



CONFERENCE REPORT AND BRIEFING

# OPINION FORMERS' CONFERENCE ON COUNTERFEIT MEDICINES

Perspectives and action

Held in London, 26 October 2009

Co-organised by the Wellcome Trust and  
the American Pharmaceutical Group



**wellcome**trust

## Opinion Formers' Conference on Counterfeit Medicines online

Visit [www.wellcome.ac.uk/counterfeits](http://www.wellcome.ac.uk/counterfeits) to access a selection of presentations given by speakers at the conference. Also available are short, filmed interviews with a number of the speakers (**Aline Plancon** of INTERPOL, **Paul Newton** of the Laos arm of the Wellcome Trust's South-east Asia Major Overseas Programme, and **Roger Bate** of the American Enterprise Institute for Public Policy Research) offering their perspectives on counterfeit medicines.

Information is also available on the APG website [www.apg.uk.com](http://www.apg.uk.com)

Published by the Wellcome Trust

Text: Ian Jones, Isinglass Consultancy

ISBN 978 1 84129 083 6

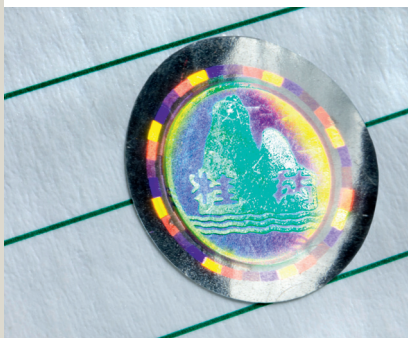
This is an open access publication and, with the exception of images and illustrations, the content may be reproduced free of charge in any format or medium, subject to the following constraints: content must be reproduced accurately, content must not be used in a misleading context; the Wellcome Trust must be attributed as the original author and the title of the document specified in the attribution.

### **Citing this report**

We suggest that you cite this report as follows:

Wellcome Trust, American Pharmaceutical Group. Opinion Formers' Conference on Counterfeit Medicines: Perspectives and action. London: Wellcome Trust; 2009.

# Preface



The Wellcome Trust's mission is to foster and promote research with the aim of improving human and animal health. Every year the Trust spends hundreds of millions of pounds on research that will ultimately provide medical benefits.

The American Pharmaceutical Group (APG) represents the major US-owned pharmaceutical companies that are based in the UK. The APG is committed to enhancing access to medicines throughout the world. About two billion people, one-third of the world's population, do not have access to essential healthcare services and medicine; many of them live in low-income countries. APG member companies are committed to enhancing access to medicines, particularly in these countries. They carry out R&D into new medicines for diseases disproportionately affecting developing countries and have developed product access programmes that provide medicines free, at cost or with significant discounts.

The illegal trade in counterfeit medicines is thus of great concern to both organisations, as well as to public health authorities and patients.

In response, the APG and the Wellcome Trust worked together to organise an opinion formers' conference on counterfeit medicines in October 2009, bringing together stakeholders. The principal aims of the conference were to draw out consensus on the key issues and, most importantly, to identify ways in which the problem could be tackled. We would like to thank all attendees for making it such a stimulating and constructive forum.

This report is a summary of the meeting, capturing what was commonly agreed upon and what next steps now need to be taken. Our hope is that it acts as a concise summary of this important area and a spur to action by all those who can make a difference nationally or internationally.

Handwritten signature of Sir William Castell.

**Sir William Castell**  
Chairman, Wellcome Trust

Handwritten signature of Dr David Brickwood.

