Supply chain integrity – Fighting counterfeiting in healthcare

The increasing, global threat of counterfeiting in healthcare

What is the problem?

Counterfeit drugs may harm the patient.

Often impossible to spot.

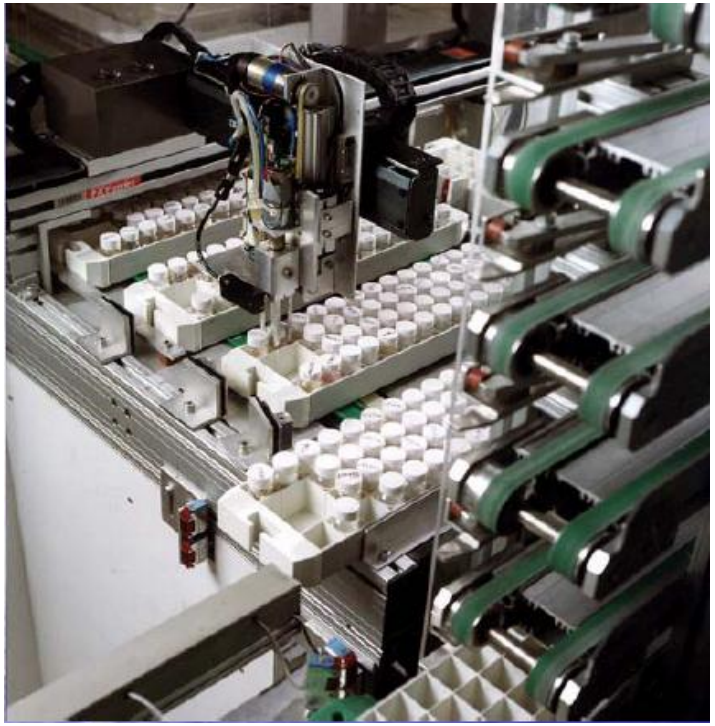
There is a lack of transparency in the Healthcare supply chain, making it **vulnerable to infiltration** by counterfeiters.

One of these medicines is fake.

Can *you* tell which?

SAFEMEDICINES.org

GMP Quality control



Quality control?

Size of the problem

- Counterfeit drugs sales estimated to reach **US$75 billion** in 2010

- WHO estimates that
  - many countries in Africa and parts of Asia and Latin America have areas where **more than 30%** of the medicines on sale can be counterfeit;
  - in many of the countries of the former Soviet Union the proportion of counterfeit medicines is **above 20%** of market value;
  - most industrialized countries with effective regulatory systems and market control have **less than 1%** of the market value, but growing.

Fighting the growing menace of fake drugs

STORY HIGHLIGHTS

- Fake prescription drugs pose major threat to patient health and safety
- Business expected to generate $75 billion globally in annual sales in 2010
- Counterfeit pharmaceuticals finding their way into every corner of world
- Fighting the problem requires international partnerships, experts say

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TEXT SIZE

By Grace Wong
For CNN

LONDON (England) -- A slim, easy-to-use device that checks the authenticity of medicines would be available in every pharmacy if Facundo Fernandez had his way.

Shoppers in Ivory Coast buy counterfeit medicine at a street market.

more photos »

The gadget he has in mind would provide consumers peace of mind about the safety and quality of prescription drugs -- something that is increasingly a concern amid a rise in fake medicines.

A self-described optimist, Fernandez doesn't think his dream is that far-fetched. "I think it's possible," he told CNN. "The technology is available. It's a matter of making this really widespread."

An analytical chemist and assistant professor at Georgia Tech, Fernandez has spent the better part of the last decade fighting the global battle against counterfeit drugs.

Taken with the intention of curing illness, phony pharmaceuticals undermine treatment, and in some cases, can have lethal consequences for

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China halts use of diabetes drug after deaths

Sat Jan 31, 2009 12:48am EST

SHANGHAI (Reuters) - China's Ministry of Health has ordered doctors around the country to stop prescribing a diabetes drug after a fake batch of the medicine was linked to the deaths of two patients.

The patients died in China's far western region of Xinjiang after taking counterfeit medication that carried the brand of Guangxi Pingnan Pharmaceutical Co but had not been produced by that company, the ministry said in a statement on Friday.

It called on medical institutions to submit their stocks of the drug to local authorities for quality testing.

China is battling a string of food and drug safety scandals.

