

## **The Genuine Danger of Counterfeit Medicines**

*Images of raid on South American counterfeit medicine factory. A man is producing fake Advil tablets.*

### **Outline Commentary**

A worker in this grubby South American shack operates an antiquated machine. Producing what appear to be aspirin and Advil pain relief tablets. But these pills are not genuine. They're made from Boric acid- more usually known as an antiseptic or insecticide. These pills would have found their way into the hands of an unwitting consumer hoping to cure a headache if the police had not moved in.

*Images of customs activity-.anonymous man on internet pharma sites  
Shots of raid on fake drug distribution centre, UK, evidence store room at MHRA (London)*

The counterfeiting of drugs is a fast growing highly profitable business not just in the developing world. Half a million fake medicines were seized by EU customs in 2005. Last year that number had shot up to more than four million.

The internet has provided the biggest boon for the bogus pill sellers. Particularly in what are known as lifestyle drugs- such as Viagra- but also for other prescription medicines. The World Health Organisation believes more than half the drugs sold on the internet are fakes.

In Britain, government investigators raid the premises of a bogus operator after tracking their movements on the web. The UK is a major distribution point within Europe for counterfeit drugs-often manufactured in India or China.

### **Interview: Mick Deats**

#### **UK Medicines and Health Products Regulatory Agency (MHRA) Intelligence and Enforcement Unit**

*This is all seized property in this evidence store. it all comes from raids carried out by MHRA officers. This is a canister with dog vitamins. When you open it up there's counterfeit Viagra inside there. In our experience counterfeiters always go for the high priced, high turnover, high demand products- they watch the markets like a hawk. This particular exhibit relates to Tamiflu- this is something that treats bird flu - massive demand for this product. Counterfeiters will be very quick to realise that's the case and they will then start manufacturing.*

### Commentary

#### *Shots of Jim Thomson on stand at European Commission Counterfeiting conference, he shows fake Plavix*

Jim Thomson campaigns on behalf of patients in Europe. In his own survey he sent off for more than thirty medicines from internet pharmacies. Nearly all were easily available without prescription and laboratory analysis has shown that 62% were either substandard or counterfeit. The results left little doubt that people's lives are being put at risk.

### Interview Jim Thomson

#### European Alliance for Access to Safe Medicines

*Plavix is a medicine for people recovering from heart transplants, heart attacks. This is actually the same drug we received wrapped in the sports pages of the Mumbai Mirror with two free Viagra tablets as a bonus taped to the outer with Sellotape.*

*Some have the active pharmaceutical ingredient- the API-some don't. You find cocktails of different ingredients in these- brick dust, lead based road paint, last month a woman died in the United States when she had fifteen times the fatal dose of aluminum in a tablet. It took five days for her to die. So this is arriving and it's killing people.*

### Commentary

*(Shots of high street pharmacies in Europe, customs seizure at Zaventem)*

There's huge concern that the counterfeits are now also making their way into high street pharmacies.

Customs officers at Belgium's Zaventem airport intercepted a huge haul of fake antibiotics from Dubai which it's feared may have turned up in the legitimate supply chain.

*(shots of Ely Lilly, Brussels and Zyprexa)*

Ely Lilly had to issue a Europe wide alert to recall a batch of its antipsychotic medicine Zyprexa when a sharp eyed wholesaler spotted a slight flaw in the packaging.

### Thomas Thorp

#### Ely Lilly

*You can see from a visual perspective it's almost impossible to tell which one's counterfeit and which one's genuine. The quality of the packaging is remarkable really. But of course this is the trait of the counterfeiter- this is what they do. They invest an enormous amount of time in making sure the packaging is absolutely perfect so that it fools people.*

### Commentary

In fact there were only tiny tell tale differences- a missing line under an identification mark and the lot number printed upside down on the blister pack. The big difference was what was in the medicine itself:

### **Thomas Thorp**

*Approximately only 60% of the active pharmaceutical ingredient- the bit that makes this product work- was found contained in this product. So this product is sub potent- it doesn't have the desired effect. It won't do what it says on the tin. And for mental health patients who take this, any variation in those people not necessarily receiving their full treatment can be incredibly hazardous.*

### **Commentary**

*(A map showing the route Zyprexa had travelled.)*

It's believed the fake Zyprexa was manufactured in China, sent to Singapore or the Maldives for packaging, Brought into Europe via Luxembourg and traded around Europe with false documents to look as though it came from Lilly's plant in Ireland.

