaceutical companies, government agencies, developing country agencies, such as NAFDAC in Nigeria, who expose violations of good practice.

Preventing the spread of counterfeit medicines should be everybody's business.

---

[i] Roger Bate and Kathryn Boateng, "Bad Medicine in the Market" *AEI Health Policy Outlook*, No. 8, June 2007.

[ii] World Health Organization (WHO), "Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation" (concept paper, WHO, Rome, January 27, 2006), available at www.who.int/medicines/counterfeit_conference/en/index.html (accessed May 30, 2007).

[iii] WHO, "Counterfeit Medicines."

[iv] A. M. Dondorp et al., "Fake Antimalarials in Southeast Asia Are a Major Impediment to Malaria Control: Multinational Cross-Sectional Survey on the Prevalence of Fake Antimalarials," *Journal of Tropical Medicine & International Health* 9, no. 12 (December 2004): 1241–46.

[v] Charles Maponga and Clive Ondari, "The Quality of Antimalarials: A Study in Selected African Countries" (EDM Research Series 30, Department of Essential Drugs and Medicines Policy, WHO, Geneva, May 2003) available at http://whqlibdoc.who.int/hq/2003/WHO_EDM_PAR_2003.4.pdf (accessed June 13, 2007).

[vi] WHO, "Counterfeit Medicines," fact sheet, November 14, 2006, available at www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html (accessed June 7, 2007).

[vii] Ian MacKinnon, "South-East Asia Awash with Fake Drugs," *Guardian* (London), February 22, 2007.

[viii] International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), "Counterfeit Drugs: A Global Health Risk," Geneva Pharma Forum, February 4, 2004.