**Dr David Brickwood**  
American Pharmaceutical Group  
and Vice-President of Government  
Affairs, Johnson & Johnson



# Executive summary

- Counterfeit medicines represent a major threat to public health, particularly in developing countries.
- The extent of the problem is difficult to judge because of a lack of hard data. It is likely that around 1 per cent of drugs in developed countries, and 10–30 per cent of drugs in developing countries, are counterfeit; in regions of South-east Asia, the proportion of counterfeit antimalarials is even higher.
- The international trade in counterfeit medicines amounts to billions of dollars (estimated at US\$75bn [£45bn] for 2010<sup>1</sup>); it is a highly sophisticated and well-organised criminal activity with ready access to global markets.
- It is an attractive market because of its size and inadequate enforcement and deterrents.
- Efforts to tackle the trade in counterfeit medicines have been compromised by a confusion over definitions and the relationship between counterfeit medicines and generic medicines, and related intellectual property issues.
- The World Health Organization (WHO) definition of counterfeit medicines emphasises deliberate and fraudulent mislabelling of products. Counterfeit medicines evade all licensing and regulatory systems; unlike genuine branded and generic products, counterfeit medicines cannot be easily traced back to their manufacturers.
- Counterfeit medicines are a subset of substandard drugs. Genuine drugs may also be substandard, but can usually be dealt with by different mechanisms (e.g. education, regulation).
- It is in the interests of patients and all stakeholders to ensure that counterfeit medicines do not infiltrate markets.
- Internationally, efforts to tackle counterfeit medicines have been led by a WHO-associated body, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).
- Successful operations to tackle counterfeit medicines have relied upon international and multiagency cooperation, involving national and international law enforcement agencies, regulatory authorities and technical experts.
- Future action is required from multiple stakeholders, including the pharmaceutical and generic medicines industries, national governments, NGOs, enforcement agencies, customs and trade organisations, national health systems and patients.

## Introduction

**Medicines have to pass through a rigorous series of clinical trials to prove their efficacy and safety. Once licensed, production is stringently regulated to ensure that drugs are manufactured to a uniformly high quality. These systems are essential if patients are to have confidence in the medicines they are prescribed. By bypassing these systems, the manufacturers of counterfeit medicines are not only illegally profiting from others' endeavours – they are also putting patients' lives at risk.**

Counterfeits have been of concern ever since medicinal products were first used. Shortly after cinchona bark was introduced as a treatment for malaria in the 17th century, adulteration with other barks undermined public confidence. Similarly, when its active ingredient, quinine, was produced in the early 1800s, it too was counterfeited. The US government accused Britain of supplying fake quinine as an underhand ploy to sabotage the USA's war with Mexico.

In 1913, Carl Alsberg of the US Bureau of Chemistry launched "a stubborn campaign against fraudulent patent medicines". He said: "Fake drugs do incalculable harm to the misguided sick, who grasp at the false hopes they hold on to." Concern about trade in counterfeit medicines thus has a long history. In the modern era, it has evolved into an organised global criminal industry worth billions of dollars.

## What is a counterfeit medicine?

The World Health Organization (WHO) has developed a definition for counterfeit medicines that emphasises fraudulent imitation:

### WHO definition of counterfeit medicine

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

The issue of counterfeit medicines has sometimes been clouded by confusion with **generic medicines** and **substandard medicines**.

**Generic medicines** are copies of patented (branded) pharmaceuticals. They may legitimately be produced when patent protection has expired or under regulatory approval mechanisms during national medical emergencies when the patent is active.

Crucially, though, generic medicines are manufactured to established quality standards and the identity of manufacturers can always be determined from the labelling of products.

**Counterfeit medicines** are quite different. They are produced fraudulently, by manufacturers who are deliberately setting out to deceive customers and disguise the origins of products. They may contain no active ingredients or, worse still, they may contain ingredients that are harmful. They are packaged to look like genuine pharmaceuticals, and it is hard to trace a product back to its original manufacturers.

**Substandard medicines** are low-quality products whose medicinal value has potentially or definitely been compromised. Because counterfeit medicines are produced outside all regulatory frameworks, they are by definition substandard. However, genuine medicines may also be substandard if they have not been manufactured to sufficiently high standards or stored properly, or are out of date. Although genuine but substandard drugs are a significant problem in many developing countries, they can generally be dealt with through regulatory processes or education without resorting to methods needed to tackle criminal activity. The origin of a genuine but substandard drug is normally identifiable, so that a reliable recall process can be initiated.

Overall, counterfeit medicines are probably less common than genuine but substandard ones. However, the health risks associated with counterfeit medicines are considerably greater,

As counterfeiters are passing off their products as someone else's, they are typically infringing trademark; counterfeit medicines are one strand of a wider 'pirating' industry. In practice, trademark infringement can be used to counter trade in counterfeit medicines.

