



## Challenges of preventing counterfeit goods:

Pharmaceuticals, food and drink, agrochemicals and toiletries are all highly susceptible to counterfeiting. Imports of counterfeit and pirated goods to the UK accounted for as much as £13.6 bn in 2016.<sup>1</sup>

### Summary

Counterfeiting is a high-profit business on a large scale, affecting all regions and sectors of the world. Counterfeit and pirated goods now make up 3.3% of world trade.<sup>2</sup> Global counterfeiting is increasingly a problem for the UK. It is becoming more difficult to spot counterfeit goods at borders and to prevent them from reaching consumers. Sub-standard or adulterated products can pose a risk to consumers' health and in some cases, may even put lives at risk. Counterfeiting is also detrimental to the economy as producers of genuine products lose out on business. This briefing sets out the issues in each sector and highlights questions that must be addressed in order to tackle the problem.

### Introduction

Attention on counterfeit goods is often focused on the top imported fake goods items by quantity: electrical items or fashion products (clothing, footwear and leather).<sup>2</sup> Pharmaceuticals, food and drink, agrochemicals and toiletries are also susceptible to counterfeiting, but measures to mitigate fake goods in these sectors have so far received less attention.

This briefing shines a light on the sector-specific challenges of these counterfeit products, which are considered together given their potential to be detected with similar analytical techniques. In recent years, incidents such as the horsemeat scandal and the trend towards greater online purchasing have brought the issues of counterfeiting in other sectors to the fore. Criminals are quick to exploit new opportunities, such as during the COVID-19 pandemic, which increased opportunities as online shopping increased. However, new advances in detection techniques have the potential to help tackle existing and emerging problems associated with the counterfeiting of these products.

This briefing is based on the outcome of a two-day 'sandpit' event attended by 16 experts including representatives from academia, the defence sector, government and its agencies. Policy considerations were identified which we hope can be used to inform thinking about how these problems could be mitigated.

### Glossary

**Active ingredient (AI)** – the biologically active component of a drug or pesticide.

**Adulterant** – a substance added to a product but not listed as an ingredient, or a substance that ends up in a product by accident when the product is made.

**Adulteration** – reducing the quality of a product by adding another ingredient.

**Agrochemical** – a chemical used in agriculture (such as pesticides and fertilizers).

**Counterfeit** – when goods are made to look like an original, usually for dishonest or illegal purposes.

**Falsified Medicines Directive (FMD)** – EU legislation adopted in 2011, which introduced harmonised measures to ensure that medicines are safe and to control trade in medicines.

**Falsified Medicines** – fake medicines passed off as real, authorised medicines. *\*This briefing refers to 'falsified' rather than 'counterfeit' pharmaceuticals. In the FMD, the term 'falsified' specifically excludes intellectual property rights infringements.*

**Piracy** - the act of reproducing movies, music, books or other copyrighted works without permission from the copyright owner.

## Sector-specific challenges

### 1. Pharmaceuticals

Falsified\* medicines can take several forms. They may have no active ingredient (AI), the AI could be in the incorrect dose, or may be mixed with another AI. In some cases, the wrong AI is used, which can result in treatments failing or even cause life-threatening allergic reactions.

Pharmaceuticals generally have a well regulated supply chain. In addition, specific regulation exists for tackling falsified pharmaceuticals: The UK currently adheres to the FMD which includes new legislation introduced in 2019 on 'safety features'<sup>3</sup> for medicines to detect and prevent falsification or tampering.

The future of the UK's approach to regulation is dependent on the outcome of negotiations on the future of the relationship between the UK and EU. Changes need to come into force at the end of the agreed transition period. If the FMD is not replicated in UK law, or an agreement is not made, the UK would not need to comply with the aforementioned safety features and could become more vulnerable to imported counterfeit medicines as a result. The exception is Northern Ireland: under the Northern Ireland Protocol, they would be required to ensure any product it places on the market comply with EU Regulations. This means they would still potentially have access to the EU repository, part of the end-to-end medicine's verification system introduced by the regulation. At the time of publication, the Medicines and Medical Devices Bill is passing through parliament which proposes a UK system to address falsified medicines, but this has not yet passed.

