

# A New Model For Combating Counterfeit Drugs

**World Health Organization**

IMPACT Meeting

Prague, Czech Republic

13 March 2007

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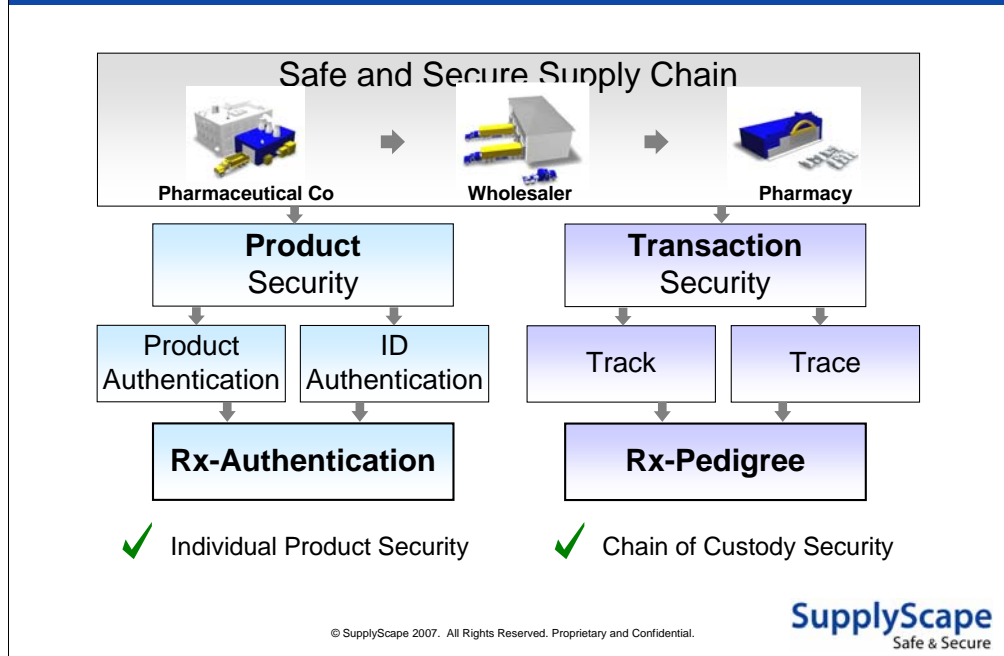
## BACKGROUND:

The Model: The Model was originally presented to the US FDA back in 2004. It was released to the standards body – GS1’s EPC Global in May 2005 where it gained considerable interest & traction. In September 2005, this model was presented to the Council of Europe.

The Presenter: Robin T. Koh, a 23-year supply chain veteran and former Director of Applications Research at the Massachusetts Institute of Technology’s Auto-ID Center, Mr. Koh spearheaded the pharmaceutical industry’s movement towards the use of RFID, serialization, pedigree and other Track & Trace technologies to fight counterfeit drugs. He works together with industry to develop the technological base for a safe and secure pharmaceutical supply chain and is currently the Chief Strategy Officer of SupplyScape.

Company: SupplyScape is a provider of supply chain software and expertise to drive maximum security and value in the pharmaceutical supply chain. A pioneer in defining both the open universal EPCglobal-standards-based pedigree solution and the EPC authentication service for the pharmaceutical industry, SupplyScape provides market-leading authentication, ePedigree, trading partner integrity, and certificate authority services and solutions that efficiently support the diverse operational environments spanning the entire pharmaceutical value chain. The company's solutions enable pharmaceutical and biotechnology companies, wholesalers, distributors, and pharmacies to maximize patient safety and product revenue throughout the pharmaceutical and biotechnology value chains. Currently in 2007, SupplyScape has the largest number of ePedigree customers and the largest Authentication network in the US Pharmaceutical supply chain.

