The role of the Pharmaceutical Security Institute
Exploring unlawful trade
Patients – the last barrier to harm
Good balance of speakers with a truly global flavor. Good for raising awareness of the issues and fostering dialogue and actions.

Jim Rittenberg, authentix

Well organised, presentations very good quality.

Rebecca Nordor, Ministry of Health, Ghana

The Forum delivered frank and candid discussions.

Gerard Norris, African Centre for HIV

Good conference, great speakers!

David Schoneker, Colorcon

Powerful stuff!

Martin Aartsen, Merck

This is ideal for pharmaceutical companies.

Glaxosmithkline

Global Forum on Pharmaceutical AntiCounterfeiting

Making AntiCounterfeiting Policy Effective

March 13-15, 2007

Prague, Czech Republic

Attended by health professionals, regulators, patients’ groups, pharma companies and anti-counterfeiting product and service providers.
# CONTENTS

**Features**

4 Working together for a solution
Astrid Mitchell introduces us to the third Global Forum on Pharmaceutical AntiCounterfeiting

5 Countering the counterfeiter
Who needs to be involved in finding a solution to the problem of fake and diverted drugs? Ian Lancaster explains

6 A deadly trade
Peter J Pitts paints a picture of the global pharmaceutical counterfeiting problem

8 Acting on evidence
Pharmaceutical companies have joined forces to form the Pharmaceutical Security Institute. Ashley How describes its initiatives

10 ‘Grey’ imports, diversion, parallel trade and counterfeits
Graham Satchwell explains the world of unlawful trade in pharmaceuticals, focusing on the dangers in the UK supply chain

13 Healthcare’s true stakeholders
Patients can and should play a key role in the fight against counterfeit drugs, says Jim Thomson

14 The counterfeiting and anticounterfeiting of artemisone
The Wellcome Trust has undertaken an in-depth investigation into counterfeit artemisone in South East Asia. Ian Lancaster and Paul Newton report

**Industry Focus**

16 Up close and personal: looking beyond RFID
Dominic Griffiths describes the benefits of unique image tablets, an on-product anticounterfeiting solution

18 Mass serialisation holography for product protection
Mass serialisation holography has many advantages over traditional techniques, explain Joachim Suesse and Claus Grobe

21 COMPANY PROFILES

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**PHARMACEUTICAL ANTICOUNTERFEITING**

A supplement to Scrip World Pharmaceutical News in partnership with Reconnaissance International

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Introduction

Pharmaceutical counterfeiting and diversion is a global menace. It threatens not just livelihoods and company profits, but critically, lives as well. It is estimated that one in 20 pharmaceutical products on the market are fake, rising to one in three in some developing countries.

Just as the problem is global, so are the solutions. And it is only by working together can government agencies, law enforcement, public health and regulatory bodies, patient care organisations and the pharmaceutical industry itself develop practical countermeasures to prevent the manufacture of counterfeit and substandard products and the distribution of these to the most vulnerable members of our societies - the ill and the incapacitated - in developed and developing countries alike.

Such countermeasures include legislation and regulation, protection and identification, detection and enforcement - none of which will be effective in isolation, and all of which are carried out by different stakeholders. Bringing these stakeholders together to discuss and implement practical solutions is a fundamental necessity for effective action, and the first and second Global Forums on Pharmaceutical AntiCounterfeiting, held in Geneva in 2002 with the World Health Organisation (WHO) and in Paris in 2005 respectively, were a major step forward in this respect.

In the two years since the second Global Forum on Pharmaceutical AntiCounterfeiting, we have seen a very welcome increase in the attention being paid to counterfeit pharmaceuticals. The public sector is paying more attention to the problem, epitomised perhaps by the Council of Europe's extended investigation. The pharmaceutical industry too is identifying ways to tackle this scourge. PhRMA in the USA has launched its Safe Medicines initiative and EFPIA in Europe is examining the best ways to protect its members' products. The WHO's new IMPACT initiative, meanwhile, combines the resources of the public and private sectors to develop a cohesive new approach to the problem.

The developing world is also paying more attention to this problem. In India there are new government and industry initiatives; China is doing more to protect its citizens, and in Africa the drug regulators are adopting more stringent policies, sometimes banding together for greater effectiveness.

And effectiveness is now the key issue for all these parties. What needs to be done - and how - to properly tackle this problem, in hospitals, clinics, pharmacies, border posts and ports?

These are the questions to be addressed at the third Global Forum on Pharmaceutical AntiCounterfeiting. Here, the regulators, manufacturers, suppliers and enforcement agencies alike will consider a range of anticounterfeiting policies - many of them emerging from discussions at previous Global Forums.

We look forward to seeing you there.

The third Global Forum on Pharmaceutical AntiCounterfeiting will take place on March 13-15, 2007 in Prague, Czech Republic.

Astrid Mitchell announces the third Global Forum on Pharmaceutical AntiCounterfeiting

Working together for a solution
Countering the counterfeiter

Ian M Lancaster, introduces us to one of the pharmaceutical industry’s biggest problems – and tells us who can offer solutions

The global nature of the pharmaceutical industry means that counterfeiting is now a worldwide problem. Prescription medicines, OTC or self-medication remedies, traditional remedies, vaccines, injectables and surgical implants are all known to have been counterfeited somewhere, sometime in the past few years.

Counterfeiting is a pernicious crime. It would be good to be able to say that it can be prevented by the judicious and committed application of an anticounterfeiting strategy, but unfortunately the criminals are too well-organised and the crime is too lucrative for there to be much hope of that happening. Some criminal elements may be deterred, but there will always be those who believe they can get away with it, and whose disregard for human life and determination to build their own bank balance is such that they will continue to produce fake pharmaceuticals. The cost:reward ratio is too much in their favour.

So, for the foreseeable future at least, the focus of those involved in pharma anticounterfeiting must be the detection of fakes before they reach the patient. This requires the introduction and implementation of a cohesive and comprehensive strategy that engages many participants. These include all those involved in the production, distribution and supply of pharmaceutical products: the brand-owners and the manufacturers (not always the same entity); importers, distributors and wholesalers; retail and hospital pharmacists and self-medication shops, as well as doctors and nurses. Even patients have a critical role: they, of course, have more at stake than others listed here, and they also have the ability to notice variations in a medicine that they take regularly for a chronic condition. Many cases of fake medicines have surfaced because a patient reported that their new prescription was “not quite right” – it tasted different, felt different on the tongue, or the packaging looked different.

There are two other groups that have a vital role to play in preventing fake pharmaceuticals from reaching the patient, even though they are not directly involved in the supply chain: law enforcement agencies and the authentication and anticounterfeiting service providers.

Three separate law enforcement agencies are involved in healthcare: customs (carrying out inspections at ports and border posts); police (and in some countries, specialist consumer protection agencies); and drug regulatory agencies (DRAs).

The role of the law enforcement agencies is to detect fake medicines before they reach the pharmacist or patient, and to investigate cases of counterfeits, hopefully to the point of arrest and indictment of those responsible. Their vigilance and efficacy will help to deter the criminals; the function of the authentication and anticounterfeiting providers is to make the job of detection as simple and as effective as possible.