Packaging is the easiest way to identify counterfeit medicines. Poor-quality or mislabelled packaging (or even glaring mistakes: one counterfeiter mis-spelled 'tablet') may indicate that a product is counterfeit. However, counterfeiters also produce highly sophisticated packaging, faking key identifiers such as batch numbers. Soon after manufacturers introduced a holographic seal on packets of antimalarials in South-east Asia, at least 16 different types of fake hologram had been developed.

If fake packaging is not a giveaway, chemical analysis may be needed to detect fakes. This generally requires sophisticated chemical analysis facilities, which may not be routinely available in many parts of the world.

## What is the scale of the problem?

Given its clandestine nature and a lack of effective reporting structures, it is difficult to obtain a clear estimate of the scale of the counterfeit medicine problem globally. Nevertheless, the evidence suggests that it is a significant problem and is not receiving the attention it deserves.

Few opportunities exist for counterfeit medicines to enter the medical supply chain in developed countries with well-established healthcare systems. It is estimated that around 1 per cent of medicines may be counterfeit. Although few hard data exist, drugs sourced directly over the internet are much more likely to be fake. Research carried out in 2008 by the European Alliance for Access to Safe Medicines<sup>2</sup> suggests that over 60 per cent of prescription medicines supplied over the internet are fake.

Counterfeit medicines are a much greater problem in less developed countries. However, reliable data are scarce. In South-east Asia, a study found that more than half of antimalarials

were fake,<sup>3</sup> while a random survey of pharmacies in Laos revealed that 88 per cent of those sampled were selling fake artesunate.<sup>4</sup>

Other studies have found evidence for significant quantities of fake or substandard medicines. Substandard antimalarials accounted for 35 per cent of samples in six African countries,<sup>5</sup> while in India 12 per cent of antimalarial, antibiotic and anti-TB drugs were low-quality.<sup>6</sup>

Given that the situation is likely to vary widely from country to country and region to region, it is difficult to extrapolate from these figures to a reliable global estimate. Suggestions that 10–30 per cent of all medicines across all developing countries are fake are plausible but difficult to verify. Even so, given that



Packaging for genuine (left) and counterfeit (right) artesunate antimalarial tablets. Wellcome Images

and hence their overall impact is likely to be higher. Moreover, they are also a growing problem.

The WHO definition emphasises that both generic and branded products can be counterfeited. Indeed, intellectual property can be divorced entirely from discussion of counterfeit drugs. Although trade and intellectual property rights are important factors affecting access to pharmaceutical products, they can be considered separately from the criminal production and distribution of counterfeit medicines.

counterfeit medicines are so dangerous, anything other than a very small percentage creates a very large problem.

From a manufacturer's point of view, counterfeit medicines represent a significant loss of earnings. For example, Pfizer reports that global authorities seized more than 8.6 million counterfeit Pfizer tablets in 2007. Most companies can consider counterfeit manufacturers collectively to be their biggest competitor.

## Why is there a problem with fake drugs?

There are several reasons why fake drugs have become such an important issue.

**High demand, limited resources:** In many parts of the world there is a high demand for medicines, which cannot always be met by official healthcare systems. In addition, where resources are limited, consumers will look to secure low-cost alternatives to genuine products. Both factors promote black-market sales and a ready outlet for counterfeit medicines.

**High margins:** Counterfeit drugs can be manufactured cheaply and sold at considerable profit.

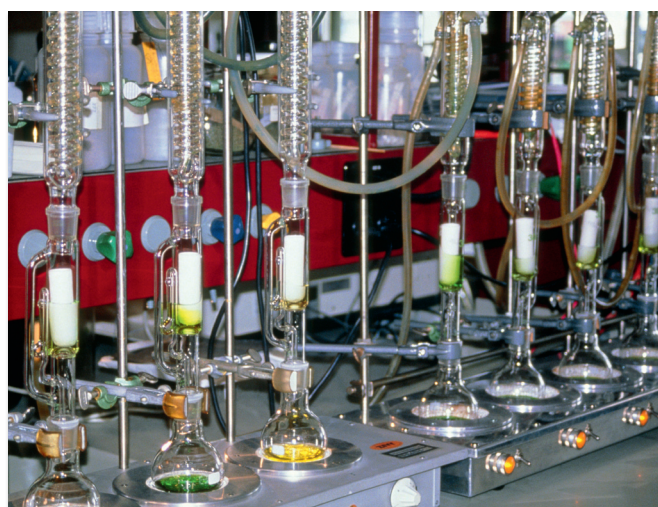
**Inadequate disincentives:** Selling counterfeit medicines is less risky than trade in illicit drugs, and the consequences of being caught are usually far less severe.

