

# Analysis of Pharmaceuticals Seized by Authorities for Suspicion of Being Counterfeit VIAGRA® (Sildenafil Citrate)

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## Introduction

- The World Health Organization defines counterfeit medicines as those that are “deliberately and fraudulently mislabeled with respect to identity and/or source...[they] may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”<sup>1</sup>
- Counterfeit seizures in the European Union increased 384% between 2005–2006,<sup>2</sup> with a further 51% increase in 2007.<sup>3</sup>
- Of the increased EU counterfeit seizures, phosphodiesterase type 5 (PDE5) inhibitors were the most commonly counterfeited class of product in Europe.<sup>4</sup>
  - PDE5 inhibitors are a prime target for counterfeiting owing to high cost and the embarrassment associated with the underlying condition.<sup>5</sup>
  - VIAGRA® (sildenafil citrate) was the most counterfeited Pfizer product in the European Union, accounting for 96% of the counterfeit Pfizer products seized in 2006.<sup>6</sup>
- The Dutch National Institute for Public Health and the Environment analyzed 370 samples of illegally sold Viagra collected from 2000–2004 and found that only 10 were genuine.<sup>7</sup>
  - Often, sildenafil was present, but in lower amounts than declared; samples often were contaminated with unrelated pharmaceutical products.<sup>7</sup>
- Counterfeit PDE5 inhibitors are closely associated with the Internet.
  - The majority of counterfeit PDE5 inhibitors in the United States are thought to enter the market via fraudulent websites.<sup>8</sup>
  - The Experts on the Operation of European Conventions in the Penal Field estimate that 44% of sildenafil sold over the Internet is counterfeit.<sup>9</sup>
  - In a US study, several different medications, including the PDE5 inhibitor Cialis® (tadalafil), were ordered from 13 suspicious websites selling prescription-only medication without a prescription.<sup>10</sup>
    - When the amount of active pharmaceutical ingredient (API) was tested by the US Food and Drug Administration, levels ranged from none to far exceeding the level allowed in US medications; API analysis by the drug manufacturer found that the contents did not meet the company’s US regulatory standards.<sup>10</sup>
- Counterfeit products pose significant dangers to patient health.<sup>8</sup>

## Objective

- Pfizer analyzed pharmaceutical products seized by authorities for suspicion of being counterfeit Viagra.

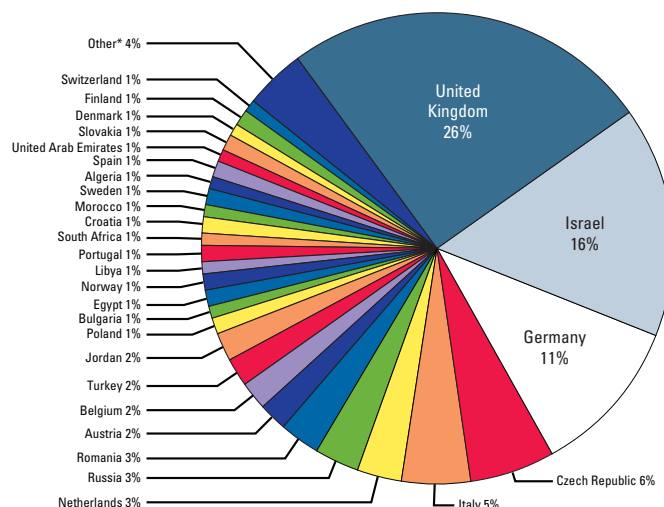
## Methods

- Pharmaceuticals seized by authorities (including customs, law enforcement, and health agencies) for suspicion of being counterfeit Viagra were forwarded to Pfizer Ltd., Sandwich, United Kingdom, for analysis between May 24, 2005, and July 8, 2009.
- The authenticity of each seizure was determined using spectral analysis.
- High-performance liquid chromatography determined purity and API concentration in a subset of samples.

