

# Medicines Online – A Global Issue

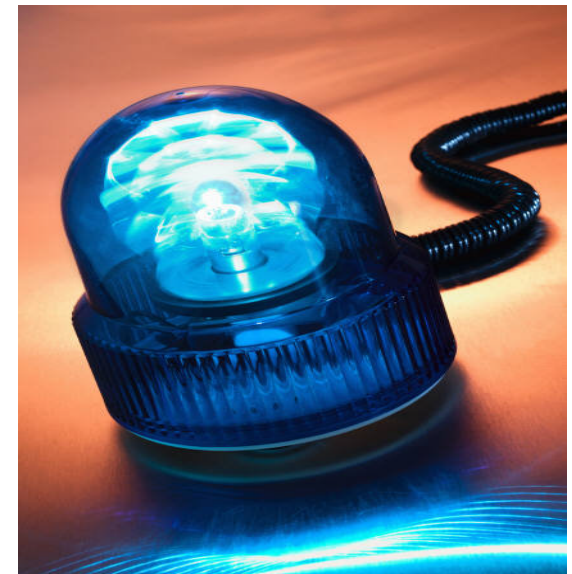
Lynda Scammell / Enforcement Group / MHRA



# UK Position – the MHRA



- In the UK, the enforcement of medicines law is the responsibility of the MHRA  
- not the Police



# UK Position – the MHRA



- Responsible for enforcing medicines in England, Scotland and Wales (not in N Ireland)
- Powers conferred by Human Medicines Regulations 2012 (Medicines Act 1968)
  - Investigation and prosecution
  - Entry - commercial premises / dwellings
  - Inspection (search), seizure
  - Undertake covert activity - RIPA 2000
  - Pursue Proceeds of Crime - POCA 2002



# UK Position – the MHRA



- Use Crown Prosecution Service solicitors
- Maximum sentence 2 years and/or unlimited fine + administrative sanctions
- MHRA will use most appropriate offence available in addition to Medicines legislation including;
  - Trade Marks Act,
  - Fraud Act
  - and Proceeds of Crime Act
  - **heavier penalties!**

