Keeping it Real 

Combating the spread of fake drugs in poor countries

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Fake medicines: how big is the problem?

Counterfeit and substandard drugs are a serious and growing problem around the world – especially in less developed countries. There are many reasons for this, including imitation, inappropriate packaging, poor manufacturing processes, and improper conditions during transportation and storage. At the point of purchase, such drugs share the common feature that they are not what they purport to be, so for simplicity we class them all as 'fakes' in this paper.

The scale of the problem remains unclear. The World Health Organisation estimates that counterfeit drugs constitute up to 25 per cent of the total medicine supply in less developed countries (LDCs). In Africa and South East Asia, more detailed sampling found that between 30 and 60 per cent of medicines were substandard. Fake medicines are also highly prevalent in Latin America and other parts of Asia. The largest producers of fake medicines seem to be India and China.

Fake drugs exist in most therapeutic classes. The problem also extends into non-pharmaceutical medical products, such as syringes and electronic medical equipment.

What are the dangers?

Fake drugs pose three direct threats to patients:

1. Failure to provide effective treatment. As fake drugs usually contain insufficient bioavailable active ingredient, a patient who believes he is addressing his disease is in fact going untreated. The disease thus progresses, often leading to death, especially in children and the elderly. We estimate that approximately 700,000 deaths from malaria and tuberculosis are attributable to fake drugs.
2. Adulteration with toxic chemicals, often leading to death or injury. There have been numerous deaths due to consumption of cough syrup contaminated with anti-freeze, including 84 children in Nigeria in 2008. In 2008 contaminated Heparin from China killed 62 people in the US.
3. If a drug contains some active ingredient but too little to kill all the disease agents, it can lead to the emergence of drug resistant strains of disease. This is a serious problem with tuberculosis, Extremely Drug Resistant strains of which are now found in 49 countries, as well as malaria, with parasites in much of Africa and Asia now resistant to most drugs, except those based on Artemisinin – but there are worrying signs of emerging resistance to these drugs too. Resistance is also a serious problem for HIV medications.

What are the causes?

The problem is caused in large part by a combination of defective legal systems and government-imposed distortions of the pharmaceuticals market.

Defective legal systems

Poor countries tend to have highly inefficient, slow and expensive legal systems, which makes it very difficult for people to be assured of the quality of the medicines they purchase:

- ***Difficulties signaling quality to consumers:*** In principle, manufacturers that are able to provide assurances regarding the quality of their goods

should have a competitive advantage. Even the very poor would be willing to pay a premium for a guarantee that a product is what it says it is. That is one of the main functions of a brand. But to signal quality effectively, manufacturers need to be able to ensure that their brands are not being counterfeited. The main mechanism for so doing is registration and enforcement of trademarks. But in many countries it is difficult and expensive to enforce trademarks.

- ***Lack of adequate civil liability:*** In principle, civil law should protect consumers against defective goods by allowing people injured by such goods to obtain redress through the courts. Unfortunately, in poor countries the courts often fail to provide such protection. (In rich countries, the courts have often been too willing to hold manufacturers liable even when potential injuries were unforeseeable – but that is another story.)
- ***Weak or absent rule of law:*** Lack of enforceable trademarks and civil liability are instances of a wider problem: the lack properly enforceable constitutional provisions protecting the rights of citizens. In such an environment, legal decisions tend to be arbitrary and designed to benefit the elite. Law enforcement tends to be corrupt, enabling criminal gangs to pay government agents to turn a blind eye to their activities.

Government-imposed distortions of the pharmaceutical market

- ***Tariffs and other import restrictions:*** Tariffs on imported medicines are very common in poor countries and drive up the price of high quality medicines. This creates opportunities for suppliers of fakes, who can then more easily undercut them. The need to pay tariffs also creates extra layers of slow moving customs bureaucracy, which leads to more opportunities for corruption. It can also lead to unnecessary delays in ports, where improper storage conditions can cause drugs degrade.
- ***Price controls:*** The usual justification for price controls is that they protect consumers by limiting the retail price of medicines, but they can lead to harmful unintended consequences. First, the erosion of profitability can cause legitimate manufacturers – who have big overheads – to withdraw from the marketplace, creating market opportunity for counterfeiters. Second, manufacturers may try to sidestep price controls by altering the nature of their product. This has happened India, which has seen the emergence of hundred of 'irrational fixed-dose combination' drugs, which may be extremely harmful to patients. Third, by limiting profits, they can undermine retailers to the point of destruction. Price controls have been implicated in the closure of dozens of rural pharmacies in South Africa, which are often the only place where the poor can obtain healthcare.

What is being done?

Government interventions

Several governments have instituted Draconian criminal sanctions, with India and China introducing the death penalty for certain offences involving counterfeit drugs. While harsher criminal penalties send strong political signals, they may drive counterfeiting further into the arms of organized criminal cells, and create greater incentives for them to develop corrupt relationships with law-enforcement agencies.

More successful has been Nigeria, which has ramped up its detection and seizure activities. The government frequently raids and shuts down street markets where fakes are sold. As a result, the proportion of counterfeit medicines on sale in street markets has reportedly declined considerably.

New regulators

India recently announced the creation of more expansive drug regulatory bodies to deal with the problem of fake drugs. There are problems with such an approach.

- Extra layers of regulation create opportunities for bribery and corruption. (Major corruption scandals within drug regulatory bodies have occurred in Nigeria and Italy.)
- Drug regulators inevitably delay access to new drugs. In South Africa regulatory approval can take up to two years. This creates yet more gaps in supply to be exploited by counterfeiters.

Identity preservation technologies

Manufacturers and suppliers of quality branded medicines have strong incentives to maintain the integrity of their drugs; their reputation and future profitability depend on it. Private have been developing technologies that enable "identity preservation," which enable consumers and/or retailers to ensure that individual packages of drugs are .

Unfortunately, counterfeiters have circumvented many early attempts to protect the identity of products, such as holograms and tamper seals. Current efforts focus on more sophisticated technologies, such as unique numerical identifiers and barcodes, combined with central registries, enabling individuals to verify the identity of a package using their cellphone message service (SMS or MMS). Such systems have been developed in Ghana, India and the USA and are currently being implemented in many parts of Africa and Asia.

For more advanced markets, technologies have been developed that operate at points in the supply chain between the manufacturer and final consumer – in particular retail pharmacies. Some of these techniques involve bar codes, SMS and RFID. One such technology under development which will be particularly difficult for counterfeiters to circumvent is synthetic-DNA coding.

The success of these private initiatives has prompted certain governments to mandate specific technologies to help in the fight against fake drugs. California has passed legislation to mandate the use of a comprehensive 'track and trace' system, for instance. While well-meaning, such mandatory requirements can present an excessive cost burden to small businesses, acting as a barrier to entry and protecting bigger companies from competition. Furthermore, by laying down particular technological requirements, such regulations will entrench technologies which happened to by favoured by officials at a particular time. This will impede the development of alternative innovative technologies, and undermine competition and innovation.