Trends like self-diagnosis, where consumers may no longer visit a GP or pharmacist, are contributing to an increase in pharmaceuticals being purchased online. The ageing population, with higher requirements for medicines, may also provide new opportunities for criminals to exploit. The COVID-19 pandemic offered a further opportunity for criminals to sell fake 'self-testing kits' and 'antiviral misting sprays'.<sup>4</sup>

While the exact number of people purchasing medicines online is not known, the Medicines and Healthcare products Regulatory Agency's (MHRA) '#FakeMeds' campaign states that 1 in 10 people in the UK have bought fake medical products in the last year.<sup>5</sup>

### 2. Food and drink

Food and drink represents a significant fraction of all trade by volume and often requires more checks than other goods, as the importation process provides multiple opportunities for criminal activity. In 2019, a joint operation by INTERPOL and Europol seized 16,000 tonnes and 33 million litres of potentially dangerous fake food and drink.<sup>6</sup> Addressing counterfeit food and drink products is particularly challenging for the following reasons:

- Trends in counterfeit products are constantly changing. For example, societal changes in eating patterns, like increasing vegetarianism and veganism, or the effects from new taxes (like sugar or alcohol), can drive counterfeit goods production.

- Testing currently occurs cyclically (where products are tested in batches or small quantities). This means not all products are tested at all times, or are only tested at the start of the process.
- A specific challenge to food is that it may be consumed, leaving no evidence behind.

Following the 2013 horsemeat scandal, which began when the Food Safety Authority of Ireland tested supermarket products and found horse and pig DNA in beef products, there has been increased attention on the adulteration of foodstuffs: The National Food Crime Unit for England, Wales and Northern Ireland, and the Scottish Food Crime and Incidents Unit were set up to tackle food crime. Testing methods have developed significantly in recent years as a result.

### 3. Agrochemicals

High quality crop protection products such as pesticides and fertilizers are essential for the UK and the global market to ensure that enough food is produced for the growing population. Agrochemicals are used for farming and food, as well as in infrastructure (killing weeds on roads and rail) and in leisure industries.

Counterfeit agrochemicals may contain too little or too much of an AI, or none at all. They may contain other harmful substances, or be missing an additive which makes the AI work in a certain way. For example, a wetting agent to ensure the AI disperses correctly on the leaves of a plant could be missing. The use of illicit agrochemicals could have serious repercussions for human health, crop yield and the environment. The prevalence of criminal activity in relation to pesticides is increasing. The European Commission estimated that 10% of the EU pesticides market is illegal.<sup>7</sup> It is estimated that €1.3 bn revenue is lost annually to counterfeit pesticides, corresponding to 13.8% of sales.<sup>8</sup>

Barriers to tackling this type of crime include the fact that responsibility for dealing with the problem is split between different agencies (such as agricultural, environmental and health) and it is difficult to identify and monitor illicit agrochemicals.<sup>9</sup> Unlike with some physical goods or pirated products, users of agrochemicals are unlikely to choose to buy counterfeit products, so counterfeiters price products carefully to disguise them. Sandpit participants suggested that counterfeit agrochemicals are often considered a lower priority than pharmaceutical products, perhaps because they have a lower profile in the public arena.

### 4. Toiletries

Online purchases of toiletries, such as perfumes, shampoos and deodorants, are increasing. It is estimated that 30% of toiletries bought online are fake.<sup>10</sup> They are the fourth most likely counterfeit product to be imported in the UK.<sup>11</sup> A demand for branded toiletries, particularly perfumes and make-up products, has led to increasing counterfeit and imitations of products. Counterfeit toiletries are often only reported when consumers have adverse skin reactions, or

when customs authorities seize suspected goods. Toiletries are currently covered by the EU cosmetics legislation.<sup>12</sup> This was introduced in 2009 to ensure consumer safety and to secure an internal market for cosmetics, which involves placing the responsibility of safety with manufacturers. The legislation includes a requirement for products to be registered in a notification portal, and for some products to be given special attention from regulators (such as those with a higher potential risk to consumer health). This legislation will cease to apply to the UK when the Brexit transition period ends, with the expectation that the UK will introduce its own legislation.

### Detecting fakes: analytical technologies

The rapidly changing landscape of counterfeiting demands fast analytical methods to test the chemical composition of products. Methods range from simple tests which may be usable in the field, to sophisticated techniques which need high-tech laboratories. The choice of technology for any situation will depend on a range of factors, such as the cost, speed, size, training required and implications for regulation. There will be no one universally applicable technology for all sectors.

