Pharmaceutical industry regulation: does the UK take the easy way out?

Pharmaceutical companies and medical professionals maintain a complex relationship, in which it is hard to avoid all conflicts of interest at both an individual and an institutional level. Clinicians' lack of awareness of the scale and tactics of bad practice perpetuates the shortcomings of the culture, while at a national level, there is some evidence that the UK may be failing to pull its weight.

In 2012, the European Union Medicines Regulations increased their maximum penalty to 5% of a pharmaceutical company's annual European Union turnover. Nevertheless, the heart of industry regulation remains in the USA, under the aegis of the Food and Drug Administration. The Medicines and Healthcare products Regulatory Agency (MHRA) was established in the UK 10 years ago, and has never successfully prosecuted a multinational company, yet since 2012 the USA federal government has levied $11 billion under the False Claims Act (Outterson, 2012).

Types of offence which have resulted in prosecution by the Food and Drug Administration include the following:

1. Concealment of risk, negative results or safety data
2. Misbranding: promoting drugs for non-approved indications
3. Dissemination of false claims of effects, such as sham advisory boards and speakers at luxury events
4. False claims of applicability in untested groups, commonly children
5. Superiority and non-inferiority claims
6. Counterfeit drugs
7. Hired medical key opinion leaders, who include doctors paid to undertake radio promotions (Moynihan, 2008) or to participate in discussion groups (Lenzer, 2011)
8. Kickbacks to medical professionals, extending from cash to golf lessons, fishing trips and holidays
9. Pay for delay, whereby a patent holder pays a rival not to bring a generic version of a branded drug to market (Roehr, 2012)
10. Pharmacy discounting systems, extra prescription bonuses, excessive free samples and sales staff inducements
11. Illegal billing practices including Medicaid fraud (Poses, 2011)
12. Direct to consumer advertising: tactics commonly include misuse of social media, covert blog participation and targeted corporate sponsored webspace (Lenzer, 2011).

Regulatory weaknesses

In the United States, corporate integrity agreements may be applied as a penalty to repeat offenders. Affected companies are scrutinized to ensure good behaviour, yet the corporate integrity agreement lapses after only 5 years. Corporate integrity agreements are recognized as being piecemeal and inconsistent (Outterson, 2012).

Culpable individuals within an affected company are rarely targeted. They typically receive a payoff, relocate and are thus free to perpetuate bad practice. The time lapse to pursuit and/or proof can easily exceed 3 years, and the fines are relatively modest for multinational companies. Indeed such fines are often regarded as a 'business levy' and the proceeds of the fraud are typically not confiscated. Finally, the Food and Drug Administration allows contract research organizations, which test new products, to invest in the parent drug company. Contract research organizations are even permitted to evaluate a new drug in return for a percentage of any marketing royalties.

UK legislation

In the UK, the MHRA investigates any illegal activities involving medicines and their availability, manufacture, import, sale, supply and administration under the Medicines Act 1968 (Service), as updated in the July 2012 Human Medicines Regulations. The MHRA's 2007 anti-counterfeiting international strategy secured confiscation orders of £15.3 million under proceeds of crime legislation, four prison sentences and 930 hours of community service, but levied only a derisory £1300 in fines (Medicines and Healthcare Products Regulatory Agency, 2013).

A 4-year MHRA investigation into GlaxoSmithKline's marketing of Seroxat generated 1 million pages of evidence but no action. The MHRA explored concerns that GlaxoSmithKline had both withheld and delayed the provision of information on adverse events of Seroxat use in the paediatric population, specifically increased risk of suicide. However, GlaxoSmithKline escaped criminal conviction on the basis that there were 'gaps' in legislation governing drug safety at the time of prosecution (Medicines and Healthcare products Regulatory Agency, 2008).

A freedom of information request of the MHRA in January 2013 in respect of the body's pursuit of bad industry practice brought the following response:

'The MHRA adopts a proportionate approach to enforcement of medicines legislation. Each case is assessed on its individual merits ... Only the most serious breaches, with the gravest implications for public health result in prosecution. Breaches by regulated pharmaceutical companies which do not fall in to this category are typically dealt with within the context of the MHRA's on-going process of inspection. Where necessary regulatory action is… suspension or withdrawal of licenses, or other regulatory sanctions.

The health-care system in the US is very different to the UK system and the regulatory enforcement regime differs also. … marketing activities ... in the UK are subject to far tighter regulation than they are in the USA. The UK accordingly does not see inappropriate marketing of medicines by pharmaceutical companies in the same way or to the same extent as the USA does.' (unpublished communication, Freedom of Information response 13/034, 2013).

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Nonetheless, inappropriate marketing is only one category of culpable offence. In addition, while UK marketing may be less direct, the internet market place is decidedly global (Ghodse, 2010). One high profile internet supplier has an online health helpline enquiry service based in Mauritius, another dispatches from India. Medicines regulation is 'everybody's business' now – a UK citizen can legally order prescription-only medication online, such as paroxetine tablets for personal use (360 tablets cost £202), provided that the website is based outside the UK.

Solutions for the future of pharmaceutical regulations

Recent progress by the pharmaceutical industry towards improved public perception of its working practices includes GlaxoSmithKline's discontinuation of sales related bonus for its American employees (Coombes, 2013), and the decision to make publically available all anonymised patient level data on both approved and failed drugs (Harrison, 2012). Although welcome, such measures must be supplemented by improved awareness of potential mechanisms for bad practice at all levels of the health-care profession.

Close scrutiny is needed particularly of areas where formal alliances are being formed between the NHS and the pharmaceutical industry, including research initiatives such as industry-sponsored trials on the National Institute for Health Research portfolio.

Any penalties levied need to be proportionate to the balance sheet of the companies involved.

Corporate accountability alone is inadequate. Individual responsibility is required, including ongoing monitoring of those who have been found to infringe regulations, notably when they relocate to another company, otherwise the cycle of bad practice is inevitably perpetuated.

Finally, the drugs market is a global concern; consumers have global access to international products. It is essential therefore to have a corresponding uniform, global regulatory approach which can be consistently applied worldwide. The MHRA must play a full part in such cooperation. BJHM

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KEY POINTS

- Health-care professionals must be vigilant against manipulation by pharmaceutical companies for commercial gain.
- The Food and Drug Administration levies enormous fines, yet there are weaknesses even in US legislation.
- The UK's Medicines and Healthcare products Regulatory Agency seems reluctant to enforce proportionate financial penalties for regulatory shortcomings.
- Although superficially appealing, new regulatory commercial partnerships create new potential loopholes.
- Effective accountability must be individual as well as corporate.

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