Quality evaluation technologies

Identity preservation is only one part of the problem. As important is ensuring that the quality of medicines is preserved from producer to patient. One technological solution would be widespread use by retailers of spectrometers, which allow instant testing of the quality of a drug. These devices are becoming smaller and cheaper.

Conclusion

In many poor countries, fake drugs often crowd out real drugs – especially in street markets where vendors have no reputation to protect. The solution must, therefore, be to enable purchasers to distinguish between what is real and what is fake. And the way to do that is to enable manufacturers to protect the identity and quality of the drugs they produce through the supply chain all the way to the ultimate consumer.

Unfortunately, pharmaceutical companies currently face many barriers to ensuring the identity and quality of their drugs. Of particular importance are weak rule of law and explicit government barriers to the importation and marketing of medicines. One common barrier is arbitrary regulation, enforced in a discriminatory and corrupt manner. In such circumstances, stiffer regulation and criminal penalties, as suggested by WHO and others, may actually entrench the corrupt symbiotic relationship between counterfeiters, lawmakers and officials. Stronger regulations are also likely to increase the time and cost it takes to bring new medicines to market, creating further opportunities for fakers.

Bolstering the rule of law is a long term process in many countries. In the short-term, the private sector should take advantage of its innovative capacity to experiment with various technological solutions that enable it to protect the identity of its products. Governments, meanwhile, should reduce those interventions which undermine the supply of quality drugs, such as taxes, tariffs, price controls and other arbitrary regulations.

1

Fake medicines: how big is the problem?

Introduction

The global trade in fake medicines is vast and growing. It results in millions of people unwittingly consuming cement, talcum powder, sawdust, paint and an array of other toxic or inert substances. It thwarts efforts to cure disease and worsens illness. And perhaps worst of all, it results in the emergence of drug resistant strains of diseases ranging from AIDS and malaria to tuberculosis and bird flu (Miller, 2007; Stevens, 2006).

In wealthy countries, the discussion of fake medicines tends to focus on dangerous counterfeits imported into domestic markets (and state-run health services).[1] While this problem seems to be worsening, the situation in poor countries – the focus of this paper – is already far more serious.

The paper is composed of four parts. The first looks at the scope of the problem in less developed countries (LDCs). The second examines the health impacts of fake medicines. The third section considers the main causes of the problem. The final section offers some possible solutions.

This paper is about substances that are sold as medicines yet are not what they purport to be. Some of these substances are deliberately mislabelled, i.e. counterfeit. Others may have been inadvertently mislabelled or the pills contaminated during manufacture. Others may originally have been exactly as they claim, but due to poor storage have degraded and are consequently substandard.

It is sometimes argued that "counterfeit" drugs and "substandard" drugs must not be spoken of together, and the World Health Organization now has two separate definitions: counterfeits are "deliberately and fraudulently mislabelled" whereas substandard drugs are defined somewhat ambiguously as "genuine drug products" that do not meet pharmacopoeial standards.

In practice, overlaps between these two terms are inevitable. Studies in areas suffering from poor quality drugs typically discover counterfeit as well as substandard drugs, according to the definitions above. It can be extremely difficult to differentiate between the two, as it is not always clear whether or not the actions leading to faulty drugs were made *deliberately*. Furthermore, the difference is of little concern to a patient harmed by bad medicine.

This is presumably why the WHO previously adopted resolutions aimed at addressing all kinds of poor quality drugs. In 1988 a resolution sought "to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, counterfeited *or* substandard pharmaceutical preparations"; again, in 1994, another resolution called for action "to ensure that available drugs are *good quality*, and in combating the use of counterfeit drugs" [italics added].[2]

> *"The Pharmaceutical Security Institute estimates that seizures of counterfeit drugs in 2007 increased by 24 per cent on the previous year."*

As it is difficult to distinguishing between counterfeit and substandard medicines, and because they both pose a considerable threat to health, for simplicity we will refer to all such medicines as "fakes".

The following statistics are often cited as demonstrations of the size of the global market:

- The World Health Organization (WHO) published estimates that counterfeit drugs constitute 10 per cent of the global drug market, rising to 25 per cent in LDCs.[3]
- A study by the Center for Medicines in the Public Interest predicted that global sales of counterfeit drugs will be worth $75 billion by 2010 (an increase of over 90 percent from 2005).[4]
- The Pharmaceutical Security Institute estimates that seizures of counterfeit drugs in 2007 increased by 24 per cent on the previous year, with 1,513 seizures recorded in 99 different countries. These fakes were replicating over four hundred different types of drugs.[5]

However, we should be wary of aggregate global figures for several reasons. First, the very nature of drug counterfeiting means that this is a trade operating below the radar, and so it is not possible to know how many counterfeit drugs go undetected. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) summarise this problem by asking: "How to measure a market that, by nature, is informal and illegal?"

Second, statistics are often overly simplified, outdated and have dubious sources. Many a media article will cite the first figure above, claiming that the WHO estimates that 10 per cent of the global drug market is counterfeit. However, this statistic originally came from the US Food and Drug Administration (FDA) and was simply reproduced on the WHO website back in 2003.

Cumulative evidence suggests that there is a vast and growing global trade in fake drugs, yet more reliable statistics can be observed in the large number of investigations into levels of fake drugs in the worst hit parts of the world.

Worst affected regions

Fake medicines are most prevalent in poor countries. Estimates suggest that counterfeits represent up to a third of medicines in some LDCs – notably in Africa (Taylor, 2008). With non-counterfeit substandard medicines also highly prevalent in poor countries, the picture is bleak. The following studies in Sub Saharan Africa reinforce this finding:

- A study that sampled 22 ampicillin drugs on sale in Senegal discovered that 21 were made of flour. (Sow et al., 2002)
- 46 per cent of drugs in Angola, Burundi, and the Congo are substandard, another study estimates. (Gaudiano et al., 2007)
- A survey in Burkina Faso found that 10.6 per cent of drugs procured from licensed sellers were substandard, and 90 per cent purchased from unlicensed sellers were substandard. (Tipke at al., 2008)
- One study in Kenya revealed over 40 per cent of sampled drugs to be outside pharmacopoeial standards. (Amin et al., 2005)

The picture is similar in Asia. In 2006 a study throughout Laos, Myanmar (Burma), Vietnam, Cambodia found that 68 per cent of artesunate (anti-malaria) drugs did not contain the correct amount of active ingredient (Alter Hall, 2006).

> *"In some areas 30–50 per cent, or even more than 50 per cent, of drugs you buy randomly from pharmacies are actually fake."*

The following year (2007) a team from Oxford University, Bangkok's Mahidol University and the Wellcome Trust conducted a survey in the same countries. Professor Nick Day of the research team is reported to have said: "In some areas 30–50 per cent, or even more than 50 per cent, of drugs you buy randomly from pharmacies are actually fake" (McGivering, 2007).