The sandpit identified two significant gaps:

- Despite a surge in research, there is still a persisting need to develop fast, cheap, easy-to-use and sensitive methods to detect common problems in the food sector, such as the adulteration of olive oils.
- The development of detection technologies for counterfeit agrochemical products has been largely overlooked. This should be a priority for further study.

A range of detection techniques are in development. At UCL, researchers are currently exploring the potential for using the 'determination of the viscosity' (often referred to as the 'thickness of a fluid') as a method, which could mean a simple optical or physical measurement could be developed to test for a counterfeit agrochemical. The team are looking for technologies suitable for a miniaturised system to identify counterfeit agrochemicals and are working with stakeholders in the farming sector to identify the optimum point in the supply chain for testing.

## Questions for policymakers

### How can the UK ensure that Brexit does not result in new opportunities for criminals?

The UK's departure from the EU requires new legislation to enable the UK to continue to trade with the EU and other key international partners. When the transition period ends there are likely to be simultaneous changes in policy. This has the potential to result in vulnerabilities in the prevention of counterfeit goods entering the UK as new trade processes are implemented, for the following reasons:

**Regulation of pharmaceuticals.** The UK's adherence to the FMD is dependent on the outcome of UK/EU negotiations.

### Cross-border enforcement and intelligence sharing.

This is fundamental in tackling the trade of counterfeit goods. There is little legal infrastructure to allow non-member states to gain access to some of the EU's border check systems.

### The Irish Border.

The Withdrawal Agreement contains special arrangements for Northern Ireland to avoid a hard border on the island of Ireland. Under this agreement, Northern Ireland will continue to follow EU rules on agricultural and manufactured goods. This means a trade border must be introduced between Great Britain and Northern Ireland, with new obligations and checks required for both customs and regulations for goods entering Northern Ireland from mainland UK.

### Creating new trade agreements and Freeports.

The UK's access to preferential trade agreements with third countries with whom the EU has trade deals will cease at the end of the transition period. New trade agreements (for example with Australia, Japan, New Zealand, the US and the EU) could result in changes to supply chains with goods passing through new or different countries to before Brexit.

This could happen via Freeports, a type of special economic zone where goods can be landed, stored, handled, manufactured or reconfigured and re-exported without being subject to customs duty. The UK Government is planning to create new Freeports after leaving the EU.<sup>13</sup> Discussions at the sandpit concerned Freeports increasing the possibility of goods arriving at the final port having changed route in transit, leaving officials uncertain of the point of origin.

Regulatory changes at the end of the transition period have the potential to affect the trade of counterfeit goods. This is of concern and such possibilities should be identified and mitigated by Government, law enforcement and border forces.

### How can human error be reduced in the compliance process?

Procedures to ensure compliance at borders currently rely on manual checks, where a lack of time and human resource for checking samples are at play. Although some checks involve technologies like handheld scanners, these still rely on operators to interpret results and make judgement calls – for example if the instrument produces an abnormal result. Such checks can therefore be compromised if the operator lacks the time or skills to complete this task. The reliability of the compliance process might be improved in several ways, but rely on agreement of priorities between agencies:

- Use of technology and automation of some processes (such as the Advanced Freight Targeting Capability) which should automate the process of identifying cargo of interest.
- Provision of clear guidance.
- Training to improve skills.
- Devices (such as hand-held scanners) designed to be low-cost and simple-to-use to encourage greater uptake.

## How can the UK increase public awareness of the existence of counterfeit goods and their risks?

There is a lack of public awareness around certain types of counterfeit products and anti-counterfeit measures. This is particularly pertinent for pharmaceuticals, as the use of online pharmacies is increasing and the potential damage to health could be significant. They can even cause life-threatening allergic reactions (such as in cases of falsified Tamiflu containing penicillin and antimalarials containing sulphadoxine).<sup>14</sup>

Consumers might not be aware of anti-counterfeit measures such as the FMD which requires online pharmacies to register and display an EU-wide logo. Sandpit participants suggested that there may be a role for public-facing awareness-raising campaigns to address this deficit.

There is an additional challenge in that some people knowingly purchase counterfeit products. This could be for a number of reasons: thinking the product was as good as a legitimate version; being unable to afford the legitimate product; having a dislike for the manufacturer of the legitimate product; thinking it is legal/moral to buy them; and the ease by which they can be obtained. While it is likely impossible to eliminate this entirely, awareness raising messaging could go some way to change people's behaviour.

