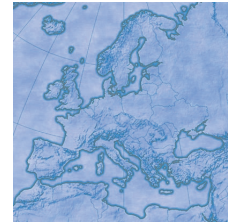


Counterfeit Drugs in Europe Fact Sheet



MAJOR CASES

DUTCH PARALLEL-TRADER: “A respected pharmacy journal in the Netherlands recently reported that counterfeit medicine found in the Netherlands at the end of last year [2004] entered the legitimate supply chain through parallel importers.”¹

BRITISH WAREHOUSE OPERATION: In November 2004, an enormous drug counterfeiting operation was exposed in the U.K. Allen Valentine was sentenced to five and a half years in jail for a counterfeit drugs operation that apparently could generate 500,000 tablets daily. Valentine's international enterprise also manufactured steroids and anti-anxiety medications.²

BACK-TO-BACK RECALLS IN U.K.: After a decade without major counterfeit outbreaks, two counterfeiting incidents were reported in the U.K. within a few weeks time in August and September 2004. Batches of Reductil and Cialis had to be recalled, the first major counterfeit recall since the discovery of fake Zantac in 1994.³ According to the MHRA (the U.K.'s FDA), at least one wholesaler involved in the recent cases knowingly purchased counterfeit product.⁴

FAKES FROM ITALY: “In 1998, counterfeit Losec was parallel-imported and spotted by the parallel importer as not appearing genuine. Some 6,000 bottles had been bought from a licensed dealer in Italy.”⁵

OPERATIONS

SEIZURES AND CONFISCATIONS: France's customs agents reported seizing 542,000 fake drugs last year.⁶ Officials recently arrested a man who tried to offload 22,000 fake pills at Heathrow Airport.⁷

INTERNET FRONT SITES: According to a press release from the Massachusetts Attorney General, who busted a Russia-based counterfeit drug ring of internet sites: “The Internet Spam Gang's operations have been tracked to Russia and other countries overseas, with domain names registered in Monaco, Australia, and France.”⁸

BULK EXPORT POINTS: The investigation for “Operation Cyber Chase,” a major DEA bust of an internet pharmacy supplier working from India, yielded allegations that European countries were shipping orders for the criminal network. “The Indian distributor allegedly would ship the drugs in bulk from India, Germany, Hungary, and elsewhere to Philadelphia and other sites in the United States, authorities said.”⁹

ORGANIZED CRIME TIES: “In 1995, an investigation that detected the involvement of the Naples-based organised crime group, the Camorra, uncovered a clandestine facility used to manufacture counterfeit pharmaceuticals.”¹⁰

Counterfeit Drugs in Europe

Case Studies



SPANISH FAKES EXPORTED TO ITALY, FRANCE, PORTUGAL

An incident occurred in Spain where Spanish police raided six laboratories in the northeastern region of Catalonia. The laboratories were producing counterfeit anabolic steroids and hormone-boosting substances as well as cancer drugs.

Quick Facts:

Sources of Counterfeit Ingredients: Mexico, Brazil, Thailand

Doses Seized: 30 million (10 tons)

Medicine Types: vials, capsules, tablets, injectables

Countries Affected: Italy, France, Portugal

According to police the operation was capable of producing more than 20,000 doses per hour, and the police estimate they seized some 30 million doses and 10 tons of tablets in all. Seventy individuals were arrested in 56 raids conducted over 13 Spanish provinces.

The counterfeit products were high quality fakes, making it extremely difficult to distinguish them from genuine products. Various packaging was used, such as packaging in Greek and Turkish.

The substances came in various forms including vials, capsules, tablets and doses for injection.

Authorities disclosed that the ingredients were



(TOP): Path of Counterfeit Ingredients to Spanish Facility



(RIGHT): Confirmed Export Paths

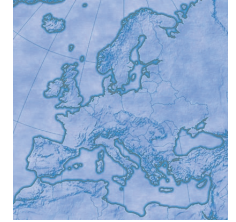
obtained to make the counterfeit products from Mexico, Brazil, and Thailand.

The products seized were destined for distribution in various EU countries. According to reports, lorries were used to transport the products to their points of sale across Europe. The products were also sold via the Internet and in health food stores run by one of the arrested.

