P06: Anti-Counterfeiting Technology

E356 – Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management (DSCM)

E356 Topic Tree

Pharmaceutical and Bio-chem Supply Chain

- Introduction to Pharma and Bio-chem
- Classification of Dangerous Goods
- Best Practices (GMP/GDP)
- Clinical Supply Chain
- Cold Chain Management

Import, Packaging and Distribution

- Import and Distribution of Medical Devices
- Import of Pharmaceutical and Bio-Chem Products
- Local Transportation of Pharmaceutical and Bio Chem Products
- Packaging of Pharmaceutical DG for Air Transport
- Declaration of Pharmaceutical DG for Air Transport

Product Tracing, Recall and Disposal

- Product Tracing (anti-counterfeit technologies)
- Drug Recall
- Disposal of Bio-chem Products in Hospital Logistics

Problem Statement

Janet, a 28 years old lady, has been suffering ***overweight/obesity problem*** over past few years. Recently, she heard that there is one particular ***weight loss pill*** which can help reduce the weight at least 15 pounds per week, according to the advertisement on the online social medial. In addition, the price of this weight loss pill is even ***cheaper*** than those alternatives sold in local pharmacies.

Hence, she was considering giving it a try.

Problem Statement

While Janet was searching internet, she happened to watch a video about a story of another young woman – Cheryl, her experience of suffering from fake weight loss pills:

https://youtu.be/KdEKm82BKkA

Think and share…

At what circumstances the medicines are considered as counterfeit?

Definition of Counterfeit Medicines

A counterfeit medicine is one

- Which is deliberately and fraudulently mislabeled with respect to identity and/or source
- With correct ingredients but fake packaging
- Wrong ingredients
- Without active ingredients
- Insufficient active ingredients

Source: World Health Organization

IMPACT International Medical Products Anti-Counterfeiting Taskforce

Research and share…

- Do some research and find out some examples of counterfeit drugs. Based on your findings, how can you tell the differences between genuine and counterfeit medicines?

Types of Counterfeit Medicine

Deliberate mislabeled product

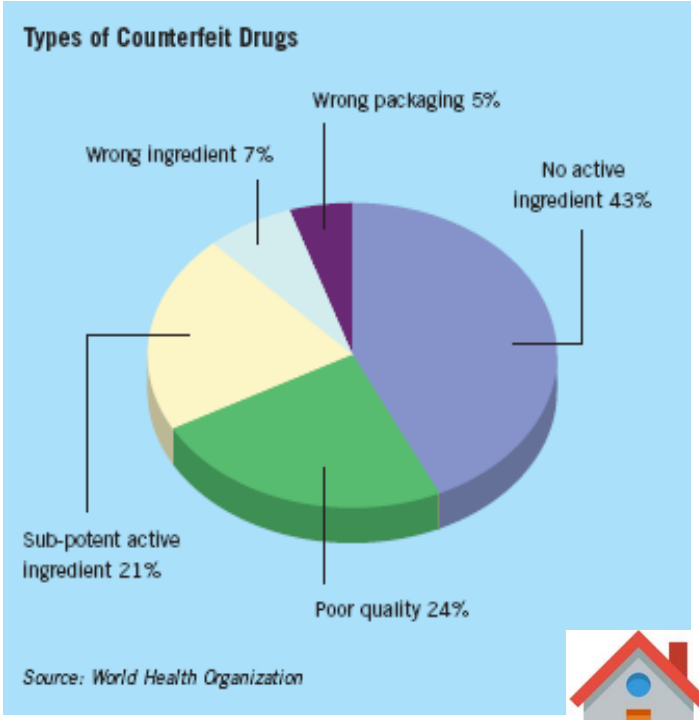
Figure 1 : Two blister packages of the antimalarial drug artesunate, A well crafted hologram on the right is the only distinguishing feature of the genuine product.

Wrong 'filler' ingredients

Figure 2 : Serostim (somatrapin), a human growth hormone used to treat HIV wasting. The filler was likely to be contaminated by dangerous metals during production in Southeast Asia and sold by a website based in Eastern Europe.

Size of problem for counterfeit medicines

- Many countries in Africa, Asia and parts of Latin America have areas where more that 30% of the medicines on sale are counterfeit.
- In other developing markets, the figure is around 10%.
- Medicines sold by rogue Internet sites are counterfeit 50% of the time.
- Most industrialized countries with effective regulatory systems and market control have an extremely low proportion of counterfeits – somewhere in the range of 1% of market value or just under – but many of the rogue web sites mentioned are selling their wares in those very countries.

