

Substandard and/or counterfeit medicines for patients

There has been genuine concern at international levels to address the global scourge of fake medicines. WHO would soon launch a multidisciplinary task force to entangle, apart from health care providers, officials in police, customs and law enforcing agencies.¹ Such efforts would fail without the availability of simple but accurate assay formats to assess the potency of medicines. Rather than retrieval to analytical laboratory premises to determine the potency of medicines offered to the masses, on-the-spot quantifications of active ingredients would be fundamental. Recent standardization of a rapid spectrometric analysis to monitor antimalarial formulations would appear to be an affirmative development.² An identical test menu suited to patients' homes or the field would assist in detection of poor-quality therapeutic agents.

Nevertheless, without any prejudice towards a genuine or fake manufacturing process for any therapeutic agent, it would be crucial to tackle faulty storage of every medicine. Therapeutic agents require constant storage at temperatures ranging from subzero to 4–8 °C, 15–25 °C or 25–30 °C. Electrically operated appliances are indispensable to ensure constant storage at the stipulated temperatures. Natural disasters or

extensive power failures adversely affect the potency of the active ingredients. The August 2005 Hurricane Katrina was accompanied by a prolonged power shutdown during which auxiliary power generators ran out of fuel.³ The consequences of similar accidental power shutdowns would be grim for genuine or fake therapeutic agents.

The proposed international medical products anti-counterfeiting task force initiative¹ would be obliged to point out defective storage and distribution practices in countries where medicines are available freely at the pharmacy sites. In urban Rawalpindi, Pakistan, most drug sellers had fragmentary knowledge regarding drug dispensing and storage. Improper dispensing practices were frequent, while only 10% had a temperature-monitoring device for electrically operated refrigerators. While refrigerators were present in 76% of pharmacy sites, only 4% had any alternative power supply for these appliances.⁴

The anti-counterfeiting initiative and pharmaceuticals industry should support basic research towards the field stability of common medicines in the adverse environments of disease-endemic areas. Experimental lots of the least stable of the common childhood vaccines, live poliovirus vaccine, have been stabilized by pirodavis and deuterium oxide. Stabilized lots resisted 42 °C temperatures for 10 hours.⁵

Certainly pre-stabilized, environment-resistant therapeutics, including antimicrobials and anti-infective formulations scrutinized in the field with portable instruments,¹ would curtail inadvertent usage of poor-quality authentic drugs. Last but not least, the stipulated storage temperatures of therapeutics should be indicated with distinct symbols on vials or infusions. Universally accepted symbols are mandatory on poisons, inflammables and radioactive substances. Such distinct marks would not increase the cost of therapeutics in any manner. ■

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References

1. Burns W. WHO launches task force to fight counterfeit drugs. *Bull World Health Organ* 2006;84(9):689-690.
2. Morris K. Malaria death due to fake drugs deemed "manslaughter". *Lancet Infectious Diseases* 2006;6:470.
3. Dalton R. Health centers and labs left reeling by Katrina. *Nature* 2005;437(7056):177.
4. Butt ZA, Gilani AH, Nanan D, Sheikh AL, White F. Quality of pharmacies in Pakistan: a cross-sectional survey. *Int J Qual Health Care*. 2005;17(4):307-13.
5. Verheyden B, Andrus K, Rombart B. Capsid and RNA stabilization of oral polio vaccine. *Vaccine* 002;19:1899-1905.

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