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Fake medicines in Asia: The importance of brands to medicine quality

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The extra regulation called for by many commentators may well entrench the corrupt relationship between criminals and certain drug regulators.

Introduction

Fake medicines are becoming a critical problem in Asia, constituting between 15 and 25% of the market in countries like India and Indonesia. Even highly regulated markets like Malaysia have a prevalence rate of around 5%, according to Ministry of Health studies. There is near consensus that concerted action is needed at the in- ternational and national level to solve this major threat to public health, with most commentary focusing on the lack of regulation in poor countries where the problem of fake medicines is most acute[1]. Is regulation the answer, or are other mechanisms such as intellectual property rights and civil law more important?

The limits of regulation

Although most commentators and policymakers argue for deeper and more comprehensive medicines regulation in the worst-affected countries, regulation is not a panacea, despite the important role it has to play in standard-setting and broad market surveillance. Such top down solutions do not properly address the causes of the problem of fake medicines, which revolve around manufacturers being unable to protect their brands from counterfeiters, who are able to ply their nefarious trade with little risk of civil or criminal legal action.

Furthermore, in countries with a weak rule of law, which tend to have high rates of fake medicines, drug regulation agencies (DRAs) are particularly susceptible to corruption because of the large amounts of discretionary powers they hold. There are many cases of local and national DRAs being implicated in corruption over the last several years, perhaps most notably when the head of the Chinese DRA was executed for accepting bribes from counterfeiters. In 2012 the Indian Central Drugs Standard Control Organisation was labelled corrupt by its own parliament.

Even discounting for corruption, DRAs are merely the icing on the cake for ensuring the quality of the medicines supply. Even though it could theoretically check each factory for Good Manufacturing Practice, it would be impossible for a regulator to check every manufactured batch, test every pill, or ensure a plant operates to the required standards at all times. Neither can they intercept and check every consignment of imported medicines or active pharmaceutical ingredient. Even a well-resourced DRA such as the US Food and Drug Administration does not attempt such a task, let alone those in Asia.

Brand competition and drug quality

The quality of medicine supply in developed markets such as the US and the EU is extremely high not because of the existence of regulators such as the FDA or EMEA. Rather, the quality of medicines is high because companies jealously defend their reputations for manufacturing products of a consistently high quality. If consumers begin to perceive that reputation is unjustified, companies would rapidly lose market share and go out of business. Central to this is a company's

1 For instance, Oxfam (2011), "Eye on the ball: medicine regulation – not IP enforcement – can best deliver quality medicines", Briefing paper 143

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brand, which signals to consumers the quality of a product. But to signal quality effectively, manufacturers need to be able to consistently prevent unauthorised copies and use of their brand. The main mechanism for so doing is registration and enforcement of trademarks, something that is easy to do in the US and EU, but difficult in many Asian countries.

Intellectual property and brand integrity

Trademarks are a form of intellectual property that enable vendors to signal the high quality of their product to potential purchasers. Trademark owners have strong incentives to ensure that the quality of their product is maintained because their reputation and hence future profitability depend upon it. In many lower and middle-income countries, it is difficult to enforce trademarks – even for local companies. Where trademarks cannot be enforced, cheaply produced poor quality copies will typically crowd out good quality drugs, as has happened in countries with a high prevalence of fake medicines such as Indonesia, India, China, Cambodia and Vietnam.

Brands are not just for multinationals

The inability to protect trademarks affects not just the well-known multinational pharma powerhouses, but also to the many local generic manufacturers who form the backbone of the industry in Asia, such as Kotra Pharma of Malaysia or Cipla of India. The reputable brands of these companies have not arisen spontaneously or through government-mandated regulation, but rather through consistent investment in the factories and manufacturing standards necessary to produce high quality medicines. Importantly, these investments have been made to gain competitive advantage, as the reputation for quality and safety – embodied in the company's brand – is the key to its continued commercial success.

In many Asian countries, however, both branded and local generic companies are unable to protect their brands against counterfeiters, posing a risk not just their bottom line, but also to unwitting patients. For instance, Indian drug manufacturer VS International is a leading exporter of the antibiotic ciprofloxacin to Africa, but the company has had to institute a range of anti-counterfeit measures due to the widespread faking of its brand in Nigeria.

