



Case Study: Lipitor® US Recall



It was the largest recall of counterfeit medicines to date in the US. Just one counterfeit case, but over 18 million Lipitor® tablets affected. In the short time from discovery to recall the fake medicines had spread to 15 US states.

Lipitor® is indicated for high cholesterol, and is the most prescribed medicine in the world. During 2003, almost 69 million prescriptions for Lipitor® were written in the US alone.

The counterfeits first came to light in April 2003 as a result of patient complaints that the tablets had a bitter taste and dissolved quickly in the mouth. Pfizer tested the tablets and, although some contained the correct active ingredient, they were found to be counterfeits. Pfizer assisted federal law enforcement in the investigation of five US companies involved in the distribution of the fake tablets. Subsequently the FDA recalled more than 18 million fake and repackaged tablets from the legitimate US supply chain.

To put that number in perspective, more than 600,000 U.S. residents, after visiting their local pharmacy or placing an order with their health plan by phone, mail, or the internet, may have received a thirty-day supply of Lipitor® that contained counterfeits.



Counterfeit Lipitor® was found in 15 US states and was suspected in a further six.

Those tablets, a combination of counterfeits and legitimate product of undetermined origin, had been repackaged by a Nebraska company and distributed primarily by a second company in Missouri.

On investigation it was shown that the counterfeits had been manufactured in Costa Rica using tooling and excipients from the United States and a pharmaceutical ingredient shipped from Hong Kong office of Swiss company.



Aside from a difference in their thickness, the counterfeit Lipitor® (left) is virtually indistinguishable from the authentic tablets.

As with many other cases of fake medicines, the final packs were then passed through shell companies to create false pedigree, making detection much more difficult. The counterfeits themselves were high quality fakes and repackagers co-mingled counterfeit tablets with those illegally diverted from foreign markets.

The ease with which goods move throughout the world permits counterfeits produced in one region to be moved to another at very high profit and with very little risk. The more times a product changes hands, the easier it is to introduce counterfeits into the system. As demonstrated in this instance where the fake drugs infiltrated 15 US states.



European Trade Group