Page last updated at 15:08 GMT, Tuesday, 3 February 2009

How fake drugs got into the NHS

By Paul Burnell
BBC File On 4

It was the highest state of alert the government's medicines watchdog can issue.

The MHRA issued four emergency drugs recall notices in June 2007

Eighteen months ago the Medicines Health products Regulatory Agency (MHRA) issued four of its Class One emergency recall notices in a matter of days to recoup thousands of packs of life saving drugs for stroke patients, men with prostate cancer and schizophrenics.

"Class One recall will be conducted where we've got some evidence to suggest we're dealing with a counterfeit medicine and it has got to patient level," Mick Deats head of enforcement at MHRA told BBC File On 4.

Three life saving medicines had to be recalled: Casodex, for prostate cancer, Plavix which is used for strokes and heart conditions and Zyprexa, which controls the symptoms of schizophrenia.

Said Mr Deats: "The meds involved had between 50-80% of the correct pharmaceutical ingredient in them."

Suppliers duped

File on 4

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Public Agenda (Accra)

Africa: Counterfeit Drugs Kill Over 700,000 People Every Year

22 May 2009

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A new report from the International Policy Network and sponsored by IMANI Center for Policy & Education details the shocking burden of fake drugs in less developed countries. Fake tuberculosis and malaria drugs alone are estimated to kill 700,000 people a year. That's equivalent to four fully laden jumbo jets crashing every day.

' The report lays bare the ballooning problem of counterfeit and substandard drugs, which can constitute one third of the drug supply in certain African countries. These dodgy drugs result in unnecessary death and increased levels of drug

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Counterfeit Drugs Sold At Alarming Rate In Europe

Posted on: Monday, 7 December 2009, 10:25 CST

The selling of counterfeit medicines on the black market has sailed past the European Union's worst fears, the European industry commissioner announced Monday.

The EU had apprehended 34 million fake medicines in only two months, Gunter Verheugen said to German newspaper Die Welt, counting fake antibiotics, cancer medicines and Viagra.

Verheugen said the European Commission was extremely worried about the circumstances and he is anticipating that the EU will work quickly to combat the threat of the counterfeit pharmaceuticals.

"The number of counterfeit medicines arriving in Europe ... is constantly growing. The European Commission is extremely worried," Verheugen noted. "In just two months, the EU seized 34 million fake tablets at customs points in all member countries. This exceeded our worst fears."

Other bogus drugs rounded up include anti-malaria medication, analgesics and anti-cholesterol pills.

The EU announced in July that a lot of the fake drugs detained in 2008 were mainly shipped from India.

Verheugen agreed with the EU that selling phony medication should be handled as a grave crime and punished harshly.

"Every faked drug is a potential massacre. Even when a medicine only contains an ineffective substance, this can lead to people dying because they think they are fighting their illness with a real drug," Verheugen said.

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Growing concern over EU counterfeit drug problem

ANDREW WILLIS

07.12.2009 @ 09:23 CET

Senior EU policy makers are becoming increasingly concerned as further evidence suggests the region is awash with counterfeit medicines.

The illegal drugs frequently contain too much, too little or no active ingredient at all, or they may contain toxic substances, posing a risk to the lives of EU patients.

On Monday (7 December), EU industry commissioner Gunter Verheugen said the extent of the problem is highly alarming.

"The number of counterfeit medicines arriving in Europe ...is constantly growing. The European Commission is extremely worried," he told the German newspaper Die Welt.

"In just two months, the EU seized 34 million fake tablets at customs points in all member countries. This exceeded our worst fears," he added.

The German commissioner insists the EU is stepping up its fight against the counterfeit drugs.

Counterfeit medicines pose a serious threat to EU citizens says the

Combating counterfeiting

Combating counterfeiting

The introduction of a unique identification for drugs or medical devices, where appropriate, will enable **authentication and traceability systems**

This will **make it much more difficult** for counterfeiters to intrude into the Healthcare supply chain

How does traceability work?

