

# When Medicines Fail

## A GLOBAL PUSH TO FIGHT DRUG RESISTANCE

### Drug Resistance: Improving Standards in the Medicine Distribution Chain

#### A PUBLIC HEALTH TIME BOMB

In an interconnected world, drug resistance increasingly threatens global health, placing a heavy burden on health systems, particularly in developing countries. Drug resistance has drastically increased the costs of fighting tuberculosis and malaria, slowed gains against childhood dysentery and pneumonia, and imperiled efforts to effectively treat people living with HIV/AIDS. Significant investment in drug research and development is undermined as therapies lose efficacy. In some cases, resistance appears almost as quickly as new drugs are appearing on the market. And if the first treatment doesn't work, alternatives are almost always more costly, harder to use, cause worse side effects, and require greater medical oversight. The problem demands an urgent and systematic global response.

#### TAKING ACTION AGAINST RESISTANCE

The Center for Global Development's Drug Resistance Working Group was convened in late 2007 to identify practical and feasible ways that governments, the global health community, private funders, multilateral organizations, NGOs, and other actors at the global level can prevent or contain the emergence of drug resistance in developing countries. The group highlighted the threats posed by this growing global crisis and outlined concrete steps that the international community can take to halt and even turn the tide on resistance.

#### PROBLEM: LACK OF STANDARDS AND MISALIGNED INCENTIVES THROUGHOUT THE DRUG SUPPLY CHAIN

When people take too little, incorrectly prescribed, or poor quality medicine, the possibility of resistance increases. Making sure a patient gets the right amount of a high-quality drug and knows how to take it correctly is a responsibility that extends across the pharmaceutical supply chain—from “upstream” manufacturers to “downstream” prescribers, dispensers, and consumers. The current reality is that collective responsibility is being undermined by perverse incentives throughout the supply chain.

Upstream, drug makers do little to monitor drug quality and use after sale: there is no incentive for them to find problems with their drugs or with how they are being used after they leave the factory. And there are no international standards or established monitoring procedures to encourage industry to engage in post-marketing surveillance of their drugs and protect them from improper use, nor to educate dispensers and consumers about proper drug use.

The situation is no better downstream. Informal dispensers of medicines—small shop owners or street sellers, many of whom are unlicensed—are the most common source of drug access for a large percentage of the world's population. They often lack knowledge about the drugs they sell and have little financial incentive or ability to determine the appropriate drug for treatment. Shockingly, appropriate dispensing of medicines is no more common among licensed professionals, who receive little, if any, systematic training in the drug resistance implications of inappropriate use of medicine.

Recently, some developing countries have improved dispensing practices by establishing certification programs for informal dispensers. Limited evidence suggests such schemes can be effective in improving access to high-quality medicines and services, yet no platform exists through which other countries considering similar programs can access information about what has worked best, nor obtain technical and financial support for implementing them.

#### SOLUTION: SECURE THE DRUG SUPPLY CHAIN TO ENSURE QUALITY PRODUCTS AND PRACTICES

Drug resistance will be slowed only by tightening the *entire* supply chain with the cooperation of the public and private sectors, upstream and downstream. The Working Group recommends a two-pronged approach: upstream post-marketing quality standards for manufacturers and downstream rational use incentives and certification standards for prescribers and dispensers.

Upstream: Companies producing and distributing medicines need a uniform set of standards to ensure product quality is tested and maintained *after* it leaves the factory. The International Organization for Standardization (ISO) offers a

process for companies and technical agencies to create these. The process would develop rigorous, transparent procedures for voluntary testing and reporting on drug quality—ultimately reducing the circulation of poor-quality drugs and restoring confidence in the global drug supply chain. It would also establish a list of other practices and agreed-upon outcomes for responsible companies to ensure that only high-quality products reach the retail market.

Achieving ISO certification would give those companies a market advantage over competitors that do not meet standards—and exert pressure on the entire industry to elevate its efforts to safeguard drug quality. ISO certification should become a procurement requirement of all donor organizations and national governments making drug purchases with donor funds.

Downstream: From roadside drug sellers to licensed doctors, the expertise of drug providers varies greatly—yet all need the knowledge and tools to ensure that drugs are prescribed, dispensed, and taken properly. A *Global Partnership of Medicine Providers* is needed to collect and promote best practices in prescribing and dispensing and to share rigorous evaluation of what works. The partnership would:

- create a global knowledge repository of proven tools to improve prescribing and dispensing practices;
- develop pharmaceutical and health provider educational curricula on best practices;
- offer a global technical assistance platform for countries to improve prescribing and dispensing practices, including evaluation; and
- identify financial resources for replicating successful programs, piloting new programs, and implementing country-specific interventions.

Partnership is also needed at the local level. *National Partnerships of Medicine Providers* should be developed to adapt the tested models to individual countries and link country efforts to financial resources. The partnerships should include health professionals, regulators, and other key stakeholders, with leadership determined by each country's capacity.

Securing the supply chain—both at the local and global level, and both upstream and downstream—is a substantial undertaking that will take focused collaboration among many different stakeholders. But, without it, drug resistance will continue to grow and millions of lives will remain at risk, now and well into the future.

## RELATED RESOURCES

### *Upstream*

- The International Organization for Standardization ([www.iso.org](http://www.iso.org)) develops standards and certifies compliance following an industry-wide, voluntary, consensus process that defines the technical scope of future standards.

### *Downstream*

- Key recommendations from the 2nd International Conference on Improving Use of Medicines ([www.icium.org/icium2004/recommendations.asp](http://www.icium.org/icium2004/recommendations.asp)).
- Sub-Saharan African certification schemes in Tanzania ([www.msh.org/seam/reports/TANZANIA\\_Final\\_ADDO.pdf](http://www.msh.org/seam/reports/TANZANIA_Final_ADDO.pdf)) and Uganda ([www.msh.org/global-presence/sub-saharan-africa/tanzania.cfm](http://www.msh.org/global-presence/sub-saharan-africa/tanzania.cfm)).
- An overview of interventions to improve dispenser practice in developing countries ([www.ajtmh.org/cgi/reprint/77/6\\_Suppl/203](http://www.ajtmh.org/cgi/reprint/77/6_Suppl/203)).

FOR MORE INFORMATION OR TO READ THE FULL REPORT, PLEASE VISIT [www.WhenMedicinesFail.org](http://www.WhenMedicinesFail.org) or e-mail [drug\\_resistance@cgdev.org](mailto:drug_resistance@cgdev.org).

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