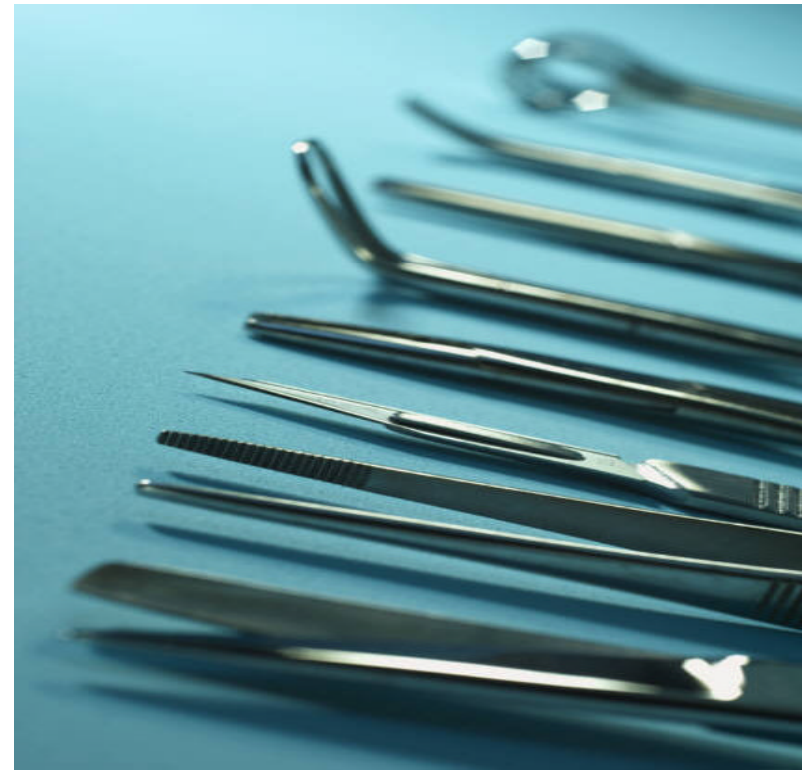




# UK Position – the MHRA



**Medicines and Medical Devices are increasingly subject to illegal trading**



# UK Position – the MHRA



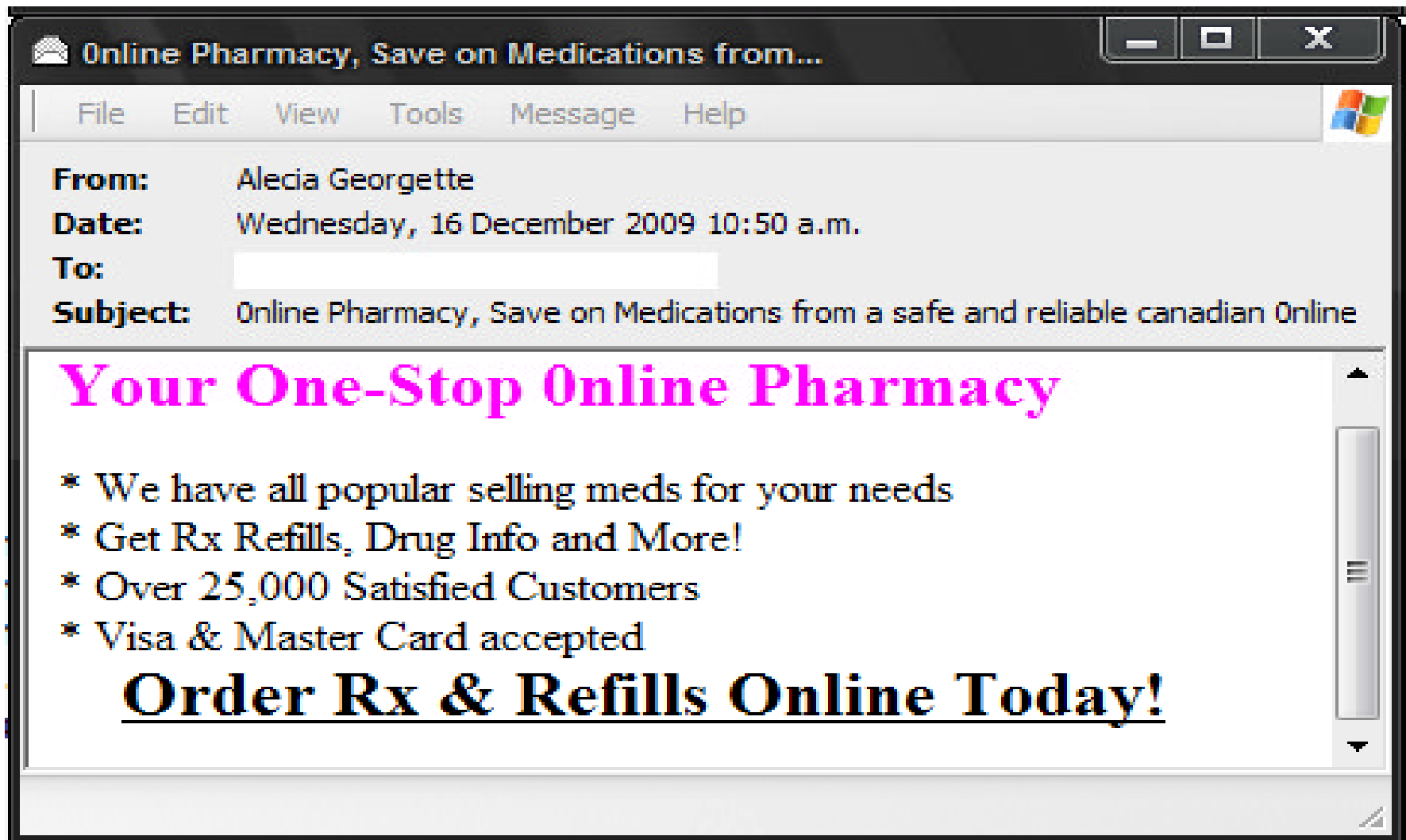
- Illegal advertising
- Illegal wholesaling
- Illegal sale and supply
- Illegal importation
- Illegal manufacture
- **Falsified medicines**



- Clinical trial fraud
- Unlicensed medicines
- **Internet supply**
- Illegal herbal medicines
- Diversion
- Stolen medicines



# Medicines Online – A Global Issue





# United Pharmacy

# 1 Internet On-line Drugstore



Currency:  
USD EUR GBP  
AUD CHF

Your cart: £0.00 0 items  
[Proceed to Checkout](#)

Language:

[Home](#)[Bestsellers](#)[All products](#)[FAQ](#)[Contact us](#)

