

Counterfeit Medicines: A First World Problem?

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Counterfeit Medicines: Definition



- **World Health Organization (WHO)**
 - A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines include:
 - Products with correct ingredients but mislabelled
 - Products with undeclared ingredients
 - Products with the wrong ingredients (16%)
 - Products lacking active ingredients (60%)
 - Product with insufficient amounts of active ingredients (17%)

Counterfeit Medicines: Definition



- Any false representation in relation to a product's identity, history or source.
- Applies to a product's:
 - Packaging
 - Manufacturing
 - Labelling

Counterfeit Medicines: Grey Market Goods

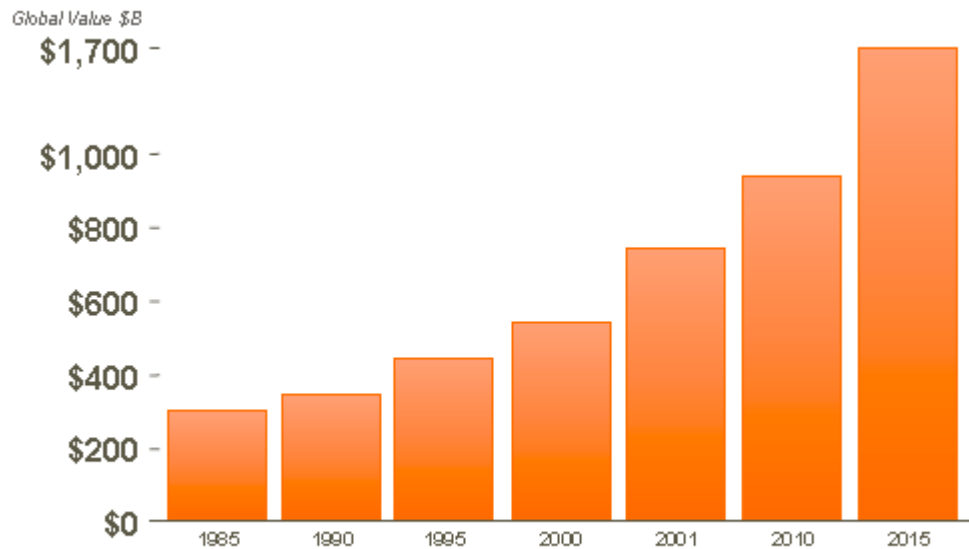


- **Grey Market goods** or parallel imports are genuine products, but imported without the authority of the brand owner.
- Diverted products destined for different markets which are resold in order to capitalize on pricing differences or currency exchange fluctuations between jurisdictions.
- Enter through “grey market” channels:
 - Distributors create secondary channels for bargains
 - Diverted from the legal supply chain

Counterfeit Medicines: Global Impact



- Trade in counterfeit goods represents an estimated 5-7% of all worldwide trade



Source: The Economic Impact of Counterfeiting and Piracy Directorate for Science, Technology and Industry, Committee on Industry, Innovation and Entrepreneurship, OECD June 2007 and International Chamber of Commerce (ICC) Feb 2011

Counterfeit Medicines: North America



- In 2013, FDA seized and shut down 1677 illegal pharmacy websites which mimicked Canadian pharmacies.
- 88% of imported privately imported pharmaceuticals were counterfeit and contained potentially harmful ingredients
- In 2012, the FDA reported as many as 1446 eBay ads selling diabetes strips which were likely counterfeits

Counterfeit Medicines: Prevalence



- The problem is prevalent and is increasing rapidly undermining the integrity of the global pharmaceutical supply chain
- Center for Medicine in the Public Interests estimates:
 - Worldwide counterfeit drugs sales rise 13% annually
 - Nearly twice as quickly as the pace of legitimate drugs
 - Fake drugs are approaching a \$75 billion industry

Counterfeit Medicines: Rationale



- Why does it happen:
 - Global market reach via the internet
 - Highly profitable - low penalties
 - Technology to copy products is widely available
- Law enforcement's ability to detect and prosecute this crime is hindered by:
 - Shortage of financial resources
 - Lack of coordination between countries
 - Weak anti-counterfeiting laws

Counterfeit Products: Tablets



Lipitor:



Counterfeit Medicines: Tablets



- Cialis and Viagra:



FIGURE 1 – Examples of samples used in the study: counterfeit Viagra[®] (A-F), authentic Viagra[®] (V), counterfeit Cialis[®] (G-L) and genuine Cialis[®] (T).

