

When Medicines Fail

A GLOBAL PUSH TO FIGHT DRUG RESISTANCE

Drug Resistance: Strengthening Regional Regulatory Networks

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: COUNTRY INTERESTS ARE CROSS-BORDER, BUT REGULATORY REACH IS LIMITED

Regulation of medicines—from development and manufacture to dispensing—is fundamental to ensuring that drugs will work when used properly. National drug regulatory agencies (NDRAs) are vital in this process, but many developing countries struggle to protect their populations from unsafe and poor-quality drugs because of limited resources and the daunting challenge of monitoring drug flows within and from outside their borders. While the weaknesses of a single national agency create health and safety risks in a particular country, poor regulatory capacity becomes an even larger problem when viewed in a regional context. A country's policies and actions—or inactions—to regulate its drug supply have implications for other countries, even those well beyond its borders.

The obstacles to good regulatory performance are both technical and organizational. On the technical side, NDRAs have uneven knowledge about the scale of drug resistance from country to country, lack common indicators of the problem, and have varying regulatory authority and capacities. On the organizational side, the regulatory task is complex—requiring a combination of scientific, legal, industrial, and law enforcement expertise—and is frequently spread among multiple agencies. Enforcement gaps are likely to grow when differing resources and efforts cause neighboring countries to take vastly different approaches to monitoring drug distribution and usage.

The result in many resource-limited settings is a largely unregulated pharmaceutical market—a "drug bazaar"—where substandard and counterfeit products circulate freely in both the private and public sectors, acting as catalysts of drug resistance.

SOLUTION: EXTEND THE REACH OF NATIONAL DRUG REGULATORY AGENCIES

Regional cooperation is a mutually beneficial way for countries to work on common problems and fortify individual NDRAs to achieve greater effectiveness and efficiency. The Working Group proposes that national and international support be provided to create new regional networks of drug regulators, enhance existing ones, and develop shared incentives to protect drug efficacy. This support should be channeled through the ongoing harmonization and strengthening initiatives of global health donors, including the Global Fund for AIDS, Tuberculosis and Malaria, the Hanshep Initiative from the UK Department for International Development, and others.

By collaborating, NDRAs operating in the same region can enhance their knowledge of poor-quality and counterfeit drugs, coordinate inspections and border control, build internal capacity to accomplish more with current resources, and align drug policies and treatment guidelines. A regional network also creates an information hub to learn about which drugs are available in different locales; to identify trusted sources of medicines; and to standardize formats for sharing information across jurisdictions. The mission and staff resources of each network should vary depending on the regulatory needs and capacities of the region.

Some countries already engage in strong regional cooperation and show promising results. In Latin America, for example, 19 countries and 1 subregion participate in a regional network to improve their national capacities to gather laboratory results and address antimicrobial resistance. The network has shared information on resistance across the region that has successfully informed policies and treatment guidelines. Using such success stories as a model, drug resistance should be incorporated into new or existing efforts to strengthen regional regulatory networks, especially in Africa.

RELATED RESOURCES

- The European Medicines Agency (www.ema.europa.eu) is a decentralized body of the European Union whose main responsibilities are the protection of public and animal health and the safety of medicines.
- The European Centre for Disease Prevention and Control is responsible for the surveillance of infectious diseases regionally in the European Union and informs policymakers about drug resistance (www.ecdc.europa.eu/en/activities/surveillance/Pages/Activities_Surveillance.aspx).
- The 2006 Annual Report of the Antimicrobial Resistance Network in the Americas (http://new.paho.org/hq/index.php?option=com_content&task=view&id=970&Itemid=206&lang=en) provides useful data to guide the rational use of antibiotics.

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