**FREE  
VIAGRA**

For Order more than £204.81

**12 Viagra pills**

For Other Orders

**4 Viagra pills**

## Viagra + Cialis = £57.34

10 pills x 100 mg

10 pills x 20 mg

[Order Now!](#)

Only on this weekend:  
order and get free **LEVITRA 12 pills**



**Viagra + Cialis**

**£57.34**

10 x Viagra 100 mg  
10 x Cialis 20mg  
**+12 free Levitra**

[Order Now!](#)



**Cialis**

**£136.49**

60 pills x 20 mg  
+4 Free pills

[Order Now!](#)



**Viagra**

**£190.44**

120 pills x 100 mg  
+ 4 Free pills + Free delivery

[Order Now!](#)

## Products:

[Bestsellers](#) ★

[Erectile Dysfunction](#)

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## Today's bestsellers



[Viagra](#)

Our price **£0.62**

Viagra is an oral medicine used for treating male impotence (e.g., erectile dysfunction).  
Viagra'...

[Add to cart](#)



[Cialis](#)

Our price **£0.18**

Cialis (Tadalafil) is an oral drug, used for treating male impotence, also known as erectile men'...

[Add to cart](#)



[Viagra Professional](#)

Our price **£0.61**

Viagra Professional is a new generation extra-strength prescription medicine that is taken orally...

[Add to cart](#)



[Cialis Professional](#)

Our price **£2.84**



[Viagra Super Active+](#)

Our price **£0.95**



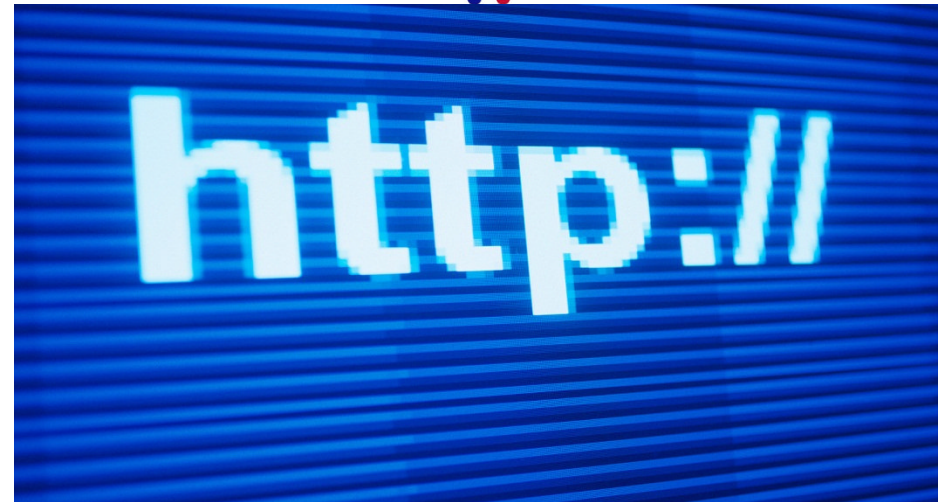
[Cialis Super Active+](#)

Our price **£1.86**



# Medicines Online – A Global Issue

- Accesses to a vast global market - more criminals have access to the Internet and more consumers are connected and able to purchase.
- The WHO has seen a direct correlation between access to the Internet and a growth in falsified medicines.
- A business model that allows affiliate websites to feed into their sales site
- An ability to operate freely due to difficulties in enforcing rules and regulations and having some anonymity.



If you type Viagra into Google then you get over 10 million hits within a fraction of a second!

Type in 'Ebola medicines' and you will see a range of medicines available that claim to prevent the virus or treat the infection – they are not only marketed at European or US markets but are aimed at those living in locations where there is the greatest threat.



