Fighting the fakes: Counterfeit pharmaceuticals and medical devices

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Counterfeits

- Problem
- Legal Strategies
- Technical Solutions

Problem

- Pharmaceuticals
- Medical devices
- Parts of devices
- Healthcare consumables
- Dental Industry

Health and safety

- Adverse health implications for consumers - potentially lethal consequences
- Non-sterile
- Poor quality
- Contain inappropriate materials

Economic

- Loss of sales
- Damage to reputation and brand
- Wider negative effect on industry
- €27billion revenue lost annually in Europe alone

Operation Pangea

- Annual Interpol co-ordinated operation
- Week of action 9 – 16 October 2018
- Police, customs and health regulatory authorities from 116 countries
- Targeted the illicit online sale of medicines and medical products
- Co-ordinated with platforms and payment card companies
- Raising public awareness

Operation Pangea

859 arrests worldwide

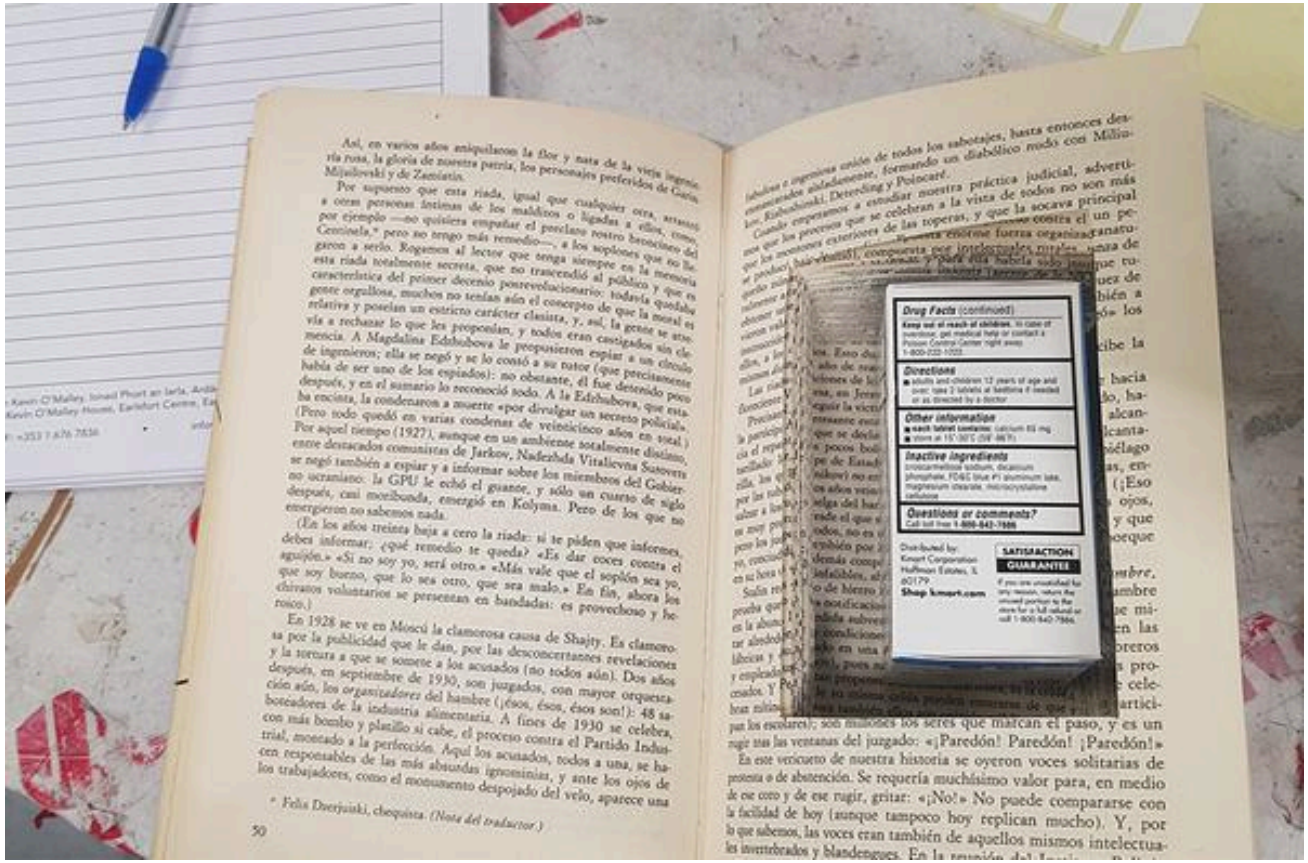
500 tonnes of counterfeit pharmaceuticals seized worldwide