# A New Paradigm

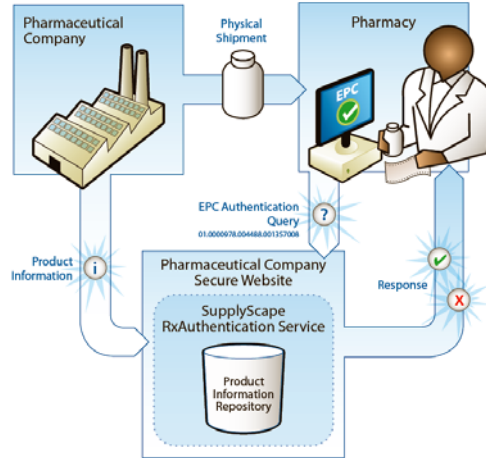


Useful Characteristics of the Model to address counterfeit:

1. It addresses both Product & Supply Chain Transactional Security. Both security streams are required to address counterfeit effectively.
2. Current Overt Product Authentication features (like Holograms, Watermarks) are fairly static. Counterfeiter game static solutions. Mass Serialization & Rx-Authentication provide a means by which companies can vary these features more frequently. This gives companies the ability to change Overt Measures more frequently – making it harder to game.
3. The model is designed to be pro-active i.e. whenever there is doubt in the supply chain, questionable product is quarantined or expelled from the legitimate supply chain.

# Rx-Authentication

Enhanced Product Integrity, Network-wide Collaboration



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Secure Product ID Authentication  
Individual Scan, or Bulk shipment processing  
DC, Pharmacy Receiving, Pharmacy Bench

Automated Product Status Management  
New, Shipped, Decommissioned  
Recalled, Stolen, Duplicated

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How Rx-Authentication works...

# Rx-Authentication





## Rx Authentication Service

[Logout](#)

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

Product Information	EPC Serial Number
 <b>MigraneMed</b> 50MG; 100 TABLETS NDC 0978-0100-50	Lot X9939293 Expires: 30-Jun-2007 urn:epc:id:pharma:ndc.978.339427 <a href="#">Anti-Counterfeit Measures</a>

### Authentication Summary **Authentication History**

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

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An example of the Authentication Screen

The Screen highlights if a serial number was issued by the manufacturer, the status of the number and physical anti-counterfeit measures (holograms, seals) if any.

Access to this screen is currently restricted.

# Rx-Pedigree

Product Information	Lot Information	Product Serial Number	Pedigree Serial Number
<b>AllergyMed</b> Acme Pharmaceuticals 65 mg, 90 tablets NDC 0978-0324-01	Lot A231556 Expires: 15-Dec-2005	01.0000978.000324.1005536707	01.0000978.000324.1005536707

## Drug Sales and Distributions

### Acme Pharmaceuticals sale to Rx Wholesaler Inc

<b>Seller:</b> Acme Pharmaceuticals	<b>Buyer:</b> Rx Wholesaler Inc
<b>Address:</b> 500 Manufacturer Road, Danville, VA 24540 USA	<b>Address:</b> 305 Wholesaler Place, Greenville, MS 38701 USA
<b>License Number:</b> 31-73651 VA	<b>License Number:</b> 46-11896 MS
<b>Date Released:</b> 19-Jan-2005	<b>Date Acquired:</b> 20-Jan-2005
<b>Certified By:</b> Michael Manufacturer Compliance Manager michael@abcpharma.com 555-123-4567	<b>Received and Authenticated By:</b> Wendy Wholesaler Quality Manager wendy@rxwholesaler.com 555-343-8044
<b>Invoice and Date:</b> WHO-66825473 on 15-Jan-2004	
<b>Quantity:</b> 1	
<b>Transaction:</b> Sale	