# Are you sleeping safe and sound?



Following the tragic death of Laura Lambden, who bought insomnia pills on the web, we look at the hazards of online drugs and test safer ways to drift off.. **By Caroline Jones**





# Medicines Online – A Global Issue



## They Kill people

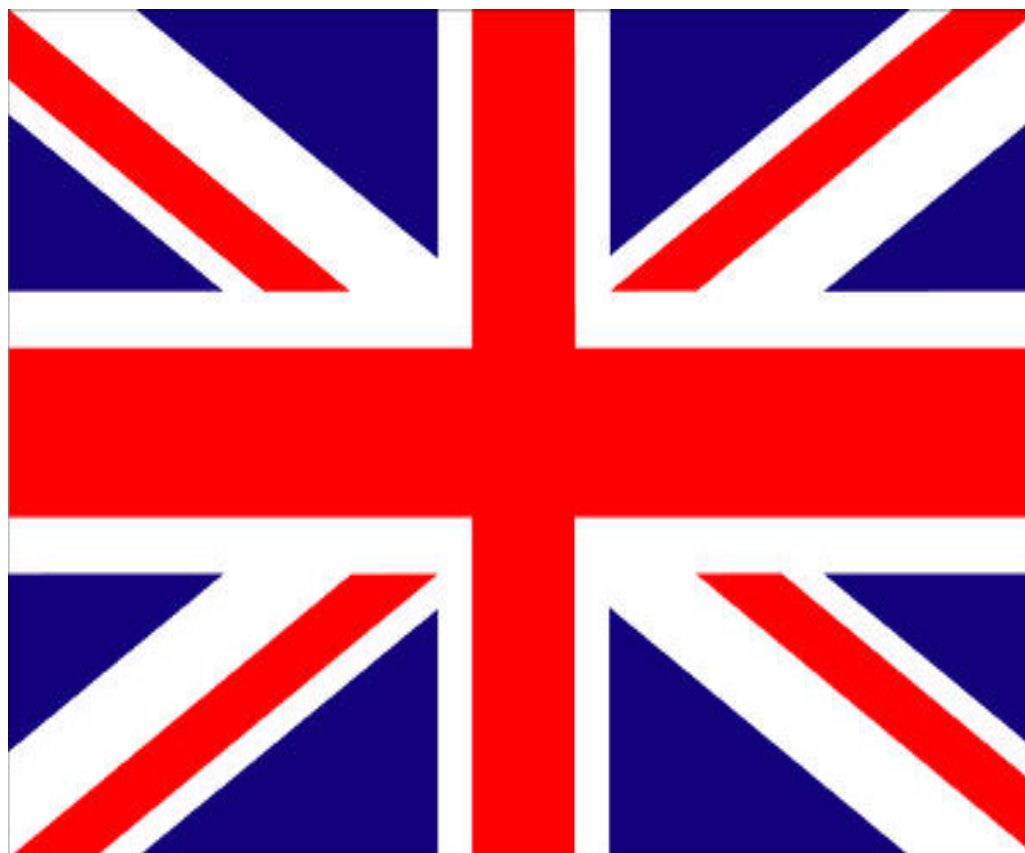


# Medicines Online



## UK Position

Currently the UK is  
1 of 3 MS within the  
EU that allows all  
categories of  
medicines to be sold  
Online without  
restriction.