**Globalisation:** Counterfeiters are highly sophisticated operations tapping into legitimate global trade routes to distribute their products.

**Denial:** Some countries or institutions have been unwilling to accept that they have a problem with counterfeit medicines.

**Respect of trademark:** In some countries or regions, there is little respect for trademark or copyright, promoting pirating activities (including counterfeiting of medicines).

**Enforcement:** In less developed countries, the infrastructure necessary for detection and enforcement is often weak. Many



Above: Manufacturing counterfeit medicines is low-cost so drugs can be made cheaply and sold at a considerable profit. *Andy Crump, TDR, WHO/SPL*

countries do not have resources to put into enforcement, or do not consider it a priority. Few international agencies devote sufficient resources to the trade – INTERPOL is the only organisation with staff dedicated to counterfeit medicines.

**Legal systems:** Definitions of counterfeiting set a very high burden of proof, making it difficult to collect enough evidence for successful prosecutions. In many countries, regulatory and legal systems are inadequate or too slow to respond.

**Whistleblowing:** There is little incentive for whistleblowers to highlight trade in counterfeit medicines – in fact, it can put their own livelihoods (or even lives) at risk.

**The internet:** The internet provides a new route of distribution that is hard to police and regulate. While not all online pharmacies deal in counterfeits, many inadvertently do.

**Repackaging:** Liberal rules on repackaging across borders and informal supply of medicines outside their original packaging can make it difficult to keep track of medicines.

**Complex supply chains:** Legitimate drug manufacturers know which distributors they supply stock to. However, farther down the supply chain, drugs may be traded repeatedly, making it difficult to follow the movement of products. The supply 'chain' more closely resembles a network.

**Corruption:** Efforts to deal with counterfeit medicines may be hampered by corruption inside countries – either high-level, when the trade in medicines is associated with politically powerful individuals, or at a local level, when corrupt staff with regulatory or enforcement roles compromise enforcement programmes.

## Who is tackling the problem?

Globally, a lead role has been taken by a WHO-associated body, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). While not formally part of the WHO, IMPACT is chaired by a WHO representative and its secretariat is supported by the WHO, emphasising its focus on public health. Its recommendations are reviewed by WHO expert committees and may become official WHO policy. It is preparing major reports on counterfeit medicines, discussion of which is planned for the 2010 World Health Assembly.

IMPACT's principal aim is to enhance the ability of WHO member countries to identify and tackle trade in counterfeit medicines. Its work is being taken forward by five working groups, covering legislative and regulatory infrastructure, regulatory implementation, enforcement, technology and communication. IMPACT also collaborates with enforcement agencies, particularly INTERPOL, to investigate criminal activities.

INTERPOL has organised operations in South-east Asia, Africa and on the internet. Operation Jupiter, a multiagency operation, led to the closure of a drug manufacturing site in China and several prosecutions (see Box 1). In Uganda and Tanzania (and more recently Kenya), it has trained multiagency groups to identify and tackle trade in counterfeit medicines.



## BOX 1

### Operation Jupiter

**Operation Jupiter was based on a partnership between INTERPOL, the WHO, a team of forensic scientists and Paul Newton from the Wellcome Trust's Major Overseas Programme in Laos.**

In a unique 'forensic pharmacological' collaboration, six laboratories undertook a barrage of tests to analyse the composition of counterfeit antimalarials – and identify their possible origins – by assessing their chemical composition and analysing gases around the tablets in blister packs and even the pollen embedded in the tablets during manufacture.

The presence of a particular type of calcite and pollen flora in the tablets

suggested that at least some of the counterfeits were made in southern China. Armed by INTERPOL with these findings, Chinese authorities made arrests in China's Yunnan Province in 2006. The suspects are alleged to have traded 240 000 blister packs of counterfeit artesunate.

Following Operation Jupiter, INTERPOL's Operation Storm led to 200 raids, 27 arrests and the seizure



of 16 million pills in seven countries in South-east Asia. In Africa, Operation Mamba targeted counterfeiters in Tanzania and Uganda, training multiagency teams from police, customs and drug enforcement agencies. Several hundred sites were investigated in the two countries and many pharmacies selling illegal medicines were closed down.