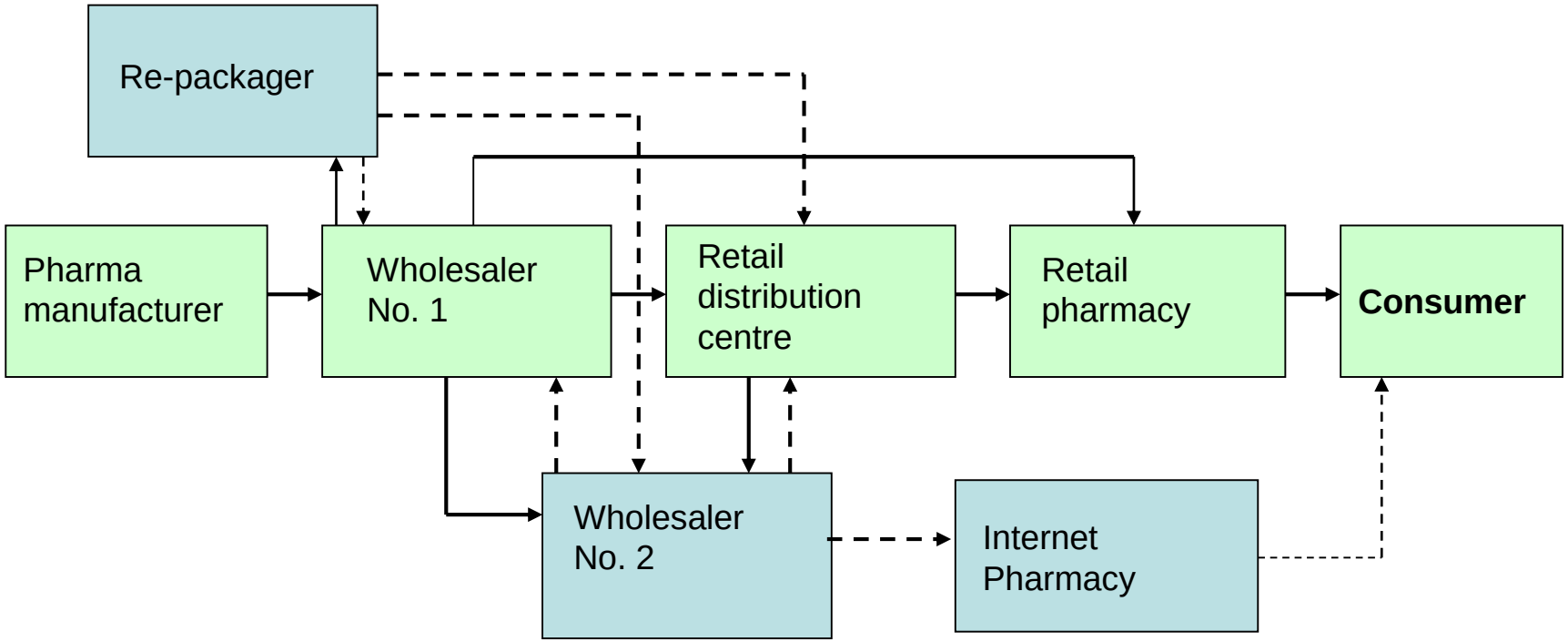


Consequence of using a counterfeit drug

Substandard and counterfeit medicines are unsafe and ineffective, leading to

- Wasted resources spent on purchasing, inventory, transport
- No improvement in health condition at best
- Therapeutic failure or drug resistance to some medicines
- Aggravate disease condition
- Death cause by toxic counterfeit medicine
- Interaction with other medicine patient, causing adverse effects
- Reduce trust in public health system to provide adequate treatment

Vulnerability in the Drug Supply Chain



Potential vulnerability

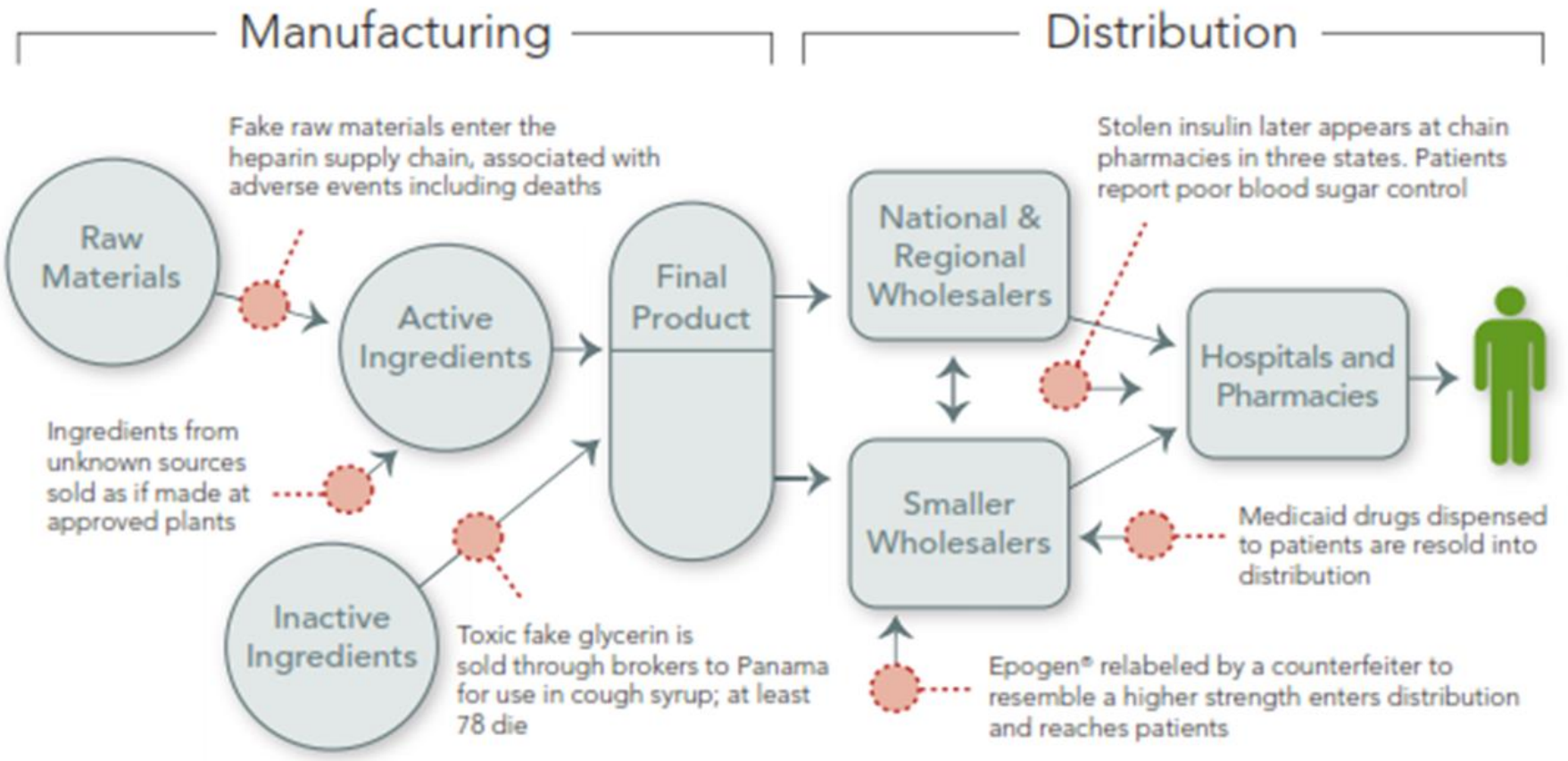
Potential illegal sales

Information source: FDA.