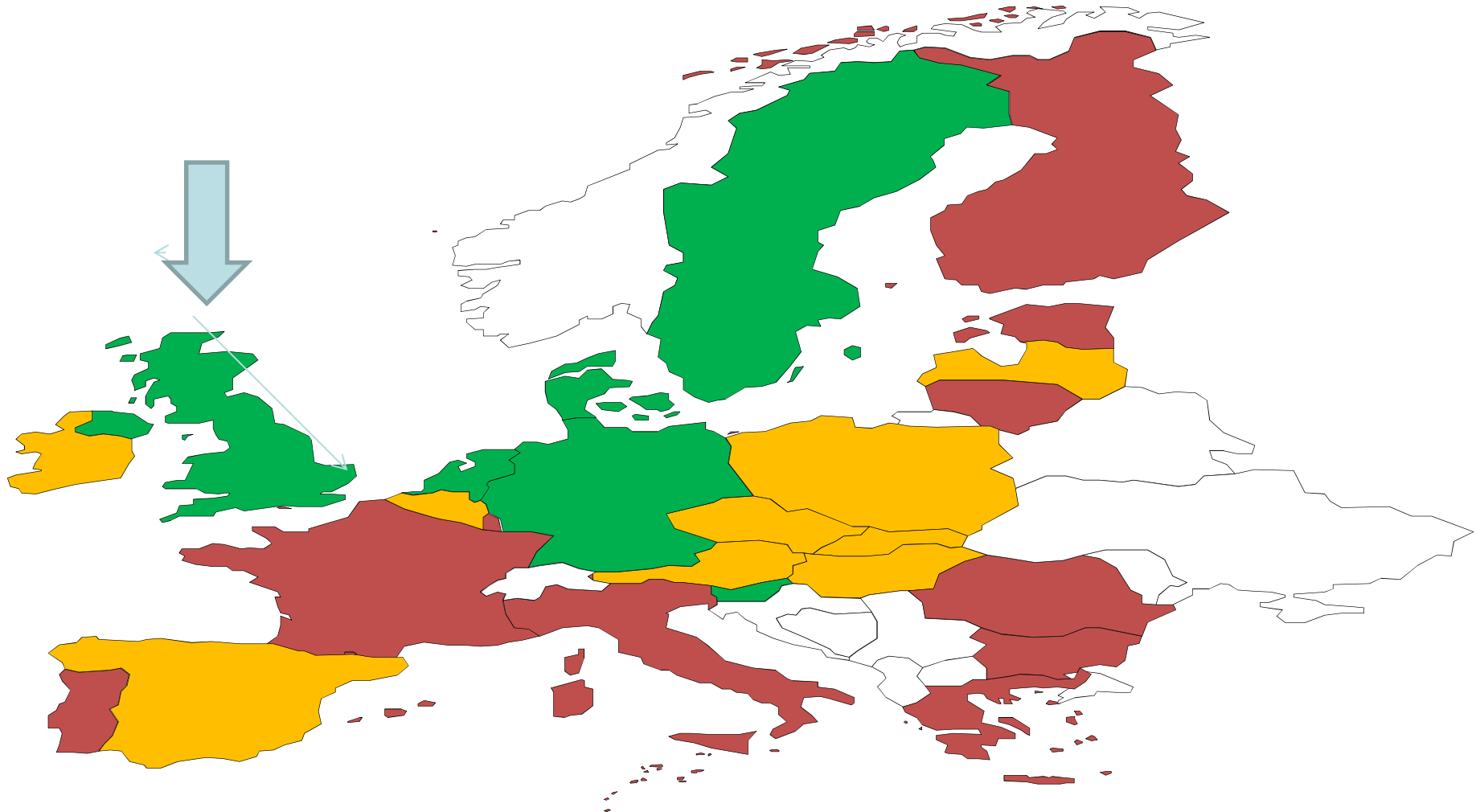
# UK Position – some facts



- A UK registered pharmacy may have a presence on the internet, however the requirements of legislation apply equally to both UK internet pharmacies and bricks-and-mortar premises.
- UK legal controls apply equally to all categories of medicines sold or supplied via the internet or e-mail transactions.
- Medicines legislation does not prohibit the remote prescribing of POM by a qualified prescriber however prescriptions must meet the usual requirements set down in medicines legislation.



# Position across EU



# Position across EU



- Only some Member States allow online sales of OTC and prescription-only medicines
- Others allow online sales of OTCs only, while the majority still prohibit both

*Both OTC and prescriptions allowed*

*Only OTCs allowed*

*No online sales allowed*



# Current UK Logo scheme



The General Pharmaceutical Council (GPhC) – UK regulator for pharmacies - operates the “Internet Pharmacy Logo” which was put in place to help members of the public identify if a website is being operated by a legitimate pharmacy in the UK.