- The GS1 Global Traceability Standards provides guidance on how to implement effective traceability solutions
  - **Unique identification**
    - Global product identification number
    - Lot/batch number or serial number (unique number at the unit level)
  - **Data capture**
    - Bar coding or radio frequency identification (RFID)
  - **Links management**
    - Managing identification from the point-of-manufacture to the point-of-sale/point-of-care
  - **Data communication**
    - Associate the physical flow of products with the information flow
    - Different information sharing models

Unique identification

SGTIN

= Serialised Global Trade Item Number

= A GS1 identification key providing access to information about that product held in computer files

Mass serialisation

Bar Code

- Linear (if packaging permits)
- 2-dimensional

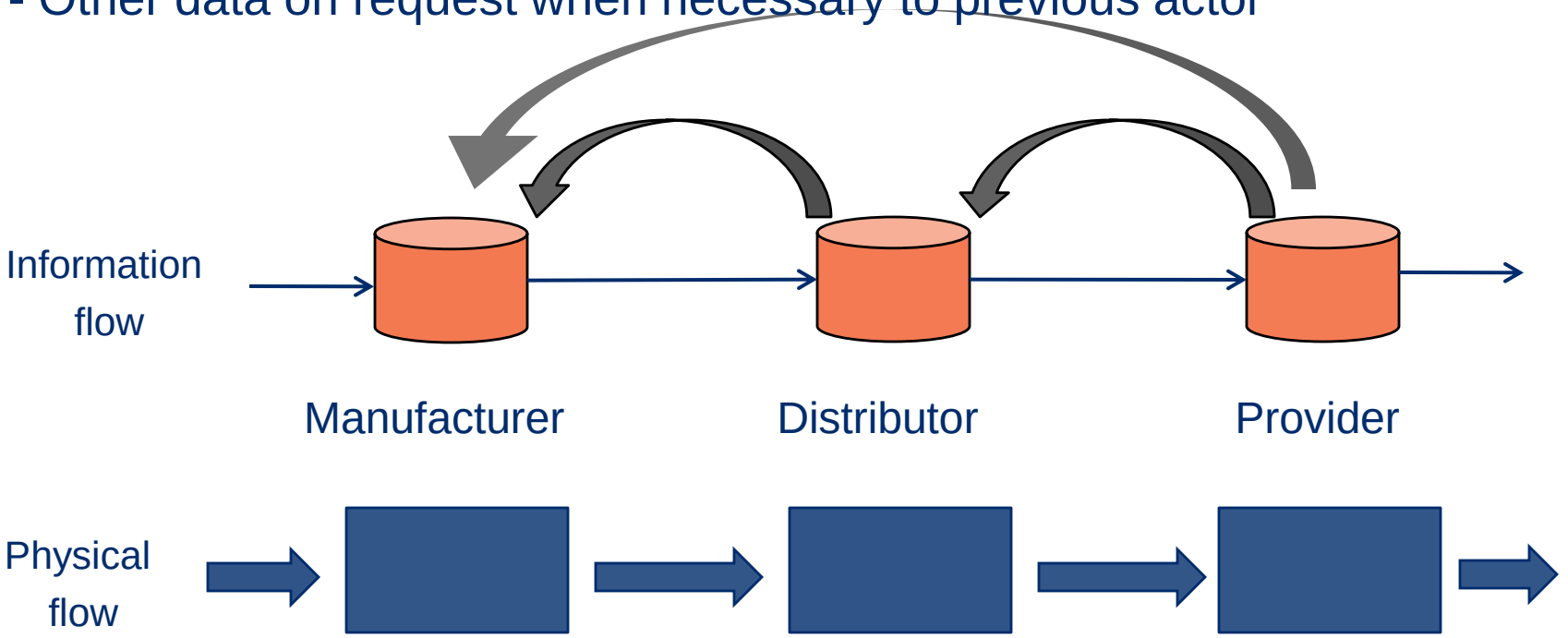
(01)07612345678900(17)100503
(10)AC3453G3