Counterfeit Medicines: Tablets



- Xanax



Counterfeit Medicines: Packaging



- **Cialis:**



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Counterfeit Products: Packaging



- Serostim



Counterfeit Medicines: Packaging and Insert



- Proscrit



Counterfeit product package insert P004677 and P007645. Package insert is printed on heavier weight paper. Package insert is not sealed.

Authentic PROCRIT package insert P004677 and P007645. Package insert is printed on light weight tissue-like paper. Package insert is sealed with tear-away glue after folding.

Counterfeit Medicines: Facilities



- Counterfeit Manufacturing Facilities



VANCOUVER

CALGARY

TORONTO

OTTAWA

MONTRÉAL

QUÉBEC CITY

LONDON

JOHANNESBURG

Counterfeit Medicines: Candidates



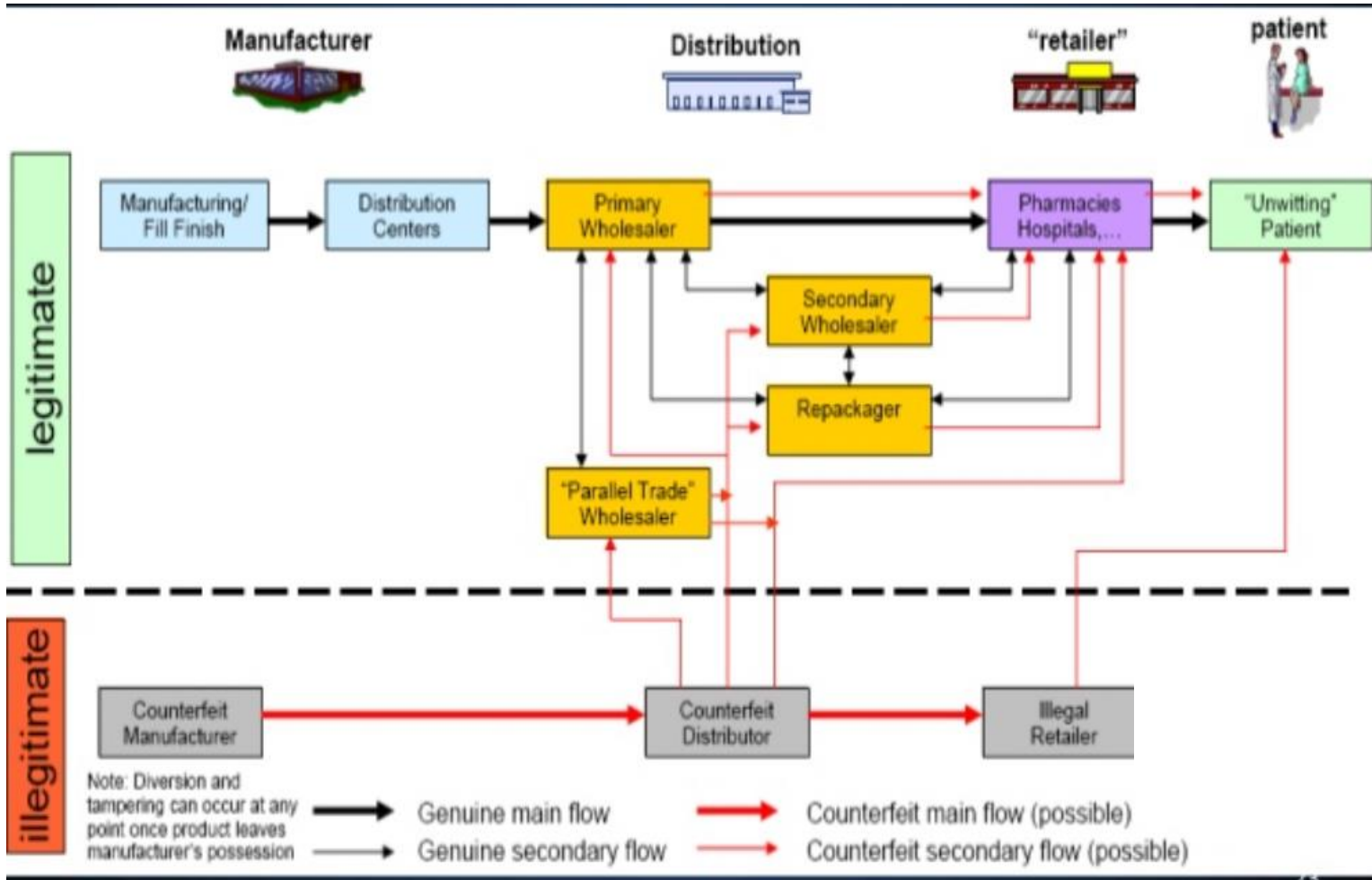
- Fast moving and well-known brands
- Easily manufactured
- Over the counter (OTC)
- Products for Export