In pharmaceuticals, the manufacturer will select the authentication system or device that will be used on its products. Ideally, manufacturers will consult with DRAs to identify a system that works well for both the manufacturer and the inspectors. Of course, there is a tension between the desire to minimise costs and the need to maximise the efficacy of the inspection process, but fortunately there are authentication systems that do not add more than fractions of a cent to costs.

The authentication process is at the heart of combating fake pharmaceuticals. It is of course important that there is a legislative regime in place in each country that makes it an offence to counterfeit medicines and to infringe intellectual property rights; it is equally important that the law enforcement agencies – especially DRAs – are committed to and adequately resourced for the fight against fake medicines, in order to implement this legislative regime. Pharmaceutical manufacturers also need to be committed to combat the counterfeiting of their products, and to work with other producers where appropriate to combat counterfeiting in general. The judiciary must also recognise the heinous nature of this crime, and sentence accordingly.

As important as these factors are, they depend on the ability to detect fake pharmaceuticals. This in turn requires investigative intelligence, corporate monitoring of sales patterns and the application of authentication systems appropriate to each product and the distribution procedures in each country. There needs to be the will and the way – the will is demonstrated through a committed DRA implementing a stringent legislative regime, the way is through intelligence and detection.

If these measures are applied effectively and consistently, deterrence will follow.

Recently there have been clear signs at national and international level that governments are waking up to the seriousness of pharmaceutical counterfeiting. In the USA, the FDA has issued important guidance on the need to authenticate medicines and to know their pedigree; in Europe, both the European Commission and the Council of Europe are examining the issue; in Asia, with input from the World Health Organisation (WHO), the Rapid Alert Network and other initiatives help to raise awareness and share intelligence, and Malaysia in particular has taken radical steps to ensure that all medicines available in the country are legitimate.

All these initiatives are welcome. Let’s hope that they lead to national and international focus and attention not just on the problem but on solutions, achieved through cohesive and comprehensive strategies for pharmaceutical anticounterfeiting.

Ian M Lancaster is director of Reconnaissance International.
A deadly trade

Counterfeit drugs are a growing problem worldwide. Peter J Pitts explains what moves have been made to counter criminal schemes and what steps must still be taken to protect consumers.

Counterfeit drugs account for 8-10% of global medicine supplies, with the proportion rising to a quarter or more in some countries, according to World Health Organisation (WHO) estimates. Meanwhile, the Center for Medicine in the Public Interest expects counterfeit drug commerce worldwide to grow by 13% a year between now and 2010 – nearly twice the rate forecast for legitimate pharmaceutical commerce. In 2010 this illegal business will generate revenue of US$75 billion, up 92% from 2005. The profits are high and the risks are low. That’s a deadly combination.

A large proportion of the world’s counterfeit medicines originate in Asia and end up in the USA and EU – in the latter, the number of seizures of counterfeit prescription drugs increased by 1,000% between 1998 and 2004. Around 12% of drugs in Russia are counterfeit, according to generally accepted estimates, and now that the Baltic nations of Latvia, Lithuania, and Estonia have joined the EU, WHO has warned of an ‘obvious’ increase in the risk of counterfeits entering the EU supply chain.

An international epidemic

To watch the international news is to witness the growth of this insidious criminal epidemic. In China, to take one recent story, 11 Chinese nationals and one American were arrested in a counterfeit medicine scheme that spanned 11 countries and involved 440,000 bogus pills and US$4.3 million. The drugs being peddled were Lipitor, Viagra, Cialis and Levitra. The USA, the UK, Switzerland and Israel were all affected.

A registered pharmacist in Hamilton, Ontario, has been charged with selling counterfeit Norvasc and the regional coroner in Hamilton is investigating the deaths of five people whose prescriptions for Norvasc were fulfilled by this pharmacy. All five died of a heart attack or stroke. The US Attorney’s Office meanwhile reports the indictment of 18 people alleged to have taken part in a multi-million-dollar international conspiracy to smuggle cigarettes and counterfeit Viagra to raise money for the Middle East terrorist group Hezbollah.

The EU recently went on the record (again) with its concern about the rise of counterfeit drugs in Europe, and Canadian authorities reported arrests made as part of their ongoing ‘Project Piranha’, with the seizure of a Hell’s Angels gang’s supply of marijuana, hashish – and counterfeit prescription drugs.

China is a main production centre. In 2001, the Chinese authorities reportedly closed 1,300 factories while investigating 480,000 cases of counterfeit drugs worth US$57 million. Between 200,000 and 300,000 people are estimated to die in China every year because of counterfeit or substandard medicine. These are just reported cases; the actual number is likely to be far higher.

There are four underlying causes of counterfeiting in Least Developed Countries (LDCs), according to Julian Morris and Philip Stevens of the International Policy Network, and while China is not classified as an LDC, the country needs to address these four issues. They are:

◆ Absent or defective intellectual property protection. One way to prevent the sale of unauthorised copies of medicines is to enable companies to register and enforce trademarks. Trademark owners have strong incentives to ensure that the quality of their product is maintained, because their reputation and hence future profitability depend upon it. In China, it is difficult to enforce trademarks, even for local companies. Where trademarks cannot be enforced, cheaply produced copies of poor quality 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 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 counterfeits. In China, however, civil law is either poorly defined or inadequately enforced.

◆ Inability to resolve disputes over property rights and contracts in independent courts. In China, an
According to the CoE report's author, Dr Jonathan Harper, an 'invisibility' factor masks the real extent of the presence of counterfeit medicines in Europe. He cites "a number of reasons, not least of which are the very nature of medicinal products (counterfeit medicines are invariably harder to detect compared to other types of counterfeited products), the lack of a commonly agreed and employed definition of counterfeit medicines by European States and a lack of awareness (in the case of several relevant authorities as well as the general public) of the threat that counterfeit medicines pose."

**Invisibility**

According to the CoE report's author, Dr Jonathan Harper, an 'invisibility' factor masks the real extent of the presence of counterfeit medicines in Europe. He cites "a number of reasons, not least of which are the very nature of medicinal products (counterfeit medicines are invariably harder to detect compared to other types of counterfeited products), the lack of a commonly agreed and employed definition of counterfeit medicines by European States and a lack of awareness (in the case of several relevant authorities as well as the general public) of the threat that counterfeit medicines pose."

**Biohazard**

Adverse Drug Reactions (ADR) associated with the inadvertent use of counterfeit medicines may be caused by inappropriate API dose - no dose at all, or one that is too small or too large - and quality issues, such as contamination.

Under-reporting of possible ADRs related to counterfeit medicine is likely to be significant, considering that ADRs are known to be under-reported even in the case of authorised medicinal products. A weakness in the existing European pharmacovigilance system is that it is not explicitly geared to detection of 'drug ineffectiveness'. The direct impact of the inadvertent use of counterfeit medicines on public health in Europe is therefore difficult to gauge from currently available data.

**System failure**

According to Dr Harper, a number of inter-related factors make Europe vulnerable to the problem of counterfeit medicines:

- Lack of awareness and perception of the problem at many authority/stakeholder levels;
- Regulatory gaps, particularly in the areas of API and the packaging and distribution chain;
- Weak export/transit regulations;
- Lack of coordination between relevant authorities, both nationally and internationally, and an inconsistent approach; and
- Inefficient cooperation between stakeholders within the supply chain and between those in the supply chain and authorities.