Diagram adapted from SupplyScape Corporation, 2003

Vulnerability in the Drug Supply Chain

pharmaceutical supply chain with examples of vulnerabilties



http://patientsafetyhub.com/wp-content/uploads/2011/08/Supplychain-safety1.png

Regulation of Medicines in Singapore

- Investigation and Surveillance Unit under the Centre for Drug Administration (CDA) in Health Sciences Authority (HSA)
- Controls for regulating medicines mainly reside in 5 separate pieces of legislation –
  - the Medicines Act,
  - the Medicines (Advertisement and Sale) Act,
  - the Poisons Act,
  - the Sale of Drugs Act
  - Health Products Act

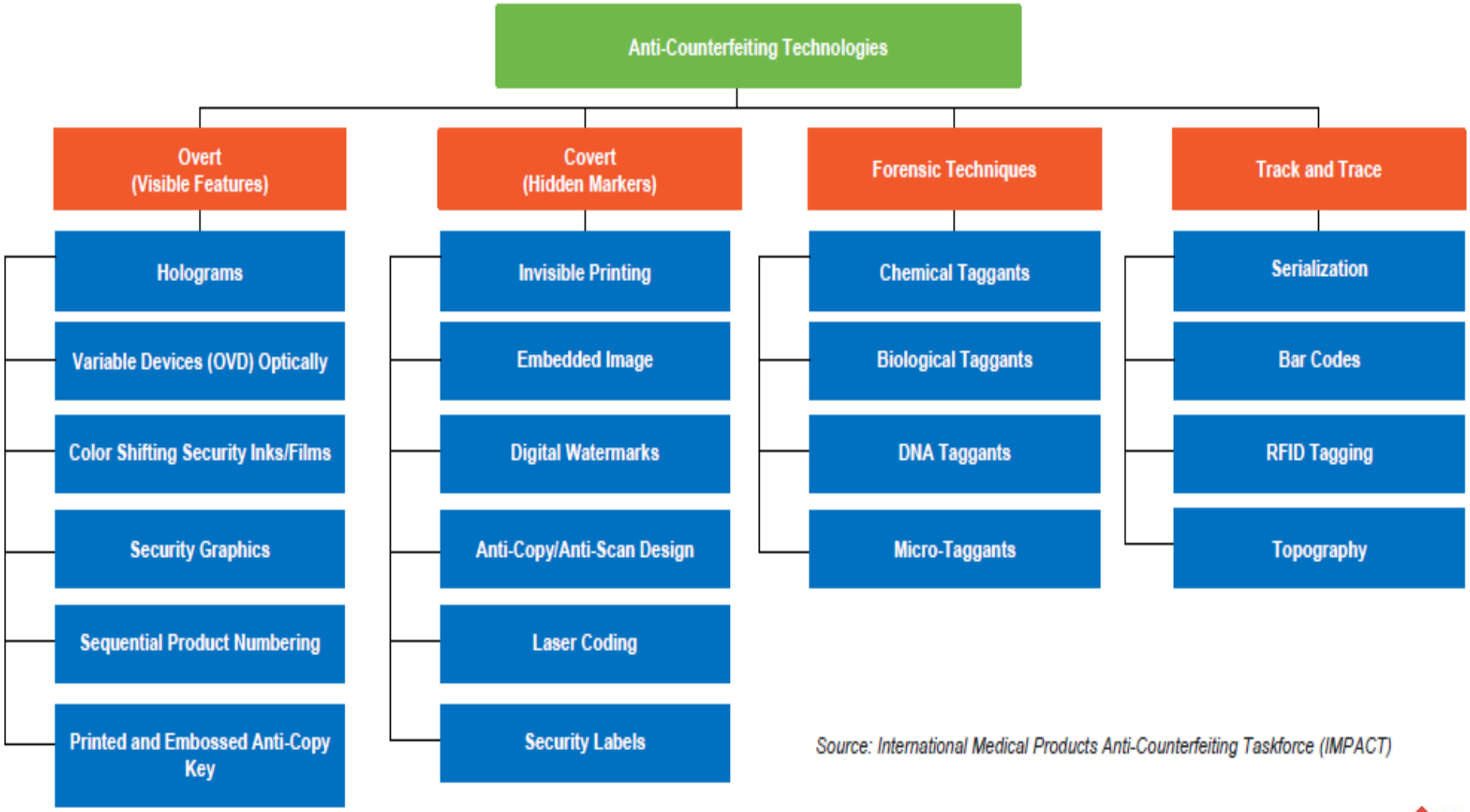
Regulation of Medicines in Singapore

- **Counterfeit drugs may breach local legislations in one or more of the following ways (not exhaustive):**
  - Manufacturing a medicinal product without a license
  - Importing a medicinal product without a license
  - Sell or supply a medicinal product without a license
  - Import, possess for sale, sell or offer for sale a poison without a license
- **HSA uses a multi-pronged approach to protecting Singaporeans from counterfeit drugs, they include:**
  - Protection of each aspect of the supply chain through strict licensing requirements.
  - Post market surveillance
  - Enforcement actions
  - Prosecution
  - International and local collaborations (Police, Singapore Customs, Immigration and Checkpoints Authority etc).
  - Collaboration with pharmaceutical companies
  - Reporting systems and recalls
  - Public education - public awareness programs
  - Counterfeit technologies

Anti-counterfeiting features in medicines

- Purpose of an anti-counterfeit feature is
  - primarily to enable authentication of an item, either by industry investigators, or ideally by the wider public
  - To deter anyone from counterfeiting a product by increasing the difficulty and cost involved to set against the likelihood of detection
- Anti-counterfeit technologies can be broadly classified as:
  - Overt, or visible features
  - Covert, or hidden features
  - Forensic techniques
  - Serialization/Track and Trace
- Note: security devices on packaging components provide no assurance on the authentication of the contents