Counterfeit Medicines: Frequently Counterfeited Drugs



- Ambien (Sleep medication)
- Combivir (AIDS)
- Diflucan (Fungal Infections, AIDS)
- Epogen (Kidney failure)
- Lipitor (Cholesterol)
- Neupogen (Chemotherapy support therapy)
- Ortho Evra (Birth control patch)
- Proscrit (Kidney Disease)
- Viagra (Erectile Dysfunction)

Counterfeit Products: How are they being sold



Counterfeit Medicines: Effects



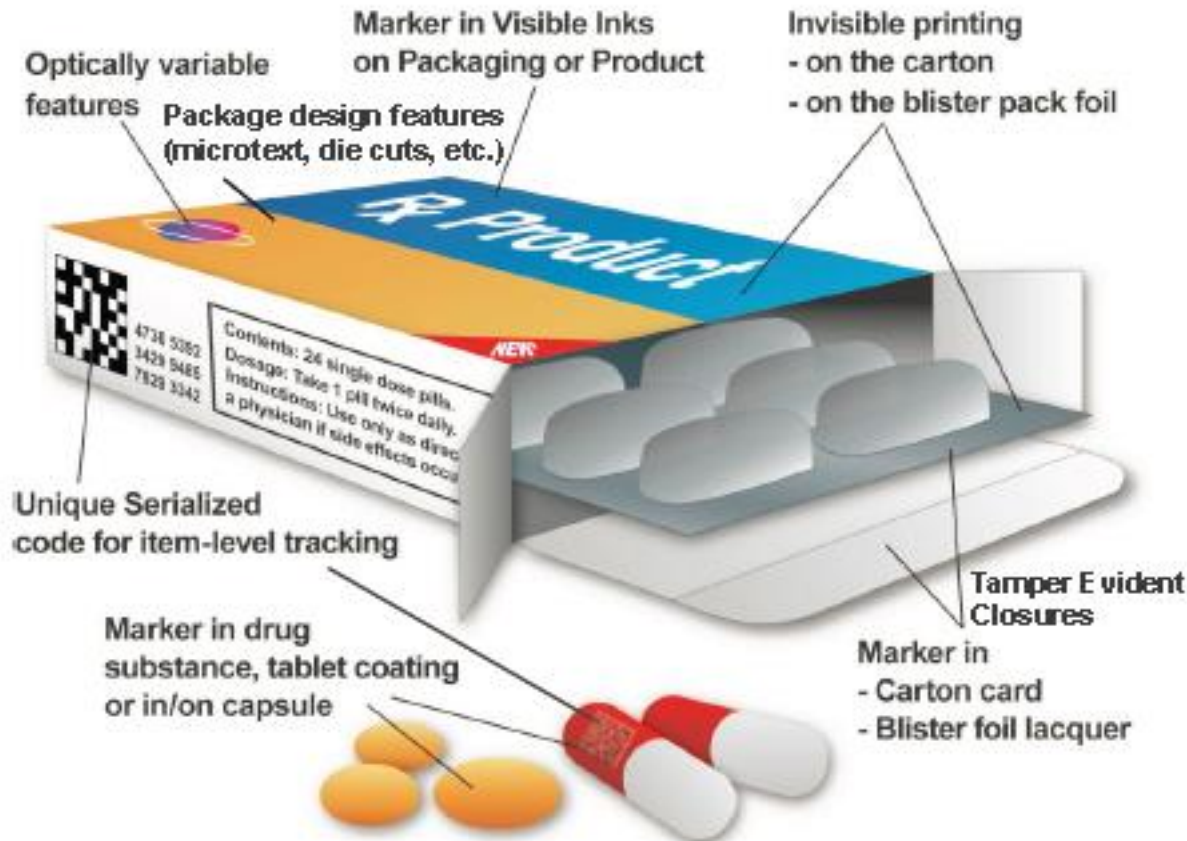
- **Government:**
 - Loss of Reputation
 - Mistrust of importers
 - Loss of Revenue
- **Consumer:**
 - Health Hazard
 - Loss of confidence in health care system and HCP
- **Industry:**
 - Loss of reputation
 - Loss of goodwill
 - Mistrust of HCPs
 - Loss of control of supply chain and faith in suppliers