**The problem of the internet**

The internet has the very real potential to become the international drug cartel of the 21st century. When the 'learned intermediary' - a doctor or pharmacist - is replaced by a greedy intermediary, such as an unregulated internet site, there is significant danger to public health. Profiteers masquerading as pharmacists threaten both safety and effectiveness. 'Let the buyer beware' is bad healthcare practice and even worse healthcare policy. When patients go outside any given national regulatory system and enter the internet's grey zone, they assist those who put profits before patient health. The online arena is often favoured not only by profiteers masquerading as pharmacists, but also by criminals intent on feeding counterfeit drugs into the marketplace.

The US FDA has developed a framework for a pharmaceutical supply chain that would be more secure against modern counterfeit threats. This includes the following elements:

- Implementation of new technologies to better protect the US drug supply;
- Adoption of electronic track and trace technology;
- Adoption and enforcement of strong, proven anti-counterfeiting laws and regulations by individual states;
- Increased criminal penalties to deter counterfeiting and more adequately punish those convicted;
- Adoption of secure business practices by all participants in the drug supply chain;
- Development of a system that helps ensure effective reporting of counterfeit drugs to the FDA and that strengthens the agency's rapid response to such reports;
- Education of consumers and health professionals about the risks of counterfeit drugs and how to protect against them; and
- Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.

The last is particularly important because, as the Chinese proverb says, "An ant may well destroy a whole dam."

Counterfeit drugs are a global challenge to all nations and criminal counterfeiting operations are increasingly operating across national borders. The FDA has stated that it intends to work with WHO, Interpol and other international public health and law enforcement organisations to develop and implement worldwide strategies to combat counterfeit drugs. Now is the time to address and defeat this very real public health threat.

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"Peter J Pitts is director of the Center for Medicine in the Public Interest and a former associate commissioner at the FDA."
Acting on evidence

The Pharmaceutical Security Institute is using a unique incident-based reporting scheme to tackle counterfeit medicines and other forms of pharmaceutical crime.

Ashley How reports

The traffic in counterfeit pharmaceuticals worldwide, especially in developing countries, can result in serious harm such as injuries and deaths due to ineffective or toxic treatments. However, the availability of counterfeiting data is limited, and all too often the problem is defined with reference to just a few well-known cases.

At other times, dubious, overly optimistic or pessimistic and highly questionable estimates are presented as fact.

Policymakers at government agencies and international organisations struggle to determine the precise extent and nature of this problem. This year the World Health Organisation (WHO), having recognised the problem for some time and having highlighted the importance of timely exchanges of information with the active participation of public and private stakeholders, has developed the WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

Meanwhile, pharmaceutical companies have had to work out how to respond to the well-organised criminal groups that manufacture, transport and distribute medicines indiscriminately and without regard to current good manufacturing practices. Several leading international research-based manufacturers have responded by establishing the Pharmaceutical Security Institute (PSI), the world's only organisation devoted exclusively to the collection and analysis of information on pharmaceutical crime. At present the membership of the PSI consists of 23 international pharmaceutical manufacturers. It maintains a close affiliation with the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), whose director-general serves as its president.

The institute is combating a range of illicit activities including counterfeiting, illegal diversion and theft. Multilingual analysts, in co-ordination with experienced investigators, manage a consistent flow of information as data is collected, analysed and disseminated in support of individual or co-ordinated inquiries. More broadly, it regularly produces strategic trend information, which is essential if the nature of the counterfeiting threat posed by international criminal conspiracies is to be fully understood.

The Counterfeit Incident System

A unique incident-based reporting mechanism, the Counterfeiting Incident System (CIS), was inaugurated by the PSI in 2002. The CIS includes pharmaceutical crime reports from open sources such as press releases, academic journals, media articles and government warnings, as well as member company reports. While an incident will be defined more fully below, generally it can be viewed as a single event which, when discovered, includes detailed information on a specific pharmaceutical crime. For example, a member may learn of the discovery of a counterfeit medicine following a government inspection. The member, using the web-based system,
schemes are often accomplished through the illegally intercepted and sold in another. These intended for sale in one country, but is then pharmaceutical product is approved and Illegal diversion occurs when a genuine pharmaceutical product is approved and then diverted to the street or open air markets.

**Counterfeit medicine**

PSI’s definition of counterfeit medicines is built upon that used by the WHO1. Counterfeit medicines are products deliberately and fraudulently produced and/or mislabelled with respect to identity and/or source to make it appear to be a genuine product. This definition applies to both branded and generic products.

Counterfeit products appear with a wide range of deficiencies. For example, counterfeit medicines have been found to contain less than or more than the required amount of active pharmaceutical ingredients (APIs) used in the authentic version. The product may even contain the correct amount of API but have been repackaged in counterfeit packaging to extend the expiry date.

**Illegal diversion**

Illegal diversion occurs when a genuine pharmaceutical product is approved and intended for sale in one country, but is then illegally intercepted and sold in another. These schemes are often accomplished through the use of false statements or declarations. Sometimes drug regulators in the second country have not approved the use of the diverted drug.

Illegal diversion may also occur within the same geographic area, the same country or the same city. Discounted medicines are diverted from one intended group of consumers to another which buys medicines in an unregulated open market. For example, in Latin America, illegal diversion occurs when a government purchases drugs at discounted prices for use in state hospitals and these drugs are then diverted to the street or open air markets.

**Pharmaceutical theft**

Pharmaceutical theft is defined as an illegal taking of medicines. Thefts include burglary, robbery and embezzlement of goods. Those responsible may be insiders such as employees, or outsiders such as professional thieves. The theft may occur anywhere in the distribution chain, such as at the site of manufacture, freight forwarder, distribution centres, warehouses, pharmacies and hospitals.

PSI believes that an intensive, systematic approach to the collection and analysis of counterfeiting incident data yields a more accurate assessment of the situation and will over time foster a clear understanding of this problem by the authorities. Timely sharing of the information/intelligence to its members, law enforcement agencies and drug regulatory authorities, as appropriate, will enable prompt action to be taken and successful conclusions achieved.

**Other PSI initiatives.**

Apart from the collection and analysis of data, PSI is also responsible for a range of other initiatives, all of which it is hoped will increase the impact that its members, law enforcement and regulatory authorities have on this pervasive crime.

These initiatives include the following:

- Development of a training programme with PSI members which:
  - focuses on all aspects of counteracting the problem of counterfeiting;
  - is aimed at customs, police and regulatory authorities; and
  - is strategically directed

- Representation of the pharmaceutical industry at various groups and forums, e.g. the WHO, the World Customs Organisation, Interpol, the Council of Europe, the European Federation of Pharmaceutical Industries and Associations, (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA);
- Working closely with national drug and healthcare regulatory authorities;
- Presenting to various governmental and non-governmental bodies and groups and at appropriate conferences;
- Providing a point of consultation for the industry; and
- Working with the Partnership for Safe Medicines, a coalition of patient, provider, non-profit and industry organisations dedicated to the safety of patients and the drug supply chains. This initiative was started in the USA and is now expanding to Europe and beyond.

In summary, the challenge posed by counterfeiting is clearly evident from the institute’s data. There have been documented increases in the number of incidents worldwide, more countries are experiencing counterfeiting than ever before, and an even wider variety of pharmaceutical products is being counterfeited, illegally diverted or stolen. Working together in an innovative public–private partnership is the most effective way to safeguard patients from exploitation by criminal counterfeiters.