In 2004, a small assessment of pediatric drugs in Bangladesh found seven out of 10 brands were substandard (Choudhury, 2004).

In Latin America, similar problems are reported. According to the Association of Pharmaceutical Laboratories (ALAFARPE), the counterfeit medicines market in Peru is worth $66 million (up from $40 million in 2002), while the Dominican Republic's Public Health Department reported that 10 per cent of imported medicines were counterfeit (Bagozzi, 2007).

The problem is less severe in more developed countries, with incident rates estimated as typically less than 1 per cent.[6] In such places, the most common counterfeits are so-called 'lifestyle' drugs such as Viagra, often purchased through the Internet. Non-counterfeit substandards are rare.

Sources of fake medicines

One set of figures from the European Commission showed 75 per cent of counterfeit drugs being imported from India,[7] home to around 22,000 small drug producers, many of which are informal (Bate, 2008). The Associated Chambers of Commerce and Industry of India estimate this market is growing by 20–25 per cent per annum (Barnes, 2008; Bate, 2008; Lal, 2008).

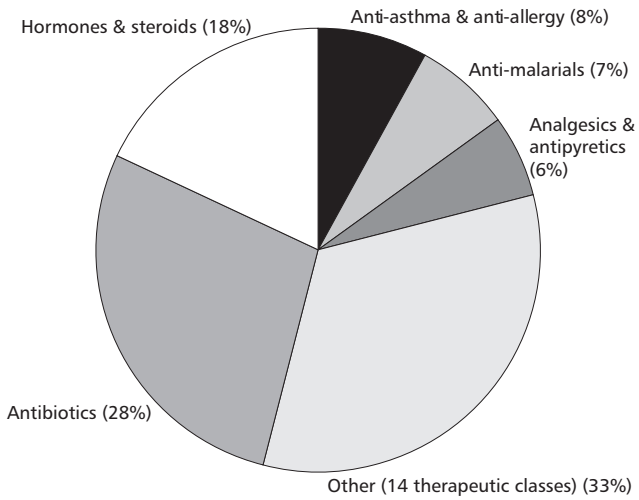
A 2004 survey of medicines on sale at a large bazaar in New Delhi found that only 7.5 per cent were genuine. A report in an Indian newspaper said that fakes are freely sold to "exporters who sell them to unsuspecting health administrators in Sub-Saharan Africa, who receive some of the millions in aid money."[8]

After India, China is the second largest source.[9] Good data are hard to come by, yet anecdotal evidence suggests that fakes produced in China are prevalent both domestically and internationally. For example, in May 2008 six out of seven people injected with immunoglobulin in Jiangxi province died; subsequently, irregularities were found in samples of the drug (Juan, 2008).

A 2008 small sample study of antimalarial drugs across Africa found that over 30 per cent of drugs originating in Asia failed quality checks. However, locally-produced drugs fared even worse, with nearly half found to be substandard. (Bate et al., 2008)

Batches of counterfeit drugs are frequently discovered being transported through the Middle East. The United Arab Emirates (UAE), for example, often features in European Commission figures listing the originating countries of counterfeit drugs. However, as signalled by Switzerland's inclusion in the same list, it is extremely unlikely that fakes are *produced* in these countries; rather, they are transported through them.

Figure 1 **Reports of counterfeit drugs by therapeutic class received by WHO, 1999–2002**



Source: WHO Impact report, updated May 2008

Most faked medicines

In LDCs, fake medicines seem to be prevalent across all classes of drugs, as evidenced by the reports of counterfeit drugs received by WHO – see figure 1. Yet most cases of counterfeit drugs probably are not known to the governments of LDCs, since there is no systematic mechanism for discovering and disclosing them. Meanwhile, even those instances that are known to the authorities are not necessarily reported to the WHO – as evidence by the fact that fewer than 5 per cent of the WHO's members have reported cases of counterfeiting (Bate, 2008).

Finally, counterfeits are only part of the problem, with other substandards also being prevalent.

The problem also extends beyond fake pharmaceuticals to medical consumables such as non-sterile syringes and gauze, and even substandard electronic medical equipment.

2

What are the dangers?

The main dangers to health posed by fake drugs are:

1. Failure to provide effective treatment
2. Direct harm
3. Drug resistance

A fake medicine typically causes at least one and often two or even all three of these effects, which we now discuss.

Failure to treat

The most common effect is the failure to provide successful treatment. This occurs when a fake contains insufficient quantity of the active ingredient, or if the delivery mechanism (the other ingredients that enable the drug to be taken up by the body) does not function properly. When a fake fails to treat a condition, the effect can vary from the relatively insignificant (such as when a fake analgesic does not alleviate a mild headache that subsides on its own) to the very serious (such as when a fake antimalarial fails to destroy falciparum parasites and the patient dies).

A particularly pernicious instance of the failure to treat occurs as a result of 'trick' counterfeits. These are drugs which are entirely ineffective against a disease but contain ingredients which fool the patient into believing that they are convalescing. For example, a batch of counterfeit antimalarial pills in south east Asia was found to contain a drug which temporarily lowers fevers (Hall et al., 2006). In such cases malaria-sufferers taking the counterfeit experience fewer fevers and believe they are recovering, when in fact their malaria is going untreated and worsening.

Direct harm

In some cases, fakes cause direct harm to the patient. For example, paracetamol cough syrup contaminated with antifreeze (chemical names: ethan-1,2-diol or diethylene glycol) has killed hundreds of patients, including 339 children in Bangladesh in 1990, 85 children in Haiti in 1995, over 100 children in Panama in 2007. As of March 2009, more than 80 children are reported to have died in Nigeria after ingesting a teething mixture named "My Pikin".[10] (Bogdanich and Hooker, 2007; Clark, 2008).

A recent batch of counterfeit heparin[11] was exported to the USA and several European countries around the beginning of 2008. By April sixty-two Americans had died from this batch (Gibb, 2008). The heparin is believed to have been contaminated in China with a substance known as 'over-sulfated chondroitin sulfate'. By tampering with chondroitin sulphate (to produce the 'over-sulfated' substance) it is possible to produce a blood-thinning effect which mimics heparin; thus explaining why the heparin was contaminated. The fatal effects were caused by allergic reactions to the contaminant.

> *"In some cases, fakes cause direct harm to the patient."*

Drug resistance

Finally, when a fake used to treat a disease caused by a virus, bacterium, parasite or other microorganism contains some active ingredient, but insufficient to eradicate the microorganisms, the remaining microorganisms breed, resulting in drug-resistant strains. As a result, the real medicine becomes less effective at treating the disease.

Resistance is currently a serious problem with tuberculosis, as stronger, deadlier mutations emerge such as the XDR-TB strain (Extremely Drug Resistant Tuberculosis), now confirmed in 49 countries ranging from Peru to Nepal (De Capua, 2008).[12] According to the WHO, 5 per cent of new tuberculosis infections between 2003 and 2007 were multiple drug resistant cases, with the rate in some countries over 35 per cent (World Health Organization, 2008).