Counterfeit Medicines: Combat Strategies



- Product based solutions
- Supply chain level solutions
- Authentication

Counterfeit Medicines: Combat Strategies – Product Solutions

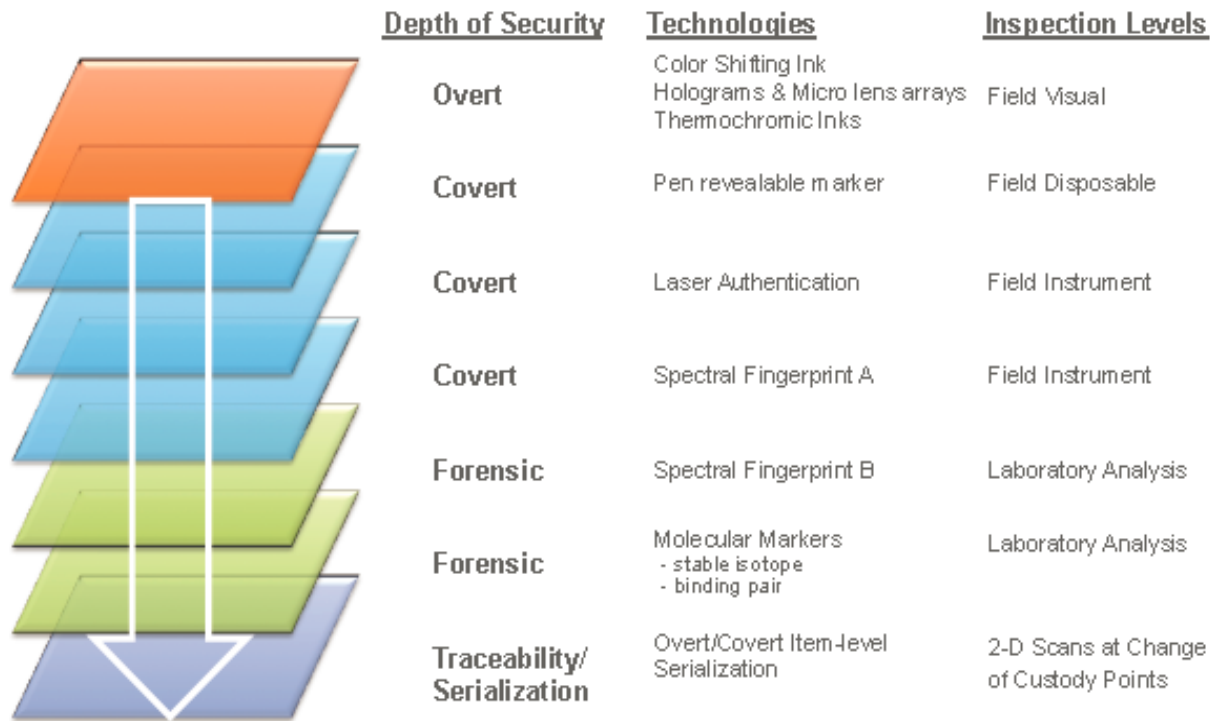


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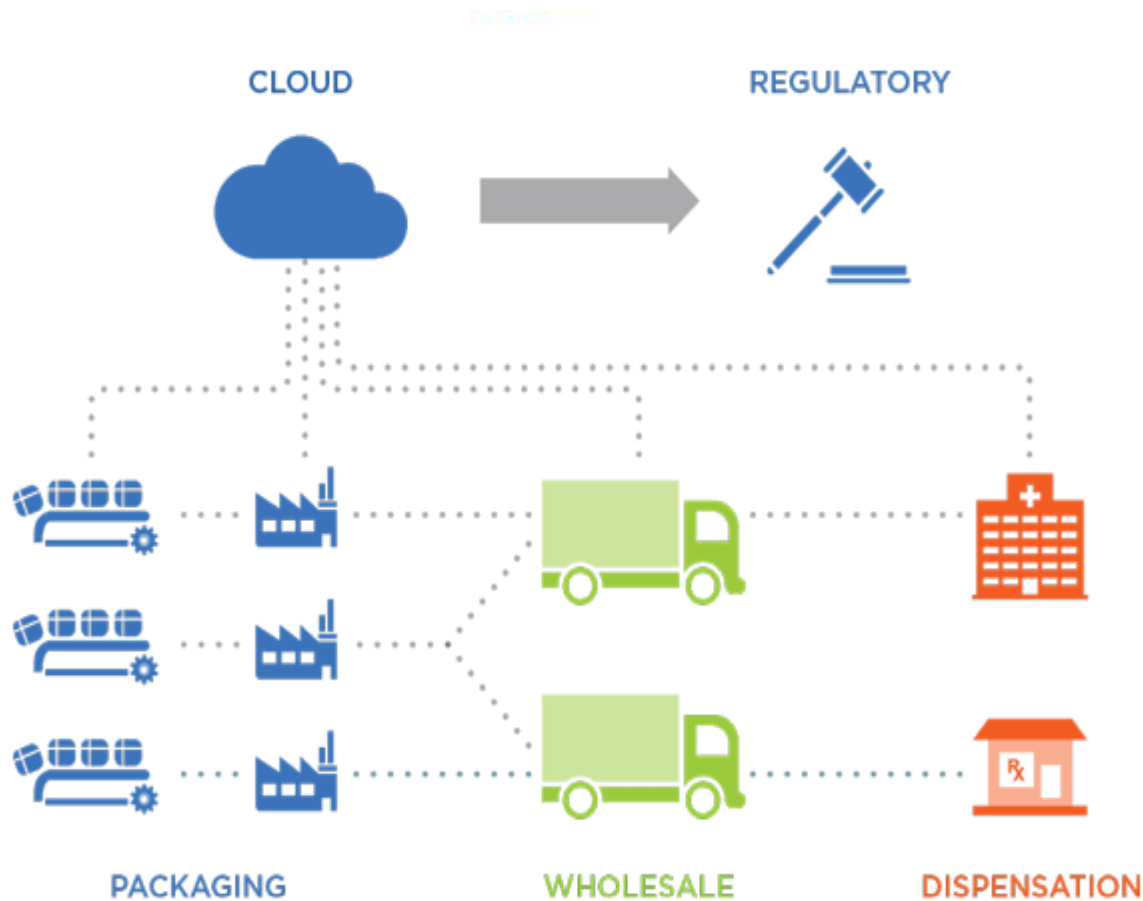
Counterfeit Medicines: Combat Strategies – Product Solutions