**References**


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It is difficult to understand the problems caused by unlawful trade, whether in counterfeit or fraudulently obtained goods, without being clear about the terms used. People often talk of the 'grey market', 'diversion' and 'parallel trade' as if they were synonymous. So here is a quick reminder.

Diversion refers to the movement of branded goods from one international market to another without the consent of the intellectual property rights (IPR) holder and contrary to their wishes. It can be illegal in certain circumstances, for instance where the goods were obtained from the IPR holder by deceiving them into believing the goods were for sale in one country when in reality they were always bound for another.

'Grey' goods are those that have been diverted in this way. Often, grey market goods will not violate the law but will be of interest to the rights holder as a breach of company policy - after all, each company seeks to maximise the price it can obtain in particular markets, and employees or contractors who facilitate export to cheaper markets to line their own pockets do so contrary to corporate interests.

'Diversion' and 'grey' goods are distinctly different from counterfeiting and have nothing in themselves to do with parallel trade. Parallel trade refers to trade that goes on legally within and across all member countries of the EU, which is fundamentally a free market without internal borders. By definition, therefore, there can be no 'diversion' of goods that have remained with the EU.

However, it is clearly not in the commercial interests of pharmaceutical manufacturers to sell their goods into southern and eastern Europe at lower prices, only to see them turn up in more expensive markets such as the UK, competing against identical products that those manufacturers market there at higher prices.

There are two main protagonists on this stage. On the one hand we have so called 'ethical' manufacturers, and on the other we have European parallel traders, whose representative association suggests that they too are manufacturers (simply because they re-package the products made by major manufacturers).

Major manufacturers call themselves 'ethical' because originally they invested in R&D to develop their own products without recourse to copying the off-patent products of their rivals. Well, those days are gone and some very well known manufacturers of patented medicines also produce generics — even if they set up separate companies to do so. The description 'ethical' is outmoded, if not actually misleading.

Buying diverted goods is a recipe for disaster, and wholesalers who do so should be aware that they could be furthering the trade in counterfeit medicines, says Graham Satchwell.
Most people would be wary of courting the company of an individual who wore a badge declaring themselves 'ethical', so why should the public be any more trusting of a corporation that does so?

Major pharmaceutical manufacturers should drop the 'ethical' tag and instead market the idea that we have no right to expect makers of medicines to be any less commercially driven than makers of software. Both software and pharmaceutical manufacturers need to be properly constrained by the law, although one (because of the nature of the goods) to a greater degree than the other.

As for the parallel traders, it is misleading to use the term 'grey goods' in relation to their trade: parallel traded goods are 'white', not black (market) or any shade in between. When the term grey is used, the implication is clear: the goods are not 'white' but a bit shady. Parallel trade properly conducted is nothing other than 'white'. It certainly does not deserve the tag that suggests it falls somewhere between legal and illegal.

We all benefit from parallel trade - whether by buying cheaper jeans or shampoo - and yet turned out to be counterfeit.

Major pharmaceutical manufacturers should more in terms of packaging and supply chain security, when that major manufacturers do more in terms of repackaging, goods purporting to be parallel traded goods from those who have also supplied counterfeit medicines. The implication is clear, and this is important - to a successful but unscrupulous businessman involved in the sale of counterfeit medicines, there can be no better bet than to counterfeit parallel traded goods.

Think about it:
- The (re)packaging of parallel traded medicines is always less sophisticated than the brand-owner's original packaging (and therefore easier to copy);
- It rarely if ever carries any anti-counterfeiting features (hologram, micro-text or shifting ink); and
- No parallel trader employs investigators and analysts to search for and detect counterfeits in the way that major pharmaceutical companies do.

In addition, given the (small) price differences between parallel and non-parallel traded medicines, one can see the growing potential for counterfeiters to exploit this opportunity. Repackaging is currently often done abroad, with goods reaching UK shores ready for distribution.

The lesson? We should insist that repackaging is conducted to certain minimum standards including the use of anti-counterfeiting design features. All repackaging for the UK market should be undertaken within these shores and therefore subject to MHRA supervision.

There is no point whatsoever in demanding that major manufacturers do more in terms of packaging and supply chain security, when those who also call themselves manufacturers (because they hold repackaging licences, or simply because they do a little purchasing of generics and have their own company name added by the supplier in Asia) do absolutely or virtually nothing. Small wonder major manufacturers feel less than warm towards 'repackers'. The MHRA must ensure regulatory change to provide better protection for the public.

One cannot escape the fact that the role of the MHRA is pivotal in all this. The agency was set up (originally as the MCA) in the wake of the awful thalidomide tragedy. That tragedy was caused by corporate greed. Understandably, the agency's raison d'être was to ensure that such a catastrophe could never happen again. During the 50 years since, that has remained its focus.

The MHRA polices the pharmaceutical manufacturers and the market with special attention to new drugs, and this is of course necessary. But it needs to look up and look around: it has begun to see the dangers that counterfeit medicines pose, now it needs a shift in culture. It needs not only to police the manufacturing industry, but to properly police the pharmaceutical market with a view to identifying and dealing with threats from outside the legitimate market.

At the moment the agency takes action against vendors selling products such as unlicensed Chinese herbs and steroids, but this is very easy. Such action is no substitute for acquiring sufficient resources and adopting a strategy to curb the rough end of the wholesale and parallel trade market.

So what else can be done? If there was a global price for each medicine, diversion and parallel trade would stop instantly and the door to counterfeit medicines would be closed a little. But will there ever be global pricing? Of course not.

So, with price differentials remaining, manufacturers can act against diversion by applying quotas to particular markets and making the appearance of medicines so different for particular markets that diverted product is quickly identified. Both these things have increasingly been happening over the past five years. However, neither will prevent counterfeiting. The only way is to have manufacturers, major and minor, invest more in unique and randomised mass serialisation systems. But even that will not in itself be enough.

At the beginning of 2006 the ease with which a wholesale dealer licence can be obtained in the UK was clearly illustrated and exposed in a public television broadcast. It pointed out that in the UK there is no check on the background of the company applying or its directors, in fact no check at all on the identity of the applicants, no need for any.
trading history, nor even the need for the applicant to be a limited company. That needs to change.

In addition, we need a harsher approach by the MHRA to exposing wholesalers who have been found in possession of counterfeit or otherwise sub-standard medicines. We need to adopt the precautionary principle in order to deter 'chance taking' by those few wholesalers and parallel traders who have no place doing business in the supply of medicines. Most of all we need an alliance between honest parallel traders and pharmaceutical manufacturers.

Now is the time for decent wholesalers and parallel traders (the majority) to help ensure that parallel trade does not continue to provide an open door for inadequately re-packaged and potentially counterfeit products.

To date, British wholesalers and parallel traders have been even more secretive and 'closed' than the major manufacturers, and this needs to change. We need to see just how the associations that represent these businesses go about policing their membership. Openness and honesty is required.

We have now had several known cases of counterfeit medicines entering the legitimate distribution chain in the UK. I say 'known' because anyone who has worked in this field will be aware of the high probability that many more incidents of counterfeiting have gone undetected than detected.

