

Tamper Evident Packaging and Seal for Medical Products

by Secure Logistics Sweden AB

Professor Sten Wandel

Industrial Management and Logistics
Lund University
SWEDEN

sten.wandel@tlog.lth.se

+46 70 728 4773

Problems Due to Counterfeit/Substandard Medical Products

- Causes the death of 500 000 – 1 000 000 annually, mostly in middle and low income countries
- 8% pharma globally is counterfeit
- 30% in low resource countries and up to 50% on Internet
- 75 Billion USD highly profitable business finances organised crime and terrorism
- At risk: Drugs against: Malaria, HIV, TB (Antibiotics), Cancer
- Too little active ingredients causes medicine resistance and further deaths
- Infections: Dirty and reused injection needles are sold as new
- 70 000 new mothers die: 70% of the Oxytocin, used to reduce bleeding after child delivery, has too little active ingredients due to heat or counterfeit
- Stock outs: Thefts and removed substandard medicine are detected too late

These problems are unknown to the public and not high enough on the agenda of the stakeholders

Current counteractions

- Strengthening criminal legislation and enforcement.

Shortcomings: Low sentences and small risk of being caught.

- Strengthening regulations. Check with track & trace that the package only is handled by certified players.

Shortcomings: The contents may be changed or manipulated.

- Monitor temperature.

Shortcomings: Most products are not handled in cold chains.

- Detect, remove, report and recall counterfeit/substandard products.

Shortcomings: Most counterfeit/substandard products are not removed.

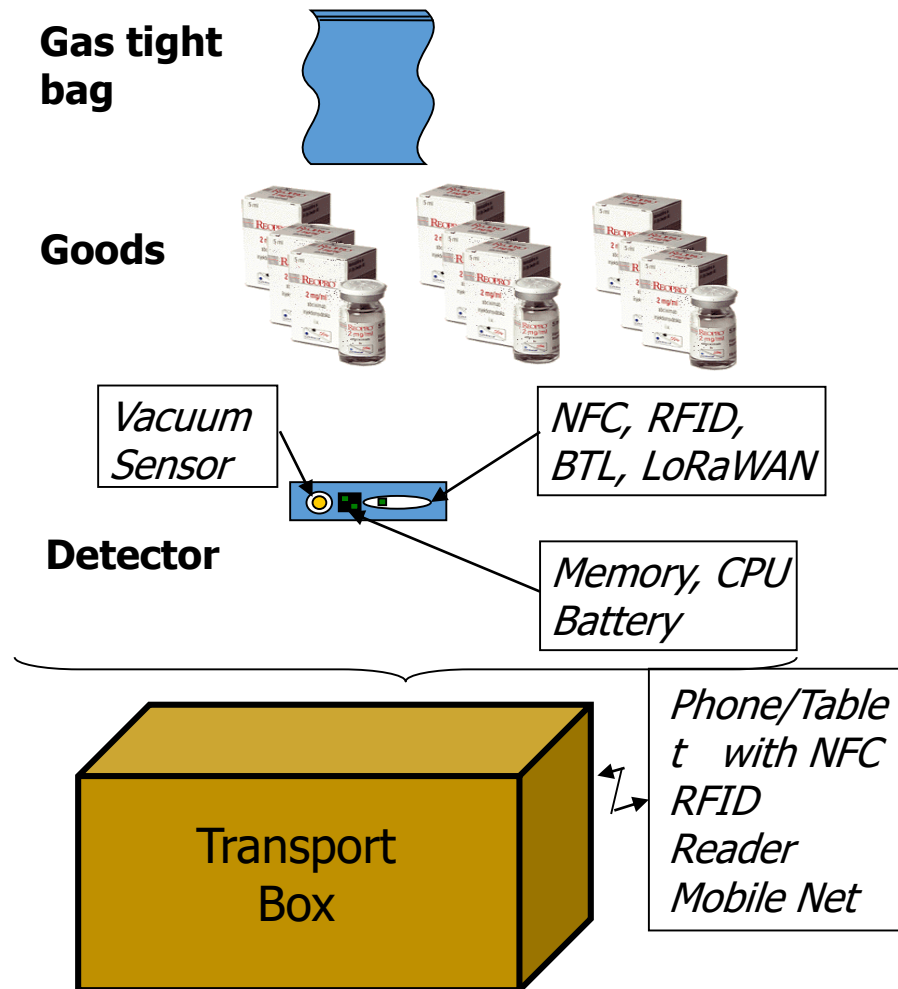
The problems persist and the market shares of counterfeit increase in many markets, since current counteractions are not effective

