Self-verifying blisters & packaging
Linking secure authentication to serialization

nano4u

Our Mission

We authenticate your products directly, using cutting edge mass manufacturing technologies.

.....We protect your supply chain.

Falsified medicines, a global issue

Man jailed for £4.7m counterfeit medicine fraud
the **guardian**

Yaz, Yasmin birth control pills suspected in 23 deaths
Most died from blood clots, He...
CBC News Posted Jun 11, 2013...

Woman dies after taking 'diet pills' bought over internet
the **guardian**
Eloise Aimee Parry, 21, from Shrewsbury, 'burned up from the inside' after taking tablets believed to contain highly toxic chemical dinitrophenol

...of fake cancer
FOX NEWS

Fake malaria drugs could 'put millions at risk'
17 January 2012 Health
BBC

units of counterfeit medicines retained by EU Customs Authorities

27.5 m

of anti-malaria drugs in Southeast Asia are fake

36%

of samples... online from web... conceal their physical address have found to be counterfeit

units of illegal medicines were seized in Africa during "Porcupine" operation

156 m

units of counterfeit and illicit medicines seized during "Pangea VI" operation

Up to

30%

of medicines in developing countries are counterfeit

10%

of the world's medicines are counterfeit

9.8 m

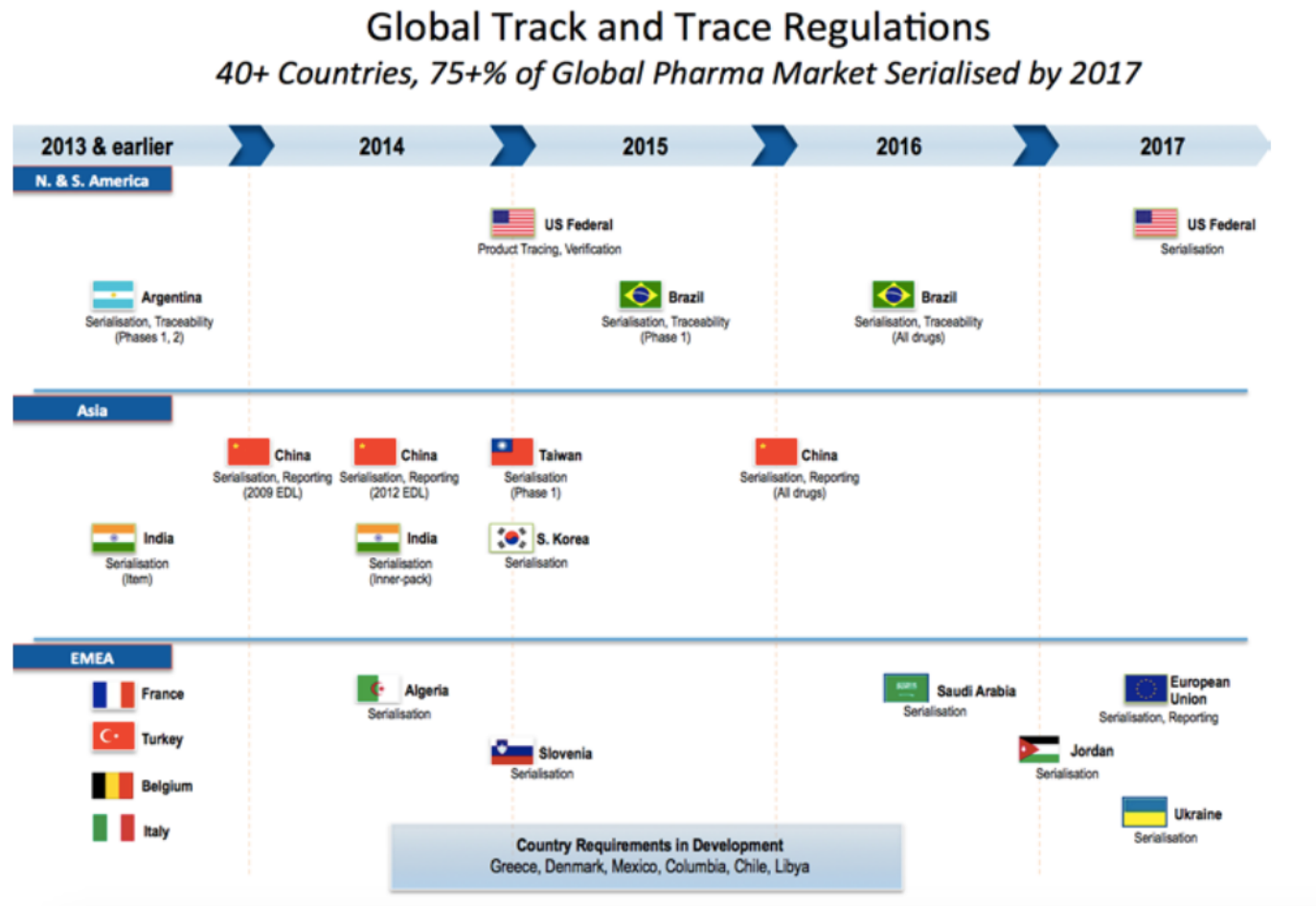Counterfeit sex drugs: 11 deaths and 24 coma cases
by Sylvia Tan