### Rx Wholesaler Inc sale to ABC Pharmacy

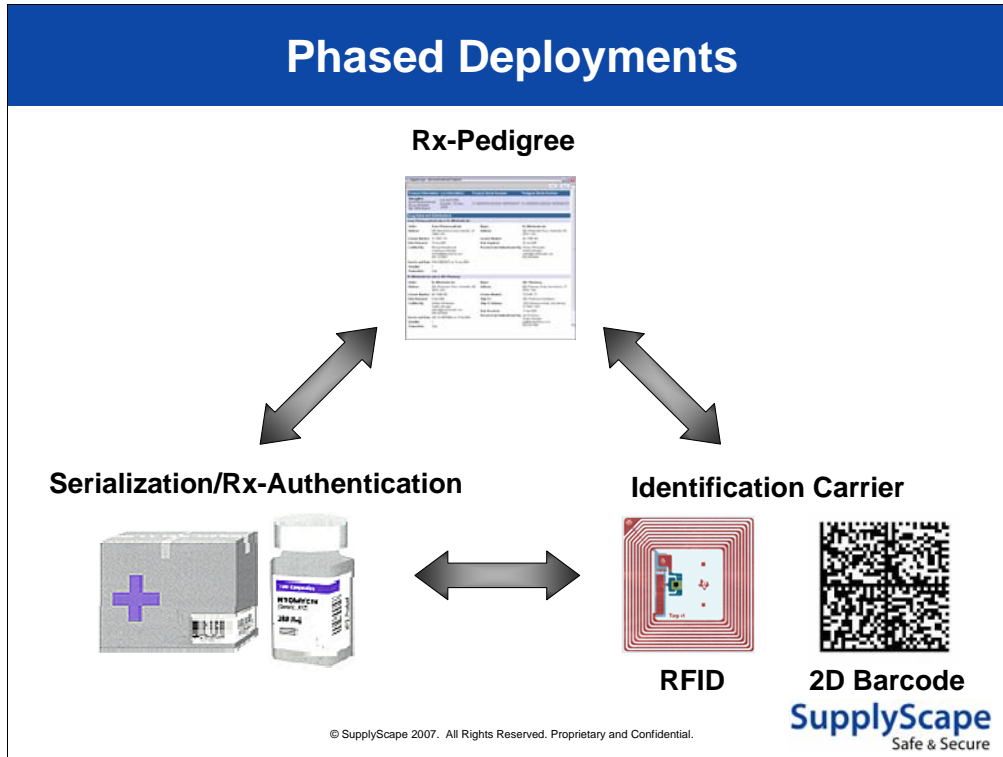
<b>Seller:</b> Rx Wholesaler Inc	<b>Buyer:</b> ABC Pharmacy
<b>Address:</b> 305 Wholesaler Place, Greenville, MS 38701 USA	<b>Address:</b> 600 Pharmacy Road, San Antonio, TX 78201 USA
<b>License Number:</b> 46-11896 MS	<b>License Number:</b> 72.01401 TX
<b>Date Released:</b> 9-Apr-2005	<b>Ship-To:</b> ABC Pharmacy Distribution
<b>Certified By:</b> William Wholesaler Quality Manager william@rxwholesaler.com 555-343-8044	<b>Ship-To Address:</b> 1200 Warehouse Road, San Antonio, TX 78201 USA
<b>Invoice and Date:</b> ABC-01-09834563 on 2-Feb-2004	<b>Date Received:</b> 11-Apr-2005
<b>Quantity:</b> 1	<b>Received and Authenticated By:</b> Joe Pharmacy Quality Manager joe@abcpharmacy.com 555-234-7890
<b>Transaction:</b> Sale	

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An example of a Pedigree – a secure digitally signed document that follows the product as it makes its way through the supply chain.

This system was designed so that it could integrate with other methods of processing pedigree – such as paper pedigrees, pdf files etc.



Manufacturers have asked how this model can be taken Global. What is being looked into:

### Serialization

- The Number structure is being adapted to suit different international environments. It must be human readable, comprehensible, carry certain pieces of information etc.
- There is active discussion of combining a few numbers to approach uniqueness – for e.g. Product Number, Lot, Date, Shipment/Invoice Number etc.

### Authentication

- Authentication does not need to happen only at the end of the supply chain – it can happen at points of risk
- Authentication does not need to happen individually, it can happen in batch. Numbers may be collected on a piece of paper and fed into a system.
- Authentication interfaces can be different – perhaps a cell phone instead of a computer terminal.

### Pedigree

- Pedigree is being developed alongside other accountability systems already in use – e.g. Bills of lading, Purchase Orders, Shipment Notices etc.
- It can take a variety of forms – e.g pdf, paper etc.