Widespread resistance is also a very serious problem with malaria. In the 1980s and 1990s antimalarial drugs such as chloroquine and sulphadoxine / pyrimethamine were used inappropriately so that parasites became resistant to them. Those drugs were superseded by artemisinin, which is now used widely, usually in 'combination therapies' (ACTs) designed to prevent resistance. However, the success and effectiveness of ACTs is threatened by fakes, with evidence of resistance in the border areas of Cambodia, Laos, Vietnam and Myanmar (Burma), where fake medicines are highly prevalent (WHO, 2008). In the border town of Pailin, successful response to ACTs has declined from 85.7 per cent in 2002 to 79.3 per cent in 2004 (Wongsrichanalai, 2008). Fake ACTs therefore portend a massive health risk, as artemisinin is currently the last line of defence against malaria (Newton, 2008).

One of the most serious instances of resistance is in the context of medicines to combat HIV/AIDS. In July 2008, the director of infectious diseases at Belgium's St. Pierre University Hospital told the *Financial Times* of his shock after finding that 30 of the 100 AIDS patients he examined in the Democratic Republic of the Congo had virus strains that resisted the standard medicines. He commented: "we are creating a virological time bomb".

Other consequences

Fakes also affect spending on R&D into new medicines. Even near-perfect copies of on-patent medicines cause harm by competing with legitimate supplies of medicines from originating companies, which reduces revenues and undermines incentives to invest in future R&D.

Furthermore, the production of substandard generic medicines can crowd out manufacturers of high quality generics, who have made costly investments in bringing their plants up to international Good Manufacturing Practice and bioequivalence testing.

If fakes are widespread, confidence in medicine is undermined, resulting in less demand and poor adherence to drug regimens (which in turn can provoke drug resistance).

Estimating the impact of fake medicines

Given the lack of hard data on the proportion of fakes and the patchiness of data on the incidence of disease, any attempt to estimate the impact of fake medicines is inevitably as much art as science. Nevertheless, we believe that the scale of the problem is such that such estimates serve the useful purpose of calling attention to the issue and as long as they are approached with caution are worthwhile.

We have made our own calculations of the likely impact of fake medicines on mortality, which are shown below. The workings behind these estimates are detailed in the Appendix. In addition to mortality, fake medicines also have an impact on morbidity, however calculating such an impact was beyond the scope of this paper.

> *"This paper estimates that around 700,000 malaria and tuberculosis deaths per annum are attributable to fake drugs."*

Estimates of the impact of fake medicines on mortality

This paper estimates that around 700,000 malaria and tuberculosis deaths per annum are attributable to fake drugs. As this figure only includes two diseases, total deaths from fake drugs must therefore be much higher.

IMPACT and a political battle

Measures against drug counterfeiting have in recent years been opposed at the World Health Organisation, in particular the development of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). This has culminated in the whole issue of counterfeits being dropped from the 2009 World Health Assembly.

At the 61st World Health Assembly (WHA) in May 2008, efforts were brought to the table to officially endorse IMPACT – in the form of a draft resolution (A61/A/Conf. Paper No. 1) and an accompanying Secretarial report (A61/16). This was referred to the Executive Board of January 2009, which dropped both.

The governments of several countries blocked the resolution. These included India, Brazil, and Thailand, who raised concerns about pharmaceutical manufacturers and organisations such as the World Trade Organization and Interpol being involved in IMPACT. They argued that the resolution needed time and deliberation, and opposed IMPACT's definition of a counterfeit medicine, arguing that it confused a public health issue with an intellectual property rights (IPR) issue.

They were joined by anti-capitalist activists who have gone so far as to claim that "big pharmaceutical companies prepared all the documents" for the resolution.

IMPACT, however, primarily consists of drug regulatory authorities (from LDCs as well as wealthier countries) and also includes international organisations, patient associations, health professionals, pharmaceutical manufacturers (from both generic and R&D sectors) and wholesalers.

IMPACT was founded at a 2006 World Health Organization conference in Rome, two years after the idea was originally mooted at an international conference of drug regulatory authorities. The group, as agreed by all 160 participants, would raise awareness of the problem and exchange information and advice.

IMPACT's definition of counterfeit drugs includes the following important line:

> *"Violations or disputes concerning patents must* **not** *be confused with counterfeiting of medical products."*

The definition has therefore been supported by the European Generic Medicines Association. Yet in spite of this, lobbying against IMPACT has continued, especially in India where newspaper articles constantly accuse IMPACT of acting against generics. On 15th January 2009 the Small and Medium Enterprise Pharma Confederation of India wrote to the Indian Prime Minister calling for "the total rejection of the work of IMPACT". Articles even link IMPACT's agenda to the seizure of generic drugs in the EU on the basis of patent-infringement – even though IMPACT's own definition would *not* result in such seizures:

> *"Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are* **not** *considered counterfeit."*

It is important to note that IMPACT clearly states that patent-infringement is not the same as counterfeiting, and that it is a collaborative advice centre without the ability to impose new laws. The political obstruction of this group does not bode well for efforts to protect the world's poor from counterfeit drugs.

3

What are the causes?

We now turn to analyzing the reasons for the prevalence of fake medicines in LDCs. A simplistic analysis might observe that there are more producers of fakes in poor countries, or claim that poor people are less willing to pay for quality medicines. While the first observation is true, it tells us little about why there are so many counterfeiters. Meanwhile, the claim that poor people are unwilling to pay for quality medicines implies that poor people are unable to make rational decisions; after all, why would someone pay for a medicine that they knew would do them no good?

We don't believe the poor are irrational. We believe that they are the victims of a combination of defective legal systems and government-imposed distortions of the pharmaceutical market.

Defective legal systems

Poor countries tend to be characterized by highly inefficient, bureaucratic, slow and expensive legal systems. In many such countries it is difficult formally to own property and to enter into contracts. We consider the implications of these and related issues in relation to the production, distribution and consumption of fake medicines.

> *"In many LDCs, it is difficult to enforce trademarks – even for local companies."*

Absent or defective trademark protection. One way to discourage the sale of unauthorised copies of medicines is to enable vendors to signal the quality of their product to potential purchasers. Trademark is one mechanism for doing that: brand 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 LDCs, 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.

Lack of adequate civil liability. Civil law protects the consumer against mis-sold or defective goods. By enabling consumers (or their relatives) to obtain redress from the manufacturer or supplier of a harmful product, such liability both compensates those who are harmed and discourages manufacturers and suppliers from selling fakes. In many LDCs, however, civil law is either poorly defined or inadequately enforced.