84 Children Are Killed by Medicine in Nigeria
By LYDIA POLGREEN
Published: February 6, 2009
The New York Times

.... with a global response

Global Track and Trace Regulations
40+ Countries, 75+% of Global Pharma Market Serialised by 2017

2013 & earlier	2014	2015	2016	2017

N. & S. America

US Federal — Product Tracing, Verification (2015)

US Federal — Serialisation (2017)

Argentina — Serialisation, Traceability (Phases 1, 2) (2013 & earlier)

Brazil — Serialisation, Traceability (Phase 1) (2015)

Brazil — Serialisation, Traceability (All drugs) (2016)

Asia

China — Serialisation, Reporting (2009 EDL) (2014)

China — Serialisation, Reporting (2012 EDL) (2014)

Taiwan — Serialisation (Phase 1) (2015)

China — Serialisation, Reporting (All drugs) (2016)

India — Serialisation (Item) (2013 & earlier)

India — Serialisation (Inner-pack) (2014)

S. Korea — Serialisation (2015)

EMEA

France (2013 & earlier)
Turkey (2013 & earlier)
Belgium (2013 & earlier)
Italy (2013 & earlier)

Algeria — Serialisation (2014)

Slovenia — Serialisation (2015)

Saudi Arabia — Serialisation (2016)

Jordan — Serialisation (2016)

European Union — Serialisation, Reporting (2017)

Ukraine — Serialisation (2017)

Country Requirements in Development
Greece, Denmark, Mexico, Columbia, Chile, Libya

Serialization Requirements: Falsified Medicines Directives
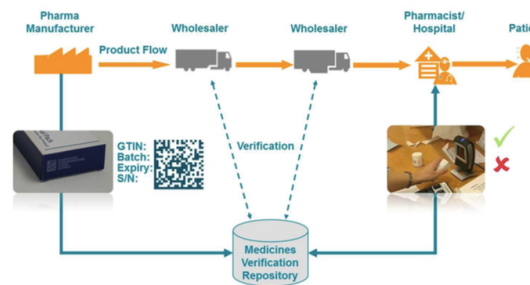
Unique Product Identifier

Every Package needs to have a unique product identifier, i.e. a random unique datamatrix code
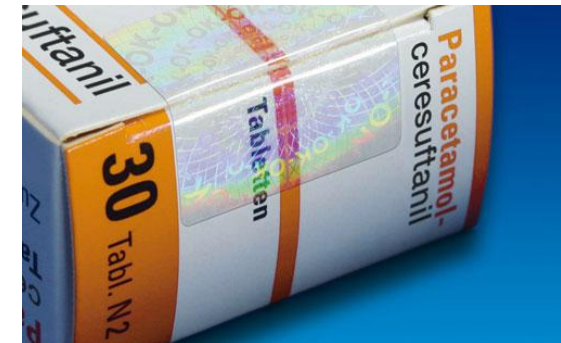