Far from being an anti-patient pro-corporate tool, then, intellectual property in the form of trademark protection is a necessary pre-condition for a marketplace filled with quality products. Trademarks protect all producers of quality products, big and small, as well as their customers. Pro-consumer advocates should therefore welcome the inclusion of trademark protection in local legal regimes and international agreements such as the World Trade Organization's TRIPS agreement (indeed, the 1994 agreement requires that the trademark laws of member jurisdictions are compatible with each other). Trademarks should not be confused with patents, which are another form of intellectual property designed to help promote innovation. The World Health Organization has clarified that patents have nothing to do with fake medicines, which is reasonable given that they tell the consumer little about a product's quality.

The role of the law in defending brands

For trademarks to perform their role of signalling quality, drug manufacturers need to be able to defend their brands; this requires strong, independent courts, a proper rule of law and efficient legal

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systems. Unfortunately many legal systems are beset with corruption, bureaucratic and are slow to judgement, making it difficult to pursue a successful trademark infringement case. This allows counterfeiters to infringe upon valuable brands with impunity, even though there are serious public health consequences from their actions.

Intellectual property rights are an important legal tool in the fight against fake medicines, but they are by no means the only weapon. Civil law also has an important role to play by protecting the consumer against mis-sold or defective goods. Civil law enables consumers (or their relatives) to obtain redress from the manufacturer or supplier of a harmful product, and this liability both compensates those who are harmed and discourages manufacturers and suppliers from selling counterfeits. In many less developed countries, however, civil law is either poorly defined, difficult to enforce or politicised. In the case of the tainted baby milk scandal that enveloped China in 2008, for instance, it appears that the government may have intervened in the usual civil litigation process to prevent victims from having their cases heard at all [2].

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In many countries, law enforcement is also corrupt. In such places, criminal counterfeiting gangs may be able to pay corrupt law enforcement agents to turn a blind eye to their activities. If a case does make it to court, the gangs may be able to pay off the judge and thereby induce a favourable judgement.

In summary, a high quality medicines supply is not a product of regulation, but rather a result of competition between different brands, and the successful interplay between civil law and trademark protection. This allows consumers to obtain redress against negligent manufacturers through the courts on the one hand, while allowing manufacturers of quality medicines to defend their brands on the other. Regulation has a role, but it is no substitute for a functional institutional environment. In the long term, therefore, a high quality drug supply can only be achieved from the bottom up, as companies seek to maintain competitive advantage through maintaining the integrity of their brands. Functioning property rights in the form of trademarks, and a strong rule of law are essential to this process.

Countries that have lower levels of fake medicines – for instance Malaysia, Singapore and Hong Kong – have paid attention to these fundamental issues, and are now reaping the benefits (even though some fake medicines still to penetrate the legitimate medicines supply, although at far lower rates than the 25% seen in countries like Indonesia).

Technological solutions to fake medicines

Reforming legal and civil institutions to create a hostile environment for counterfeiters is a long-term process. In the short-term, shortcomings in legal and regulatory systems can be circumvented by new technologies which allow consumers to verify the quality of medicines, and manufacturers to defend their brands against counterfeiters.

The private sector has made various attempts to use technology to make their products sufficiently difficult to copy as to make it uneconomical to produce counterfeits. Early efforts focused on the use of trademarked branding, combined with idiosyncratic pill shapes and colours. Counterfeiters quickly learnt how to mimic these forms, so companies began to introduce tamper-evident packaging. As these too became subverted by counterfeiters, more sophisticated measures had to be taken, including the use of holographic images on packaging.

2 "Beijing's food safety problem", Wall Street Journal, 15 October 2008, available at http://online.wsj.com/article/SB122400110147832865.html

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The private sector should use its innovative capacity to experiment with different technological solutions to brand infringement.

Malaysia's Meditag scheme

Malaysia in 2005 made it a requirement for the packaging of all traditional and Western medicines to bear a hologram with a serial number issued by the Ministry of Health. However, Malaysia quickly found that counterfeiters were able to fake the official hologram itself, leading the Ministry to introduce a more sophisticated version in 2006. High quality counterfeit holograms have also been well documented in anti-malarial drugs sold in South East Asia [3]. This raises questions about the long-term viability of the Malaysian Meditag scheme in its current form, as holograms have proven to be insufficiently sophisticated to deter the most determined counterfeiters.