This is a voluntary scheme - LOGO





# Falsified Medicines Directive – Sales at a Distance

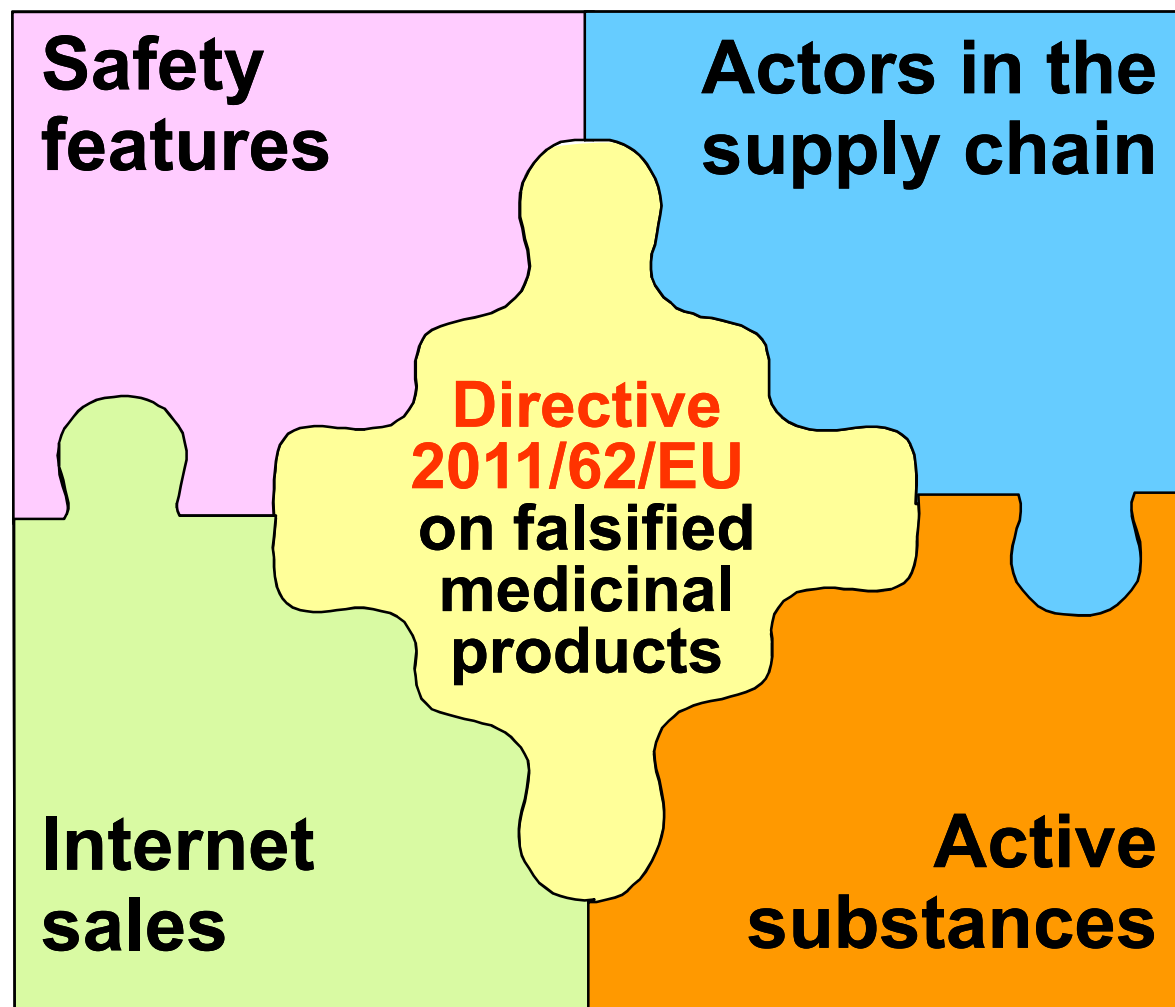


The Big Bang

1<sup>st</sup> July 2015



# EU Falsified Medicines Directive



# FMD Requirements



- The Directive requires Member States to introduce national arrangements to register suppliers of medicines “at a distance”.
- This will involve the establishment of a national website and the adoption of the common EU logo.
- All websites supplying medicines at a distance will be required to display the EU logo and provide a hyperlink to the national website of the Member State in which the person offering to sell medicines at a distance is established.



# FMD Requirements



- The EU logo has been agreed and implementing legislation was published on 24/6/14
- MS have until 1/7/15 to implement national systems



Click to verify  
if the website  
is operating  
legally





# UK IMPLEMENTATION



# UK IMPLEMENTATION



**In the UK, the MHRA is discussing implementation plans with stakeholders.**

- The MHRA, the General Pharmaceutical Council, the Royal Pharmaceutical Society are discussing which organisation is best place to run the logo and database.
- Technical discussions with IT Departments on Logo security.
- Public awareness campaigns and publicity for the scheme are being planned.



# UK IMPLEMENTATION



- The UK receives a vast amount of falsified and unlicensed medicines ordered across the Internet. During Operation Pangea VII we seized 1665 parcels containing 3.57 million units of medicine arriving from 18 countries and with medicines across a wide spectrum from painkillers to cancer medication.
- However, we are also used as a transit country and act as an exporting country to some extent with criminals redistributing medicines from the UK so that they appear to have a UK stamp of approval and further legitimise them.
- However, today's predominantly export or transit country could well be tomorrow's import country!