Operation Pangea targeted internet distributors. In an international day of action in November 2008, premises thought to house illegal internet distribution centres were raided and several sites were closed down.

Newton PN et al. A collaborative epidemiological investigation into the criminal fake artesunate trade in South East Asia. *PLoS Med* 2008;5(2):e32.

Left: Dr Paul Newton.  
*J Dimock/Wellcome Images*

Customs operations can effectively block trade in counterfeit medicines. The EU is taking strong action to crack down on this trade, as part of its 'Pharmaceutical Package' initiative launched in 2008. In December 2008, a two-month 'Medi-Fake' programme led to the seizure of 34 million illegal pills, including the largest single haul – a seizure of 1.6m counterfeit painkillers and 0.6m counterfeit antimalarials at Brussels Airport.

More controversially, Dutch customs officers at Schiphol Airport seized generic medicines manufactured in India and bound for Brazil. The medicine in question, Losartan, used to treat high blood pressure, is not patent-protected in either India or Brazil but is in the EU. The episode raised fears that crackdowns could be used to block the movement of generic medicines to less developed countries.

However, while there is a need to ensure that regulations and enforcement do not inhibit legitimate trade in medicines, branded or generic, this issue needs to be tackled as part of international trade and intellectual property discussions. There is a separate need to protect patients in all countries from counterfeit medicines. Notwithstanding the isolated Schiphol case, customs operations are a key component in the battle with counterfeiters and need to be part of multiagency teams tackling the counterfeit medicine trade.

While counterfeit medicines are part of a wider piracy industry, and trade-related mechanisms can be used to counter it, trademark infringement cannot be the only way that the problem is tackled. Counterfeit medicines do not necessarily infringe trademarks. And a fake drug is potentially far more serious than a fake T-shirt or DVD. Customs and trade control will be important but will not offer the complete solution. This is particularly true in countries with large and porous borders, where illegal movement of products can readily circumvent official trade routes.

## What problems are associated with the trade in counterfeit medicines?

The most obvious problem is that counterfeit medicines contain no (or very little) active ingredient, so will provide no benefits to a patient. For drugs treating serious conditions, this may result in serious harm or even death. Worse still, they may contain ingredients that are themselves harmful. In 2001, use of diethylene glycol in paracetamol preparation led to some 200 000 deaths in China; in the USA, fake heparin may have led to more than 60 deaths in 2008. Deliberate production of fake drugs can thus be equated with manslaughter, possibly even murder.

As well as these immediate consequences, counterfeit medicines cause other problems. Some fake antimalarials contain small amounts of active product, in order to fool chemical detection systems. These are highly dangerous, as exposure to low levels of a drug promotes the development of resistance. This is a particular concern in malaria, where signs of resistance to the leading class of antimalarial drugs, artemisinin-based compounds such as artesunate, have been seen in South-east Asia.<sup>7</sup> Although this may be linked primarily to the use of artesunate monotherapy, the existence of counterfeit medicines with low levels of artesunate undoubtedly increases the risk that resistance will develop.

Over the longer term, the existence of counterfeit medicines erodes the trust that must exist between drug manufacturers, suppliers and the general public. The public rightly expect that



Above: Public engagement is key so that patients choose reputable suppliers of drugs. C Penn/Wellcome Images

medical products have been tested and manufactured in such a way as to maximise health benefits and minimise harm, and a company's visual identity should reassure consumers that their interests are being protected. The existence of counterfeit medicines undermines this relationship. This is of concern to both the traditional pharmaceutical and generic industries.

## How can the counterfeit medicine trade be tackled?

Trade in counterfeit medicines is a complex issue that will not have simple solutions. Successfully combating the trade will call for concerted action from a variety of groups – indeed, it will not be halted unless all bodies take responsibility to act within their spheres of interest.

**Capacity development:** Many less developed countries require practical support to enable them to set up the infrastructures needed to identify counterfeit medicines, including equipment and people with the appropriate technical skills. This could build on the work on IMPACT and organisations such as MeTA (the Medicines Transparency Alliance) and the US Pharmacopeia, which have supplied 'mini-labs' to a range of countries to enable testing of drugs.

