ENGINEERING PHARMACEUTICAL INNOVATION

Supply chain and brand protection – Track and Trace

ISPE Central Region September 2007

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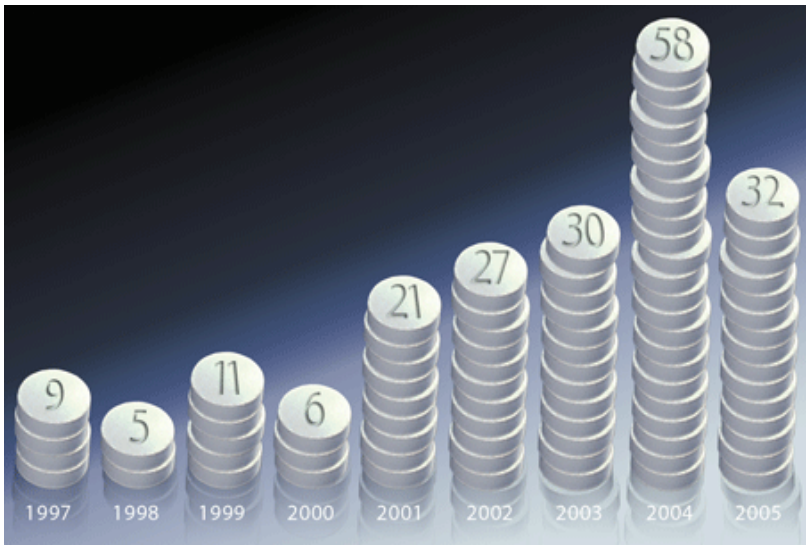
Laetus

Supply chain and brand protection

- Within the USA there has been no major breakout of known toxic or contaminated counterfeits in the past year, although the number of investigations opened by the FDA Office of Criminal Investigation (OCI) remains at a high level.
- However outside the USA the picture is more depressing, the number of counterfeiting incidents was up 40% from 2004 to 2005, reaching 781 incidents.