RFID

Information sharing model 1

One up, one down

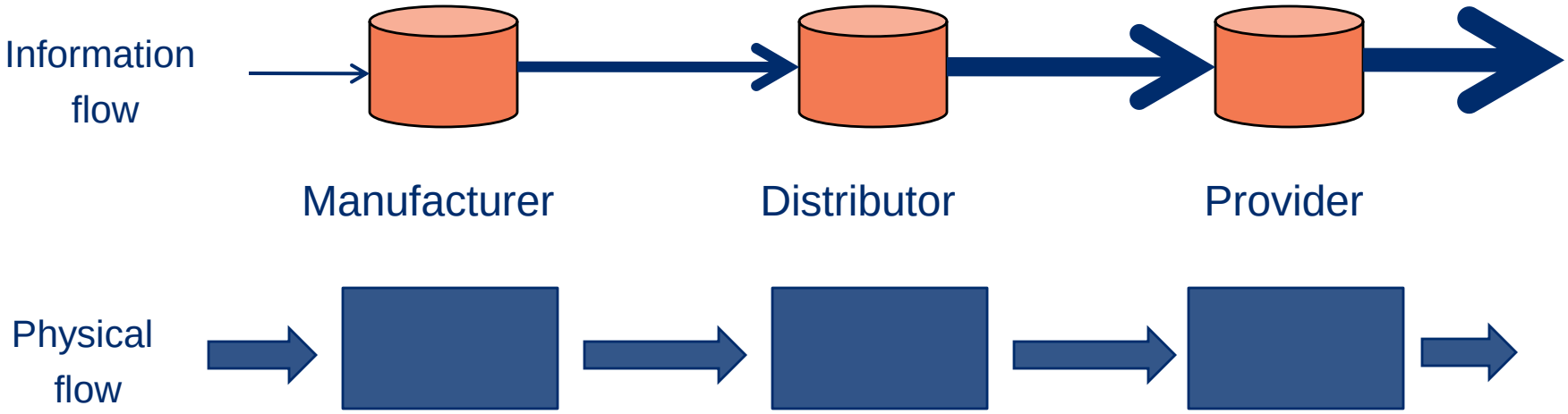
- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor



Information sharing model 2

”Chain of Custody” or “Chain of Ownership”

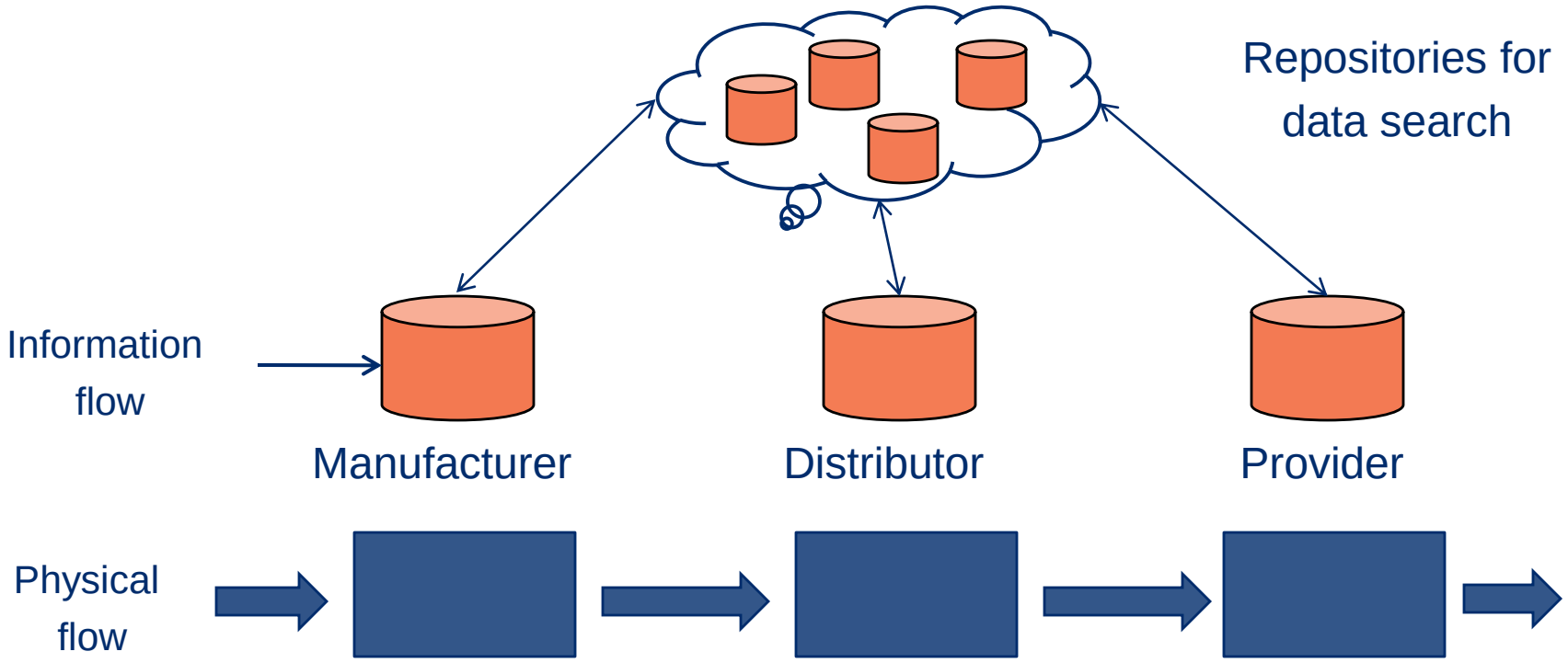
- Point-to-point information sharing of cumulated product history information
- No request or discovery is supposed to be performed