**Regulatory/legal frameworks:** In some countries, the regulatory and legal frameworks are inadequate and need to be strengthened. However, such frameworks are necessary but not sufficient: regulation can be successful only if enforced effectively.

**Enforcement:** Successful enforcement calls for collaboration between different agencies, such as customs officials, law enforcement agencies and drug regulatory bodies. Often these bodies have not previously worked together or are inadequately resourced. The success of INTERPOL's training programmes in East Africa suggests a model by which joint working can be accomplished.

**Political will:** Very little will be achieved unless countries demonstrate the political will to tackle counterfeit medicines. Countries' leaders need to signal their commitment, and make intervention measures a high priority. Politicians in countries producing counterfeit medicines need to clamp down on illicit drug production.

**Public engagement:** The public have a key role to play. There is an education need, to encourage patients to choose reputable suppliers of drugs and to be aware of the risks of counterfeit medicines. New technologies such as mobile phones may also enable consumers to act as monitoring agents, checking the validity of medicines by text messaging (as happens in Kenya). The public can also apply political pressure, encouraging politicians to take the matter more seriously. Social attitudes may also be a way of discouraging



people from contributing to the trade in counterfeit medicines. Ideally, citizens should consider it a social responsibility to alert authorities to counterfeit medicines.

**Supply chain management:** The pharmaceutical and generic industries could both do more to ensure that products can be traced through the supply chain to the ultimate end user, the patient. There is potential for a variety of new technologies to be used in this area (Box 2).

**Technological innovation and practical deployment:** Currently, detection of counterfeit agents typically requires sophisticated laboratories and complex equipment, although some devices can be routinely used in the field with a minimum of training. There is an urgent need for cheap, reliable and portable devices to support enforcement in the field.

**Regional cooperation:** Each country will need its own internal systems, but there is also a need for regional cooperation – particularly where goods can easily bypass border controls. A network spanning several countries in the Greater Mekong Subregion, for example, shares information about antimalarial drug quality. Shared resources – such as libraries of packaging materials and the results of chemical analyses, which can reveal the sources of counterfeits – can help countries to tackle counterfeit trade jointly.

**Openness and communication:** A great deal of secrecy has surrounded counterfeit medicines. Neither pharmacies nor companies want to be associated with ineffective drugs, which will damage reputations and affect sales of genuine products. Countries may also be unwilling to acknowledge that they have a problem. Without full sharing of information, however, it will be difficult to coordinate and prioritise action.

**Corruption:** Coordinated attempts to eliminate trade in counterfeit medicines will be severely hampered by corruption. Governments must signal a commitment to protect their citizens by rooting out officials or business leaders involved in manufacture or trade of counterfeit medicines. Agencies must ensure that their enforcement activities are not compromised by corrupt officers.

**Advocacy:** Some bodies can play a role in raising awareness of the impact of counterfeit medicines. Apolitical bodies with philanthropic missions can act as ‘honest brokers’ and catalyse action. There is a need to ensure that the subject is discussed at the appropriate international forums. Potentially, some form of international convention could emphasise the importance of the issue.

**Engagement with other stakeholders:** Many other groups can play a significant role in stemming the tide of counterfeit medicines. Pharmacies, for example, could have an important monitoring role, but will need to be incentivised. Donor agencies are major purchasers of drugs and could ensure that their funds are used to buy only authentic products. One NGO unwittingly purchased 100 000 antimalarial tablets that it later discovered were fake.

**Research/data gathering:** Although there is a growing body of research on counterfeit medicines, the number of academic papers remains small and the full extent of the problem remains unclear in much of the world. Very few random sampling studies have been carried out. More

research may be needed to quantify the effects of trade in counterfeit medicines, to support advocacy and to inform policy making. Without good data, it is also hard to plan education or intervention campaigns or to know what works. There is certainly a need for testing and validation of devices for assessing drug quality in the field. Health systems research may also help to identify ways in which prevention, monitoring and enforcement can be integrated into healthcare delivery.