The products have been confirmed to have been exported to Italy, France, and Portugal.¹¹

Counterfeit Drugs in Europe

Case Studies



FAKES IN GERMANY FROM SUSPECT SWISS BUSINESS

An investigation started when, during the summer of 2002, a pharmacy in Germany referred a patient's complaint about potential tampering of a medicine. In early 2003, German authorities raided a major wholesaler.

Quick Facts:

Value of Seizure:
almost one million Euros, 2 pallets

Medicine Types:
AIDS drugs

Countries Affected:
Germany

Countries Involved:
Switzerland, Israel¹²

They seized two pallets of counterfeit AIDS drugs valued at almost one million Euros.

The packaging, inserts and capsules did not correspond to the original. The chief of sales for the manufacturer said that no pharmacist would have noticed the difference.

The authorities suspected the products were sold outside the EU and that the complete packaging, including capsules, was replaced with counterfeits to make it look like products for marketing in Germany.

The trace of evidence led to a post office box company in Switzerland and to Israel.¹²

LARGEST COUNTERFEIT BUST IN SPAIN, MARCH 2004

In March 2004, a police operation dubbed "Sledge Hammers" resulted in the largest seizure of pharmaceuticals in Spain to that date.

The investigation was initiated after the police detected illegal shipments of pharmaceuticals in the mail system. 500,000 dosage units of counterfeit and illegal medicines were recovered. In addition, law enforcement agents seized 375,000 empty bottles, 160,000 inserts and 1.2 million labels. The market value of the pharmaceuticals was estimated at six million euros.

Quick Facts:

Value of Seizure:
Six million Euros(est.)

Medicine Types:
AIDS drugs, cancer drugs

Countries Affected:
Spain

The products included those used to treat serious conditions: for example, human growth hormone and a version of epoetin alfa, used to boost red blood cells. The criminal network received shipments with supplies from Eastern Europe and the United States.

The manufacturing facility was located in Valencia but the products were distributed countrywide. The front enterprise operated as a retailer of dietary products.¹³

Counterfeit Drugs in Europe

What NGOs Are Saying



U.K. PATIENTS' ASSOCIATION (SEPTEMBER 2004):

“We are increasingly concerned not just about counterfeit medicines, but also the growth of unregulated internet pharmacies, and the patient safety implications of repackaging medicines through parallel trade.”¹⁴

SOCIAL MARKET FOUNDATION (MAY 2004):

“The complex nature of the supply chain across Europe, results in some medicines exchanging hands many times before reaching the patient. This creates more opportunities for counterfeit products to enter the supply chain than if the products were sourced nationally. Combined with the accession of ten member states that are significantly poorer than the rest of the EU and that have both current and historic trading ties with the former Soviet Union (where the WHO already estimate the medicines supply chain to contain up to 10% counterfeit product)” it is almost inevitable that counterfeit medicines will enter the EU supply chain.”¹⁵

INTERNATIONAL ANTI-COUNTERFEITING COALITION (2004):

“The Polish border is open to imports and exports of counterfeit goods that range from counterfeit medicines to cosmetic products, both having potential health risks for consumers. Asian-sourced counterfeit pharmaceutical products have been found imported into Poland by member companies.”¹⁶

Counterfeit Drugs in Europe

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- 3.) See recall alerts on <http://www.safemedicines.org/safety/counterfeit.html>. On Zantac, see Graham Satchwell, *A Sick Business* (Stockholm Network, 2004), p. 49. "In 1994, a UK wholesaler found that 'good quality' counterfeit Zantac (a GlaxoSmithKline product) had been delivered to him in the UK from Greece. This was the fourth occasion on which this product had been seen in Britain."
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- 16.) <http://iacc.org/teampublish/uploads/2004-301.pdf>, p. 44.

Counterfeit Drugs in Europe

About this Document



WHO WE ARE

The Partnership for Safe Medicines is a coalition of patient, physician, pharmacist, university, industry and other professional organizations committed to the safety of prescription drugs and protecting consumers against unapproved, counterfeit, substandard, mishandled or otherwise unsafe medicines. For more information, visit us online at <http://www.safemedicines.org>.

UPDATING OF THIS FACT SHEET

It may be updated at the discretion of the Board of Directors. The initial version was approved by the Board on July 18, 2005. Updates will be posted at: <http://www.safemedicines.org/>. Please feel free to contribute information for inclusion on this fact sheet by writing to information@safemedicines.org.

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