## How can information sharing between organisations be improved?

Information sharing between agencies was highlighted as a key area of improvement at the sandpit. When intelligence is collected by the UK Border Force, law enforcement, and intelligence units at agencies such as the MHRA, Intellectual Property Office and the Office for Product Safety and Standards, the information can be incomplete – for example if insufficient detail is gathered or the wrong questions are asked. A tendency to be risk-averse can result in some agencies not sharing information.

Delegates also raised a lack of consistency in IT systems and databases. Even if database integration occurred within agencies, it does not happen between agencies. For example, in the police, each force operates a different database. The Police National Database was created to improve intelligence sharing within forces and is an example of good practice: it works, is trusted, has not required modification since inception and keystrokes are logged to avoid misuse. However, it is not widely used and its use is not enforced.

The use of technology, such as blockchain, could provide a method of sharing sensitive information securely without allowing tampering. If the integration of databases across agencies proves to be unfeasible, an alternative would be to use blockchain technology to create a system for retrieving information from existing databases securely, only allowing access to certain types of information to those who have the requisite security clearance level.

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## Funders

**This research was funded by the Dawes Centre for Future Crime at UCL. The Centre was established to identify how technological, social or environmental change might create new opportunities for crime and to conduct research to address them.**

The Dawes Centre is funded by the Dawes Trust and UCL. These funds are limited and so we invite additional funding from the public and private sector. By funding the centre you will contribute to helping society better prepare for crimes of the future. We are also able to undertake research upon request, contributing to organisational goals and strategic thinking.

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<sup>1</sup>OECD, 2019. Trade in counterfeit products and the UK economy. Available at: <http://www.oecd.org/gov/risk/trade-in-counterfeit-products-and-uk-economy-report-update-2019.pdf>

<sup>2</sup>OECD, 2019. Trade in fake goods is now 3.3% of world trade and rising. <http://www.oecd.org/newsroom/trade-in-fake-goods-is-now-33-of-world-trade-and-rising.htm>

<sup>3</sup>UK Government Guidance, 2019. Implementing the FMD Safety features. Available at: <https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features>

<sup>4</sup>UK Government new story, April 2020. Available at: <https://www.gov.uk/government/news/uk-medicines-and-medical-devices-regulator-investigating-14-cases-of-fake-or-unlicensed-covid-19-medical-products>

<sup>5</sup>MHRA #FakeMeds campaign. <https://fakemedics.campaign.gov.uk/>

<sup>6</sup>Interpol, 2019. Available at: <https://www.interpol.int/en/News-and-Events/News/2019/Illicit-food-and-drink-seized-in-global-operation>

<sup>7</sup>European Commission, 2015. Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU. Available at: [https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_ppp\\_illegal\\_ppps\\_study.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_illegal_ppps_study.pdf)

<sup>8</sup>The economic cost of IPR infringement in the pesticides sector. Available at: <https://euipo.europa.eu/ohimportal/en/web/observatory/ipr-infringement-pesticides-sector>

<sup>9</sup>UNICRI, 2016. Illicit pesticides, organised crime and supply chain integrity. <http://www.unicri.it/topics/environmental/research/>

<sup>10</sup>MarkMonitor, 2017. Global Online Shopping Survey 2017 - Consumer Goods. Available at: <https://www.markmonitor.com/g/consumer-goods-global-online-survey-barometer-2017/>

<sup>11</sup>OECD, 2017. Trade in Counterfeit Products and the UK Economy: Fake Goods, Real Losses. doi:10.1787/9789264279063-en

<sup>12</sup>European Commission Regulation N° 1223/2009 on cosmetic products. Available at: [https://ec.europa.eu/growth/sectors/cosmetics/legislation\\_en](https://ec.europa.eu/growth/sectors/cosmetics/legislation_en)

<sup>13</sup>UK Government Press release on Freeports, February 2020. Available at: <https://www.gov.uk/government/news/innovative-new-freeports-across-the-uk-as-government-lays-out-plans-to-boost-economy>

<sup>14</sup>Sengaloundeth, S. & Green, M., 2009. Stratified random survey of the proportion of poor quality oral artesunate sold at medicine outlets in the Lao PDR - Implications for therapeutic failure and drug. Malar. J. 8, 172.