

GRACKING COUNTERFEIT



Dr Mark Porter, GP

FOREWORD

THE WORLD REALTH ORGANISATION (WHO) ESTIMATES THAT 10% OF ALL - FRAUDULENT FAKES MARKETED AS THE REAL THING!

European countries like the UK are being increasingly targeted by counterfeit manufacturers – seizures at EU borders have rocketed from just over half a million articles in 2005, to more than 4,000,000 in 2007.^{2,3}

Part of this growth can be put down to increasing demand for "lifestyle" medicines like those taken for erectile dysfunction and weight loss.1 A market that has been further fuelled by the growth of online suppliers - according to the WHO, half of all medicines now available from sites that conceal their physical addresses are counterfeit.1

But erectile dysfunction (ED) and weight loss are not the only therapeutic areas targeted by the counterfeitersrecent seizures by the authorities in the UK have also included treatments for life threatening conditions such as heart attack and cancer.1

Industry journal, The Prescriber, states that the UK is being targeted by counterfeiters because the price of medicines is high.4 Has the market for counterfeits grown purely to meet the demand of people seeking cheaper alternatives, or are there other factors?

There is plenty of research uncovering the enormity of the counterfeit medicine market, but do we really understand why people are choosing not to engage with their GP or pharmacist and instead opting to risk their health by buying through illicit sources?

Cracking Counterfeit gives an insight into why the public is buying prescription only medicine from illicit sources. While the pharmaceutical industry works with health regulators, global customs and trade organisations to uncover counterfeiters and bring them to trial, this report uncovers why people, particularly men, continue to fuel the market.



EXECUTIVE SUMMARY

IN SEPTEMBER THIS YEAR, PFIZER COMMISSIONED THS, A MATOR MARKET RESEARCH COMPANY, TO QUESTION 935 MEN AGED 35+ IN MATOR UK GITIES.

In this survey respondents were asked about their knowledge and behaviours surrounding the purchase of certain medicines without a prescription, including from sources such as unregulated websites.

The research was undertaken to better understand the mindset of men and why they're turning to illicit sources to buy medicines, often without prescription or consulting a healthcare professional.

The reason men are the focus of this research is because it's been proven that they're far less likely than women to visit or even be registered with a GP.5 Furthermore, a third of men would risk their health by not going to the doctor's quickly enough.6

Cracking Counterfeit uncovers the reasons why bypassing the health system to purchase medicines is becoming such a problem in the UK, particularly relating to counterfeit medicines and how we can work with regulators and health organisations to help remedy this. Using consumer insight from the TNS and third party research we look at why purchasing medicines from illicit sources is such a risk, how consumers are obtaining medicine and in what quantities, and importantly, why they're taking that risk.

The findings paint an interesting picture and help us to further educate the public around the risks of purchasing medicine through unregulated sources, ultimately reducing exposure to counterfeit medicine. We hope you find them as insightful as we do.

Dr David Gillen, Medical Director Pfizer UK

Some of the key findings from the group of men interviewed:

- > 1 in 10 have purchased medicines without a prescription.7*
- > 50% of the men interviewed purchasing medicine without prescription, have done so via the Internet.7**
- > Nearly a third of the men buying without a prescription (32%) see taking prescription only medicine without a prescription as low or neutral risk.7"
- > Over half (60%) of the men who have bought prescription medicines without a prescription admit that if there was a possibility their medicine was counterfeit, it would have a great impact on their likelihood to purchase.7*

Chapter One COUNTERFEIT GASINO

Counterfeit Casino

1 in 10 of the UK men interviewed – which would equate to more than 335,931 living in major cities alone - admit to purchasing prescription only medicines without a prescription, implying they're going direct to illicit sources to seek their treatment.7*,8 The big question we'll be addressing in this report is: should they be questioning their behaviour?

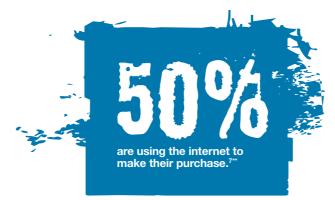
Is There a Risk?