- Authentix (Service provider) suggests layering multiple technologies:



Counterfeit Medicines: Combat Strategies- Supply Chain Solutions

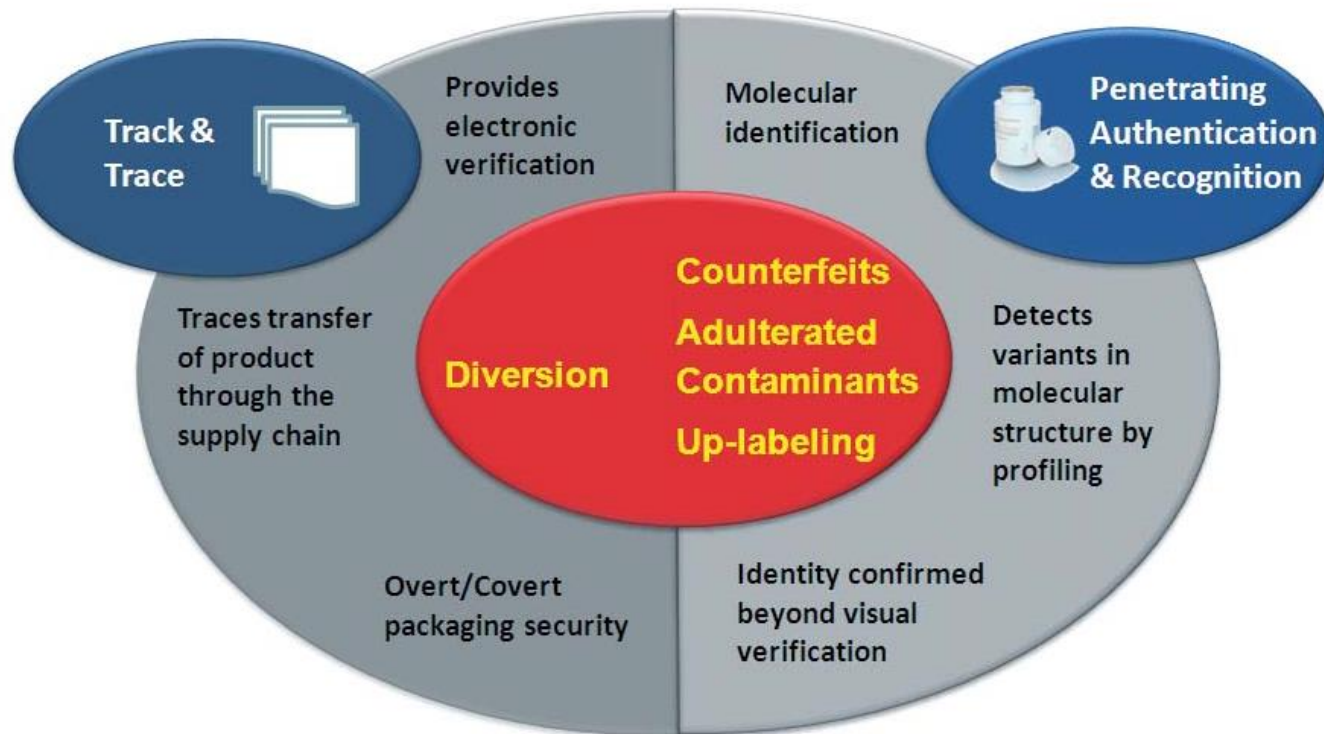


Counterfeit Medicines: Authentication



Track and Trace vs. Authentication

“ There is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome than any single method...” --- FDA Initiative 2007

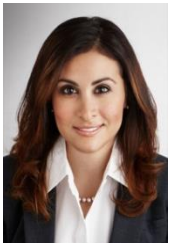


Counterfeit Medicines: Final Words



- Counterfeit drugs are a significant and growing threat
- Internet provides an uncontrolled outlet for fake drugs
- Any drug could be a target
- Manufacturers are taking steps to confront the threat
- Governments are working to address the threat
- Consumers need to be aware and vigilant

Questions



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