EDITOR'S CHOICE

Time for global action on fake and substandard drugs

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In an article this week a self defined “diverse group of authors from the health professions, health charities, legal and medical academia, and former or current government officials in health” present us with a troubling paradox: the world currently has tighter laws to tackle fake tobacco products than it does to tackle fake drugs (doi:10.1136/bmj.e7381). At the moment, as they explain, there are laws that promote an open global medicines trade but no binding international health law on drug safety. The result is that fake and substandard drugs continue to harm and kill people around the world, affecting both proprietary and generic drugs, and haunting rich countries as well as poor. As Andrew Jack explains (doi:10.1136/bmj.e7836), the rapid growth of unregulated internet sales of drugs has raised the stakes even further. In the accompanying podcast, Amir Attaran emphasises the absurd situation by which trading fake medicines is currently legal under international law, and Sania Nishtar highlights worryingly weak pharmacovigilance systems in Pakistan (www.bmj.com/multimedia).

Why the lack of progress on this globally damaging health problem? There’s no simple answer to what is clearly a complex problem, but the authors suggest that the main barriers have been the lack of an internationally agreed terminology and a focus in law on commercial interests rather than public health.

Progress has also been hampered by a lack of good data on the scale of the problem. WHO estimates that over 10% of drugs in developing countries may be “counterfeit”, but getting a better idea of the impact is proving difficult. The drug industry keeps records of “medicine crimes,” but these are held in secret so are not available to researchers or governments wanting to raise awareness and improve patient safety. But recent incidents are focusing minds. Contaminated methylprednisolone has killed 28 people from meningitis in the United States this year (*BMJ* 2012;345:e7095) and more than 125 people were killed in

Pakistan by generic isosorbide-5-mononitrate tablets adulterated with a toxic dose of antimalarial (*BMJ* 2012;344:e951). These incidents are the visible tip of a vast iceberg of failed treatment, adverse reaction, and death.

With less than a third of WHO member states having well developed drug regulation, reliance on national governments to resolve things is unlikely to work. In a linked commentary, Thomas Dorlo and colleagues call for more resources to support national regulators (doi:10.1136/bmj.e7518). The *BMJ* “diverse group of authors” has come together to call for global action. They propose a treaty modelled on the successful Framework Convention on Tobacco Control and, to help get us there, a simpler terminology. In place of WHO’s current all encompassing working definition “SFFC”—which stands for spurious, falsely labelled, falsified, counterfeit medical products, and which in some versions has an additional “S” for substandard—they propose a clearer focus on falsified and substandard drugs.

Both categories cause harm but they require different remedies. “Falsified medicines are deliberate, intentional frauds and should be prohibited using criminal measures. In contrast, substandard medicines are unintentional or negligent errors that require regulatory measures to correct.” The US methylprednisolone incident looks likely to have been caused by poor standards rather than criminal intent. In Pakistan, if allegations are confirmed that the company knew of the error and sold the drug anyway, the incident may be reclassified as falsified.

This week, WHO member states met in Buenos Aires to try to take things forward. They could do worse than to follow these authors’ advice.

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