Detect and Remove Counterfeit /Substandard Products

1. Testing the ingredients before use, e.g. with a spectrometer
*Shortcoming: **Not feasible to test every pill.***
2. Ensuring the original product is the same at point of use as at production. Packaging on all levels - consumer pack, bundle, case and pallet - should be protected by:
 - 2.1. Serialization. Each package gets a unique random ID-code, which is reported to a database. Before opening the code is checked, and if it is in the database, the product is supposed to be safe to use, else it is removed. Soon mandated in most countries.
*Shortcoming 1: **The ID-code can be copied and placed on a package with counterfeit or diluted medicine.***
 - 2.2. Security marker (s) or extra ID-code(s) on the package is checked to detect when a copy of the first ID-code has been placed on another package.
*Shortcomings 2: **The package is opened to steal, divert, smuggle, exchange with fake, or adulterate the original product.***
 - 2.3. Tamper evident packaging/seals checked to detect unauthorized opening of the package.
*Shortcoming: **Far too easy to open and reclose without being detected,***
since void tape or a mechanical seal over the opening is considered sufficient

Seals are the weakest link. Higher requirements on tamper evident packaging seals will save lives

The New Patent-Protected Tamper Evident Seal



At manufacturing or repacking

- Gas tight bag placed inside a transport box
- 10-200 patient packs placed in bag
- Detector is placed in the bag
- The bag is vacuum sealed

At terminal and before use

- Status of detector checked with NFC
- If vacuum all the time, all inside untouched and safe to use
- If not: remove from supply chain
- Stored information for forensic analyses
- No need to check all patient packs

It completely envelops and protects products, ID-code, security markers, loggers and itself

Additional Features of the New Patent-Protected Tamper Evident Seal

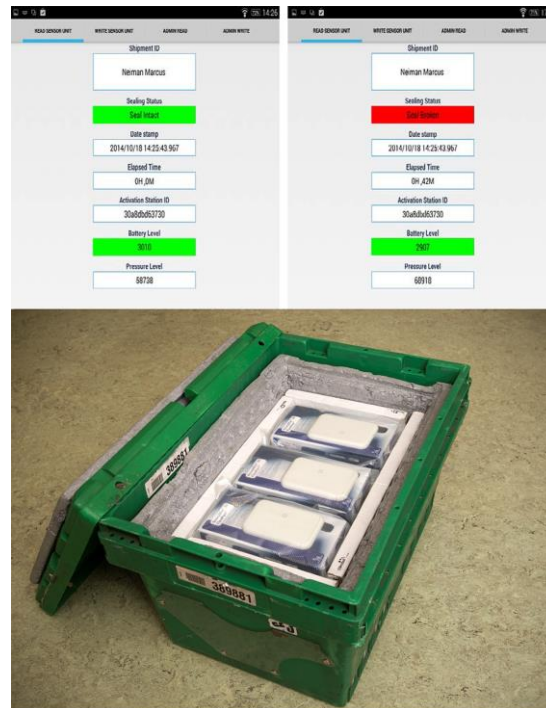
Optional

- + Track & Trace, e-pedegree
- + Display on package: OK or NOT OK for low resource settings
- + More sensors are logged: Temperature, shock, humidity
- + Positioning: LoRaWAN (30m), GPS (1m), BTL/WLAN (0.3m)
- + Real-time intrusion alarm BTL (100m), LoRaWAN (3 000+m)

Seal Manufacturing

- Vacuum packaging well known for food and explosives
- From envelope to ISO container
- Detector cost:
 - USD 20 using traditional manufacturing (8 sensors, 2 CPU, memory, battery, NFC, BTL)
 - USD 2 (in 2 years) using printed electronics (2 sensors, CPU, memory, battery, NFC, Display)
 - USD 0.3 (2 RFID, vacuum switch that kills one RFID)

Protecting insulin in a cold box



Requirements on Secure Seals

- **No back door.** *Detects all intrusions immediately, not only through doors or lids.*
- **Non erasable unique ID.** *Cannot be changed*
- **Not possible to copy the seal.**
- **Non erasable tamper evidence.**
- **The seal protects itself.** *All parts inside the package*
- **Detects small holes in the package.** *Prevents sabotage*
- **Automatic reading.** *Not possible to bribe inspectors. Low reading cost*
- **Stops water, gases, dirt, scratches**
- **Fit all packages from envelopes to ISO containers**
- **Low cost to produce and use**

Comparison between Tamper Evident Seals

Require- ments	Secure Foil Void tape	One Seal Mecha- nical Loop seal	Brooks Electro- nic Loop seal	IBM- Maersk TREC Door Sea container	Fraun- hofer- DHL Box with RFID reader	SQS Case Mesh of electrical wires Cash	Lockheed Martin Mesh of opto fibre Nuclear material	SecLog Gas tight barrier Vacuum sealed
No backdoor						++	++	++
Non-erasable ID			?	+	+	++	++	++
Not possible copy			?	+	+	++	++	++
Non-erasable tamper evidence	?	?	+	+	+	++	++	++
Automatic read technology			++	++	++	++	++	++
Seal protects itself						++	+	++
Detects small holes						?	?	++
Stops water, gases, dirt, scratches						+		++
Cost USD per package	< \$1	\$2-40	\$25- 200	\$700- \$2,000	\$160- \$2,500	\$8,000	\$20,000	\$3 envelope \$40 pallet

