

US and Europe At Risk from Substandard Medicines

Guest blog by **Helen Disney**, Chief Executive and Founder of the [Stockholm Network](#), a pan-European think tank.

When most of us look at taking a new medicine we tend to think it will make us better. Some of us may think about possible side effects but few of us expect the medicines we take to actually be dangerous. Recently, the public and policymakers have become more aware of the issue of counterfeit medicines — especially as patients increasingly learn about how to shop safely online for pharmaceuticals. But scant attention has been paid to a safety issue that is also important to patients — the problem of substandard medicines.



Unlike counterfeits, which have been much more widely discussed, substandard pharmaceuticals have been legally authorized for manufacturing and, more often than not, approved for market and sale by a national or regional drug regulatory authority. Despite this, these medicines nevertheless do not meet the required quality or safety requirements for that particular drug or treatment, compromising safety and efficacy.

It may appear that this is more likely to be a problem affecting developing countries such as China, India or Latin American countries, and indeed these countries are certainly affected. But this issue is not just one that affects developing countries. Especially now that global supply chains bring medicines quickly and easily from one country to another, substandard medicines can reach also American or European patients. While safety regulations may look good on paper, several countries are still failing to meet

the required standards and the consequences for public health are worrying. Regulators need to take a closer look at what is happening on the ground.

A new report by the Stockholm Network, [*Keeping Medicines Safe*](#), cites examples and case studies from China, India, Brazil, Argentina and Turkey to demonstrate the lethal effects that counterfeit and substandard drugs can have on public health. It shows how bad, non-existent or unenforced regulations can play a serious part in this process.

For instance, current regulations in India divide regulatory responsibilities between state and national authorities. The delegation of inspecting and enforcing Good Manufacturing Practices (GMP) to the state level has resulted in substantial variation in the quality of medicines produced, despite all manufacturers having been certified by the relevant authorities. Some Indian states do a good job of maintaining high levels of manufacturing practices but other states do not. As a result, substandard medicines can easily move from one state to another.

In Argentina, the government and national drug regulator actively promote the prescription and use of a category of medicines called 'similar.' These drugs are advertised as being generic drugs, but in actual fact 'similar' have not been tested for bioequivalence — a prerequisite in much of the developed world for labelling a drug a generic.

China's national drug regulations are comparable to those of Europe or North America, but the lack of implementation and enforcement is glaring. China is one of the world's largest producers of both substandard and counterfeited medicines. One of the main reasons for this is wide-spread and pervasive corruption, even among government regulators. Indeed, only five years ago the head of the national medicines regulator was executed on charges of corruption.

All of these circumstances are causes for concern, but there is a further wrinkle in the ointment. The development of biological drugs makes the problem of substandards potentially far riskier — especially when it comes to similars. As the use of this type of drug increases, patients and policymakers

can expect to encounter more problems with defective medicines than they did before.

Policymakers and regulators need to acknowledge the problem of substandard drugs and improve the regulation of drug manufacturing and the enforcement of good manufacturing processes. If they fail to do so, some patients who faithfully take a seemingly innocuous white pill could be doing themselves more harm than good.

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