This is reflected in the recent cases of fake ingredients in products ranging from pet food to baby milk manufactured by Chinese companies (melamine was added to products because it mimics protein in simple tests). While many Chinese victims have been unable to obtain redress from the perpetrators, American groups have sought compensation from the suppliers of Chinese pet food containing deadly fake ingredients and reports suggest the settlement could be in the order of $32 million.[13] In the future pet food suppliers in the US will likely take greater care to avoid selling fake ingredients. Meanwhile, the only recourse Chinese parents have over the death of their children caused by contaminated baby milk is to sue a US subsidiary of one of the Chinese companies that produced the milk – in a US court![14]

The Confederation of Indian Industry lists the "inadequacy of civil jurisprudence" as one of the main reasons behind counterfeiting in India. They describe civil law procedure as "lengthy and cumbersome", and note that brand owners therefore view intellectual property theft as inevitable in the Indian market.[15]

Inability to resolve disputes over property rights and contracts in independent courts. In many cases, underlying the lack of civil liability and weak IP protection are costly and inefficient legal systems. It can often take years for cases to be heard and cost more to bring a case than the value of any outcome. Under such circumstances, few cases will ever come to court and the nominal protection offered by civil liability is of little value.

Weak or absent rule of law. Many LDCs lack constitutional provisions protecting the rights of citizens. In such countries, political and legal decisions tend to be arbitrary and designed to benefit the elite. Meanwhile, law enforcement also tends to be corrupt (Schleifer and Vishny, 2003). As a result, regulation designed to combat counterfeiting is often ineffective. 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.

Added layers of government can increase opportunities for corruption, which are already rife in the health sectors of LDCs. Workers in state-run hospitals and clinics routinely resell 'free' pharmaceuticals on the black market, sometimes replacing them with counterfeit products. In February 2009 a report from Sierra Leone suggested that a pharmacy owned by an ex-registrar of the pharmacy board was selling donated drugs, some of which were fake. The report stemmed from an investigation by Sierra Leonean BBC journalist Sorious Samura, who has uncovered drugs donated by UNICEF being sold in pharmacies. One culprit admitted: "The government sold it [the pharmaceuticals] to us and that is not a secret." The drugs are "sold everywhere, even by petty traders in street corners."[16]

> *"BBC journalist Sorious Samura … has uncovered drugs donated by UNICEF being sold in pharmacies."*

Maureen Lewis, formerly of the World Bank, has brought attention to many similar examples, such as the "rampant stealing of public sector drugs" in Ethiopia. There a health officer is quoted as saying "most health workers are involved in such things [theft]". Another investigation shows an average leakage rate for drugs in Uganda at 73 per cent. (Maureen Lewis, 2006)

Table 1 **Average overall taxes and tariffs on pharmaceutical goods**

Kenya	38%
Brazil	29%
Pakistan	26%
Mexico	25%
China	24%
Ghana	22%
India	20%
Morocco	18%
Thailand	18%
Laos	17%
Nigeria	16%

Source: Bate et al., 2005

Government-imposed distortions of the medicines market

Governments in LDCs compound the problem of fake medicines through various interventions into the pharmaceutical market, such as taxes, tariffs, licensing regimes and price controls. These interventions lead to additional layers of bureaucracy, which in LDCs with a weak rule of law are easily exploited by unscrupulous officials and criminals. They also often exacerbate the imbalance between supply of and demand for high quality medicines. These gaps in supply of genuine medicines are readily exploited by criminals.

Tariffs and other import restrictions

Many governments in low and middle income countries impose tariffs on imported drugs (even, sometimes, when they are donated). (Bate et al., 2006) Such tariffs have the effect of driving up the price of good quality imported medicines, undermining efforts by drug companies to sell at lower prices in low income areas, and even deterring them from entering the market at all.

By increasing the price differential between quality medicines and fakes, such barriers create opportunities for counterfeiters.

Table 1 demonstrates some levels of taxes and tariffs. Yet not all countries have such high barriers to entry – a separate study in the same year showed that 72 per cent of high income countries had no tariffs imposed on pharmaceutical goods. No high income countries had tariffs in excess of 10 per cent. Also, 41 per cent of *all* countries had zero tariffs on pharmaceutical goods (WHO, 2005). These figures call into question the motives behind governments who impose high tariffs and taxes on medicinal products. A nine country study has shown that such government-imposed measures, including tariffs and licensing, added an average of 68.6 per cent to the cost of imported pharmaceuticals (Levison & Laing, 2003).

"importers of genuine products face numerous bureaucratic hurdles that can be exploited by criminals."

The need to pay tariffs creates extra layers of slow-moving customs bureaucracy. In addition, importers of genuine products face numerous bureaucratic hurdles that can be exploited by criminals. These tariffs and regulations often result in customs officials soliciting bribes in order to decide which drugs are held up and which are fast-tracked – a situation which favours importers willing to behave illegally, such as those supplying counterfeits.

This is worsened by the complexities of tax and tariff systems, which can be near impossible to understand (allowing corrupt officials to invent their own rules). A 2007 study submitted to the UK Department for International Development on medicines in India noted that "Informants at all levels of the public and the private supply chain agreed that the tariff system is overly complicated, with abatements and tariffs levied multiple times." The study draws attention to the "lack of transparency" which results and concludes with the recommendation that "Government … remove all tariffs on medicines." (Kotwani & Levison, 2007).

To make matters worse, importers of legitimate medicines suffer the double whammy of paying high tariffs and having their medicines stored inadequately in customs warehouses, leading them to degrade. This not only has the effect of increasing the number of substandard (and potentially resistance-inducing) drugs in the market, it also undermines confidence in reputable, branded drugs. According to Andy Macaleer, Director of Pharmaceutical Solutions at Acsis (a company working on pharmaceutical supply chains), "the leading reason for the return of prescription drugs is due to products sitting in the supply chain too long and expiring before they can be dispensed". Macaleer, 2008; Stevens, 2008).

Numerous studies have been performed into the degradation of drugs in transit (Hogerzeil et al., 1991; Hogerzeil et al., 1992; Nazerali et al., 1996), and some report particularly poor conditions in customs. In their study on factors leading to drug resistance, Okeke et al. cite the conditions drugs are exposed to in "tropical ports while they await lengthy port clearance". Another paper (Hogerzeil et al., 1992) also stresses the conditions at tropical ports: "Extreme climatic conditions occurred especially during time in the harbour and in bond in the port area, and during transport over land", adding that time spent at sea is "less of a problem". This suggests that transport itself is not inherently a cause of substandard drugs, but rather bureaucratic delays and conditions within recipient countries can be culpable.

Governments that impose tariffs and license requirements on imports do so primarily to protect domestic industry and raise revenue. By driving up the cost of high-quality imports, and increasing the proportion of those imports that become substandard through excessively lengthy and inadequate storage, such measures reduce the incentives for local manufacturers to maintain high standards. Tariffs and licenses particularly affect the poor, who are least able to afford higher-priced imports. As most patients in LDCs pay for medicines directly from their own pockets, they are likely to seek cheaper alternatives where possible. This can be readily exploited by suppliers of substandard and counterfeit medicines.

It is perhaps unsurprising, therefore, that in a recent survey, about half the locally-produced drugs tested in

six African cities were found to be substandard. (Bate *et al*, 2008). Meanwhile, countries with the highest tariffs, such as India, China and Nigeria, also tend to have the highest rates of fake medicine production and/or consumption.