Manufacturers (properly so called, not 'repackagers') need to bite the bullet and work at shortening the supply chain. As I reported more than two years ago, supply chains in Europe often have more than 20 links, and each link represents an opportunity for error or infiltration. This needs to stop.

It is understood that late in 2006 members of the MHRA gave talks and presentations at which they described a classification for different 'types' of counterfeits. They are apparently now divided by that agency into 'dangerous' and 'non-dangerous'.

This action represents an approach to the problem by our regulators which I had hoped had disappeared. Undoubtedly they have made some progress recently, particularly with the appointment of the new head of investigations. He needs to take a firmer line and ensure that each member of his team understands that there are, by definition, no safe counterfeits.

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Graham Satchwell has written extensively on the subject of counterfeit medicines and diversion and is an acknowledged expert. He is a former director of corporate security for GSK responsible for Europe, Middle-East and Africa. He is a law graduate, former detective superintendent and Fellow of the Royal Society of Arts. (Copyright owned by Graham Satchwell. To be reproduced in whole or part with the specific written permission of the author only.)
The true stakeholders

If patients are the only people guaranteed to suffer from the use of substandard medicines, why are they the last to be considered in the fight against counterfeiting? Jim Thomson reports

Here’s a quick test. Have a look at any government policy document, promotional brochure for a major conference or, God forbid, an internal briefing document from a major pharma company. I guarantee the word that will leap from the page with monotonous regularity is ‘stakeholder’. Don’t even bother to look at anything from a PR company – the word will be all over it like a rash.

Stakeholder is one of the most over-used words of our age. It has acquired meanings beyond what it actually says. For example, I often hear manufacturers, distributors, pharmacists, regulators et al. referred to as stakeholders in anti-counterfeiting. But what is their stakeholding? If a fake version of a manufacturer's medicine turns up in the supply chain, the share price might wobble for a day or two, or they may have to recall a batch. These are painful to the company – but life goes on. If a distributor or pharmacist is found to have counterfeits in their stock, their reputation may suffer - but life goes on. Indeed, in today’s climate, they are very unlikely to suffer any substantive hardship at all. If the regulator fails to identify a counterfeit medicine in the supply chain, life goes on. However, if that fake medicine reaches a patient, it is entirely possible that life will not go on. Or that a chronic condition might not be managed as it should be. Or that a GP might wrongly attribute a setback to lack of efficacy and needlessly change a treatment regime.

These and other outcomes harm not only the patient, but also their confidence in their medicine - and therefore the likelihood of concordance with the treatment plan. This may not seem important until we understand that by taking the seemingly simple step of using a medicine as prescribed, patients would increase pharma profits by 25%. Most reasonable people would think that reason enough for taking seriously this particular group of stakeholders.

In the murky world of counterfeit and substandard medicines, the only person guaranteed to suffer is the patient. Now that’s what I call a stakeholding. Yet patients are often the last ones considered when stakeholders discuss how best to combat counterfeits. It is felt by some that patients are not sophisticated enough to understand the issues, or that if they are made aware of the patient safety risks of counterfeit medicines, confidence in medicines will be shaken. Of course, this is palpable nonsense. Confidence in fakes, not medicines, would be shaken and confidence in our porous supply chain just might be as well. Neither of these is a negative.

The last barrier to harm

In the campaign for safe medicines for all, the stakeholder best placed to protect the patient, is the patient. The one who puts the medicine in their body. The one who knows what to expect of it. The one with the lived experience of what the real medicine does for their condition. The patient is the last barrier to harm and we need to accept this and use it against the crooks.

Surely, in the fight against counterfeiters, it is better to have several million investigators (each with a strong vested interest in their own safety) than it is to have a few dozen. The status quo isn’t fit for purpose. In the ten years to 2005 the UK medicines regulator, the MHRA, randomly sampled 25,000 packs of medicine. At last year’s prescribing level, that equates to 0.000385% of the supply – a miniscule needle in a very big haystack. Obviously the MHRA works in other ways, but is clearly hampered by lack of resources.

If we accept that the patient is the last barrier to harm, then the only remaining question is how best to involve them in the fight against bad medicine. The obvious answer is through the relevant patient groups and the representative bodies of the health professions. These groups are trusted sources of information and support, and many are ready and willing to be part of the solution.

At its global congress last spring, The International Alliance of Patients’ Organizations (IAPO) ran a workshop on counterfeit medicines. The most-requested resource was a guide for patient groups to distribute to patients. The International Council of Nurses last year published an excellent toolkit for its members and made counterfeits the focus for International Nurses Day. The Washington-based Partnership for Safe Medicines publishes an eight-step guide for patients, as well as a global email alert system and a massive library of information on counterfeit medicines. A UK company has just launched a service that delivers batch-authenticated medicines direct to the patient. Various technology developers are working feverishly to put in the hands of patients in the developed and developing world, the low–cost means to authenticate their medicines. All of these developments directly address the stated needs of patient groups and associated professions, eager to help protect their constituents. And this is set to mushroom in the coming months.

In January 2007, an alliance of, sorry, ‘stakeholders’ will come together to take strategic, pan-European action to combat counterfeits and campaign for a secure supply chain. The alliance will include, inter alia, patient groups, the healthcare professions and the pharma industry. Their work will build on previous initiatives and will feed into others - for example the World Health Organisation’s (WHO’s) IMPACT. It will be action-orientated and will work towards specific positive outcomes. The seemingly disparate interests within the alliance will be united by a common charter. Of course, each member of the alliance will have their own priorities but they are coming together as allies in order to take real and lasting action to improve patient access to safe medicines. This development places, at the heart of the fight against fake medicines, those who have the greatest vested interest: patients, the last barrier to harm.

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Focus on SE Asia

The counterfeiting and anticounterfeiting of artesunate

Ian M Lancaster and Dr Paul Newton report on the Wellcome Trust’s investigation into fake artesunate in South East Asia and discuss what can be learnt from the problem of counterfeit drugs in this region

Artesunate was discovered in the 1970s by the Chinese, who were examining traditional herbal remedies used to treat malaria. They found the artemisinin in the leaves of artemisia annua bush to be the active ingredient that made one of these herbal treatments effective, and developed a process to synthesise it, creating the compounds now known as artesunate. In combination with lumefantrine, this is now the treatment for malaria recommended by the World Health Organisation (WHO) in all areas where there is chloroquine resistance. This means that this Chinese-manufactured drug is the leading malaria treatment in SE Asia, China and parts of Africa.

As the leading treatment for such a widespread disease, widely available and widely taken, artesunate has become a target for counterfeiters. The first known counterfeits were discovered in 1998, and by 2001 the public was being warned about fakes and given information on how to identify them. For example, The New Light of Myanmar Online published the following story on November 9 2001:

“During post market surveillance, the registered 'Injection Artemether' produced by Kunming Pharmaceutical Corporation, China is found to be an imitation. The comparison of the genuine (registered) and fake (imitation) Injection Artemether are noted as follows:

- The colour on the lower left side of the outer front package of the genuine Injection Artemether is previously dark-blue and recently red and the fake is bluish; the manufacturing date and expiry date of the genuine drug are stated on the back of the outer package and there is no statement on package of the fake drug; Myanmar Registration Number is stated on the back of the outer package of the genuine drug and there is no statement on the package of the fake drug; liquid in the ampoule of the genuine injection is oily and liquid in the fake injection is watery. The laboratory analysis of the fake (imitation) drug is found to have no active ingredient of Artemether.”

