

THE FAKE MEDICINE SCANDAL

We all trust the drugs we get on prescription. But as this chilling report reveals, ruthless counterfeiters are flooding the system with pills that are useless or downright dangerous



By TOM RAWSTONE

AN EARLY spring day and police raid a shabby industrial estate in Wembley, North London. They're looking for the premises of kitchen appliance salesman Allen Valentine, and when they enter his third-floor storage unit they can hardly believe their eyes.

Stacked against the walls are 250,000 fake Viagra tablets, 330,000 diazepam sleeping tablets, a £15,000 blister packaging machine and a press capable of making 1,500 tablets a minute.

Five thousand miles away in a garage in Bogota, Colombia, a stash of 800,000 anti-inflammatory and antibiotic pills have been discovered. They've been made from boric acid — a pesticide that can cause gastric problems — and bound together with brick dust. Mixed in a cement mixer, yellow paint normally used for road markings has been added for colouring with a drop of floor wax for a final sheen.

Forget fake handbags and knocked-off sunglasses. When it comes to earning a fast buck, the talk in criminal circles today is all about counterfeit medicines.

Easy to make with huge mark-ups and a fraction of the risks associated with the trade in cocaine and heroin, the figures speak for themselves: ten per cent of medicines sold around the world are believed to be fakes, a figure that rises to 40 per cent or more in some developing countries.

But living in Britain offers no immunity from this sick trade. Take, for instance, the events of last July when health chiefs here rushed to recall 120,000 pirated packets of Lipitor — an anti-cholesterol drug for which 11million prescriptions are issued each year.

What was most worrying was the fact that these fakes weren't being distributed at a car boot sale or sold on the internet. Instead, they were earmarked for pharmacies up and down the country.

A year earlier and the UK prescription supply chain was penetrated twice, forcing health watchdog the Medicines and Healthcare products Regulatory Agency (MHRA) to recall batches of the impotence and weight loss drugs Cialis and Reductil.

Fortunately, on these occasions, no one who took the drugs is believed to have suffered any adverse effects. But there are real concerns that there is a tragedy waiting to happen and that action needs to be taken now to clamp down on the situation in the UK.

Forget, for a moment, the wild-west market that is the internet. What is causing most concern is the potential for tapping into the supply chain that feeds Britain's 20,000 pharmacies. 'It's entirely

feasible that you could go to your pharmacy and pick up a counterfeit medicine,' Jim Thompson, of the UK-based patient group The Centre For Mental Health.

'The problem with these drugs is that while they may not kill you — and even if they do, this is usually almost impossible to prove — they won't make you any better.'

Concern, in particular, is focusing on a practice known as parallel trading. It goes on across Europe, but is most prevalent in Britain.

What it involves is the purchase of drugs by hospital trusts and retail pharmacies from intermediate suppliers — known as parallel traders — rather than directly from drug firms. The parallel traders, in turn, will have purchased the drugs in other EU countries where the prices are lower than here.

SOME £2 billion worth of drugs — about one-fifth of the NHS's annual drugs spend — are bought into Britain in this way each year. Supporters of the practice argue that it allows the NHS to make savings, but it also offers potentially one of the easiest routes for counterfeit drugs to enter the system.

Medicines imported in this way will have to be opened and repackaged several times before reaching

their final destination. In some cases, say industry analysts, a packet of medicine may be handled by up to 30 different intermediaries before it reaches the patient.

Such convoluted supply chains clearly present counterfeiters with opportunities to slip their fakes into genuine supplies, as well as making enforcers' jobs more difficult.

'When products are imported

from one country to another, medicines frequently have to be repackaged so that the labels are in English,' says Brian Ludhouse, a pharmacist from Sarratt, Hertfordshire. 'When a product is repackaged, any anti-counterfeit security devices, such as holograms, are pulled off and destroyed — or stolen to use on fakes.

'It's not difficult to manufacture a tablet which looks identical to the real thing. And, unless you were to test every single product, there's no way even an experienced pharmacist can tell the difference.'

Some of the fake drugs may be chemically identical copies of the branded medicines, usually sourced from India or China, which have been repackaged to look like the genuine article. They should still do the job they're supposed to do, but that cannot be guaranteed.

Then there are those medicines that are entirely bogus and contain little or none of the medication or, worst of all, substances that could cause actual harm.

Other batches, as James Christian, head of global security for Swiss-based pharmaceutical giant Novartis, explains, may be a mixed bag. 'In the Nineties, when you

pulled one tablet from a shipment and tested it, if it was counterfeit you could pretty safely say everything was counterfeit,' he says.

'Now if you do a raid, you can run into a mix of counterfeit, genuine, expired and stolen products. If someone took out one capsule and it turned out to be genuine, it doesn't mean the rest are genuine.'

As a result, patients could take a course of pills for months and neither they nor their doctors would be likely to put their condition's lack of improvement down to the fact that the tablets don't work.