## BOX 2

### Tracking medicines

**A possible technological solution, suitable for developed countries with well-established medicine-dispensing infrastructures, has been developed by Aegate Ltd and is being used in Belgium, Greece and Italy. Each pharmaceutical package dispensed in these countries – branded and generic – is uniquely labelled. The label is read at the final point in the supply chain, when a pharmacist dispenses medicines to a consumer. As the product is being scanned, the unique identifier is checked to ensure that the product is genuine, not out of date and has not been recalled, a process completed in less than a second.**

To date, around 0.8 per cent of packages have turned out to be suspect in these three markets. An illustration of this system's success was an incident in Belgium when a supposedly unique label appeared 76 times in one day. On investigation, the medicines were found to be genuine – the problem was traced to a printing error.

This system has the advantage that it piggybacks on existing practices and is invisible to the pharmacist (unless a problem is detected). It relies on a dispensing infrastructure, which may not exist in less developed countries. In an alternative approach, mobile phones can be adapted so their cameras act as barcode readers. It takes slightly longer, around five seconds, to return information. This system can be used by groups such as NGOs to check batches of medicines. Although flexible, it cannot (unlike the pharmacy system) confirm that the unique identifier has not been seen before.



# What technological solutions are available?

Broadly speaking, there are two ways in which technology can ensure that patients receive genuine medicines. First, spot checks at the point of dispensing, or at other key points of the supply chain, can be used to authenticate medicines. Secondly, closed-loop 'track-and-trace' or 'pedigree' systems can be used to monitor a product from production to consumption.

Spot authentication using chemical analysis can provide rigorous assessments of quality but is not always practical, and puts the onus on 'downstream' stages of the supply chain to detect fakes (it also does not prevent the counterfeiter from making money). Barcoding of packaging can empower consumers. In Kenya, for example, patients can use texting to check the authenticity of medicines.

More automated, centralised track-and-trace systems can be used when a dispensing infrastructure is in place. This could be based on 2D barcode or RFID technology, or even more innovative approaches such as marking of individual pills. Although several systems are in use in developed countries, they have yet to become standard practice. Approaches that piggyback on existing systems could be particularly powerful (Box 2).

## Conclusions

It is striking that there is so little disagreement about the trade in counterfeit medicines. It is universally seen as a social evil that is both dishonest and potentially deadly. It benefits no one except criminals. It is in the interests of everyone – patients, the R&D-based and generic pharmaceutical industries, and governments – to solve the problem.

Progress may have been slow in the past because of a lack of awareness of the extent of the problem. In addition, there has been an unfortunate conflation with the production of generic medicines and the protection of intellectual property rights. If these entirely distinct issues can be separated, it should be possible to make more rapid progress.

Nevertheless, it must be acknowledged that trade in counterfeit medicines is a complex issue impinging on many aspects of global trade, law enforcement and public engagement. As with all complex problems, there will be no simple or short-term solutions. The answer will be for all parties to work collaboratively towards common goals – the most important of which is the enhanced access of patients to potentially life-saving medicines.

## References

- 1 Pitts P et al. 21st Century Health Care Terrorism: The perils of international drug counterfeiting. New York: Center for Medicine in the Public Interest; 2005. [www.cmpi.org/uploads/File/21st-Century-Terrorism.Report.pdf](http://www.cmpi.org/uploads/File/21st-Century-Terrorism.Report.pdf) [accessed 11 November 2009].
- 2 European Alliance for Access to Safer Medicines. The Counterfeiting Superhighway: The growing threat of online pharmacies. Surrey: Malcolm Group Ltd; 2008. [www.eaasm.eu/Media\\_centre/EASAM\\_reports](http://www.eaasm.eu/Media_centre/EASAM_reports) [accessed 11 November 2009].
- 3 Dondorp AM et al. Fake antimalarials in Southeast Asia are a major impediment to malaria control: multinational cross-sectional survey on the prevalence of fake antimalarials. *Trop Med Int Health* 2004;9(12):1241–6.
- 4 Sengaloundeth S et al. A stratified random survey of the proportion of poor quality oral artesunate sold at medicine outlets in the Lao PDR – implications for therapeutic failure and drug resistance. *Malar J* 2009;8:172.
- 5 Onwujekwe O et al. Quality of anti-malarial drugs provided by public and private healthcare providers in south-east Nigeria. *Malar J* 2009;8:22.
- 6 Bate R et al. Pilot study of essential drug quality in two major cities in India. *PLoS One* 2009;4(6):e6003.
- 7 Dondorp AM et al. Artemisinin resistance in *Plasmodium falciparum* malaria. *N Engl J Med* 2009;361(5):455–67.