At this time, an early random shopping survey revealed that 38% of shop-bought artesunate was counterfeit, containing no active drug. A second, more rigorous survey in 2003 found that 53% of 188 items of shop-bought blister-packed artesunate were fakes, with no active ingredient. In Laos, an incredible 89% of 27 samples were fakes, with no active ingredient. The Wellcome Trust SE Asian collaboration team assessed the incidence of fake artesunate in the region, based on their purchases. In only five of 27 locations did they find no incidences of fake artesunate. In 15 locations only fakes were available.

Such depth of knowledge about the penetration of counterfeit drugs in a given region is unusual. Very few similar studies - if any - have been conducted in such detail and with such rigorous methodology.

The bigger picture

While the information gleaned from this study is important, it is not possible to extrapolate from this data that more than 50% of all medicines available in this region are counterfeit. Nor can we say that more than 50% of artesunate in other countries is fake. This is a particular region with a particular health problem with a particular treatment regime and a particular regulatory and enforcement regime, in close proximity to places where fake drugs are known to originate. The unique combination of these factors causes very high levels of fake artesunate.

Nonetheless, these are alarming figures which indicate the seriousness of this problem and we can conclude that it is probably not confined to this region and this one medicine.

Fit for purpose?

The discovery of fake artesunate prompted Guilin Pharmaceuticals, the manufacturer of the product in blister-packed form, to investigate the measures they could take to combat counterfeiting. They elected to use a hologram incorporated into the blister foil. At the time, there were not many producers that could incorporate holograms into blister foil. This in itself was thought to be something of a deterrent to the counterfeiters. The hologram itself though was a relatively simple design, although it incorporated certain hidden image elements.

The first artesunate with a counterfeit hologram appeared within months of the introduction of the hologram blister pack. However, it was very crude and anyone familiar with the genuine hologram would
Focus on SE Asia

have no difficulty in differentiating the fake from the genuine.

That last statement raises critical questions about the design and introduction of an anticounterfeiting feature: Who is familiar with the genuine hologram? Who will pay attention to the hologram anyway? What is the purpose of the hologram - or any anticounterfeiting feature? Is it to be examined by the patient, the buyer of the drug, or is it designed to be examined by a knowledgeable team of inspectors (perhaps customs officers or drug regulators), trained and equipped for this purpose? If so, who are those inspectors and who is responsible for training and equipping them?

An anticounterfeiting feature should not stand alone. It needs to be part of a holistic strategy that draws on the resources of the commercial sector (the drug manufacturer and legitimate distributors), the public sector (police, customs and drug regulatory agencies), and the patient/customer. But this is often not the case.

The WHO estimates that only 20% of Drug Regulatory Agencies (DRAs) worldwide have a “well-developed functioning capacity” while 30% have “no drug regulation or a capacity that hardly functions.” It doesn’t take much imagination to realise that most of those 20% are in the developed world and that the 30% with no drug regulation are in the developing world.

So Guilin Pharma has adopted a hologram to its mark its genuine product, but who is there to examine it in the markets of SE Asia? The patient, who - no matter how much effort has gone into educating the customer about the characteristics of the hologram - is not properly trained to do so?

Furthermore, the counterfeiters are increasingly familiar with the artesunate hologram and with hologram production techniques: 12 types of fake hologram have now been identified and there may be more not yet found; each is ‘better’ than the previous fake (in that it is closer in appearance to the genuine hologram). None - yet - is a 100% accurate copy; all the fakes are identifiable as such - if only there were the inspectors who were trained and equipped to spot them.

A health disaster

Anticounterfeiting, and pharmaceutical anticounterfeiting in particular, cannot depend on the efforts of the manufacturer to use anticounterfeiting devices or systems. These are necessary, but are most effective when supported by a suitable inspection regime. The WHO encourages DRAs to adopt effective policies, but often the resources to make these policies effective are not available. Patients are very often left to make their own decision about whether a given medicine is genuine or fake. But they may not even be aware that fakes are in circulation. And in many parts of the world they don’t have the education, never mind the training, to examine and identify fake products.

This is a potential health disaster. It can be contained, but only with the right resources and, above all, the will to do so. The counterfeiters are greedy and determined and faking medicines is often easy and lucrative. But if the health sector and enforcement agencies put enough resources and effort into identifying fake medicines and tracking down those responsible for them, the counterfeiters will turn their attentions elsewhere.

Pharmaceutical anticounterfeiting can probably never stop the counterfeits, but it can reduce them - significantly.

Ian M Lancaster is director of Reconnaissance International.
Up close and personal: looking beyond RFID

With Pfizer stating that its recent RFID initiative isn’t going to solve the problem of counterfeit Viagra, what else is out there? Dominic Griffiths explains how an on-product anticounterfeit measure has many benefits for patients, doctors and pharmaceutical companies alike.

The global extent of counterfeit medicines is a subject of intense debate (and is being dealt with elsewhere in this supplement). While the precise prevalence depends upon whom you ask there are a number of points on which those involved in the debate agree:

◆ Counterfeit medicines were historically perceived to be an issue for the developing world. Recent well publicised incidents of counterfeiting demonstrate that this is no longer the case;
◆ Since the US FDA Task Force report in 2004 the pharmaceutical industry has been making efforts to address counterfeiting and traceability throughout the supply chain;
◆ That, of the myriad anticounterfeit technologies, radio frequency identification (RFID) is emerging as the front runner, particularly in the USA;
◆ That there is no ‘silver bullet’ – a multi-pronged approach to this problem is required; and
◆ Counterfeiting is on the increase and a lot more needs to be done by governments, regulatory agencies and industry stakeholders to prevent it.

From a patient perspective, how damaging are counterfeit medicines? In the developed world adverse events from taking known counterfeit medicines are thankfully the exception rather than the rule. It is the developing world that has suffered most at the hands of counterfeiters and remains the market in most need of a solution. In these countries it is the life-saving – anti-malarials, anti-HIV, for example – rather than lifestyle drugs that are most often prone to illegal copying.

From a brand owner (i.e. the pharmaceutical company) perspective, if a patient suffers an adverse event following consumption of a counterfeit dose that was mixed amongst authentic medicine it could be very difficult to prove which tablet caused the side-effect – and therefore who is liable for the harm caused to the patient. For example, Bristol-Myers Squibb and Eli Lilly were reported to have paid an estimated US$71m in 2002 to settle more than 200 lawsuits that arose as a result of a pharmacist distributing diluted doses of Gemzar and Taxol to cancer patients in the USA.

So what is the pharmaceutical industry doing about this growing problem? Many pharmaceutical companies have established internal taskforces, and have been advised by the FDA to consider combining both ‘overt’ and ‘covert’ approaches to anticounterfeiting. To date most companies have focused on elements of the packaging process to make it harder for counterfeiters to penetrate the supply chain. Due, at least in part to the FDA’s recommendation of track and trace solutions, the leading contenders for broad-scale anticounterfeit protection centre on RFID.

The objectives of RFID are straightforward: to allow manufacturers and distributors to precisely track products as they move through the supply chain from the point of manufacture to the point of dispensing. The technology creates electronic ‘pedigrees’ that should improve patient safety by allowing wholesalers and retailers to rapidly identify, quarantine, and report suspected counterfeit drugs.