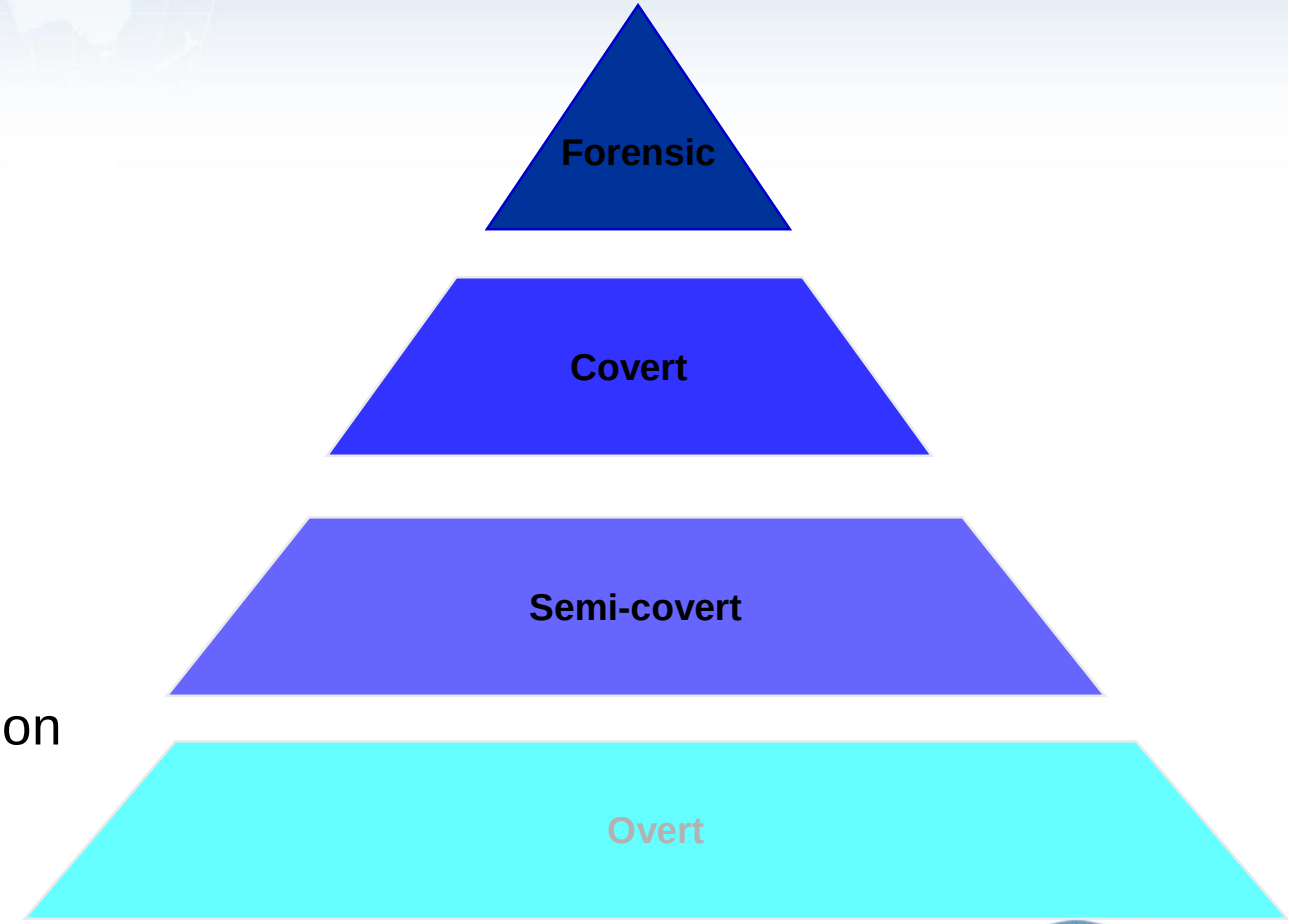


Supply chain and brand protection

- However, not all threats to patient safety originate from the problem of counterfeit medicines, misadministration also poses a problem.
- The effect of misadministration errors upon the general patient population is profound.
- Patient safety is a key political issue for the UK government. It is known in the UK that 34% of all medication errors that cause problems for patients are associated with drug administration and 50% of estimated 72,000 deaths in the NHS are caused by medication errors.

Supply chain and brand protection

- **Forensic**
  - DNA marking
  - Chemical marking
- **Covert**
  - Invisible taggant
  - RFID labels
- **Semi Covert**
  - Microtext
  - Watermarks / Intaglio
  - Barcodes
  - Print / Mark Serialisation
- **Overt**
  - Holograms or OVD's
  - Optically variable inks



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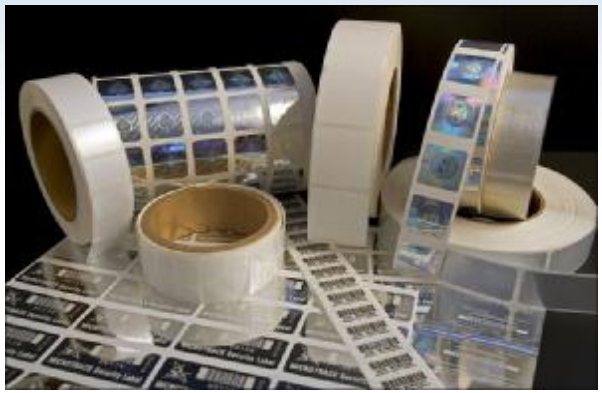
- Holograms, more correctly referred to as Optically variable devices (OVD) are becoming ever more popular as tools to provide security for documents and products subject to counterfeiting.
- Issues faced during the design and implementation of OVD's for a specific security application include matching the proper security feature for its intended function, determining the method of the security features authenticity and incorporating effective anti-counterfeiting protection for the OVD itself.