Information sharing model 3

Real time (one source)

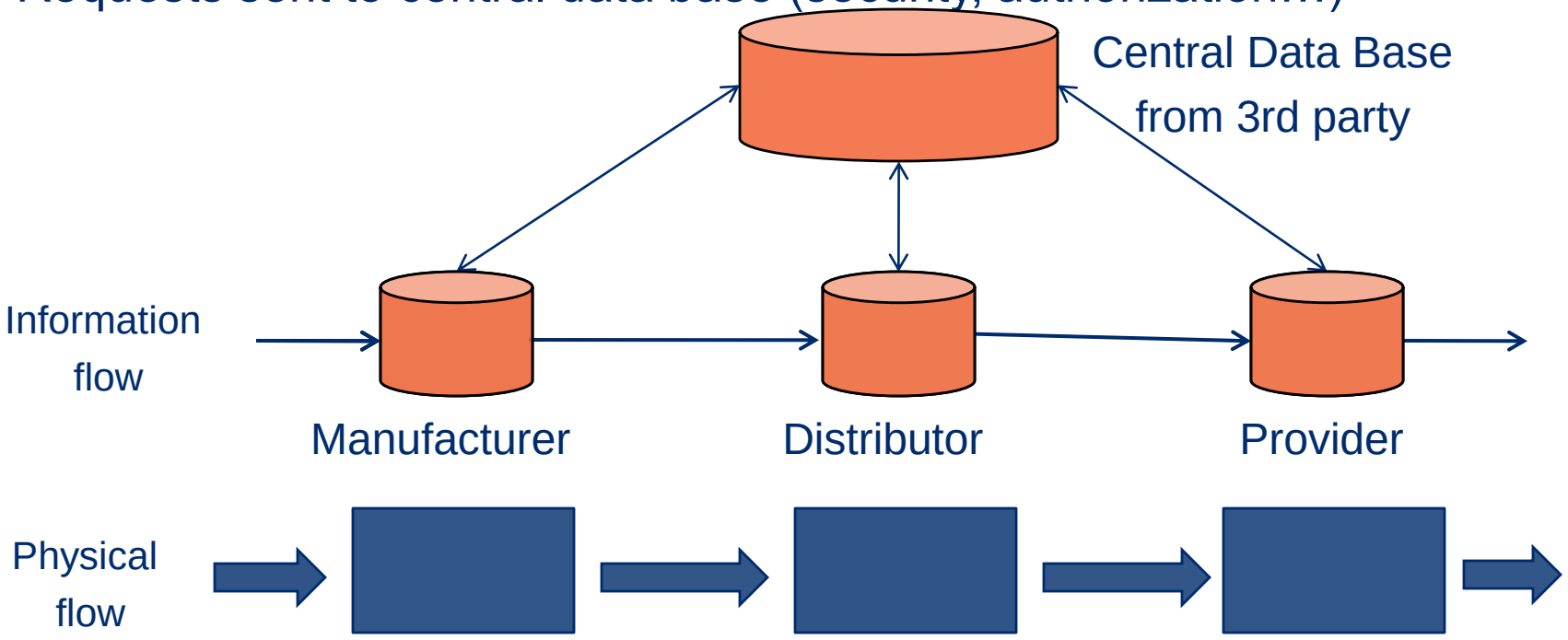
- No point-to-point information sharing
- All data on request based on traceable item identifier



Information sharing model 4

Central data base

- Point-to-point information sharing for day to day operations
- Duplication of data in a central data base held by a 3rd party
- Requests sent to central data base (security, authorization…)



Major global developments

Global developments

- **World Healthcare Organization**
  - IMPACT (International Medical Products Anti-Counterfeiting Taskforce)
- **USA**
  - FDA Amendments Act 2007
  - California pedigree legislation
- **European Union**
  - European Commission legislative proposal on counterfeit medicines
  - EFPIA vision

GS1 supports WHO IMPACT

IMPACT
International Medical Products
Anti-Counterfeiting Taskforce

An initiative by the World Health Organisation to combat counterfeit medical products