RFID involves the tagging of pharmaceutical packaging material using transmitters. The need to detect the signal from such transmitters places technology requirements on each element of the supply chain. Implementing RFID is therefore by no means straightforward. Indeed, in 2006 the FDA stated that it was unlikely that the pharmaceutical industry would meet its target deadline of 2007 for RFID implementation.

However, notable successes including Pfizer’s tagging of Viagra bottles in the USA indicate that progress is being made (although Pfizer has stated that this initiative alone will not eliminate counterfeiting). The limitations of RFID would appear to be:

◆ That it is currently proving difficult to apply RFID across an entire product range;
◆ That it is currently proving difficult to apply RFID across an entire product range;
◆ The IT required to support RFID is complex and costly - and not easily available in some territories; and
◆ RFID does little to convince patients that a product is authentic.

While RFID remains a technically elegant way of monitoring units of product throughout the supply chain, it is not failsafe, nor is it suitable for all. What else is out there?

Closing in on the product

A fundamental limitation of RFID and many other packaging-based counterfeit measures is that they do not enable identification of counterfeit product at the level of the dose form. This is relatively unimportant if the final packaging unit provided to the patient contains the counterfeit measure. However, even in developed markets such as the UK and USA, packages released from the manufacturer are often re-packaged as they move through the supply chain – for example, to provide a set number of tablets for a course of treatment.

It makes sense therefore to either more rigorously control the supply chain to minimise the likelihood of repackaging or to move the anticounterfeit measure even closer to the individual dose form. In an unprecedented move, Pfizer is pursuing the former strategy, recently announcing a deal in the UK which makes UniChem the sole distributor for its products in the UK market. This has triggered a predictably negative response from other supply chain participants,
and at the time of writing the UK government is considering whether or not this move constitutes anticompetitive behaviour. So what about the dose form? Swallowing the tablet is the final patient experience of consuming a medication. Ultimately it is the drug, rather than the packaging, that must be trusted by the patient to be authentic. Surely, then, customised and difficult to imitate tablet designs that can easily be recognised by the patient would be the best way to provide an immediate visible indication of tablet authenticity? Every tablet would be protected, rather than every tablet pack.

In the past, implementation of tablet-level anticounterfeiting measures was prevented by the widespread availability of tablet presses and coating equipment. Counterfeiters could, therefore, fairly easily make tablets that appear authentic in shape and colour. Indeed, counterfeit tablets are perhaps the most common form of abused medication.

Today, companies offer technologies that can coat tablets in a way that provides excellent protection from counterfeit (see Figure 1). The main advantages of these 'unique image tablets' are that, as well as being virtually impossible to counterfeit, they can be customised for a given territory giving the pharmaceutical company the ability to track product diversion and re-importation without the need for extensive and expensive IT infrastructure. In addition, the technology used to create such tablets is:

- Proprietary - the product's appearance is protected by intellectual property and considerable know how.
- Restricted - the technology owner controls the machine supply and the raw materials used in the manufacture - giving the pharmaceutical company increased confidence in the safety of their product.
- Cost-effective - because implementation of this anticounterfeiting measure involves the replacement, rather than the addition, of a processing step, the cost implications of the technology are minimised.

Brand benefits

In addition to providing an excellent anticounterfeiting measure, unique appearance tablets offer pharmaceutical companies the opportunity to strengthen their products’ brands. Tablet appearance can be used to enhance brand image in two ways: by 'passive' association, where a patient associates a particular tablet design with the manufacturing company and links their positive experience of the medication with its proprietor, and by 'active' association where unique appearance tablets are seen to add value to a product. For example, elderly patients are typically required to administer several drugs per day, each often having a different dosing regimen. Distinctive tablets could help them (and other poly-pharmacy patient groups) to more easily tell one tablet from another, leading to improved compliance and therefore increased drug effectiveness. And if the patient recognises these benefits (and consequently requests a specific medication), it is likely that their doctor will too.

Furthermore, several studies have demonstrated an association between tablet colour and the perceived effect and efficacy of a treatment. For example, in one study patients suffering with rheumatoid arthritis received red, blue, green, or yellow placebo tablets. Patients reported significant pain relief when taking the red tablets - in contrast to the blue, green, or yellow tablets, where little or no pain relief was observed. Matching expectation with appearance could therefore add brand value by improving a product’s perceived benefit - and therefore compliance.

It is also of particular note that, in a recent US survey of 150 pharmacists, 79% of respondents blamed look-alike medications for dispensing errors - errors that cost in excess of 7,000 lives per year in US hospitals.

No silver bullet

Key players in the regulation, manufacture and distribution of pharmaceuticals worldwide are putting in place measures to combat the prevalence of counterfeit drugs. The most proactive market is the USA where the FDA has recommended a range of anticounterfeiting measures, the lead one of which is RFID. However, the FDA’s targets will not be met and RFID will not deliver the ‘silver bullet’ that solves the problem globally. It has been recognised by all that no single solution exists, however taking counterfeit protection to the tablet level offers the pharmaceutical industry a cost-effective option that empowers the patient to join the fight against counterfeit drugs. This technology can give patients and prescribers alike the confidence that the dose form itself is authentic (rather than having to trust the package it came in). That the technology also enhances brand value is a considerable additional advantage of this innovative technology.

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Mass serialisation holography for product protection

Mass serialisation holography provides secure item-specific coding. This is an effective tool for securing product tracing data applied to pharmaceutical packages that are susceptible to counterfeiting or misuse, explain Joachim Suesse and Claus Grobe.

Effective counterfeit protection for pharmaceuticals can only be achieved with security technologies that are inaccessible to counterfeiters and prohibitively difficult to imitate. For product protection on a broad scale, the application of mass-serialised codes is rapidly becoming a key security requirement. It enables the pharmaceutical industry to trace products through the supply chain and to verify their identity by means of an electronic 'pedigree'. While the security effect of a pedigree is self-evident, mass-serialised codes (for example, barcodes) are often applied with printing technologies that are technically easy to replicate or manipulate. Consequently, incremental protection may be required for high-risk products or countries.

Holospots

An example of mass serialisation holography is tesa scribos's 'Holospot' lithography. Holospot lithography produces individualised, computer-generated holograms, which are inscribed into a polymeric, self-adhesive security label by a high-resolution lithographic laser. As the holographic information is stored inside the material - and not on its surface - it is especially protected against counterfeiting or manipulation.

The smallest Holospots are just 1mm² in size, thus being well suited for small-sized pharmaceutical products with limited space for security features, such as vials or ampoules. Data storage capacity is sufficient to store serial numbers, brand names, and company logos. Variable data can be included in every single security feature, giving each pharmaceutical product its own secured identity.

With Holospot lithography, security data is stored in up to four different levels of information in order to address individual protection needs (see Figure 2). Overt holographic information visible to the naked eye can be combined with high-resolution micro text as well as hidden information, which is stored in analogue and digital form.