The new vacuum seal is as good as the very best, but to a fraction of their costs

Business case – pharmaceuticals

TamperSeal on each pallet

Today: Developing countries receive about 135,000 pallets / year and WHO estimates that 25% are counterfeit. Assume 100,000 patients will be killed by these counterfeit drugs. That is 0.74 death per pallet on average. Assume TamperSeal™ reduces counterfeit and mortality by only 5%

Assumptions

1 pallet with 15,000 consumer packs@ \$4 ea valued	\$60,000
Value of lost products 0.25 x \$60 000	\$15,000
1 saved life is worth \$100 000	
Value of lost lives 0.74 x \$100,000	\$74,000

Without saved lives

Business revenue from less lost products (5% of \$15,000)	+\$ 750
Customer price per TamperSeal incl. bag and labour	- \$ 150
Net business revenue per pallet excluding lives saved	+\$ 600

Business Revenue/Cost Ratio

5

Very good business case even when saved lives are excluded and only 5% of the fake are detected

With saved lives

Benefits from saved lives (5% of \$74,000)	+\$ 3,700
Social benefits per pallet including lives saved	+\$ 4,450
Net social benefits per pallet including lives saved	+\$ 4,300

Social Benefit/Cost Ratio

29,7

Extreme good cost-benefit result when saved lives are included

Business case – pharmaceuticals

TamperSeal on each Case/Box

Today: Developing countries receive 135,000 pallets / year and WHO estimates that 25% are counterfeit. Assume 100,000 patients will be killed by these counterfeit drugs. That is 0.74 death per pallet on average. Assume one pallet has 30 cases with 500 consumer packages each. Assume TamperSeal reduces counterfeit by only 10% and cost \$40 per case including detector, bag and labour. Cost will be much less if the detectors are recycled or produced by printed electronics.

Assumptions

1 pallet with 15,000 consumer packs@ \$4 ea valued	\$60,000
Value of lost products 0.25 x \$60 000	\$15,000
1 saved life is worth \$100 000	
Value of lost lives 0.74 x \$100,000	\$74,000

Without saved lives

Business revenue from less lost products (10% of \$15,000)	+\$1,500
Customer price per TamperSeal \$40x30	- \$1,200
Net business revenue per pallet excluding lives saved	+\$ 600

Business Revenue/Cost Ratio

1.25

OK business case even when saved lives are excluded and only 10% of the fake are detected

With saved lives

Benefits from saved lives (10% of \$74,000)	+\$7,400
Social benefits per pallet including lives saved	+\$8,900
Net social benefits per pallet including lives saved	+\$7,700

Social Benefit/Cost Ratio

6.42

Very good cost-benefit result when saved lives are included

Benefits of TamperSeal

- Reduce mortality and suffering by detecting and removing substandard medicine before it is used, even in transit
 - Detects attempts to open package from any side, other seals only secure the lid
 - All parts of the seal inside the bag are protected, other seals has parts on outside
 - The evidence of a breach with time stamp and the unique serial number of the seal are almost impossible to tamper with
 - Almost as secure as the fibre optic seals used for nuclear materiel, but 1/100 of the cost
- Enhance reporting and criminal investigation: automatic reporting, know time of breach, use that to trace place and responsible actor
- The bag also protects from: moist, dirt and keeps products sterile, sterility is monitored
- Reduce out of stock: early removal, better and more even access at point of use, better health
- Designed for low-resource settings: no training, no electricity, no Internet, no reader if display on package
- Preferably combined with temp monitoring, serialisation and logistics tracking: much lower cost than applying four separate systems
- Much lower cost protecting the contents of the transport box than each of the 200-500 patient packs in the box

Better seals will save lives.

TamperSeal is as good as the best but to a fraction of their cost

Secure Logistics' Patents

Patent family #1 “Tamper”

A Method and a Device for Detecting Intrusion into or Tampering with Contents of an Enclosure

- **Granted Patents**

US7659816	2010-02-09
SE528760	2007-02-13
EP1886286	2012-07-11
CA2607731	2015-04-21
AU2006248151	2006-05-18
MX274141	15/02/2010

Patent family #2 “Monitor”

Method and a System for Monitoring the Handling of an Object

- **Granted Patents**

US9251679 2016-02-02

- **Patent Applications**

CA2881805 (APD 2012-08-16)

EP2745281 (APD 2012-08-16)

Examples of applications protected by Secure Logistics' patents

- **Packages** from envelopes to sea containers. Detection of intrusion into packages for theft, counterfeiting, sabotage etc.
 - Pharmaceuticals
 - Medical Devices
 - Food & Beverages
 - Classified & Confidential Documents
 - Electronics
 - Evidence at crime scenes
 - Drug tests of athletes
 - Hazardous material – Explosives & Chemicals
- **Retail Theft Alarm** Detects when the theft tag is removed and when the package is placed in a bag clad with aluminium foil that blocks the radio signals from theft tags.
- **Fixed installations** Double layered shell around
 - Telecom infrastructure with high risk for sabotage.
 - Safes