Price controls

Many governments impose price controls on medicines. Ostensibly, these are intended to reduce the cost to consumers, be they individuals or Ministries of Health. However, they also result in many unintended harmful consequences.

Such price controls have several adverse effects. First, they discourage companies from registering products in certain markets. Most disturbingly, it is often the producers of the highest quality brands who withdraw from the market, because they tend to have a higher cost base and their margins will be most affected by the price controls. Meanwhile, producers of cheaper, lower quality medicines and outright counterfeits are favoured.

> *"price controls encourage manufacturers to alter the nature of their products."*

Second, price controls encourage manufacturers to alter the nature of their products, in order to circumvent the controls. This problem is perhaps most acute in India, where there has been a surge in so-called 'irrational fixed dose combinations' – combinations of two or more drugs that have no clinical justification. Such combinations result in the consumption of unnecessary drugs, since patients often take the drug primarily for only one of its components. In addition, such combinations have rarely undergone clinical trials, so present unknown dangers to patients. As Urmila Thatte of BYL Nair Hospital and Research Centre in Mumbai points out, "The drugs may interact with each other, or may interact with food. They may even cause adverse reactions and a physician may find it impossible to identify which drug has caused it."[17]

60 per cent of the top-selling 300 drugs in India are irrational FDCs. 90 per cent of total retail sales are constituted of FDCs that are not mentioned in standard textbooks of medicines.[18] The Drugs Controller General of India (DCGI) has indicated that it will review up to 1,300 FDCs available in India, and will remove those that are irrational. Yet, the DCGI accepts that it is the government's price controls that are in all probability responsible for most of these irrational FDCs being on the market. An official from DCGI the told the Hindu newspaper in July 2007: "The price of one drug molecule, e.g., paracetamol, may be fixed. The pharma companies will add another molecule – like tizanidine or aceclofenac in combination with paracetamol and introduce it as a new drug in the market to escape the price control order." (Maya, 2007)

74 drugs are currently subject to price controls in India, down from 347 in 1979 (*Drugs (Prices Control) Order 1979*; *Drugs (Prices Control) Order 1995)*, though there have been calls to increase this number again. In 2004 then-Minister for chemicals and fertilisers Ram Vilas Paswan declared the government's intention of bringing 300 "essential" drugs under price control.

In addition to incentivizing the creation of irrational FDCs, price controls in India have discouraged manufacturers from producing certain products, causing shortages. A 2004 article in the British Medical Journal reported that "drugs [have] became unavailable … and a black market – as well as spurious and counterfeit drugs – flourished" (Kumar, 2004).

In South Africa, price caps imposed on certain drugs have been implicated in the closure of at least 103 pharmacies (Tren, 2005). By reducing the margins that pharmacies could obtain from the sale of the medicines, the price caps made it unprofitable to continue operating. Such caps particularly affect pharmacies in rural areas, where supply costs are higher. However, there will clearly continue to be demand for medicines in these areas, which in the absence of legitimate supplies will be met by illegitimate supplies, which is likely to include all manner of fake medicines, from smuggled substandards to counterfeits.

Patents. Some have claimed that patent protection in LDCs is a direct driver of counterfeit medicines. Such an argument is based on the premise that patents artificially drive up prices, thereby providing a significant opportunity for counterfeiters who only

need to make a marginal profit over their production costs.

While theoretically plausible, this hypothesis has major flaws. First, as Amir Attaran has shown, more than 98 per cent of the WHO's Essential Medicines List is not patented in any poor country. Moreover, rights-holders rarely challenge patent infringements that take place in the poorest countries, particularly ARVs (Attaran, 2004). Second, most drugs sold in poor countries are off patent – and this pattern is reflected in the sales of counterfeits, suggesting that the price differential required to incentivize the production and distribution of fakes is small and that therefore the additional margin on patented medicines is not a relevant consideration in most cases.

A media report in January 2009 examining counterfeit drugs in Sierra Leone stated that "Everyday products such as painkillers and antibiotics are the most commonly counterfeited".[19] In April 2009 a similar report, this time in Tanzania, also listed common "antibiotics, [and] painkillers" as being prolifically counterfeited, along with other off-patent products such as vitamins.[20]

In 2007 a literature review on fake drugs concurred with Figure 1 (page 9), which portrays a large proportion of counterfeit drugs being antibiotics. Common antibiotics such as amoxicillin, cephalexin, and ampicillin are off-patent. The review explains that "the drugs that are most needed there, are the counterfeiters' favourites", demonstrating that demand is a higher determinant of which drugs are counterfeited than patent status (Kelesidis, 2007).

4

What is being done?

This section discusses some of the main actions that are being taken by both governments and the private sector to address the problem of fake medicines.

Government interventions

In recent years, national governments and intergovernmental organisations have begun to develop policies to tackle the problem of fake medicines. While some of these measures may help, most are simply reactive and do not address the root causes described above.

One approach has been to increase spending on detection and seizure of counterfeit medicines. For example, between 2001 and 2006, authorities in Nigeria destroyed over $100 million worth of seized counterfeit medicines (Bate, 2008). Although each seizure has the positive effect of stopping counterfeit drugs reaching victims, its impact on the long-term problem is less clear. In spite of the series of high profile seizures by Nigerian National Agency for Food and Drug Administration and Control (NAFDAC), the vast trade in counterfeits appears to remain, with new cases constantly being discovered. As of December 2008 NAFDAC had seized and destroyed around N25 billion worth of counterfeit drugs and had 60 cases against accused perpetrators pending in courts.[21]

Similarly, NAFDAC regularly raids and sometimes closes down the large street markets where medicines are sold. Again, this does not address the root causes of the trade in counterfeit medicines. As long as consumers/patients lack reliable means of ensuring that the medicines they are buying are real, the incentive to sell counterfeits will remain – and vendors will find ways to sell them, circumventing measures through bribery or other criminal behaviours. Furthermore, closing down these markets affects the other non-drug related trading activities taking place, which are extremely important to local economies. Heavy-handed interventions between trading citizens is not a sustainable method of tackling counterfeiting.

Certain governments have suggested heftier criminal punishments for people involved in the trade in counterfeit medicines. In June 2008, laws against counterfeit drug trading were tightened in Peru, for example, with the introduction of a maximum sentence of ten years imprisonment for anyone found guilty of selling, storing, packaging or producing counterfeit medicines (Khond, 2008). Tougher criminal penalties in the United Arab Emirates were also announced in 2008 (Underwood, 2008).

> *"Stronger criminal penalties will likely drive activities further into the hands of organised criminal cells."*

At the extreme end of this scale, India and China have introduced the death penalty for certain offences involving counterfeit drugs, though so far only China has actually invoked the penalty. In September 2008 the former head of the State Food and Drug Administration (SFDA) was executed after being convicted of accepting bribes to approve untested medicines.