Anti-Counterfeiting Technologies



Source: International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

Overt, or visible features

- Overt features enable end users to verify the authenticity of a pack
- Examples of overt features include:
  - Holograms
  - Optically Variable Devices (OVD)
  - Colour shifting security inks and films
  - Security graphics
  - Sequential product numbering
  - On-product marking/Printed and embossed anti-copy key

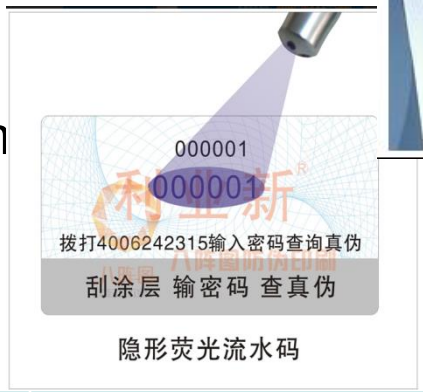
Holograms

Colour Shifting Inks

Advantages	Disadvantages
User verifiable	Require user education – not always widely understood
Newer technologies more secure	May be easily mimicked/For close enough to confuse consumer
Can add to decorative appeal	May add significant cost
Can be a deterrent to counterfeiters	May rely on cover features for authentication
	May be re-used or refilled
	May give false assurance

Covert, or hidden features

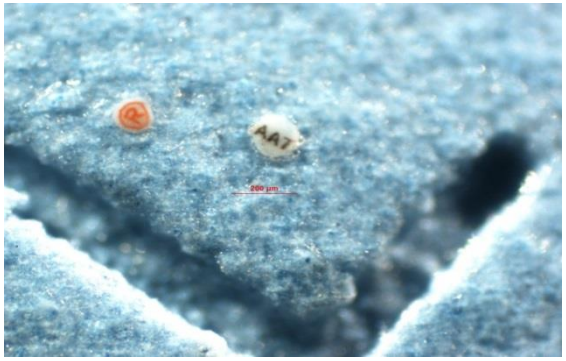
- Covert features enable the brand owner to identify a counterfeit product
- Examples of covert features include:
  - Invisible Printing
  - Embedded image
  - Digital watermarks
  - Hidden Marks and Printing
  - Anti-copy or Anti-scan design
  - Laser Coding
  - Substrates
  - Odour



Advantages	Disadvantages
Can be simple and low cost to implement	Need strict secrecy – “need to know”
Needs no regulatory approval	If widely known or used, may be easy to copy
Can be easily added or modified	More secure options add supply complexity and cost
Can be applied in-house or via component suppliers	If applied at component suppliers, greater risk of compromise

Forensic Techniques

- Usually require laboratory testing or dedicated field test kits to scientifically prove authenticity
- Examples of forensic techniques include the use of:
  - Chemical taggants
  - Biological taggants
  - DNA taggants
  - Isotope ratios
  - Micro-taggants



Advantages	Disadvantages
High tech and secure against copying	Licensed technologies usually limited to one source
Provide positive authentication	Significant cost
May be disclosed for overt purposes	May be difficult to implement and control across different markets
	Wider use increase risk of compromise
	Unlikely to be available to authorities or public

Serialization/Track and Trace Technologies

- Involves assigning a unique identity to each stock unit during manufacture
  - If serialization is sequential, it would be predictable and level of security is very low
  - “random” serialization using secured algorithm of method of encryption will increase the security of product
- Remains with the product throughout the supply chain till consumption
- Identity will normally include details of product name, strength, lot number and expiry date
- May take the form of a unique pack coding which enables access to the information held on a secure database
- Enables **product authentication** and **transaction security**

Serialization/Track and Trace Technologies

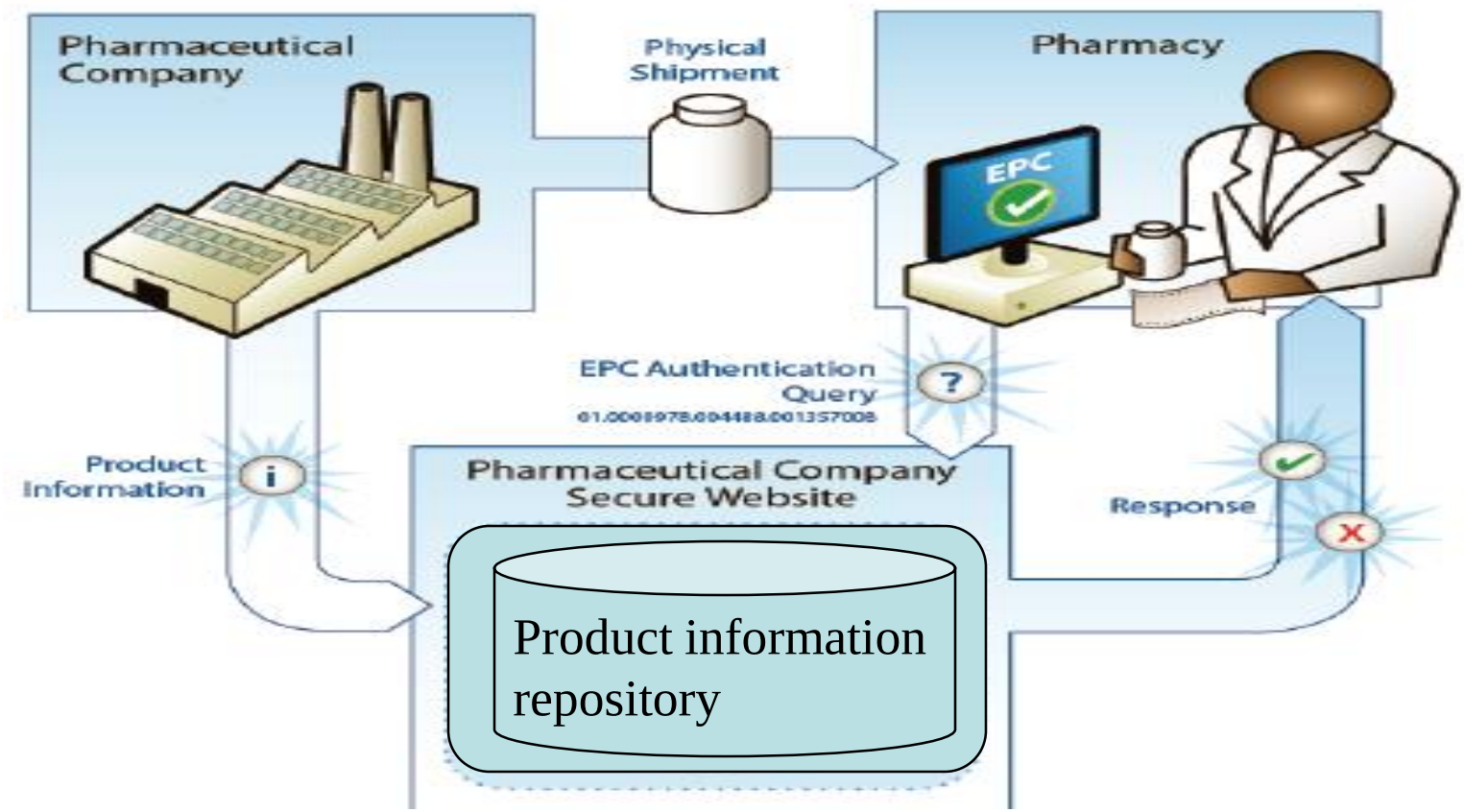
- Examples of unique pack coding includes
  - Serialization
  - Bar code
  - RFID tags
  - Unique surface marking or topography

