

GoodHealth

As counterfeit medicines reach local chemists, are YOU at risk?

By **BARNEY CALMAN**

LIKE many men suffering from erectile dysfunction, Steven didn't tell anyone about his problem. The 44-year-old financial lawyer was too embarrassed.

After months of making excuses to his wife, he decided to take action. But instead of going to see his doctor, he turned to the internet.

'I felt ashamed,' says Steven. 'I know I should have gone to see the doctor but I couldn't even admit to my wife what was happening, let alone tell a man I hardly knew.'

He found an internet pharmacy that sold Viagra without prescription. 'The testimonials seemed convincing,' Steven paid around £20 with his credit card, and a few days later 16 tablets arrived by post; the distinctive blue pills were sealed in blister packs labelled '100mg sildenafil citrate', the active ingredient in Viagra. There was no box or information leaflet.

Steven took one an hour before bed, as advised by the website. 'It was incredible. I was able to resume a normal life with my wife,' he says. 'Of course, I didn't tell her about the tablets. I placed a second order for more pills straight away.'

However, with the second batch he immediately noticed something different. 'Within half an hour of taking one tablet I had a throbbing headache and my face went bright red. There was also the desired effect, but I felt so awful I had to sit in the bathroom until the headache subsided — about an hour later — and then went to bed.'

'I couldn't understand why it had this effect — the tablets looked identical to the last ones, and the blister packs were the same. A few days later, I tried again and had a similar experience. This time I also felt nauseous.'

Steven finally admitted everything to his wife, who persuaded him to see his GP.

'From my reaction, the doctor said it was likely I'd bought counterfeit drugs with a much higher dose of active ingredient than was safe,' says Steven. Symptoms of a Viagra overdose include chest pain, nausea, irregular heartbeat and feeling light-headed or fainting.

His GP said other patients had described similar problems. Steven was then prescribed a drug similar to Viagra and was advised on ways to reduce stress (a possible cause of erectile dysfunction).

'I feel like an idiot now,' says Steven. 'I put my health at risk because I was too embarrassed to seek help.'

Steven's experience is far from unusual. The global trade in counterfeit medicines is worth £10 billion a year — and while drugs for impotency and hair loss are popular targets, fake statins, blood-clotting drugs and even cancer medicines are also being pushed on to an unsuspecting public and healthcare professionals.

Criminal gangs are now so sophisticated that they buy the same packaging equipment as drug companies and even attend trade fairs, explains Eric Noehrenberg, of the International Federation of Pharmaceutical Manufacturers and Associations.

'It makes it difficult, if not impossible, to tell true products from fakes, except through extensive chemical tests,' he says. 'Britain is a lucrative market for counterfeiters. Sometimes people take medication and it doesn't work. Nobody thinks to ask what was actually in their pills and whether they were genuine. But if you are unlucky, you will get serious health effects.'

COUNTERFEIT medications tested by the Medicines and Healthcare Products Regulatory Agency (MHRA) have found traces of brick dust and rat poison, says Mick Deats, head of enforcement for the drugs watchdog. 'Some contain no active ingredients at all; others have much higher doses than is safe. This is a major health risk.'

Until now, it's the Third World that has really suffered from drug counterfeiting. Half the malaria medicines in use in Africa, for instance, are thought to be fakes. But over the past two years, the problem has become endemic in Europe, too; in 2005 there were half a million single doses of fake medicines discovered in Europe — last year that figure shot up to 2.5 million.

Only last month, a Hertfordshire businessman was jailed for four-and-a-half years for his role in a multi-million pound trade in fake Viagra. Ashish Halai, with his fellow conspirator Gary Haywood — who is awaiting sentenc-

ing — had smuggled the pills into the UK from China, India and Pakistan, then distributed them to customers via the internet.

Undercover officers filmed Haywood trying to sell fake drugs — including Cialis, a drug for impotency, and Propecia, for male pattern baldness. He claimed he was a pharmacist and international sales manager for Viagra manufacturer Pfizer and had got the drugs 'on the cheap'.

Haywood had paid as little as 25p each for a tablet, and charged up to £20. When officers visited his home in Barwell, Leicester, they discovered boxes of counterfeit pills worth around £1.5 million. The investigation led to another 12 convictions in

America, with £13 million of counterfeit pills seized in Miami.

However, experts believe this is the tip of the iceberg. The World Health Organisation (WHO) now estimates that up to 50 per cent of drugs bought online are fakes.

Yet the problem is not confined to the internet, says Jim Thompson, chairman of the pressure group the European Alliance for Access to Safe Medicines.

Halai and Haywood had also managed to get some of the counterfeit products on to chemist shelves; 10 per cent of all prescription medications globally are counterfeits, says the WHO, and this figure is set to grow.