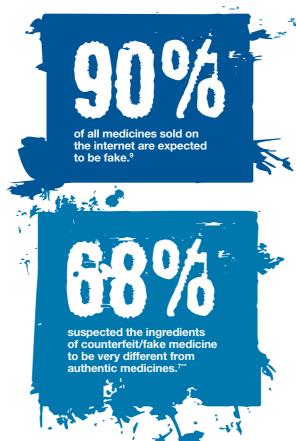
Of the men interviewed who had purchased prescription medicine without a prescription, 50% are using the internet to make their purchase – a worrying statistic when you consider that 90% of all medicines sold on the internet are expected to be fake.^{7**,9}

The reality is, if men are buying from illicit sources, they are more likely to be taking fake medicine than the real thing. And among the majority of men interviewed for this report, there seems to be a degree of acceptance that pills purchased from illicit sources are not going to be the genuine article – 68% of all respondents suspected the ingredients of counterfeit/fake medicine to be very different from authentic medicines.7

It would seem that men are turning a blind-eye to the health risks associated with purchasing counterfeit medicine from unregulated sources and are particularly naive about the ingredients that counterfeit medicines might contain.

38% of respondents, who thought the ingredients would be different, were unable to list any.7*







Genuine atorvastatin tablets: counterfeit atorvastatin tablets



Difficult to Detect

"If you knew what you were buying, you'd expect it to be what you thought. I'd probably buy Omeprazole online because I'd recognise it when it turned up. I think if it was something I was taking all the time and I knew what it looked like then I would know when I got it."

Kevin, 53, Taunton

The fact is, it can be almost impossible to detect if a tablet is genuine or not. The counterfeit medicine industry has grown in sophistication and size over the years partly because counterfeiters have become so good at making their medicine look like the real thing. In fact, often only laboratory analysis can detect if it's real or not.1

Wendy Greenall, Senior Chemist at the Pfizer Counterfeit Lab, Sandwich, UK, echoes this;

"The counterfeit medicine we see is either obviously fake, or very close to the real thing and it can take weeks of testing to analyse. For example, the active ingredients in erectile dysfunction (ED) medicines are often included in counterfeit tablets, but they won't contain the correct dose. They can

also contain different active ingredients, such as metronidazole™, a commonly used antibiotic which is quite often found in fake Viagra® (sildenafil citrate). This can be dangerous, as when combined with alcohol can make you violently sick.

"Equally we have found a counterfeit cholesterol lowering medicine, containing no active ingredient at all, just talcum powder.

"We often see high levels of non-active substances or bulking ingredients, such as lactose, sucrose and chalk, and they regularly contain paracetamol.

"Counterfeit medicine can also contain high levels of toxic solvents. Rat poison, for example, has been found in a counterfeit blood pressure lowering treatment, while boric acid and lead based road paint have both been found in a counterfeit medicine used to ease severe pain."

If you knew what you were buying, you'd expect it to be what you thought. I'd probably buy Omeprazole online because I'd recognise it when it turned up. I think if it was something I was taking all the time and I knew what it looked like then I would know when I got it.

Kevin, 53, Taunton

ONE IN 10 UK MEN ADMITTED TO PURCHASING MEDICINES FROM UNREGULATED SOURCES, WITHOUT PRESCRIPTION.7*







Production of counterfeit medicine in Egypt and China

The Killer Question

Are men who obtain medicine from illicit sources risking their health?

The regular use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance; in some cases it can lead to death.¹⁰

Respondents who believed there would be more side effects from counterfeit medicines than genuine ones listed some of the following side effects:

- > Only 16% cited death as a potential side effect.7**
- > Just 1% stated it might react with other prescription medicines.^{7**}
- > Just 8% suggested vomiting as a potential side effect.7**
- > 25% did not know what the side effects would be.7**

Today, 12% of UK men like to gamble online.¹¹ Almost the same proportion, 11%, may be literally gambling on life through purchasing potentially counterfeit medicine.⁷

TODAY, 12% OF UK MEN LIKE TO GAMBLE ONLINE." ALMOST THE SAME PROPORTION, 11%, MAY BE LITERALLY GAMBLING ON LIFE THROUGH PURCHASING POTENTIALLY COUNTERFEIT MEDICINE."

THE REGULAR USE OF SUBSTANDARD OR COUNTERFEIT MEDICINES CAN LEAD TO THERAPEUTIC FAILURE OR DRUG RESISTANCE; IN SOME CASES IT CAN LEAD TO DEATH.10



01%

did not know what the side effects would be.7**



cited death as a potential side effect.7**



suggested vomiting as a potential side effect.7**



might react with

stated it might react with other prescription medicines.7**

Despite strong evidence, many respondents did not know about the side effects posed by counterfeits.