Seizure of USD 14 million worth of potentially dangerous pharmaceuticals and devices

110,000 medical devices including syringes, contact lenses, hearing aids and surgical instruments were seized worldwide

3,671 web links closed down, including websites, social media pages, and online marketplaces

Ireland – counterfeit sleeping pills



UK - counterfeit contraceptive pills

Pangea in the UK

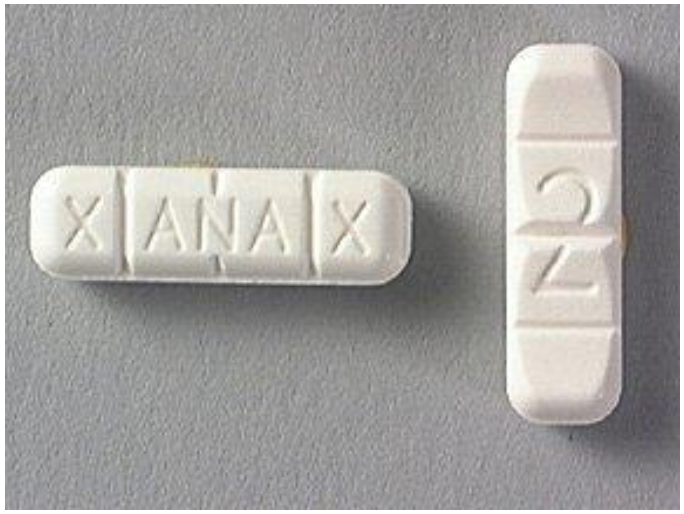
- UK authorities intercepted more than a million doses of drugs worth £2million
- Seizures in UK included sedative diazepam, modafinil - a drug to treat narcolepsy, and dermal fillers.
- Arrests made

Problem in the UK

- MHRA has seized over 14,500 items since turning its attention to dental equipment
- Poor-quality root canal files that could break in a patient's mouth
- X-ray equipment that used cheap kitchen foil to block radiation
- Fake thermometers – giving misleading reading which were being sold over the internet
- Sophisticated copies - include the CE markings, the instructions, the logos and the packaging

XANAX - Alprazolam

- Used to treat anxiety and panic disorders
- Rare in the UK - 2016 was only prescribed on 14 occasions by GPs
- NHS issued warnings after alprazolam was implicated in more than 20 deaths
- From 2015 to 2017, more than 1.5m counterfeit Xanax pills in UK
- Sold online described as “Pfizer Xanax”
- Stopped by law enforcement agencies



Legal Steps

- Trade Marks
- Designs
- Patents

- Cover countries where the counterfeit may occur are likely to originate (typically, China, Hong Kong, India, Turkey and the UAE)
- Consider distribution routes (generally, major transit hubs and international trade ports)
- Review what you protect – brands, sub brands, packaging, device shapes
- Keep registrations current
- Actively monitor online and offline market places
- Take appropriate enforcement actions

Customs

Customs Enforcement Actions

Regulation (EU) No 608/2013

- EU customs authorities may detain goods under their control which are suspected of infringing IPR.
- Need a registered right as a basis
- EU rights v National rights
- Intervention of the customs authorities usually takes place upon prior request of the right holders
- Customs also may detain those goods if no request has been made beforehand, in order to give right holders the opportunity to make such a request
- More information that you provide to customs the better
- Destruction of infringing goods

Customs Enforcement – post Brexit

- The Customs (Enforcement of Intellectual Property Rights) (Amendment)(EU Exit) Regulations 2019
- Ensures that UK customs can continue to be able to enforce intellectual property rights at the UK border in the event that the UK leaves the EU without a withdrawal agreement.
- Allows rights holders to apply to UK authorities for protection
- Establishes a UK stand-alone database and the processes which will be carried out by the customs authorities at the UK borders
- Under the new legislation, there will be no obligation to share the information collected with the EU

Online Counterfeits - not just Amazon

- Social media sites don't charge fees for the sale of products in the same way as online market places
- Open groups are used to advertise and link to pirate websites and off-site payment methods
- Closed Groups provide relative safety to counterfeiters in selling products
- Five times more counterfeit goods are sold in closed groups rather than open groups on Facebook and Twitter
- Content and links can be easily shared, "liked", retweeted and regrammed
- Comments written under posts are often fake and give legitimacy to the post in order to lure buyers to purchase
- Counterfeiters will often use photos of genuine products and reproduce the logos of the brand

Liability of Platforms

- Platforms will benefit from the "hosting defence"
- It is an exemption for certain activities and not a total exemption
- There will be no liability as long as:
  - It does not have **actual** knowledge of the unlawful activity or information and, as regards claims for damages, is not aware of facts / circumstances from which the unlawful activity or information is apparent
  - Upon obtaining such knowledge or awareness, it acts expeditiously to remove or disable access to the unlawful activity or information
- Platforms approach is that they do not need to be proactive but rely on "take down" procedures to avoid liability

