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THE CONVERSATION

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China's pharma scandal and the ethics of the global drug market

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China is in the midst of conducting a series of corruption investigations of pharmaceutical companies that have been operating in the country.

It all started with the investigation of officials from pharmaceutical company GlaxoSmithKline, who were reportedly engaged in "[bribery and corruption](#)" in China. The officials apparently used travel agencies [to funnel illegal payments to doctors and government officials](#).

That was in July. In August, [Associated Press reported](#) French drug company Sanofi was being investigated for bribing Chinese doctors in 2007.

And late last week, [South China Morning Post reported](#) that German pharmaceutical conglomerate Bayer had joined the ranks of companies being investigated by the Chinese. That report mentioned pharmaceutical companies Eli Lilly, Novo Nordisk, H Lundbeck, AstraZeneca and UCB had also been contacted by Chinese investigators.

This wide-ranging, ongoing scandal highlights the many regulatory and ethical challenges of globalised drug development.

Globalised drug development

The development of prescription pharmaceuticals has long been an international endeavour, and in recent times the locus of activity has shifted from North America and Europe to Asia (particularly India and China), Eastern Europe, and Latin and South America.

Until recently, these regions participated primarily in the manufacture and testing of prescription pharmaceuticals, while North America and Europe remained the major sites for their sale.

[Ethicists became concerned](#) about the exploitation of research participants, who might be coerced into participating in research and would not have access to the medicines tested on them.

At the same time, scientists, clinicians and regulators worried about the [validity and generalisability](#) of research results derived from populations with different genetic profiles, diets, co-morbidities, life expectancies, and so on.

They also worried about the quality and safety of medicines, particularly the possibility of [tainted or counterfeit medicines](#) making their way to the West.

More recently, the pharmaceutical industry has become alert to the rapid economic progress of developing countries. Their enormous populations are increasingly seen as major “emerging markets” for the sale of patented as well as generic prescription pharmaceuticals.

Chronic, lifestyle (non-communicable) diseases such as diabetes, heart disease and respiratory illness are affecting people in these countries at rates comparable to those in the West. This makes them prime targets for many “blockbusters” drugs, which make the most money for pharmaceutical companies.

Marketing medicines

While access to medicines that are effective in the prevention and treatment of non-communicable diseases is undoubtedly a good thing, the sale of medicines in developing countries raises a new suite of regulatory and ethical issues.

Many of these issues have been extensively debated in the developed world, and resulted in an incremental increase of regulations controlling the activities of pharmaceutical companies.

It's now broadly accepted in most developed countries that [advertising medicines to the public](#) needs to be tightly controlled (currently only the United States and New Zealand allow direct-to-consumer advertising of prescription pharmaceuticals).

It's also widely accepted that professional and regulatory controls should limit promotion and marketing activities by the pharmaceutical industry so that they don't inappropriately influence research, medical education, policymaking and prescribing.

The [code of conduct](#) of Australia's pharmaceutical industry body, Medicines Australia, for example, now allows pharmaceutical companies to provide doctors with medical and educational items that enhance patient care, but these cannot be branded with drug names.

While an anatomical model might still be allowed as a gift, the ubiquitous branded pens and post-it notes will soon be a relic of the past.

Companies also must disclose their interactions with doctors. And pharmaceutical company representatives need to undertake formal training to ensure that they understand relevant legislation and guidelines.

Physicians have developed similarly detailed guidelines governing their interactions with the pharmaceutical industry, such as [those of the Royal Australasian College of Physicians](#) (currently being revised).

The debates surrounding these intricate guidelines stand in stark contrast to the blatant corruption being investigated in China.

A global issue

But it would be a mistake to see this issue simply as evidence of high-level industrial and professional corruption in a less regulated emerging economy.

Inappropriate corporate behaviour and professional practice still flourish in developed countries despite regulations. Indeed, these are frequently more extensive than those recently reported in China.

GlaxoSmithKline, for instance, agreed to [pay a fine of US\\$3 billion](#) in 2012 to settle charges of inappropriate promotion of antidepressants and failure to report safety data about the diabetes drug Avandia.

Physicians, likewise, have been complicit. In 2007, for example, [orthopaedic device manufacturers](#) paid 939 orthopaedic surgeons in the United States US\$198 million to use their devices. In 2008, following a lawsuit by the US Department of Justice that was settled, this figure increased to US\$228 million!

This makes the [estimated US\\$3.34 million](#) that fraudulently exchanged hands in China in the GlaxoSmithKline case look like peanuts.

As well as being a reminder of the need to concentrate on local as well as global corporate practices, the scandal highlights the need to think through the responsibility of corporations for their employees' actions in a globalised world.

GlaxoSmithKline's chief executive officer, for instance, [denied any knowledge](#) of the corruption in China. The denial may be plausible given the company has more than 100,000 employees worldwide, but it's nearly impossible to promise corporate integrity in the face of large-scale global expansion.

This raises questions about the power and purpose of "corporate integrity agreements", such as the [one signed by GlaxoSmithKline](#), in the wake of its fraud settlement with the US government. That included the provision that the company would change the way its sales force was compensated.

Scandals implicating pharmaceutical companies, such as the one unfolding in China, show that we need better strategies if "corporate integrity" is to mean anything in the globalised medicine market.