The visible holographic structures, such as a serial code, have a diffractive, shimmering appearance and are suitable for authentication by pharmacists, customs officials or patients. A simple magnifier gives access to the micro text, which serves as a second step of authentication, for example for wholesalers or other distribution partners. Special reading devices are required to gain access to the hidden analogue and digital information, which is stored in a projection hologram and activated by laser light. These devices should be restricted to internal specialists or investigators, so that access to covert data is always under the control of the brand owner. Hidden analogue
Tracing and authentication

Information serves as a third security layer for authentication, while the inclusion of machine-readable digital data in the projection hologram, such as data matrix codes, allows product tracing information to be secured.

All information levels can be logically linked to each other, for instance by using alphanumeric coding, or they can independently carry information that is unique to the item being labelled.

**High-risk scenarios**

Mass serialisation – identifying each single product package with a unique code – is being implemented throughout the pharmaceutical industry today.

Some identification systems depend on printed barcodes or data matrix codes and, in some test projects, radio frequency identification (RFID) technology.

In each case, a connection to a databank is required for product identification, verification, and product matching with the stored code.

In some countries or regions, however, the technical infrastructure to authenticate products via a database may be limited. Additional securing of printed tracing data may also be necessary for those pharmaceuticals, for which counterfeiting of the barcode or data matrix code itself has been observed or suspected. Both scenarios require additional protection measures to allow reliable product authentication without the need – and the risk – of databank-based verification systems.

Mass serialisation holography makes possible the product protection required in these high-risk scenarios. Individual product codes contained in a barcode are linked with the holographic information contained in a Holospot, which is applied next to the barcode tracing information (see Figure 3). The barcode data is effectively secured against counterfeiting and, at the same time provides on-the-spot, easy authentication of the holographic security features, without the need for databank access.

**Proven efficacy**

Holospot lithography is in use in a variety of industries and countries. One of the best documented cases of the Holospot system involved counterfeiting of a personal care brand – Nivea – in Russia, a country where counterfeiting activity has grown enormously within recent years. Counterfeit Nivea products were first discovered in 2003, exhibiting a packaging appearance virtually identical to genuine products; however, the counterfeit product contents were of low quality, jeopardising the overall brand’s reputation. In 2004, the counterfeit rate of the affected product group reached 30% and a decision was made to introduce the Holospot technology for product protection.

Products were secured with Holospot labels (see Figure 4), containing the brand name and an individual serial number in the micro text, while additional coded information was stored in the projection hologram. The supply chain was informed about the security measure and the visible features for authentication. Field investigation was activated for store checks and market analysis. In 2005, turnover shot up by 40%, and no counterfeits of the secure product have been found in the market to date. Payback period with respect to technology cost was less than seven months.

Joachim Suesse has been managing director of Germany-based tesa scribos since its foundation in 2001. Before joining tesa in 1992, he worked in the pharmaceutical industry for more than 10 years, holding various marketing and sales positions with Eli Lilly and Baxter Healthcare. Claus Grobe has been head of marketing at tesa scribos since 2005, focusing on security and identification solutions in the fields of counterfeit protection, protection against product diversion, and theft protection. He worked in the chemical industry for more than eight years, holding various marketing and R&D positions with tesa AG.
A UniQ way to combat counterfeiting

UniQ distinctive on-product branding takes counterfeit protection to the dose form

UniQ brand enhancement extends brand identity, helping to build customer loyalty and improve patient compliance

You’ve spent $500m getting your tablet to market
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Proprietary tablet coating that stands out from the crowd

COMPANY DESCRIPTION

Phoqus is a drug delivery and tablet coating company based in the UK. Phoqus has developed a proprietary solution for anticounterfeit and product branding — UniQ™ — based upon its platform technology of electrostatic dry powder deposition. Tablets coated using UniQ™ are novel in appearance and can be used to create or enforce a specific product or corporate brand. These tablets cannot be copied by existing tablet coating systems. UniQ™ therefore provides an effective on-product, overt counterfeit deterrent that delivers protection to every single tablet. Phoqus controls the supply of materials and equipment to the pharmaceutical industry which provides further protection from would-be counterfeiters. The UniQ™ system can be combined with other anticounterfeit measures such as secure packaging, tablet printing, or covert markers.

Phoqus is collaborating with Cardinal Health, a global provider of services to the pharmaceutical industry, to offer contract manufacturing services for products developed using the Phoqus technology.

PHOQUS’ SERVICES:

• Formulation development
• Tablet manufacture
• Tablet coating
• Contract manufacture

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tesa scribos
Protecting your brands and interests

COMPANY DESCRIPTION

tesa scribos is an affiliate of tesa AG, one of the world’s leading providers of adhesive tapes and labels. Its products offer effective anti-counterfeiting and product tracing capability, as well as manipulation protection and document security.

tesa scribos offers expert advice, practical security measures and a wide range of modern security technologies. As part of the global tesa network, tesa scribos is able to provide innovative security support on a worldwide basis.

TESA SCRIBOS’ EFFECTIVE TECHNOLOGIES ARE:

• tesa Holospot®, a discreet, forgery-proof information carrier label that can be attached easily to any product. It features human and machine readable data that is individualised on item level in conjunction with a distinctive optically variable appearance. Brand owners benefit from multiple overt and covert security levels for maximum counterfeit protection with the possibility of identifying every single product individually. Authentication is possible with or without special devices and can be adapted to the brand owner’s needs.

• tesa IdentSeal®, a security label material for standard industrial laser markers. It offers excellent contrast for clearly visible text or high density bar codes. Easy to use overt product protection and identification is combined with effective tamper-evidence. Brand owners can choose between specific surface structures, non-removable imprints or fluorescent UV features to further enhance security.

• tesa® SecuritySeal adhesive tapes and labels for protection against manipulation and theft by means of an irreversible optical proof of first opening.

• tesa® SecurityPrint labels with security print, such as guilloches, luminescent inks, thermoreactive and color-shifting inks, and anti-copy protection.

• Customer-specific security labels that incorporate a number of security features.

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Dear counterfeiters:
Sorry, your illegal business will become substantially harder.
From now on, each and every genuine product can be easily protected with tesa Holospot®. This means individual diffractive security features, traceability at item level and easy proof of authenticity at any time and all over the world.
tesa scribos developed this new type of security technology to protect brand owners from financial losses as well as damaged brand reputation. In addition to tesa Holospot®, tesa scribos offers further solutions for high level product security. IdentSeal® and SecuritySeal – product identification and manipulation prevention at its best. Watch out for the complete line of tesa scribos security solutions – protection against counterfeiting, manipulation and theft! Beware of tesa Holospot®, which contains detailed overt and covert information right on the product – visible evidence and complex data, enough to get your crimes uncovered. Dear counterfeiters, it’s time to quit your business. At least when you face this spot...
Today’s Seal with Tomorrow’s Technology

West Spectra ID is the only seal that provides multiple layers of protection for your packaged drug product. West Spectra ID enhances patient safety with point-of-use instructions, combats drug counterfeiting and helps keep your supply chain secure.

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- West Spectra ID seals with full-color graphics and text provide item-level information such as a vial’s contents, product or brand name, dosage or strength of the drug, cautionary statements and storage instructions.
- The unique characteristics of Spectra ID seals help deter drug counterfeiting.
- West Spectra with an embedded RFID tag provides electronic item-level track-and-trace identification and read/write capabilities for product authentication.
- West Spectra technologies are integrated into West’s existing tamper-evident Flip-Off® seals. To find out how West Spectra ID can provide security for your drug product, call your West account manager.

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