



The global scourge of counterfeit medicines

Pharmaceuticals are a prime target for organised crime



The statistics are truly disturbing, with an annual death toll of around 100,000 from falsified and counterfeit medicines, according to the European Commission, and a criminal enterprise that the World Customs Organisation estimates could generate £1bn worth of illicit business in 2017.

But industry and regulatory authorities are fighting back with new measures to identify rogue shipments and coordinated action to disrupt the supply lines that criss-cross the globe.

The trend to seek medical aid online has made it easy for bogus medicines - containing anything from paint and antifreeze to brick dust and floor wax - to be mailed around the world. The Alliance for Safe Online Pharmacy in the EU (ASOP EU) warns that 130 million people in Europe are risking their health by ordering from the 30,000 illegal pharmacy websites that have flooded the Internet.

Industry also has to consider the damage to its reputation from the corrosive impact of falsified and counterfeit medicines. 'Fighting Counterfeit Medicines' was debated at the recent Medicines for Europe conference (MFE) in Croatia, which drew together the leading voices in generic medicines.

A major concern is that generic medicines may be confused with substandard medicines peddled by criminals to a public struggling to understand the scale of the problem.

Delegates learned about increased safety features that will be implemented by February 2019 in the European Commission's Falsified Medicines Directive (FMD) which boosts verification at manufacture, distribution and pharmacy. Its features include unique serial numbers and identification features on packs, tougher inspections, strengthened record-keeping and an EU logo to signify legal online pharmacies.

A key element is that the FMD will criminalise the acts of making and selling bogus medicines to create a credible deterrent.

The measures were further bolstered by a strategy meeting held at Google's offices in Brussels, where campaigning groups and regulators joined forces to face the threat head-on. The group will meet again in September to share best practice and build on plans to address the 'knowledge demand' by raising public awareness, as market research reveals the public is largely ignorant to the dangers of buying medicines online.

The reputational damage is clear, according to Adrian van den Hoven, Medicines for Europe director general, because persistent stories about dangerous medicines can breed mistrust. Elke Grooten, an MFE board member told the conference: "It is important that we have these discussions in an international context because falsified medicines put patients and the general public at risk across the world - it is a crime against patients."

“ [Industry must] repel the tide of dangerous internet medicines that operates outside the legitimate supply chains ”

“It is also an issue for healthcare providers caring about their patients because falsified medicines create mistrust in medicines and it is an issue for us as pharmaceutical companies developing and manufacturing high quality medicines - it affects all medicines.”

Van den Hoven highlighted that the new system, working in harmony with industry, will serialise 14 billion prescription drugs a year and enable pharmacies and hospitals to spot counterfeits.

“There have been serious issues. About a year ago there was a theft of empty vials and bottles from a hospital in Italy which were refilled with a liquid and exported to Austria and Germany in quite substantial amounts for serious treatments like cancer,” he said.

“There was an issue of trying to find those products because they disappeared and then reappeared in two different countries through completely illegal trading. They were found and to my knowledge didn't reach patients but the investigation is still continuing and it was still a scare. The new system will make it extremely difficult for this to happen.”

Mike Isles, executive director of ASOP EU, believes the FMD clampdown must be matched by a twin effort to repel the tide of dangerous internet medicines that operates outside the normal and robust legitimate supply chain.

“It is a massive problem with 18% of the population going online to buy medicines and potentially endangering their lives,” he said. “These sites do not require a prescription and their medicines may have no active substance, too little or even too much. And they may contain toxic substances like floor wax, paint or antifreeze.”

“Customers also risk having their credit card details stolen. The problem is that most people do not know these websites are operating illegally.”

He also feels industry, with its significant reach, can play an important role in educating healthcare professionals.

“The benefit is that it will help to prevent patients taking themselves out of their national health systems and potentially damaging their health. Industry is reacting well and has dedicated security people who are the first line who go into a country, compile the evidence and then pass it on to local law enforcement and customs, enabling Interpol or Europol to get involved.”

He added that Google is supporting information campaigns in Europe and the US to help educate patients to enable them to move away from bogus sites and is working on techniques to ensure only legitimate pharmacies are shown in online searches.

An educational campaign by ASOP EU and the European Alliance for Access to Safe Medicines, using Google AdWords to attract online buyers in Italy, revealed that 80% of people were unaware that the majority of online pharmacies operate illegally. A large majority said they would revert to their doctor or pharmacy after learning about the danger.

On the supply side, the task of catching the criminals is huge but Interpol, Europol, national customs' forces, governments and credit card firms are engaging in the fight.

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An Interpol-led investigation earlier this year closed 4,932 sites and seized 12.2 million counterfeit drugs for cancer, depression, asthma and high cholesterol, along with slimming pills, infertility drugs and bodybuilding steroids. The crackdown across 103 countries resulted in 393 arrests.

Benoit Goyens, of the World Customs Organization (WCO), told the conference that the global value of illegally traded medicines could stretch to £1bn, adding: “The growth is exponential and we are not catching up.”

Research by ASOP EU highlighted that 65% of the public order online believing they are connecting with reputable pharmacies. The number of people using online sites for medical help is growing and ASOP estimated that some gangs haul in £1m in profit a month.

Pharmaceutical products now account for more than half of all goods seized, according to the WCO which reported that painkillers were the most frequently intercepted illicit drug at 36,324,200 in 2014. More than half of the 95,273,060 counterfeit medicines impounded last year came from India and China. Among the seizures was a supply of erectile dysfunction pills that contained a drug that could cause kidney failure.

Crime gangs are attracted to illicit drugs because the profits are high and sentences are rarely more than token fines.

The WCO has launched smart-phone technology to help identify and track shipments, and drugs firms, credit card companies and internet registers have pledged to disrupt the crime gangs' deadly supply chain.

"This is a widespread and profitable criminal activity, and tackling it requires strong cooperation from all those involved in the pharmaceutical supply chain," said Pierluigi Antonelli, head of the Western Europe region for Sandoz. "Falsified medicines are responsible for the deaths of thousands of people every year and risk the health and safety of many more.

"We support and drive a range of measures to increase patient awareness of the risks of falsified medicines, increase penalties and sanctions for counterfeiters, close illegal pharmacy websites, introduce serialisation of the legal distribution chain and increase regulatory actions to seize falsified medicines.

"We also strongly urge all concerned to avoid misleading and inaccurate comparisons between illegal falsified medicines and legally authorised, high-quality generic medicines produced by recognised pharmaceutical companies following loss of patent protection. Generic medicines account for 56% of all pharmaceutical prescriptions in Europe today, but only 22% of the cost."

The fight is on for the health and safety of the public and the pharmaceutical industry's reputation.

| Top five drugs seized | |
|-------------------------|------------|
| Painkillers | 36,324,200 |
| Anti-inflammatories | 19,633,000 |
| Tuberculosis treatments | 19,403,468 |
| Erectile dysfunction | 5,830,570 |
| Antibiotics | 5,433,270 |

*World Customs Organization 2014 Report