

EDITORIALS

What to do about unsafe medicines?

Because buyers cannot be aware of deceit in the sale of drugs, regulators need to balance the scales

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“Let the buyer beware,” lawyers have cautioned since medieval times.¹ This is good advice when buying grain or livestock, but for as long as there have been markets people have recognized that some products’ defects are not readily apparent to even the savviest shopper. This problem, now called information asymmetry, is perhaps most acute in the medicines market, where falsified and substandard drugs blend almost perfectly with good ones. Because buyers cannot be aware of the deceit in the sale of drugs, regulators need to step in and balance the scales. In much of the world, however, the regulation of drugs is neglected. In this vacuum, drug quality declines and patients suffer.

It is difficult to measure the human suffering caused by unregulated medicines, a recent Institute of Medicine report concluded.² Whereas the burden of specific diseases can be expressed in disability adjusted life years, quality adjusted life years, morbidity, or mortality, poor quality drugs go unnoticed by design. Some contain no active ingredient or reduced doses of the labeled drug. Others may mimic a therapeutic effect, disguising, for example, paracetamol in antimalarial packaging. Only through postmarketing surveillance do these problems come to light. Pharmacovigilance data give an understanding of what drugs are compromised and where they circulate. A better understanding of such trends could inform estimates of how much ineffective drugs cost society, translating the threat into concrete terms that compel governments and donors to act.

The irony of the problem is that the very data that could motivate investment in drug regulation depend on market surveillance. In a 2010 assessment, the World Health Organization found that only five of 26 drug regulatory authorities in sub-Saharan Africa had functional pharmacovigilance systems.³ The situation in major drug producing nations is no better. In China and India, for example, short staffed regulatory agencies struggle to inspect and license thousands of manufacturers, with little staff time left for market surveillance. A 2012 Institute of Medicine report identified poor surveillance as one of the main barriers to developing drug safety systems in low and middle income

countries.⁴ The report recommended that the US government and international organizations invest in pharmacovigilance in these countries. In a larger sense, the report argued for more donor investment in medicines regulation in the developing world.

Donor countries stand to benefit from this investment as well. Modern drug manufacturing relies on ingredients sourced from around the world. Supervising multinational supply chains is an insurmountable job, even for well funded regulatory authorities. Drug importing nations would welcome investments in the technical skills of regulators in drug producing nations, because these regulators have the first responsibility for manufacturing oversight. Building health systems, especially drug regulatory systems, also protects donors’ interests in global health. Development agencies have invested heavily in reducing maternal and child mortality and in treating major infectious diseases. These programs depend on effective medicines, something that cannot be ensured without a commensurate investment in drug regulation.

Regulators in developing countries should help initiate these investments. Their agencies have many competing needs: equipment, training, staffing, reference standards, and infrastructure. The scope of the needs can be overwhelming, leading to inaction. The Institute of Medicine report on falsified and substandard drugs recommended that regulators in low and middle income countries draft strategic plans for agency development.² This plan would identify the agency’s priorities and guide decisions about where to invest first, a manageable first step even for a small agency. Regulators could then use the plan to advocate for better support from their ministers and to identify places where donors could contribute.

Investment in regulatory systems could bring about meaningful improvements in the health of the world’s poorest people. These improvements are already well under way. The past 20 years have seen great advances in global health, but disease treatment programs may soon face the prospect of diminishing marginal returns. Their continued success depends on corresponding

investments in health systems, of which the drug regulatory system is an important part. Until governments can ensure that the drugs in their countries are safe and reliable, patients face a hopeless disadvantage in navigating the drug market alone. Life saving drugs, although apparently plentiful, will remain out of reach for many.

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- 1 LeViness CT. Caveat emptor versus caveat venditor. *Md L Rev* 1943;7(177).
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