Serialization with bar code

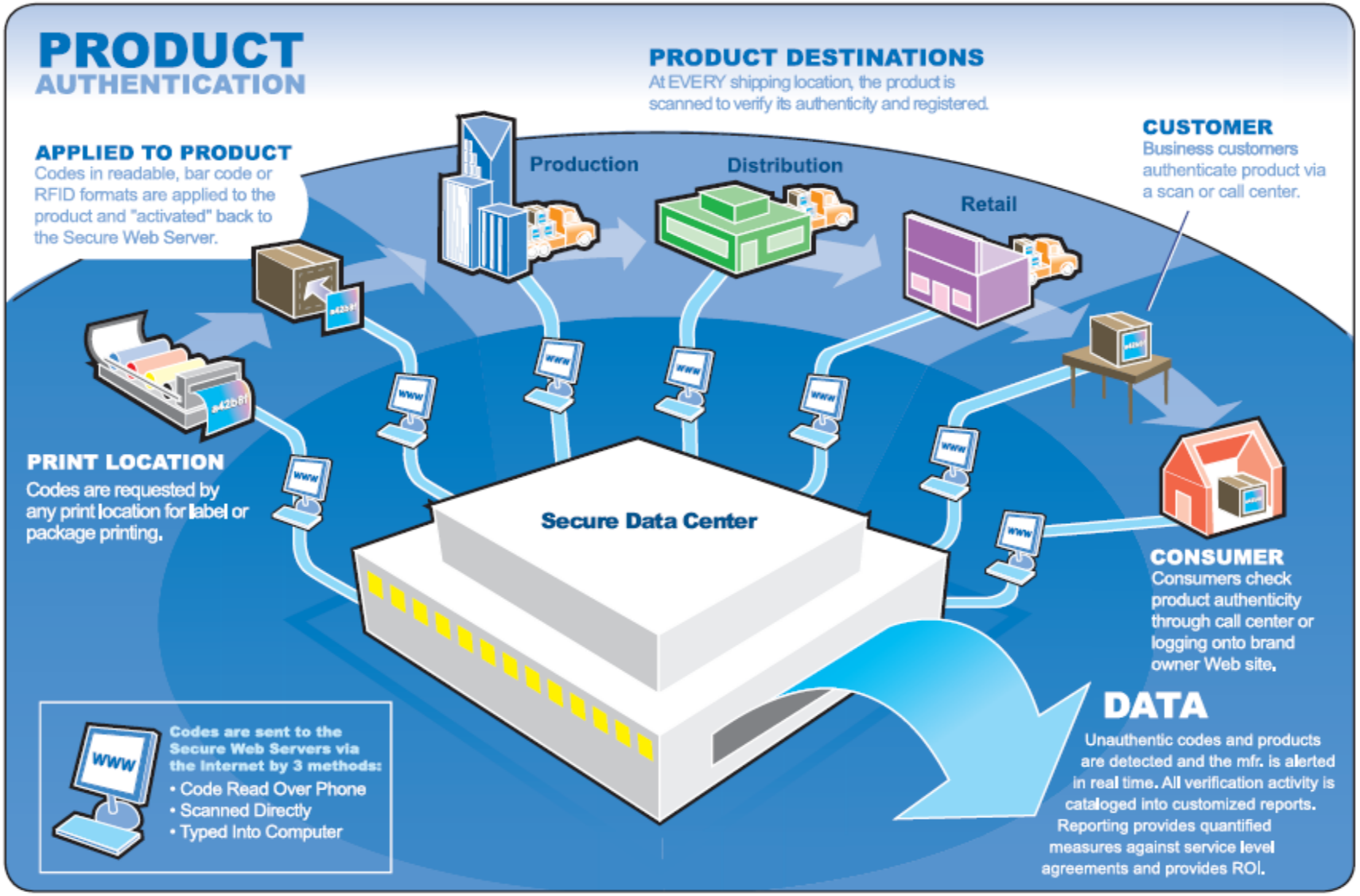
Advantages	Disadvantages
High-tech and provides better security against copying, Can also be authorized by investigators without compromise	Involves significant cost to implement
Helps to eliminate dispensing errors and Speedy recall of defective products	Difficult to implement and access control to different markets e.g Labels, when damaged during transit causes readability issues
Remote authentication is possible via phone or internet	May be difficult to implement and control across different markets
	It is required for optimum result standards needs be harmonized

