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How to achieve international action on falsified and substandard medicines

Substandard and falsified medicines kill patients, yet progress on the twin challenges of safeguarding the quality of genuine medicine and criminalising falsified ones has been held back by controversy over intellectual property rights and confusion over terms. Amir Attaran and colleagues propose a global treaty to overcome the problems

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Globalisation has helped increase the risks of counterfeit drugs endangering human life. Andrew Jack looks at the scale of the problem and the latest attempts to crack down on crime



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# Too much information and not enough time?

### **BM** Masterclasses

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## **BMJ**

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#### PICTURE OF THE WEEK

Doctors who have launched a new political party that promises to make the NHS one of the key issues at the next election gathered in London last week. They aim to oppose the government's changes to healthcare and to protect the NHS from the threat of austerity measures. The party hopes to put forward up to 50 parliamentary candidates in 2015 in carefully selected areas and in local elections.

#### RESPONSE OF THE WEEK

This article makes explicit the approach that many general practitioners feel they already aspire to, and being aware of our personal biases and cognitive processes during the consultation can only help us to become better doctors. Unfortunately, in the UK this approach is coming under increasing threat.

Despite the government's mantra 'no decision about me without me,' the reality is that with the increasing demands from performance management, GPs are under pressure to disregard patient preferences and to manage them according to strict and simplistic protocols. The proposed new GP contract threatens to intensify this. In one of the many internal tensions within the current NHS, the claim to honour the wishes of the patient is at odds with the desire to micromanage how we treat them. As the QOF juggernaut hurtles blindly onward, shared decision making will be one of the casualties.

Jonathan D Sleath, general practitioner, Hereford, UK, in response to "Stop the silent misdiagnosis: patients' preferences matter" (*BMJ* 2012;345:e6572)

Last week's poll asked: "Is the Liverpool care pathway fit for purpose?"

73% voted yes (total 467 votes cast)

▶ Feature (*BMJ* 2012;345:e7644)

This week's poll asks: "In view of increasing antimicrobial resistance worldwide, have you changed your prescribing practice for antibiotics?"

- ▶ News (*BMJ* 2012;345:e7778)
- Vote now on bmj.com

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#### **MOST READ**

Clinical trial data for all drugs in current use

Minerva

Psychotic depression

Plantar fasciitis

Association between fish consumption, long chain omega 3 fatty acids, and risk of cerebrovascular disease



#### MOST COMMENTED ON

Psychotic depression Clinical trial data for all drugs in current use

Promoting cosmetic surgery
Breast screening is beneficial,
panel concludes, but women
need to know about harms
A licence to bill

#### **EDITOR'S CHOICE**

## Time for global action on fake medicines

The world currently has tighter laws to tackle fake tobacco products than it does to tackle fake 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 (p 23). 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 (p 28), the rapid growth of unregulated internet sales of drugs has raised the stakes even further. In the accompanying podcast, Amir Attiran 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 (p 27).

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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