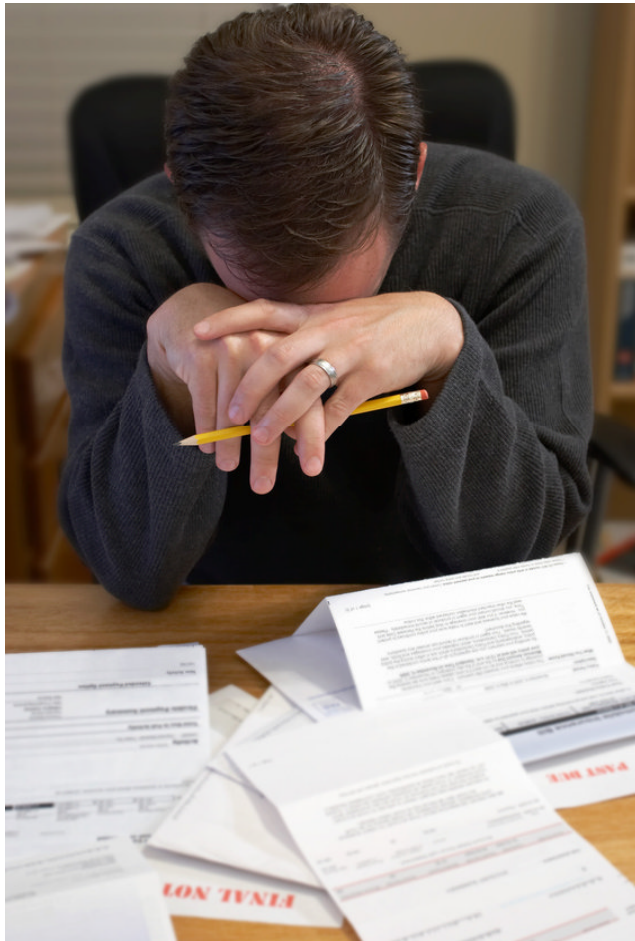
# Threats to Public Health



- Adverse reactions
- Dangerous Ingredients
- Interaction with other medicines
- No improvement in health conditions
- Disincentive to take prescribed medicines
- Loss of faith in healthcare systems



# Economic Factors



- Goods fail to arrive
- Credit Card scammed
- E-mail address hacked





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# Deadly abortion pills sold to desperate teenage girls on internet for 78p

Jan 25, 2014 09:00

By **Ben Rossington, Martin Bagot**

9 Comments

Share



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+1



Email

A Daily Mirror investigation has found that the black market tablets, which are used in NHS abortions, can kill if taken in the wrong dosage



Some desperate teens are turning to the internet for abortions



# Medicines Online

## Tackling the Illegal Supply Chain



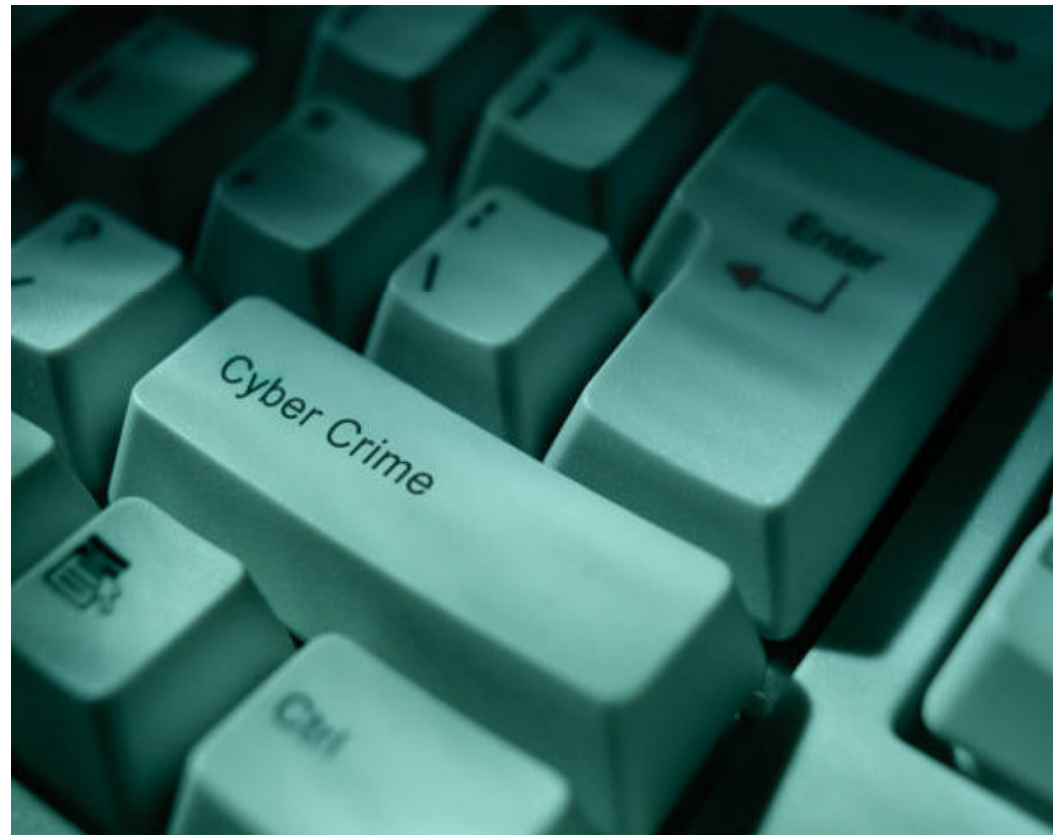
- In order to dismantle these criminal enterprises we must attack and remove each component part.
- If you remove the hosting platform it may cause disruption but they will find another host.
- If you take away the domain name it is likely that they make a small adjustment the domain websites will return.
- However if you attack all three areas: the host, the domain and in particular the removal of the payment method is essential – if they can't get paid then they cannot operate – they are not selling fake medicines to improve peoples health they are doing it for the profit.
- An example of how effective this can be - working with Nominet the provider of the Dot UK domain space, the MHRA has been successful in removing websites involved in the illegal supply of medicines in the UK.