IMPACT focus areas

- Legislative and regulatory infrastructure
  - E.g. increasing penal sanctions
- Regulatory implementation
  - E.g. improving control on importation, exportation and distribution of medical products
- Enforcement
  - E.g. improving skills of enforcement officers through training, Internet sales monitoring
- Communication
  - E.g. increase awareness
- **Technology** (GS1 is member of this work team)
  - **Assessing anti-counterfeiting technologies, including bar coding, RFID, traceability**

Securing the pharmaceutical supply chain: U.S. FDA's efforts and perspectives

Product integrity considerations

- Globalization has created unique challenges to supply chain security: private & public sector
- Need to consider the lifecycle of the product

Starting materials → Administration of finished dosage form

- Existing, new, and emerging technologies for track and trace hold promise

Framework– U.S. Action Plan

"Anti-counterfeiting strategy must be a multi-layered approach"

- Secure:
  - ***product and packaging***
  - ***movement of drugs*** through the supply chain
  - ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- Increase International ***collaboration***

Secure the movement of drugs through the supply chain

- **Pedigree – documenting each sale or transaction of the product**
  - Knowledge of:
    - » Who had the product
    - » When they had the product
    - » How long they had the product
    - » Who they bought it from
    - » Who they sold it to
    - » Other information…..
- **Universal and Uniform Pedigree**-- *ideal*
  - Identical format for all 50 states
  - Passed by all supply chain stakeholders
- **Electronic Pedigree** -- *ideal*

Regulatory Tools

- **Pedigree laws**
  - Federal law – Prescription Drug Marketing Act
    - Challenges in the current pedigree law
    - Not all transactions
    - Need new law for universal and uniform pedigree
    - Litigation – *RxUSA v HHS*
  - State laws
    - Florida
    - California
- **Food and Drug Administration Amendments Act of 2007 (FDAAA)**
  - Authority to develop standards for Drugs
  - Authority to develop standards for Unique Identifier for Devices

Example: California

Pedigree legislation in California to fight counterfeiting

- "Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution" (Russian doll model)
  - Electronic track and trace system for prescription drugs at the smallest package or immediate container
  - Established at point of manufacture
- Implementation date: **2015**

Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector

Focus on: Legislative proposal on ‘counterfeit’ medicines

Placing on the market/manufacturing (1) – Obligatory safety features

The issue:

No legal basis for harmonisation of safety features

Proposed change (Proposed new Article 54a):

- Legal basis for harmonised approach in Community
- Scope: prescription medicines & risk-based
- Characteristics set out in implementing measures …

Placing on the market/manufacturing (2) – Characteristics obligatory safety features