## Anti-Counterfeit Use-Cases

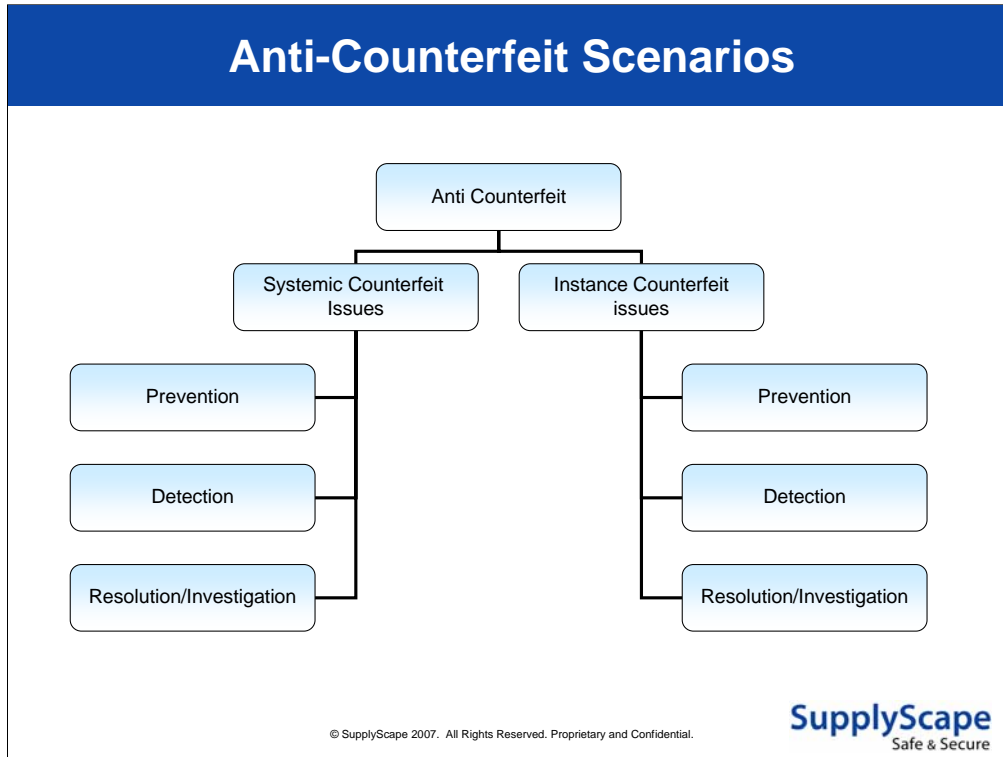
- Completely Fake Product
- Re-labeled Product
- Substitute of content
- Adulterated Product
- Unauthorized Re-Pack
  - Scrapped Product
  - Recalled
  - Samples

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The system was designed so that various types of Product Integrity issues could be addressed.

Otherwise – there is the danger of transferring the problem from one area to another.



Besides addressing a variety of product integrity issues, the model also provides 2 different approaches to counterfeit:

**Systemic** – addressing the problem of introducing large quantities of counterfeit product into the legitimate supply chain

**Instance** – addressing the problem of being able to know if a particular bottle of medicine is real or fake.

Use-cases are being developed to solve both issues.

Ultimately – for Instance scenarios – the decision is often binary – Go/No-go whereas for Systemic Scenarios – we are looking for Patterns, Pace & Place.

## Characteristics of the System

- Product and Transaction Integrity
- Backwards and Forwards Accountability
- Systemic and Instance
- Proactive
- Dynamic
- Global
- Flexible
  - Technology
  - Time
  - Granularity
- Comprehensive
  - Use cases
  - Scenarios
- Basis for Measurement

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## Status of the System

- Components are being developed & piloted
  - Pedigree
  - Serialization
  - Authentication
  - Barcodes
  - RFID
- Pilots  $\Rightarrow$  Projects  $\Rightarrow$  Commercial Deployment
- Extension into global markets being studied
  - The integration of different levels of technology sophistication into one coherent product security system

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## For More Information...

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