'There is no doubt that fakes have entered the legitimate supply chain,' says Mr Thompson. Counterfeits can often contain some active ingredients. However, some may have more than the recommended dose, which puts people at risk of overdosing.

'Counterfeiters don't necessarily want to harm patients — if someone dies or becomes ill, it raises suspicion and they don't want to get caught. So the drugs simply may not work — which is also risky for the patient.'

On three separate occasions between 2005 and 2006, the MHRA found fake versions of the cholesterol-lowering drug Lipitor being sold, unwittingly, by pharmacists.

The counterfeits were so sophisti-



Picture: WWW.IMAGESOURCE.COM posed by model

ARE YOUR PILLS FAKE?

cated they carried forged security codes on the packs, impossible to distinguish from the genuine article. But they were found to contain an unlicensed statin. To identify the fakes, Pfizer, the legitimate manufacturer of Lipitor, was forced to recall 120,000 packs of its drug. This summer, drugs manufacturers had to order a recall of three drugs, Plavix (to prevent blood clotting), Casodex (to treat prostate cancer) and Zyprexa (an anti-psychotic) after fakes were unwittingly handed out by pharmacists.

Mr Thompson believes it's impossible to gauge the true scale of the problem. Between 1995 and 2005, the MHRA tested around 25,000 packs of medicines, randomly sampled from pharmacy shelves — less than 0.001 per cent of prescriptions handed out over that period.

'We simply don't know how many fakes there are out there,' says Mr Thompson. 'No one is even looking.'

Criminals get into the legitimate supply chain by taking advantage of the fragmented way drugs are traded across the European Union.

People can buy and sell medicines like any other commodity, says Julian Mount for Pfizer Pharmaceuticals Worldwide. 'The same rules that govern the trading of soft drinks and jeans apply to pharmaceuticals. It's a free-for-all at present and not safe for the supply of medicines.'

European law allows licensed traders to buy and sell medicines freely. This means that once a medicine has left the manufacturer's gates, it can be sold on — and repackaged — any number of times before it reaches a pharmacist.

DRUGS in the UK are more expensive than in other European countries; dealers can make a profit by buying cheaply in Greece, for example, then selling the drugs to UK pharmacists.

Because patient information leaflets must match the native language of the country where the drug is sold, it is permissible for the product to be repackaged by third parties. This provides a way for counterfeiters to enter the legitimate supply chain.

Pharmacists don't realise they are buying fakes. As David Pruce, of the Royal Pharmaceutical Society of Great Britain, explains: 'They are victims, too. In many cases — including the Lipitor case — fakes have been sold to them by reputable wholesalers, who had unwittingly bought batches of counterfeits.'

The profits are huge and the risks are very small compared with trafficking narcotics,' says Mr Noehrenberg. 'With the expansion of the EU, the threat is only increasing.'

Mr Thompson says it is a problem both the MHRA and the Government need to address. 'They have no control over what is going on and they won't even admit it's their system that's at fault.'

However, Mick Deats, of the MHRA, believes the system — all traders are licensed by the MHRA — is safe, and that reports of counterfeits being sold to pharmacists and the NHS are greatly exaggerated.

'There have only been nine known occasions that counterfeits have ended up on pharmacy shelves, and in just four of those cases a licensed wholesaler was involved.'

Of course, the real need is to tackle the problem of fake drugs at source. Seven illegal factories in China were closed as a result of the Viagra scam.

However, the general view is that the manufacture of medicines is poorly regulated in countries such as China and India where fake drugs often originate.

As Mr Deats explains: 'We can only pass on information to regulators in other countries and hope they act on it.'

Victor Chen, the Chinese-based manufacturer who supplied Gary Haywood with drugs, is still at large.

'Neither we nor our counterparts in China have any idea where he is,' says Mr Deats. 'There would be nothing stopping him from setting up shop under a new identity.'

And peddling his wares to even more unsuspecting consumers.

HOW TO PROTECT YOURSELF

SO WHAT can you do to protect yourself against fake medication? JIM THOMPSON of the European Alliance For Access to Safe Medicine suggests the following...

- **BUYING** drugs via the internet is a huge risk and all the experts agree it should be avoided.
- **AS** for drugs obtained from a pharmacy, vigilance is the key. When you get a new prescription of your medication, check if there is anything unusual about it. It's worth keeping an empty box to compare each new batch to.
- **IF** the packaging is different or if you notice a

change in the way the medicine looks or tastes, if it seems to work differently or there are unusual side-effects, speak to your pharmacist.

- **COUNTERFEITS** can often contain some active ingredients — some may contain far more than the recommended dose, putting patients at risk of overdosing. 'As a patient, you have the right to insist that you receive the exact same drug from the same manufacturer and dealer every time,' says Mr Thompson. 'Your pharmacist should be able to guarantee this.'