Shall allow for

- identification check
- authenticity-check
- tracing

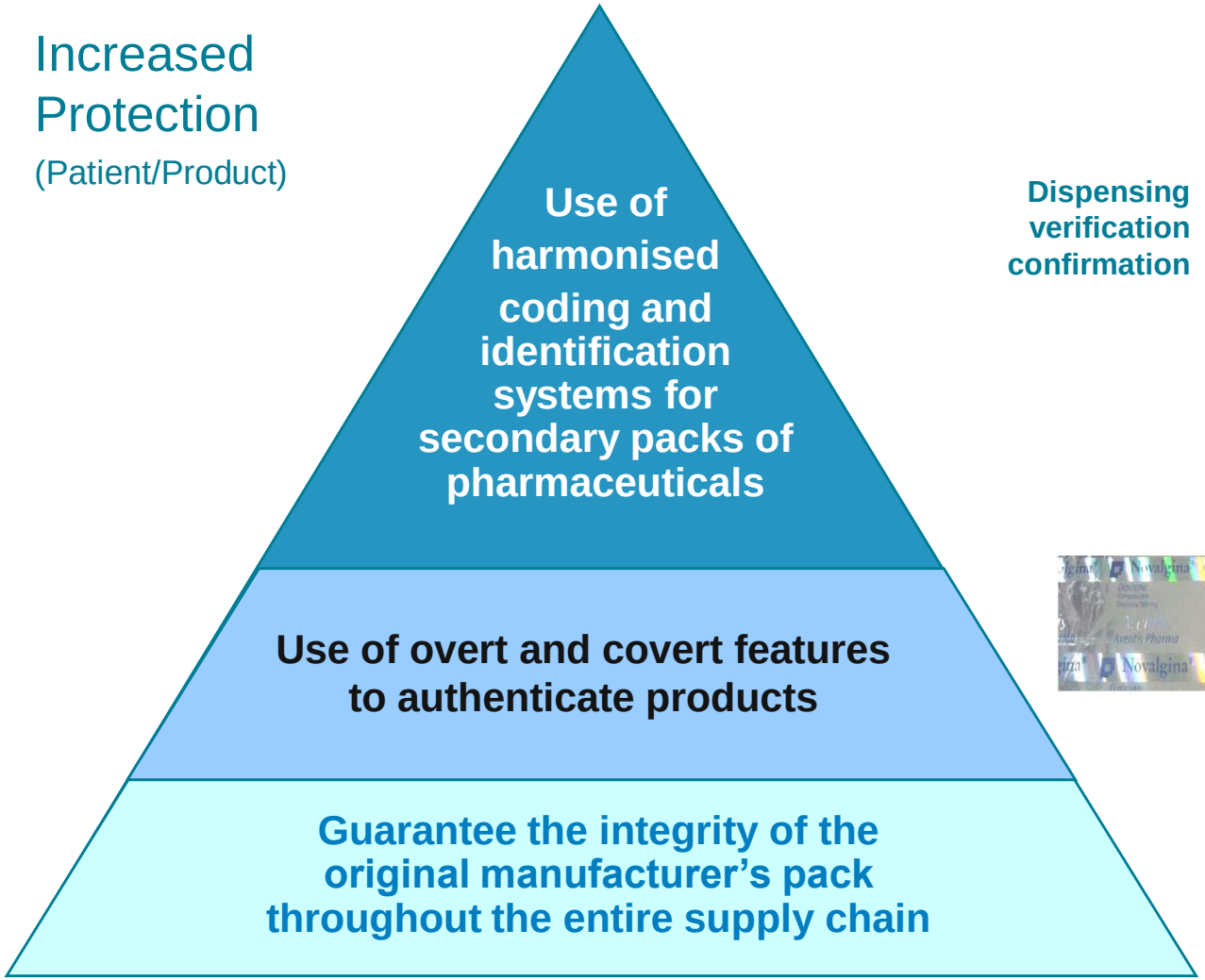
To this end, it shall allow to perform verification of