Chapter Two

THE GATEWAY TO GOUNTERFEIT

"I imagine it would be easy [to purchase medicine] without a prescription. I know people who have [visited] websites, they call it the embarrassing products website... but there's always a risk that it won't be real or genuine."

Phil, 48, Cornwall

Almost half (45%) of men interviewed taking the gamble and purchasing prescription only medicines without a prescription agreed that it was easy to get hold of.^{7**}

Arguably the one source fuelling accessibility to counterfeit drugs is the internet.¹²

50% of the men purchasing prescription only medicine without prescriptions are doing so using the web.^{7**} Again, this statistic increases to 67% for men purchasing erectile dysfunction (ED) medicine.^{7**}

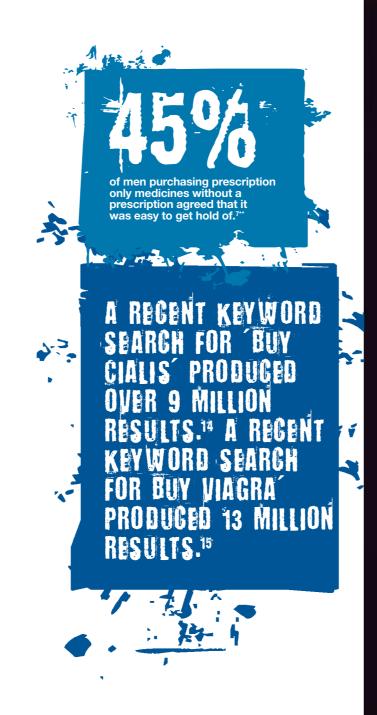
While there are a handful of legitimate sites that sell prescription medicine, listed on the Royal Pharmaceutical Society of Great Britain (RPSGB) website, www.rpsgb.org, there are many more that aren't legal.¹³

The exact number changes daily, but a recent keyword search for 'Buy Cialis' produced over 9 million results. A recent keyword search for 'Buy Viagra' produced 13 million results. 5

Buying Medicine Online

Buying behaviour of those men interviewed who admitted to purchasing without a prescription:

- > 26% buy from overseas websites.7**
- > 32% buy from UK sites.7**
- > 36% buying ED medicine, buy from overseas sites.^{7**}
- > When researching where to make a non-prescription purchase, 31% would Google™ a number of sites and go with the one that looks the most professional.^{7™}
- > 4% admit they had purchased via an email/ spam offer.^{7*}





I imagine it would be easy (to purchase medicine) without a prescription. I know people who have websites, they call it the embarrassing products website... but there's always a risk that it won't be real or genuine.

Phil, 48, Cornwall

Men are putting their faith in the internet. Only 18% of respondents would follow a friend's recommendation about where to purchase from, and shockingly only 6% would seek advice from a pharmacist or GP first.7**

In addition to purchasing counterfeit medicines via the internet, a number of UK men interviewed have also purchased without a prescription whilst overseas or on holiday abroad (11%), in shops (34%) and, in some cases, at a pub or nightclub (3%).7**

"A few of my friends have had those drugs [erectile dysfunction medicine] through the back door... not that they needed them but I think it was quite a bloke thing to do at the time."

Mark, 38, Manchester

Doctor, Doctor... What Are Men Taking?

Three guarters (75%) of purchases of prescription only medicine without prescriptions are for smoking cessation, erectile dysfunction or weight loss (from the list of medicines given).7**

The remaining quarter of purchases are for medicines to treat either depression or high cholesterol (from the list of medicines given).7**

The Money Being Made On Counterfeit

Just because it's bought on the black market, doesn't make it cheaper. On average, the men interviewed claimed to spend £30.61 every year on medicines potentially from illicit sources – that would equate to £10,282,847 potentially being poured into the counterfeit medicine market annually.7*,8

The Center for Medicine in the Public Interest, based in the US, predicts that counterfeit medicine sales will reach approximately €55.5 billion globally by 2010 - an increase of more than 90% over just five years.16

THE CENTER FOR MEDICINE IN THE PUBLIC INTEREST PREDICTS THAT COUNTERFEIT MEDIGINE SALES WILL REACH APPROXIMATELY €55.5 BILLION GLOBALLY BY 2010.16

UK MEN ARE POTENTIALLY POURING £10,282,847 INTO THE GOUNTERFEIT MEDIGINE MARKET ANNUALLY.7*,8



Chapter Three

THE E-MBARRASSMENT FACTOR

The E-mbarrassment Factor

Why do men feel the need to purchase prescription only medicine without visiting their doctor? Convenience and speed (37%) are two key reasons cited for purchasing medicine without prescriptions.7**

"I get prescribed Omeprazole because I have an acid stomach. Over here I have to queue up and wait for a repeat prescription and order it in advance which is a pain. So I just buy it in America."