'When someone dies from a pre-existing condition, there will always be an assumption that the drugs they have used have been genuine,' says Graham Satchwell, a former CID chief superintendent who has recently written a report

on counterfeit drug crimes. 'In such circumstances there is no post-mortem and no one knows.'

For this reason, among others, Mr Satchwell dismisses as nonsensical the MHRA's claim there is 'no evidence' of fake medicines entering the legitimate UK pharmaceutical supply chain through parallel trading.

He argues that this lack of evidence is unsurprising given that each year the MHRA tests just 3,000 samples of medicines — a minuscule figure compared with the 600 million items prescribed annually in the UK.

'The World Health Organisation estimates that between eight and ten per cent of drugs are counterfeits,' Mr Satchwell says. 'The NHS buys £10 billion of drugs a year, which means that £1 billion worth of medicines in circulation in this country could be fake.'

'Now, many people will say that is ridiculously high. So let's just look at

the amount that is imported — the £2 billion — and if we say that ten per cent of that is counterfeit, then we are still talking about £200 million worth of counterfeit drugs in this country.'

Does he believe anyone has died in this country from taking fake drugs?

'I think it is highly likely that people have died from taking counterfeit medicines that are either completely ineffective, dangerous in themselves or provide such a light dose that the disease wins,' he says.

Concerns about parallel trading were highlighted in a report into counterfeit drugs published by the Council of Europe last month.

It's author, Dr Jonathan Harper, a former NHS doctor turned management consultant, told the Mail: 'A lot of people on the council's committee were against me commenting on parallel trading at all because by criticising the system in medicine, you are basically undermining the single market European trading system.'

'I disagree with that, and there is certainly evidence that the parallel trading system in medicines does facilitate the entry of counterfeit medicine into the European market.'

WHILE arguments over the extent of the potential problem posed by parallel trading look likely to run and run, the position concerning the internet is far more cut and dried.

A counterfeiters' paradise, it is estimated that up to 80 per cent of so-called POMS (prescription-only medicines) sold online are fake and the MHRA is investigating more than 100 cases of online counterfeit sales.

'We will always advise of the risks of purchasing medicines without a prescription from anywhere and especially over the internet,' says Nimo Ahmed, the MHRA's head of intelligence. 'The clear message is that a member of the public would be risking their health as well as potentially funding other criminal activity.'

The most common internet fakes are drugs related to 'lifestyle' problems such as impotence, obesity and baldness. Alongside the impotence treatments Cialis and Viagra, other favourites are weight-loss drugs such

as Ephedra, which was banned in the U.S. after being linked with serious side-effects, and Propecia, a male hair loss treatment which can cause serious harm to women who handle it.

Charles Walker, the Conservative MP for Broxbourne, Hertfordshire, has taken the parliamentary lead in the campaign against counterfeit medicines and has highlighted the particular dangers posed by the lack of regulation on internet sales.

'There are more than 2,300 websites selling drugs,' he says. 'In almost all cases they are unlicensed to sell or prescribe

prescription medicines.'

For the criminals who make the counterfeit medicines and then sell them on, it is a high-margin, low-risk activity. Consider the case of Allen Valentine, 47, whose drugs factory could produce more than 500,000 fake pills a day.

Some of his fake Viagra pills contained no active ingredients while batches of so-called diazepam tablets, often taken to relieve anxiety, contained nitrazepam, which can actually have the opposite effect.

So good was business that just 24 hours before Valentine's arrest in 2004, he had made a cash offer for a £1.5 million Edwardian mansion on a private estate in Hertfordshire.

But despite the scale of his operation, Valentine received only a five-and-a-half-year prison sentence, with his infringement of Pfizer's Viagra copyright — and not his serious threat to public health — forming the basis of his sentence.

With experts warning the amount of fake medicines is growing year by year, it is the most vulnerable sections of society who will suffer and spotting fake products is far from easy.

Advice offered includes comparing the appearance, taste, texture, and reaction between prescriptions of the same drug.

If drugs do not seem to have the same taste, or if the patient feels different to when they take them usually, they are advised to contact their doctor or pharmacist immediately.

MEANWHILE, efforts to prevent counterfeiters penetrating the legitimate UK pharmaceutical supply chain are focusing on improving traceability so that even if packaging is changed, a pharmacist can check a drug's authenticity with the manufacturers using barcodes and internet technology.

'The pharmaceutical industry needs to invest in the right technology and more secure procedures and systems of product identification,' says Graham Satchwell. 'We need increased resources for the regulation of medicines, and unless we see all these steps implemented, innocent people will continue to be exposed to unnecessary danger.'

Charles Walker, meanwhile, warns that the pharmaceutical supply system is 'a Bermuda triangle formed by parallel trade, counterfeits and online pharmacies'.

While risks to British patients remain relatively low, without decisive action it is a Bermuda triangle into which public confidence in our medical supplies

could fast disappear.

■ *ADDITIONAL reporting:*

Norman Miller and Eva Gizowska.