- authenticity
- pack-identification
- pack-tampering

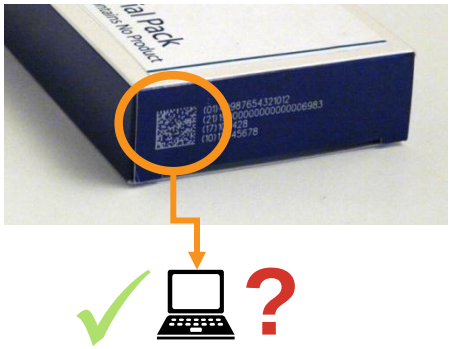
Proposed new Article 54a

Three measures to protect packs

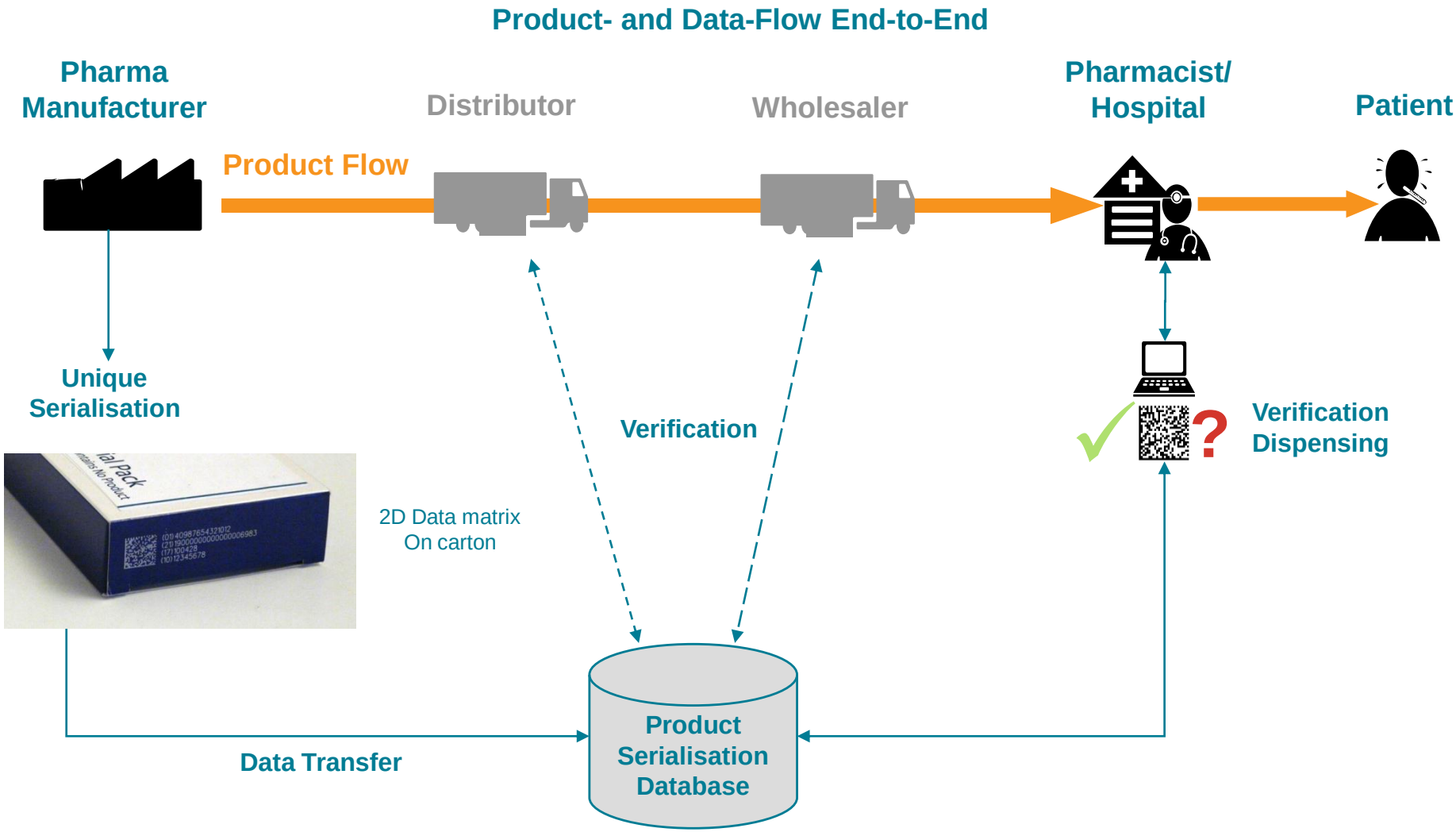
Increased Protection
(Patient/Product)



Dispensing verification confirmation



The verification model EFPIA's supports



EFPIA Recommendation for Coding of Pharmaceutical Products in Europe

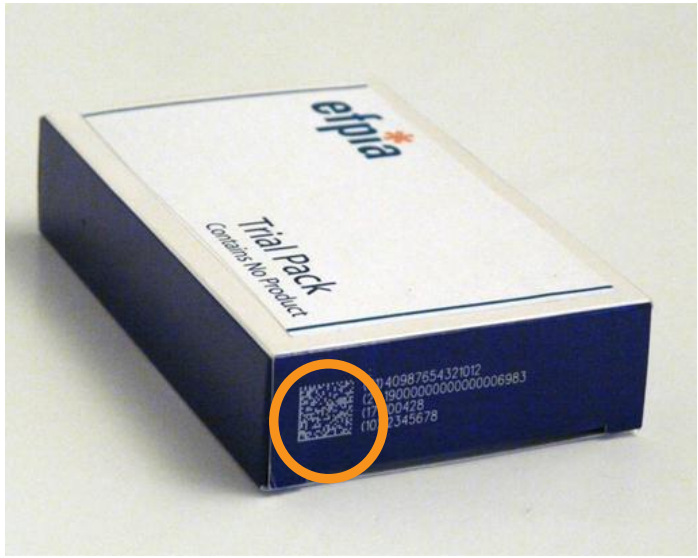
Data Matrix – Coding proposal derived from GS1 standards (Data matrix ECC200 with application identifiers)

Product Code (GTIN)	14 digits
Unique Serial Number (randomised)	up to 20 alpha-numeric characters
Expiry Date	6 digits (YYMMDD)
Batch Number	up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811



Conclusion

GS1 Healthcare GS1 Standards in Healthcare

- Enable automatic identification systems - **interoperability**
- Enable **global** traceability systems

GS1 Standards in Healthcare improve patient safety worldwide

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