2D and QR barcodes

.As a result of the limitations of technologies such as holograms, researchers have begun to explore other avenues, many of which take advantage of the massive upsurge in mobile and smartphone ownership that has taken place in many developing countries. One model developed by mPedigree in Ghana consists of a scratch-off panel on the packaging that reveals a 2D barcode. The patient then simply uses a mobile phone to SMS the code to a Freephone number, which then confirms if the product is genuine.

Quick response (QR) codes are another promising avenue. These printed squares are an advanced version of the 2D barcodes, which allow camera-enabled smartphones to scan the package for instant authentication by the manufacturer.

Radio Frequency ID (RFID) tags are used by Pfizer in the United States to protect frequently-counterfeited products such as Viagra, while other companies are developing DNA coding, in which synthetically-produced strands of DNA are fitted into a label and a checking device. Both systems can be used all along the supply chain to ensure that products are genuine. They also have the advantage of not requiring 'line of sight' in order to be read by a specialised scanner, so can be used in combination with tamper resistant packaging.

However, such technologies are expensive when compared to barcodes and scratch panels, and their high cost makes them unsuitable for the item level in poorer countries. Then there is also the fact that members of the public do not carry specialised scanners required for these technologies, effectively removing the consumer from the authentication process. There are also concerns that the heating effect of RFID can affect covalent bonds in protein and biologic products. The US FDA has therefore advised against using RFID tags on biologics and protein drugs, although recent research suggests radio frequency radiation has no detectable effect on such products [4].

The dangers of government mandated technology

These technologies are all highly innovative, and can work well in certain contexts to help manufacturers protect their brands. There is now an entire private-sector industry dedicated to developing new technologies and methods to safeguard brands, ensuring that the technology will always be one step ahead of the counterfeiters. However, this could be potentially undermined when governments attempt to make particular technologies mandatory in an attempt to stem the trade in fake medicines. India has recently gone down this route, making it mandatory for all pharmaceutical exporters to print barcodes on their outer-most packaging,

3 Newton, P et al (2008), "A collaborative epidemiological investigation into the criminal fake artesunate trade in South East Asia", PLOS Medicine, available at http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050032

4 Uysal et al (2012), "Effects of Radio Frequency identification – related radiation on In Vitro Biologics", PDA Journal of Pharmaceutical Science and Technology, 66:4, 333-345

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as did Malaysia with its Meditag hologram scheme, implemented in 2005.

Mandatory requirements can place excessive costs on small manufacturers and retailers, acting as a barrier to entry and protecting larger companies from competition. It may also hamper access to medicines for the poorest, who are sensitive even to the slightest rise in the price of a medicine. And even if the cost of a technology is a few US cents per unit it may significantly impact on the ability of pharmaceutical companies to manufacture profitably mass volume generic medicines, which are the staple of the pharmaceutical industries of many Asian countries.

Furthermore, by laying down specific technological requirements, such regulations will entrench those technologies that happen to be favoured by officials at a particular time, be it the hologram in Malaysia or the 2D barcode in India. This will crowd out the spontaneous development of alternative, innovative technologies, undermining competition and stifling further innovation.

Conclusion

The most fundamental cause of the spread of fake drugs in Asia has been the inability of manufacturers to protect the identity of their products. This is largely down to a lack of functioning rule of law, which makes it very difficult for manufacturers to protect their trade- marks and brands via the civil and criminal courts – thereby handing a free rein to counterfeiters. The extra regulation called for by many commentators may well entrench the corrupt relationship between criminals and certain drug regulators.

Strengthening the rule of law is a vital but long-term process. In the meantime, the private sector should take advantage of its innovative capacity to experiment with different technological solutions to brand infringement. It is well placed to lead this process, as it has unparalleled access to the entire pharmaceutical supply chain, as well as the clear financial incentive to protect its revenue. Governments should encourage this process, but refrain from mandating specific technologies or systems.

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