Pfizer, who make the real Viagra, have also had problems with other counterfeits products- such as cholesterol lowering drugs-turning up in the supply chain. Worldwide, thirty million fake Pfizer tablets have been seized by investigators over the past three years.

### **Stuart Hurst**

#### **Pfizer**

*This isn't a trade issue, this isn't an economic issue, this is a patient safety issue and we need to ensure that patients are guaranteed they receive safe and efficacious medicine when they go to their pharmacy.*

*You see where we are today, this is the Pfizer manufacturing plant in Belgium –if you compare that to with some of the pictures of the illegitimate supply chain for example with Viagra being made in cement mixers, it's truly frightening.*

### **Commentary(Ext. and interiors of European Commission Anti Counterfeiting conference)**

So how to beat the counterfeiters? The theme of a recent conference at the European Commission in Brussels.

Sound in:

*Charlie Mc Creevy:... “ to debate and discuss the main issues and to work for finding solutions to this modern day highway robbery ...”*

The Commission is preparing new legislation on medicines counterfeiting but Commissioner McCreevy also believes there could be better enforcement of existing laws:

### **Charlie McCreevy**

#### **EU Internal Market Commissioner**

*What I've tried to do in my visitations to member states is to emphasise to them that it's in their own particular interest to make sure they're not being used as an*

*area where counterfeit or pirated goods are being distributed from, Because I think effective enforcement of what they have on their statute books is the way to go. And I would accept that not all member states treat these issues as seriously as some other member states.*

Commentary (Images of EFPIA offices and people discussing publicity campaign, inside French pharmacy, exteriors of sanofi aventis, Paris)

In the meantime, the pharmaceutical companies are not sitting idle. They're running a public awareness campaign and they're also busy working on their own ways to beat the bogus operators.

But the industry is being hampered by the way medicines are traded in Europe. What you buy at your pharmacy may have changed hands 20 or 30 times since leaving the manufacturer. Because prices are set by national governments, it's perfectly legal for medicines to be bought by a wholesaler in a cheaper priced country and sold on to another country with higher prices. That usually means the pills need to be repackaged so that patient information is in their own language.

And that poses a problem for any attempts to incorporate workable anti counterfeiting features on the packaging.

The French pharmaceutical company sanofi aventis is spearheading an industry wide European track and trace system. A 2D data matrix code which will allow pharmacists to authenticate a product.

But for this system to work- the same packaging must stay in place from start to finish:

**Jean-Marc Bobée**

**sanofi aventis and European Federation of Pharmaceutical Industries Associations (EFPIA)**

*The key elements to fight counterfeiting is to maintain the pack integrity. And we need to maintain the pack integrity of the manufacturer's products all along the supply chain. And to do that we need two things: we need to have an official ban on repackaging in order to be sure that the code that the manufacturer puts on the pack will be maintained. And the second one is to implement tamper evidence on all products in order to be sure that we can guarantee that the content of the pack- the drug product- is well protected with the protection of the pack.*

Commentary(images pharmacies, pharmaceutical products)

The pharmaceutical industry wants to work closely with politicians, and pharmacists to beat the counterfeiters who kill. Experts want to see much tougher penalties- jail sentences to match those given to a cocaine smuggler instead of the fines most European countries impose today.

Mick Deats

MHRA,UK

*We've seen websites operating out of an upstairs bedroom of a house with over a million pound turnover. In relation to counterfeit medicines coming in from China for the regulated supply chain these cost a fraction of a penny to manufacture. The mark up is enormous. Often you're dealing with trade exceeding 6-7 or 8 million pounds. This is high profit, low risk and I think we have to change that risk balance so this becomes too risky for them to operate.*

Commentary(*Shots of UCB pharma production line, Brussels.*)

What matters is that patients feel confident that the medicine they are using comes from somewhere that looks like this.

(Shots of fake pills being made)

And not from somewhere like this where the only active ingredient in the pills may be brick dust .