## Further reading

WHO General information on counterfeit medicines: [www.who.int/medicines/services/counterfeit/overview](http://www.who.int/medicines/services/counterfeit/overview) [accessed 11 November 2009].

International Medical Products Anti-Counterfeiting Taskforce. Counterfeit Drugs Kill! IMPACT; 2008. [www.who.int/impact/FinalBrochureWHA2008a.pdf](http://www.who.int/impact/FinalBrochureWHA2008a.pdf) [accessed 11 November 2009].

Bate R. Making a Killing: The deadly implications of the counterfeit drug trade. Washington, DC: American Enterprise Institute for Public Policy Research; 2008. [www.aei.org/book/930](http://www.aei.org/book/930) [accessed 11 November 2009].

Harris J, Stevens P, Morris J. Keeping it Real: Protecting the world's poor from fake drugs. International Policy Network; 2009. [www.policynetwork.net/health/publication/keeping-it-real-protecting-worlds-poor-fake-drugs](http://www.policynetwork.net/health/publication/keeping-it-real-protecting-worlds-poor-fake-drugs) [accessed 11 November 2009].

Taylor D, Craig T. Trading in False Hopes: A review of medicines counterfeiting as a world-wide threat, and the need for strengthened international collaboration to reduce pharmaceutical crime and promote global health. School of Pharmacy, University of London; 2009.

Kelesidis T et al. Counterfeit or substandard antimicrobial drugs: a review of the scientific evidence. *J Antimicrob Chemother* 2007;60(2):214–36.

# Speakers and roundtable participants

## Speakers

### **Roger Bate**

Fellow at the American Enterprise Institute for Public Policy Research

### **Brian Elliott**

Executive Director of the Medicines Transparency Alliance (MeTA) Secretariat

### **Ron Guido**

Vice President of Global Brand Protection at Johnson & Johnson

### **Julian Harris**

Research Fellow at the International Policy Network

### **Hans Hogerzeil**

Director of Essential Medicines and Pharmaceutical Policies at the World Health Organization

### **Paul Newton**

Head of the Wellcome Trust–Mahosot Hospital–Oxford Tropical Medicine Research Collaboration in Laos.

### **Aline Plancon**

INTERPOL-IMPACT Project Manager, INTERPOL

## Roundtable participants

Speakers were joined by a number of other experts on a concluding roundtable session to establish areas of agreement, and define steps forward and priorities for the future.

### **Andrew Jack (Chair)**

Pharmaceuticals Correspondent at the *Financial Times*

### **Michael Boyd**

Director General of the International Federation of Pharmaceutical Manufacturers & Associations, Geneva, and Vice President of Public Affairs International, Schering-Plough Corporation

### **Sir William Castell**

Chairman of the Wellcome Trust

### **Pedro Velasco Martins**

Principal Administrator in charge of IPR Enforcement at the European Commission DG for Trade

### **Sir Mark Walport**

Director of the Wellcome Trust

### **Hashim Yusufu**

Director of Enforcement, National Agency for Food and Drug Administration and Control, Nigeria



## American Pharmaceutical Group

The American Pharmaceutical Group (APG) was established in 1985 to improve understanding of the industry, and the healthcare contribution of the American companies in particular, among the UK Government, Parliament and interested stakeholders.

The APG works closely with the UK industry's trade body, the Association of the British Pharmaceutical Industry, but with the US being the most competitive market for medicines in the world and accounting for over half of the developed world's R&D, the APG is able to add a special perspective.

The APG Workstream Secretariat  
40 Long Acre  
London WC2 9LG, UK

**T** +44 (0)20 7395 7175  
**F** +44 (0)20 7395 7182  
**E** [APG@fleishman.com](mailto:APG@fleishman.com)  
[www.apg.uk.com](http://www.apg.uk.com)

## Wellcome Trust

The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending over £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.

For further information, please contact:

David Evans  
Wellcome Trust  
Gibbs Building  
215 Euston Road  
London NW1 2BE, UK

**T** +44 (0)20 7611 8514  
**F** +44 (0)20 7611 8742  
**E** [d.evans@wellcome.ac.uk](mailto:d.evans@wellcome.ac.uk)  
[www.wellcome.ac.uk/counterfeits](http://www.wellcome.ac.uk/counterfeits)