Kevin. 53. Taunton

For nearly a fifth (19%) of men purchasing erectile dysfunction (ED) treatment, avoiding the embarrassment of having to go to the GP is a motivation.7**

"The majority of men about my age would probably choose to buy without a prescription because it would be an embarrassment going to a GP and having ED diagnosed."

Stephen, 26, Birmingham

Finally, a fifth of men interviewed who purchase without prescriptions, claim to buy through this channel because they say it's cheaper.7"

Knowledge is King

Alarmingly, there is confusion among men about which medicines require a prescription and which do not. This could be a key factor in fuelling the counterfeit industry and driving men to unregulated websites and other sources.

"No I didn't know I needed a prescription **IED** medicinel."

Ray, 49, London

"No I didn't realise that - mainly because you can buy it on the internet anyway."

Mark. 21. London

"Prescription medicine...that could be anything from the pill to pile cream."

Phil, 48, Cornwall

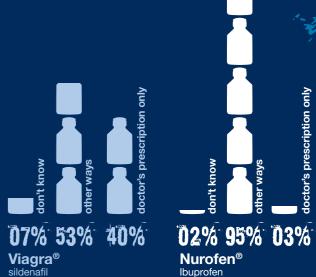


The majority of men about my age would probably choose to buy without a prescription because it would be an embarrassment going to a GP and having ED diagnosed.

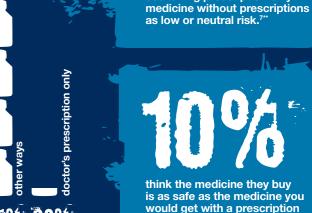
Stephen, 26, Birmingham



While men are unsure when a prescription is required, a large number are also oblivious to any risks in buying from illicit sources. Nearly a third, 32%, of those interviewed that buy medicine from sources other than via a doctor's prescription, see taking prescription only medicine without prescriptions as low or neutral risk.7 Furthermore, 10% of those men agree that the medicine they buy is as safe as the medicine you would get with a prescription from a GP.7**



Ibuprofen



see taking prescription only

because it's cheaper.7*

from a GP.7

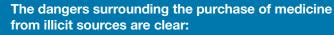
Conclusions

GRACKING COUNTERFEIT

FOR THE MOST GOUNTERFEITED MEDICINE, MORE THAN HALF OF THE MEN WE INTERVIEWED BELIEVE THAT YOU DON'T NEED A PRESCRIPTION TO GET IT.7**,18

medicine to be unsafe, they would visit their GP rather than continuing to purchase in this manner.7

possibility their medicine was counterfeit, it would have a great impact on their likelihood to purchase.7*



- > The risk of purchasing fake medicine over authentic medicine is high.9
- > The ingredients used in counterfeit medicine can be harmful. 10
- > People have died in some parts of the world from taking counterfeit medicines, and many more have fallen sick.¹⁰

So, in the UK, are the 1 in 10 men currently risking their health through purchasing potentially counterfeit medicines, doing so knowingly?7*

Our research points to a significant disconnect between how men perceive the medicine they buy themselves and how and what they perceive to be a trusted, regulated source;17 they are not necessarily marrying one with the other.

The majority (60%) of respondents who have bought medicine without prescription admit that if there was a possibility their medicine was counterfeit, it would have a great impact on their likelihood to purchase.7** 37% who have purchased prescription only medicine without prescriptions also said if they found their medicine to be unsafe, they would visit their GP rather than continuing to purchase in this manner.7"

For the most counterfeited medicine, more than half of the men we interviewed believe that you don't need a prescription to get it.7**,18

Research suggests that with better awareness and knowledge, the number of men putting their health at risk from counterfeit medicine could be reduced dramatically.17

Currently men are fuelling growth of the counterfeit market - a trend Pfizer is campaigning to reverse.