# Medicines Online



## Target Supply and Demand!





**FAKE MEDICATION ONLINE. YOU COULD END UP  
PAYING WITH MORE THAN JUST A CREDIT CARD.**

**GET REAL. GET A PRESCRIPTION**

visit: [realdanger.co.uk](http://realdanger.co.uk)



Medicines and  
Healthcare products  
Regulatory Agency



Great Britain



## Operation Pangea – a global initiative for a global problem.



# The Scale of the Problem – Operation PANGAEA VII



- Seizures at Mail Hubs: Approx. 1,855,884 doses seized at all mail hubs
- Approx. 30,498 doses of suspected counterfeit medicines seized (1.64%)
- 1,862 websites taken down by MHRA Internet Infrastructure Investigator
- MHRA leads the way in targeting illegal adverts on Social Media Websites: 18,671 YouTube videos removed, 356 YouTube accounts terminated.
- Wide range of medicines seized – analgesic/pain relief, acne, narcolepsy, anti-anxiety, erectile dysfunction, weight-loss, antibiotics, asthma, diabetes, epilepsy, anti-depressants
- Press coverage: BBC Fake Britain, Daily Telegraph, Reuters, Herald Scotland, Manchester Evening News, Yorkshire Post













FRIDAY, OCTOBER 5, 2012 | THE DAILY TELEGRAPH

## Worldwide swoop closes 18,000 illegal drugs websites

**By Daily Telegraph Reporter**

MORE than 18,000 websites selling illegal medicines have been shut down during a worldwide crackdown on an illicit internet trade in pharmaceuticals.

The domain names of the websites have been taken down or the payment facilities removed, the Medicines and Healthcare products Regulatory Agency said. In Britain, 384 domain names have been suspended and a further 120 are being shut down.

In the worldwide operation, conducted by Interpol across 100 countries, counterfeit and unlicensed medicines worth more than £6.5million were seized.

The operation, which ran from Sept 25 to Oct 2, resulted in 79 people being arrested, including two in Britain. More than £3.8million of unlicensed medicines have been seized by the agency and the Border Force, a spokesman said.

Nimo Ahmed, the acting head of enforcement at the agency, said: "We



## Use of Social Media

- Engagement
- Accessibility
- Targeted
- Mass audience

The ability to advertise to millions through social media at a minimal cost

– MHRA has removed over 20,000 videos with links to sites selling medicines illegally from YouTube alone.



# Collaboration

- Industry
- Patient Groups
- Drug Regulators
- Law Enforcement
- Payment Providers
- Distribution Chain
- Government
- Everybody!





**Thank you**



Thank you for listening



**Lynda Scammell**  
Senior Policy Adviser  
Enforcement Group