Take Downs

- Burden is on brand owner to find and report instances of counterfeits
- Takedown notifications have become the default way of dealing with counterfeits on social media sites
- Unless a test purchase is carried out brand must rely on the images used by the sellers to identify counterfeits
- Even if accounts are blocked they will often reappear in a matter of hours / days under a new profile name
- Take downs are therefore time consuming and ultimately don’t provide an effective solution to the problem of counterfeits

Direct Action

- Restrict the platforms selling branded products
- Control your global supply and distribution network - eliminate product diversion
- Control your brand content vigilantly –platforms can have multiple product listings resulting in content being indexed higher up on Google searches than the brand's own website.
- Take down notices
- Targeted actions against infringers
- Education of supply chain and consumers

Falsified Medicines Directive (FMD)

- Introduced to address the issue of falsified medicines entering the legitimate medicines supply chain across Europe
- World's first continent-wide scheme to eliminate fake or falsified medicines from the supply chain
- All new packs of prescription medicines placed on the market in Europe from 9th February 2019 onwards will have to have two safety features:
  - a unique identifier (UI) in the form of a 2D data matrix (barcode);
  - an anti-tampering device (ATD)
- European Hub passes data to the relevant National Medicines Verification System (NMVS) and pharmacies will be able to check the status of each pack during the dispensing process
- The system will be notified of products known to have been recalled, withdrawn, stolen or tampered with

FMD

Scope of the Directive

- Virtually all prescription medicines with a Marketing Authorisation
- All non-prescription medicines are out-of-scope, with the exception of two omeprazole products (which were subject to falsification in the past).
- Unlicensed products, including specials and clinical trial supplies are out-of-scope
- Any licensed products being incorporated into them (such as ingredients for specials) would have to be authenticated and decommissioned before they could be used.
- Medical devices are out-of-scope

FMD Process

- Manufacturer generates randomised unique identifiers and prints these on relevant packs as a barcode and (space permitting) in human readable form
- Unique identifiers for a batch of product will be uploaded by the manufacturer to the European Hub
- The European Hub validates the unique identifier data and transfers it to the relevant National Medicines Verification System(s)
- Pharmacies scan the UI to verify the product and to “decommission” that pack. They also check the anti-tampering device
- Parallel traders also decommission the unique identifier and then upload new unique identifiers

FMD

MHRA - “in the interests of public safety, we will evaluate the options around a future national falsified medicines framework”.

- On 11 November 2018, a pack of insulin was thought to be the first medicine to be decommissioned under FMD procedures at Aintree University Hospital NHS Foundation Trust
- The National Pharmacy Association has advised pharmacists to prepare themselves for FMD but to “avoid signing long-term contracts” with FMD solution providers
- If the UK leaves the EU without a deal, access to the EU database which is the heart of FMD compliance will be revoked
- MHRA has said that the legal obligation to adhere to FMD regulations “would be removed for actors in the UK supply chain” in the event of a no-deal departure

Medical Devices?

The EU Regulation on Medical Devices 2017/745

- Most devices will be required to have a UDI on their label and packaging, and for certain devices, on the product itself
- UDIs will be phased in over several years, starting with the highest risk devices, such as heart valves and pacemakers

How Effective?

Effectiveness of medicines authentication technology to detect counterfeit, recalled and expired medicines: a two-stage quantitative secondary care study - BMJ

- Research into the effectiveness of a medicines authentication technology in detecting counterfeit, recalled and expired medicines within a large UK hospital setting
- More than 4,000 serialised medicines were entered into a hospital dispensary over two separate 8-week stages in 2015, and medicines were authenticated using secure external database cross-checking, triggered by the scanning of a 12-digit serial code
- 4% of medicines included were pre-programmed with a message to identify the product as either expired, pack recalled, product recalled or counterfeit

How Effective?

- Technology's technical detection rate was 100%
- Not all medicines were scanned
- Those that were scanned not all that generated a warning message were quarantined
- Only 31.8% of counterfeit medicines, 58% of recalled drugs and 64% of expired medicines were detected
- Human element

Education

- Employees
- Consumers
- Intermediaries

- Staff, distributors, retailers and users
- Important that they know what to do when they spot potential counterfeit or unauthorised sales
- Consider running general seminars to make your employees aware of the importance of IP and the threat posed by the trade in fakes
- Specific training for those employees that are on the ground to help them recognise and report counterfeit products
- Information to others in the supply chain

Thank you

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