The Cracking Counterfeit report is the catalyst for a public education campaign Pfizer is launching to **better inform** people around the issues of purchasing medicine from unregulated sources and the risks posed by counterfeit medicine. As the world's largest pharmaceutical company, Pfizer leads the way in raising awareness of the risks posed by counterfeit medicines and is committed to ensuring threats to patient safety are tackled.

In response to the growing threat to patient safety, Pfizer has invested in state of the art forensic facilities at its Counterfeit Lab in Sandwich, and over the past ten years has built a team of security experts to investigate, monitor and tackle patient safety issues in the UK. The practice of counterfeiting medicines poses potentially serious health risks to patients and Pfizer is committed to taking whatever action is deemed appropriate to stop this illegal activity and protect patients.

The industry as a whole recognises the potential dangers of counterfeit medicine - The Royal Pharmaceutical Society of Great Britain (RPSGB) provides a list of legitimate, approved online pharmacies on its websites for people to check.¹³



I can see why some people might consider buying prescription medicines online from unregulated "pharmacies" - it's convenient, relatively anonymous and often cheaper but they shouldn't. Any apparent benefits are more than outweighed by the risks of ending up with counterfeit medicines. Fakes that are unlikely to contain what they are supposed to, and which often contain chemicals they shouldn't. At best they are useless, and at worst potentially lethal. Why gamble with your health?

Dr Mark Porter, GP



REFERENCES

- MHRA Safety Information on Counterfeit Medicines and Devices.

 Last accessed 30.10.08 from http://www.mhra.gov.uk/
 Safetyinformation/Generalsafetyinformationandadvice/
 Adviceandinformationforconsumers/
 Counterfeitmedicinesanddevices/index.htm
- 72 Report on community customs activities on counterfeit and piracy, European Union, Taxation and Customs Union, 2007. Last accessed 20.10.08 http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf
- 73 Faucherand, P. The evolving problem of counterfeiting and piracy. Presentation at Workshop in the Application of Targeted Risk Management on IPRs for Customs and Economic Police. 2-6 April 2007. Last accessed 20.10.08 http://www.ecap-project.org/fileadmin/ecapll/pdf/en/activities/national/Vietnam/customs_apr_2007/pierre_faucherand_engl.pdf
- Chaplain, S. The MHRA's three-pronged strategy to tackle counterfeits. The Prescriber 2008;19 (18): 51-53.

- 15 Laterlife.com. Last accessed on 22.10.08 from: http://www.laterlife.com/features/laterlife-national-mens-health-week.htm
- 06 999today. Last accessed on 22.10.08 from http://www.999today.
- 7 TNS survey data, September 2008. 187874: PR Consumer Survey. Participants: 935. Cities included Belfast, Birmingham, Bristol, Cardiff, Edinburgh, Greater London, Greater Manchester, Leeds, Norwich, Southampton. Medicines included were erectile dysfunction medicine, smoking cessation medicine, weight loss medicine, cholesterol-lowering medicine and anti-depression medicine
- ONS Census 2001
- jg In-PharmaTechnologist News. Last accessed 08.10.08 from http:// www.in-pharmatechnologist.com/Industry-Drivers/The-globaldisaster-of-fake-internet-pharmacies
- WHO and IMPACT factsheet. Counterfeit drugs kill! Last accessed on 08.09.08 from http://www.gphf.org/images/downloads/impactbrochure.pdf

- Jacques, R. One in ten men gambles online. Computer Shopper. Last accessed 08.10.08 from http://www.pcpro.co.uk/shopper/news/228588/one-in-ten-uk-men-gambles-online.html
- 12 European Alliance for Access to Safe Medicines: The Counterfeiting Superhighway, 2008, Medicom
- 13 Royal Pharmaceutical Society of Great Britain news release. Millions risk health buying drugs online. Last accessed on 10.10.08 from http://www.rpsgb.org/pdfs/pr080110.pdf
- 29th October 2008, Google search results, 'Buy Cialis'
- 9th October 2008, Google search results, 'Buy Viagra'
- [6] Center for Medicine in the Public Interest (2005).

 Last accessed on 09.10.08 from http://www.cmpi.org/testimony/
 counterfeit-drugs-and-china/
- 17 Pfizer data on file
- WHO Fact sheet number 275. Substandard and counterfeit medicines. Nov 2003. Last accessed on 16.10.08 from http://www.who.int/mediacentre/factsheets/2003/fs275/en/

- * TNS weighted data
- ** TNS unweighted data