## Results

- There were 2383 seizures from Europe, the Middle East, and Africa, most commonly from the United Kingdom (Figure 1).
- Of the total number of seizures, 1958 (82.2%) were deemed counterfeit (Figure 2).
- There were 483 seizures (20.3%) that had been ordered through the Internet, of which 369 (76.4%) were deemed counterfeit (Figure 3).
- Of 316 samples that were labeled “Viagra 100 mg” and analyzed for API, only 32 (10.1%) contained sildenafil citrate (the active ingredient in Viagra) or a related sildenafil derivative within 10% of the labeled concentration (Figure 4).
  - 78 (24.7%) contained no sildenafil.
  - 21 of the 316 samples labeled “Viagra 100 mg” contained nonsildenafil APIs in addition to sildenafil.
  - An additional 27 samples with the “Viagra 100 mg” label contained only metronidazole as the API, and 2 samples contained only tadalafil.
  - Of the 316 analyzed samples that were labeled “Viagra 100 mg” and analyzed for API, 60 were purchased through the Internet.
    - 45 (75.0%) of these samples contained <90% of the advertised sildenafil content (Figure 5).
- Commercial grade paint and talcum powder were found as contaminants in counterfeit Viagra.
  - Printer ink was used in some samples to color tablets blue.

Figure 1. Countries From Which Counterfeit Pharmaceuticals Were Seized by Authorities (Including Customs, Law Enforcement, and Health Agencies) for Suspicion of Being Counterfeit Viagra and Analyzed by Pfizer.



\*Includes Hungary, India, Bosnia, France, China, Ireland, Qatar, Slovenia, Malta, Saudi Arabia, Serbia, Kuwait, Botswana, Greece, Lebanon, Thailand, Andorra, Canada, Cyprus, Estonia, Georgia, Kazakhstan, Latvia, Macedonia, Moldova, Namibia, Tunisia, and Yemen.

Figure 2. Authenticity Determination of 2383 Seizures

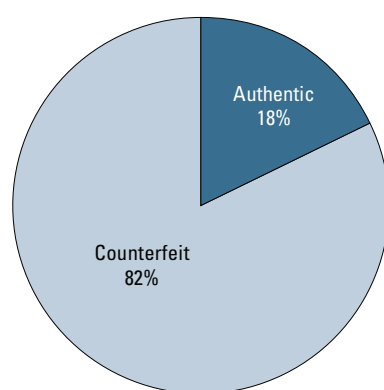


Figure 4. Analysis of Sildenafil or Sildenafil-Related Derivative Content of 316 Samples Labeled as “Viagra 100 mg”

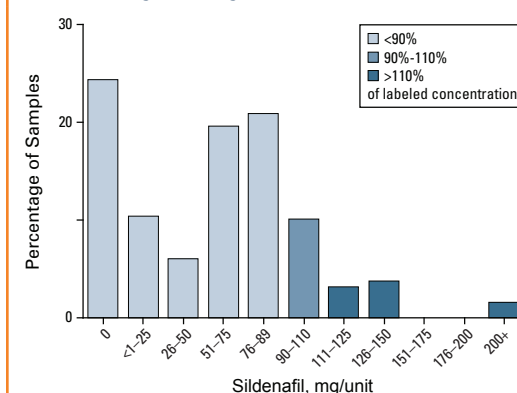


Figure 3. Authenticity Determination of 483 Seizures That Were Ordered Using the Internet

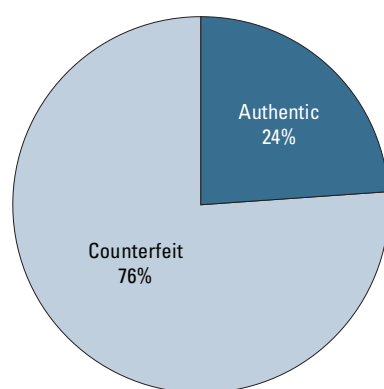
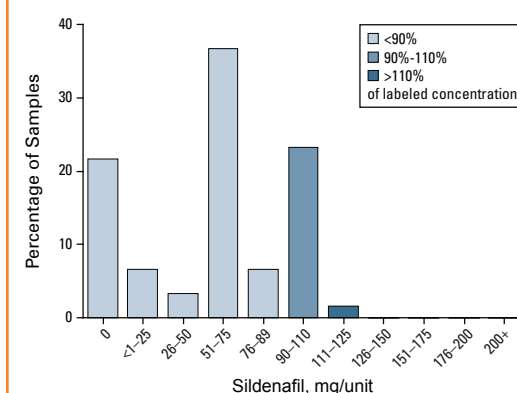


Figure 5. Analysis of Sildenafil or Sildenafil-Related Derivative Content of 60 Samples Labeled “Viagra 100 mg” That Were Ordered Through the Internet



## Conclusions

- Pharmaceuticals seized for suspicion of being counterfeit were overwhelmingly counterfeit, including more than three quarters of those ordered through the Internet.
- Counterfeit Viagra rarely contained the proper dose of API, and others were contaminated with hazardous substances.

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