Product Authentication with Serialization/Track & Trace

- Product authentication with secured information repository
- Product status management – new, shipped, recall, etc…



Product Authentication with Serialization/Track & Trace



Product Authentication with Serialization/Track & Trace

- Historical trace of authentication

Rx Authentication Service

Logout

You are logged in as **Neighborhood Pharmacy - Store #32**

Product Information		EPC Serial Number	
 **MigraneMed** 50MG; 100 TABLETS NDC 0978-0100-60	Lot X9939293 Expires: 30-Jun-2007	urn:epc:id:pharma:ndc.978.339427	Anti-Counterfeit Measures

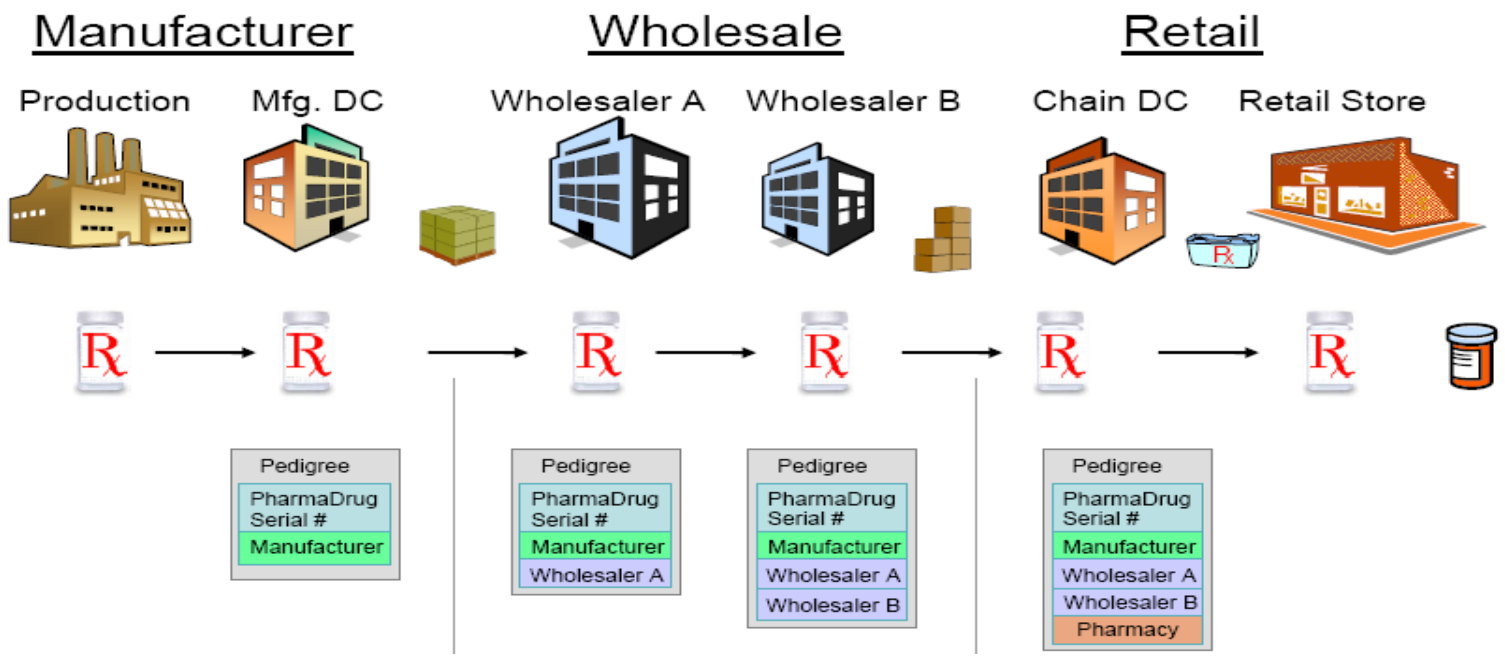
Authentication Summary | **Authentication History**

Authentication Result	Authenticated By	Authentication Location	Date Verified
EPC Issued	Acme Pharmaceuticals 3456 Pharma Way Trenton, NJ 20145	Manufacturer Shipping	16 Oct 2005
Authentication Success	Rx Wholesaler 24 Distribution Center Drive Fort Worth, TX 93929	Wholesaler Shipping	21 Dec 2005
Authentication Success	Neighborhood Pharmacy - Store #32 300 Main Street Long Beach, CA 20145	Pharmacy Receiving	10 Jan 2006
Recall - Class I	Neighborhood Pharmacy - Store #32 300 Main Street Long Beach, CA 20145	Dispensing	13 Jan 2006