While these measures suggest that powerful signals are being sent to those who produce and peddle counterfeit medicines, their actual effect may be less beneficial and in some cases could even be counterproductive. Stronger criminal penalties will likely drive activities further into the hands of organised criminal cells. They will also

likely result in further corruption, as the criminal cells seek to infiltrate law-enforcement agencies. Moreover, the introduction of mandatory Draconian punishments often has the effect of discouraging judges and juries from finding defendants guilty, because of the very serious consequence of making an incorrect decision, so may actually reduce the number of successful prosecutions.[22] If these consequences do materialize, then public trust in the medicines supply chain is likely to be eroded further.

New regulators

In addition to imposing more Draconian penalties on those involved in the sale of counterfeit medicines, the governments of some countries have announced that they plan to create more expansive regulatory bodies. For instance, the Indian government announced in January 2008 that it proposes to create a federal drug regulator. The intention of such regulations is to overcome the problems created by weak – and often corrupt – regulators in certain states. However, as with the heftier penalties, the impact is not unambiguously positive.

First, extra layers of regulation create opportunities for bribery and corruption, especially in countries where the rule of law is weak. For example, in 2000 then-President of Nigeria Olusegun Obasanjo sacked the entire management of the National Agency for Food and Drug Administration and Control (NAFDAC), which had been established only seven years previously, due to evidence of corrupt practice. Likewise, in Italy in 2008 several senior officials from the country's drug regulatory agency were arrested in a 'cash-for-licenses' scandal.[23]

> *"extra layers of regulation create opportunities for bribery and corruption, especially in countries where the rule of law is weak."*

Of course, the fact that these instances of corruption have come to light and their perpetrators dealt with is a positive sign, suggesting that perhaps in future corruption will be less of a problem. However, to the extent that control of corruption rests on political intervention, there is a danger that as power changes hands, such controls will not be applied so rigorously. Worse, the ability to remove 'corrupt' officials may itself be applied in a corrupt manner, furthering the interests of those in power and their supporters, which might include manufacturers of fake medicines, rendering the legislation counterproductive.

A further problem with drug regulators is that they (inevitably) delay access to new drugs. In the US, regulatory approval for new medicines typically takes between 12 and 24 months.[24] And that is after the drug has gone through all the required stages of testing, which can take from seven to twelve years. In South Africa, new drugs that have already been passed by regulators in the US or EU face delays of up to two years at the hands of the Medicines Control Agency. This creates yet more gaps in supply to be exploited by counterfeiters.

Identity preservation technologies

The manufacturers and distributors of high quality branded medicines have strong incentives to act against counterfeit and substandard medicine because such fakes remove legitimate business and harm the reputations of their brands. Unsurprisingly therefore, both pharmaceutical companies and retailers are taking steps to address the problem.

Early attempts by the private sector to prevent counterfeiting focused on the use of trademarked branding, combined with idiosyncratic pill shapes and colours. Later on, tamper-evident packaging systems were introduced. Gradually, more sophisticated measures were taken, including the use of holographic images on packaging. However, even these have now been copied by counterfeiters, so more drastic measures are necessary. Current efforts focus on mass serialisations systems, using technologies based on barcodes, RFID tag systems or simple scratch panels. It is believed that such systems are sufficiently complex to render any attempts at counterfeiting extremely uneconomical.

End-to-end technologies

Mobile phones are now sufficiently widespread in LDCs

that access can be considered near-universal. This has enabled the development of a range of technologies that enable purchasers of medicines to check the authenticity of their packs using text message (SMS) services. The systems rely on a unique identifying code in the form of a simple series of numbers, which is printed on the pack and then concealed. When the packet is bought, the purchaser scratches off the concealing panel to reveal the code and then sends the code by SMS to a central registry, which contains a copy of each code made for that medicine. If the code is unique, then the purchaser will shortly receive an SMS response informing them that the medicine is real. If the code is not in the system or is not unique, then they will be told that the medicine is likely to be a counterfeit. Such SMS systems have been developed in Ghana, India and the USA, and are currently being offered across Africa and Asia.

> *"SMS systems have been developed in Ghana, India and the USA."*

Supplier to pharmacy technologies

The SMS systems described above seek to ensure that the identity of a product is preserved from the time it leaves the manufacturer to the time it is purchased by the end 'consumer' (which in most cases will be the patient, but might be a relative or friend). Other services have been developed which focus on other points in the supply chain – in particular retail pharmacies. Essentially, these can be end-to-end systems if the pharmacist checks the product *at the point of sale* to the patient. This safeguards against products expiring or being manipulated within the pharmacy.

Like the end-to-end SMS system, most use codes to identify packages of medicines. The specific coding systems vary, however, with some using a number (as with the SMS system), some use a bar code (which is scanned and sent to a central registry for evaluation), while some use radio-frequency identification (RFID).

Scientists are developing methods of labelling and serialising products that are increasingly difficult for counterfeiters to circumvent. One further example of this is DNA coding, in which synthetically-produced strands of DNA are fitted into a label and a checking device. This can be used to check that products are genuine all through the supply chain, as can RFID. The latter has the advantage of being able to check devices quickly as they pass and is the same technology as used, for example, with travel cards on some public transport systems. It is, however, expensive when compared to barcodes and scratch panels, and there are concerns that the heating effect of RFID can affect covalent bonds in protein and biologic products. The FDA in America has therefore advised against using RFID tags on biologics and protein drugs.[25]

Furthermore, in order to prevent counterfeiters inserting fake drugs into legitimate packaging, some of the above methods are combined with security seals, which themselves are becoming increasingly difficult to tamper with.

State-supported serialisation

Most of the above-described technologies have emerged through private organisations simply responding to the problem of counterfeit medicines – without prompting or intervention from government. Yet their success is now resulting in calls for governments to require specific technologies. For instance, the state of California has already passed legislation to mandate use of a comprehensive "track and trace" system. Such measures, again, may be well-meaning, but can in fact cause more harm than good.

Mandatory requirements can place excessive costs on small businesses, acting as a barrier to entry and protecting larger companies from competition. For example, small pharmacies in California could face costs of between $84,000 and $110,000 to implement the first year of the "track and trace" system. Meanwhile the EU's lastest proposals admits "pharmacies are going to bear costs of approximately €157m", with up to €11 billion of costs falling on manufacturers and importers of medicinal products.[26] Furthermore, by laying down specific technological requirements, such regulations will entrench those technologies that happen to be favoured by officials at a particular time. This will crowd out the spontaneous development of alternative,

innovative technologies, undermining competition and stifling further innovation. To the extent that these technologies are themselves susceptible to fraud and counterfeiting (e.g. through hacking of the computer systems utilised to convey information), such mandates could ultimately be counterproductive. If end-to-end technologies are successful, there is no need for governments to attempt to track the entire supply chain.