Stored in Central Database

All codes to be stored in a central repository, verification of codes is done through access to this database

Safety Features for Authentication

The package needs to have safety features for authentication and give evidence of tampering
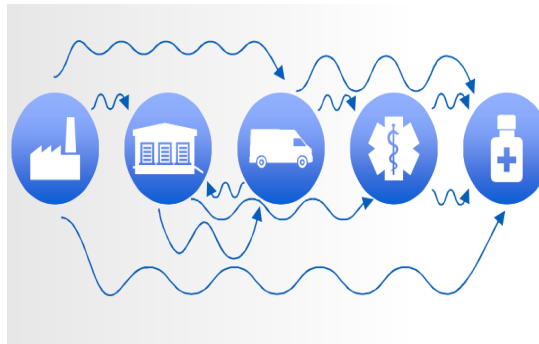
Serialization: What is the problem?

Unique Product Identifier

- There are a lot of codes, i.e. billions
- Significant administration
- Every error is very expensive as packaged goods need to be destroyed

Stored in Central Database

- Complex supply chains
- Errors on all levels likely
- Destruction of goods necessary, if code can not be verified

Safety Features for Authentication

- Package very easily faked
- No secure antitampering exists
- Content easily exchanged and not authenticated

Serialization: Unsolved key issues

• At high volume cost of not so secure packaging remains high and scales linearly with production volume

• Tamper evidence quite easily faked

• Content not directly authenticated

• Multiple identical code generation by counterfeiters threatens to overload database systems

• In the EU every package and its content that can not be authenticated has to be ultimately destroyed, resulting in significant financial loss

Self-verifying blister

Inside the tablet press, every stamp is slightly different and can be structured on the nano-scale. These variations and structures are transferred to the tablet.

Once the tablet is packaged in the blister the variations and nano-structures are measured inline in real time on the blister machine. The information is cryptographically encoded and linked to other packaging elements.

A secure link between the properties of a particular blister and the barcode is formed.

Multi-level secure serialization of blisters

- **Overt level:** Visible security holograms, authentication by human eye.

- **Semi-overt level**: Authentication by magnifying glass, laser pointer, mobile phone camera or simple microscope.

- **Cryptographic level**: Authentication by mobile phone requiring no database or database access.

- **Covert level**: High speed nanoscale measurement with dedicated equipment in production and in the field.

Easy Authentication by Laserpointer

Your Advantage

• No database / database access is required.

• No additional production steps necessary.

• Easy introduction into mass-manufacturing.

• No new/additional materials introduced.

Allows you to achieve

- High security of your products:
  Reduce danger of illicit products to a
  minimum, including illegal reimports

- Fast return on investment as costs decrease
  with increasing production volume

- Achieve transparency on and safety in
  product flow

- Fully comply with global requirements for
  serialization

From manufacturing
to packaging
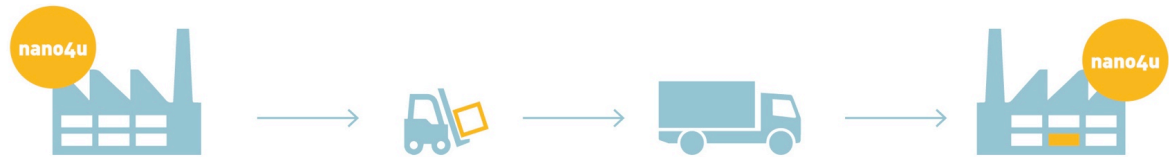
From packaging
to wholesaler

From wholesaler
to customer

…We achieve transparency and safety in your product flow

Thank you !

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