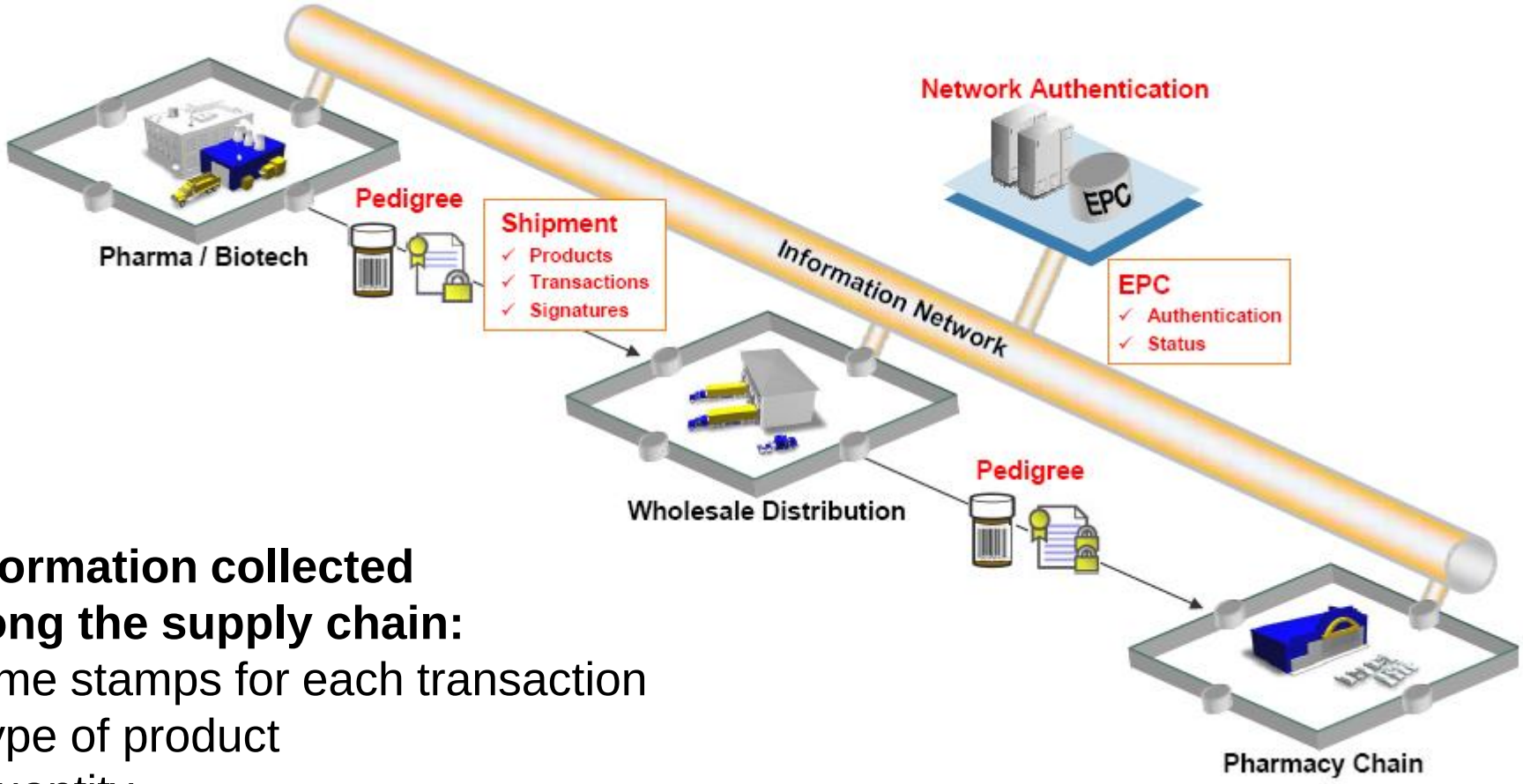
ePedigree Track and Trace

- A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them.

Pedigree : A Chain of Custody Across the Supply Chain



ePedigree Track and Trace



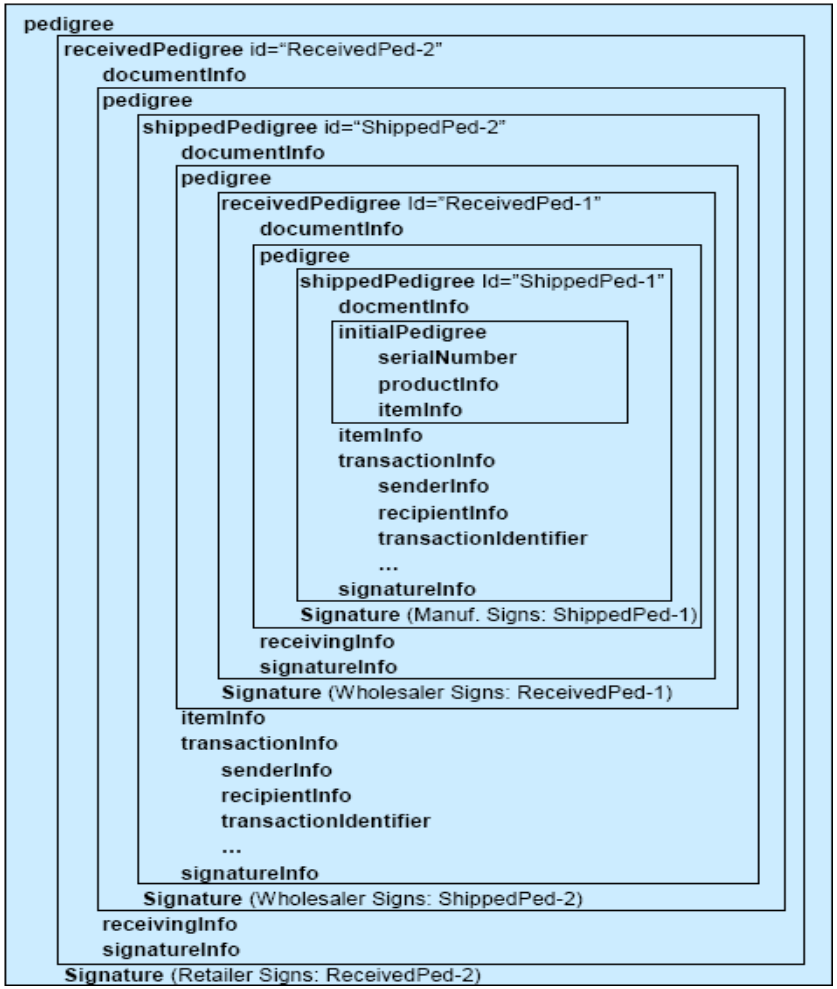
Information collected along the supply chain:

- time stamps for each transaction
- type of product
- quantity
- expiry date
- batch
- seller and buyer along the supply chain

ePedigree Track and Trace

A typical electronic pedigree (ePedigree)

- Uses Extensible Mark Up Language to allow easy exchange of information across different platforms.
- Uses Digital Signatures that are legally binding.
- Tampering makes the pedigree and drug void