Quality evaluation technologies

In an ideal world, everyone would purchase their pharmaceuticals from reputable pharmacies, which would in turn source from reputable distributors, who use reputable logistics companies, and so on back to the manufacturer. Meanwhile, at each point in the chain, the pharmaceuticals would be stored and handled according to standards established by the manufacturer and their identity through the chain secured using technologies such as those described above.

Unfortunately, we do not live in an ideal world and at least for the time being many people are likely to continue to source their medicines from street hawkers with no pharmacy qualifications, who have purchased the medicines from distributors that move them from place to place in the back of a small truck that reaches 40C for extended periods. Meanwhile, these distributors purchase their medicines from wholesalers, many of whom store medicines for months in warehouses that lack air conditioning and who often take consignments from intermediaries of dubious repute.

In this less than ideal world, end-to-end verification systems (including producer to pharmacy systems) should help to eliminate counterfeit medicines. Even producer-to-pharmacy systems might work, if hawkers had sufficient incentive to use them. But still it is possible that perfectly legitimate drugs might no longer work properly simply because of inadequate storage and handling.

What is needed is a means by which users or at least retailers can check the quality of the drugs, so that these substandard medicines can be avoided. One such technology is the spectrometer. These devices, which are becoming smaller and cheaper, can determine whether or not a drug contains the correct ingredients in the correct amounts. Some can even detect this through the packaging, so that the drug need not be removed from its package.

Raising awareness

If private companies are able to implement solutions to the problem of identity preservation and quality assurance, such as those described above, they would then have strong incentives not only to advertise their products but also to educate the public about the nature of the problem.

In addition, there may be a role for third party groups, such as health advocacy NGOs. Such groups have done important work educating the public in Sub-Saharan Africa about the problem of HIV-AIDS. Given the scale of the problem of fake medicines, it seems plausible that such groups could be persuaded to get involved in proactive education campaigns describing the nature of the problem and the need to ensure that medicines are from reputable sources and are, so far as can be ascertained, what they say they are.

Other private companies might also be encouraged to join such a campaign. Manufacturers of retail goods, for example, are acutely aware of the problems created by fakes, so might be willing to support a general campaign educating the public about the importance of buying the Real McCoy.

5

Conclusion

The fight against fake medicines has the advantage that many criminals involved are unlikely to have a particular commitment to this activity. At present it is simply an easy and convenient way to make money. By addressing the root causes that enable such profitable opportunities, their incentives can be diminished, thereby reclaiming the market for high quality medicines.

This paper suggests that the supply of fake drugs could be considerably reduced by:

1. Strengthening local institutions, in particular the rule of law
2. Governments intervening less in the pharmaceutical market
3. Better use of technologies for identity preservation

The most fundamental cause of the spread of fake drugs in less developed countries 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 trademarks and brands – thereby handing a free rein to counterfeiters. In this context, the stiffer criminal penalties called for by WHO and other bodies may actually entrench the corrupt symbiotic relationship between counterfeiters, lawmakers and officials.

Many existing licensing systems for pharmaceuticals in LDCs serve practically no purpose other than to restrict the sale of legitimate products manufactured by foreign companies. As such, they offer a boon to suppliers of fakes. However, we are cautious about the introduction of stronger and more rigorous regulations, since these are likely to add significantly to the cost and time it takes to bring new medicines to market, thereby providing further gaps in the market for fakers to exploit. And if such regulations are applied in an arbitrary and corrupt manner, they may end up being counterproductive; undermining rather than improving confidence in the pharmaceutical supply chain.

Although highly desirable from the perspective of wider economic development, bolstering the rule of law in LDCs is a long term and uncertain process. We must therefore consider the most effective steps that can be taken in the short-term. Happily, those in the best position to secure the integrity of branded pharmaceuticals (both patented and generic), the manufacturers, are already taking steps in this direction. 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 also have a role to play beyond improving the rule of law. Many government interventions in the pharmaceutical market have restricted supplies of quality medicines, driving up prices and simply leading to gaps in the market. These have then been exploited by purveyors of fake medicines. Governments could substantially reduce these problems by removing impediments to the supply of quality medicines, such as taxes, tariffs, price controls and arbitrary regulations.

Appendix

Statistics calculations

The World Health Organization has previously calculated that approximately 200,000 malaria deaths per annum could be prevented if the medicines available were of acceptable quality.

This figure was calculated using statistics from the Africa Malaria Report 2003, and a paper on the quality of antimalarial drugs in Africa. The calculations assumed that there were £1 million annual deaths from malaria, with only half of these victims being diagnosed and receiving any treatment at all. Of these half a million receiving treatment, a fifth were estimated to have been resistant to chloroquine and sulfadoxine-pyrimethamine, leaving 400,000 lives capable of being saved through treatment (given existing levels of coverage). The study asserted that, according to the research in The Quality of Antimalarials – A Study in Selected African Countries, up to half of antimalarial drugs in some areas were substandard, and therefore up to half the 400,000 preventable deaths were due to substandard products.

We believe this figure can now be considered conservative. First, resistance to chloroquine and sulfadoxine-pyrimethamine could be removed from the equation, due to the wider dissemination of artemisinin-based drugs. This alone would increase the figure to 250,000 deaths. Second, as explained on page X of this report, drug resistance is significantly exacerbated by fake drugs, with increasing levels of drug resistant malaria along the Thai-Cambodian border attributable to the widespread substandard drugs in that region. Many deaths from drug resistant strands of disease can therefore indirectly be attributed to fake drugs.

According to WHO data, there were 9.3 million new cases of tuberculosis in 2007. Global coverage of DOTS (Directly observed treatment, short course) is said to be 94 per cent, with half of untreated sufferers expected to die. Data on levels of fake tuberculosis drugs is scarce, yet one reliable study (Laserson, 2001) of six countries showed levels of fakes at 10 per cent. By these figures we assume that around 900,000 tuberculosis sufferers are at risk from fake drugs, half of whom (450,000) will die due to the ineffective treatment.

Our total figures for malaria and tuberculosis therefore show 700,000 deaths attributable to fake drugs. It must be noted that due to paucity of reliable data, these are rough, yet conservative, estimates.

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The outbreak of swine flu yet again brought fake medicines into the limelight, with Interpol warning of a quick spread in fake cures. Counterfeit and substandard medicines increasingly plague all corners of the world, causing death, suffering and provoking new drug resistant strands of disease.

Up to a third of medicines in poor countries are counterfeit, according to the UK's Department for International Development, while surveys in poor parts of the world show up to half of medicines are fakes.

This paper estimates that 700,000 suffers of malaria and tuberculosis alone die annually due to fake drugs. This is the equivalent of four fully-laden jumbo jets crashing every single day.

The root causes of the scourge of fake drugs must be understood in order to tackle the problem, with defective legal systems and government distortions of pharmaceutical markets largely to blame.

Fortunately a new wave of technologies can protect the identity of high quality medicines, and are sufficiently complex to make counterfeiting economically unviable. Combined with stronger trademark laws and lower barriers to high quality medicines, these technologies offer real hope to the world's poorest people.