Serialization/track and trace solution benefits supply chain

- Information can be used to
  - Improve supply chain cycle time
  - Improve product availability
  - Electronic proof of delivery to enhance cash to cash cycle time
  - Monitor and reduce inventory
  - Alert retail for expiring items
  - Improve promotion
  - Eliminate medication errors
  - Historical trace enables speedy recall of defective product batches

Product Authentication with mPedigree

https://youtu.be/JISbMEmXO54

Product Authentication with mPedigree

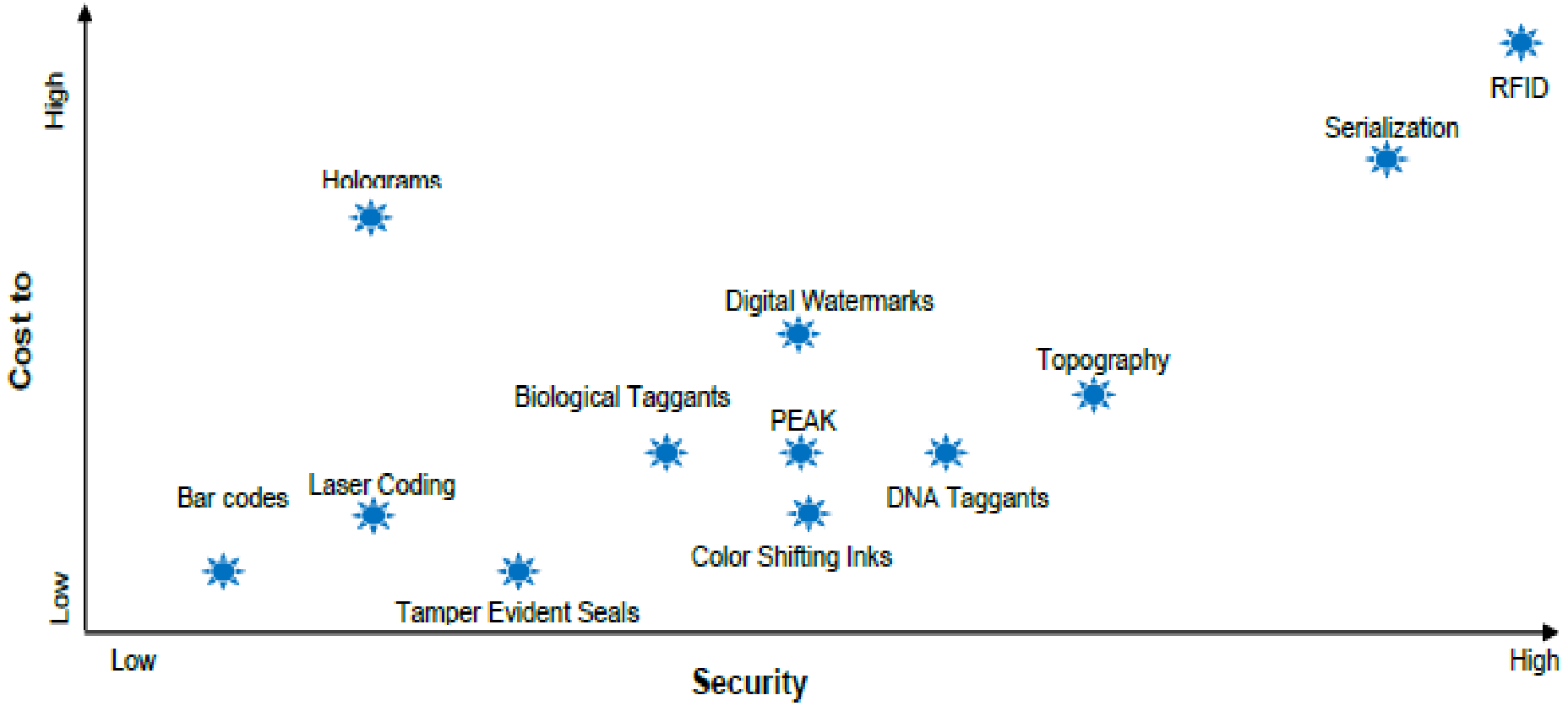
- **mPedigree** advocates for the development of strategies to fight drug counterfeiting. It is a platform that interconnects GSM mobile networks in the Ghana to a central registry wherein pedigree information of product brands belonging to participant manufacturers are stored, as well as the organization that has emerged in the country to manage and promote this registry to organizations and firms.

- Manufacturers who sign on to the mPedigree scheme upload pedigree information of each pack of medicine into the central registry using standard mass serialization methods.

Product Authentication with mPedigree

- The mPedigree solution system empowers prospective drug consumers to detect if drugs are counterfeit at the point of purchase through text messages to a selected number
- mPedigree works by placing a scratch-off label on products, and then when consumers purchase a product, they scratch off the label to reveal a unique, random code.
- The code is then sent via SMS to a country-specific short code, and the consumer receives a reply almost instantly indicating whether the product is genuine or not.
- It is currently being used by several pharmaceutical companies in the fight against counterfeit drugs.

Cost-Security Matrix of Different Anti-counterfeiting Techniques



Source: World Health Organization

Today's Problem

Pharmaceutical company can make use of various technologies in fighting counterfeiters:

- **A combination of anti-counterfeiting features**
  - Overt features: Holograms, unique markings like laser coding,
  - Covert features: hidden images
  - Bar-code serialization/track and trace system
  - ePedigree/mPedigree

Pharmaceutical Supply Chain Security Using applied DNA Sciences

https://youtu.be/yevRf_dch-E

Learning Outcomes

- Discuss the issues of counterfeit drugs introduced into the supply chain and its consequence.
- Recognize the importance of tracking and tracing pharmaceutical products in the interest of ensuring public health.
- Explain current and developing technology to enable an accurate tracking process of pharmaceutical products.
- Compare and discuss the advantages and disadvantages of various anti-counterfeiting technologies
- Identify the right kind or combination of anti-counterfeiting technologies for different products