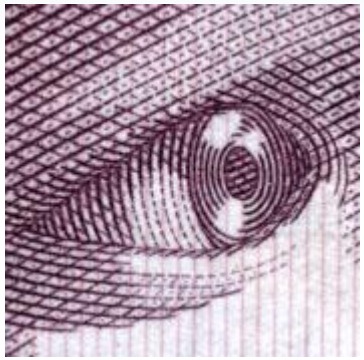


Supply chain and brand protection

- Optically variable inks or OVI contain tiny flakes of special film which changes colour as the viewing angle is varied. The result is an ink which has this same optical property, changing colour as the viewing angle is varied.
- They are very expensive inks and generally only used in small areas. An OVI feature is printed using the silk screen process.
- They do however offer excellent protection against all counterfeiting methods.

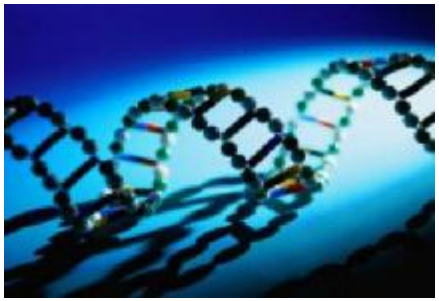
Supply chain and brand protection

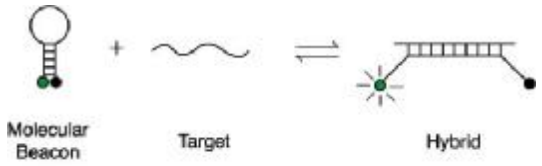
- Perhaps the oldest example of printing as an anti-counterfeiting device is intaglio printing. **Intaglio security printing** is a super micro raised print with micro text and micro image implemented in the surface with visual appearance along with a coarse texture you can feel
- A more simplified version is being used today to produce aluminium blister lid foil with embossed human readable text. Since this can only be done by the aluminium manufacturer if becomes a powerful anti-counterfeiting tool



Supply chain and brand protection

- Security tags that use unique DNA authenticators that can be used as labels, or actually built into a product along with a logo. A strand of DNA from twenty to tens of thousands of base pairs long is synthesized or extracted from a plant genome. This DNA strand is assigned a unique product name, and then is replicated to produce bulk quantities of pure DNA material. This material can then be mixed with ink for tags or actual use on the product itself; it can even be mixed directly into pharmaceuticals. Inspectors can easily test this DNA in real-time in the field using a special test kit with a reverse complement of the DNA tag. Only a perfect match will spark a fluorescent reaction; this reaction authenticates the product for the inspectors





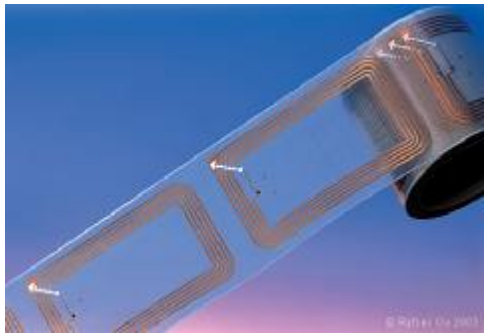
Supply chain and brand protection

- When discussing either bar code or RFID utilisation as a control in the supply chain additional facts must be considered regarding using such data carriers as part of a ‘track and trace system’
- The pharmaceutical supply chain in Europe and the US is a complex industry with many millions of medicinal packs in free flow each year, becoming more and more fragmented, leading in turn to a decrease in the ability to track medicines
- To do this precisely, it is necessary to assign a unique serial number to each product at the individual, secondary package level, contained within a barcode or RFID chip, and have some method of securing this unit of sale by tamper evident systems

Supply chain and brand protection

- EFPIA is introducing a 2D (2 Dimension Data Matrix) Bar Code system across Europe. This mechanism would include the use of unique serialisation numbers for each secondary packaging unit distributed and sold across Europe. It would enable the identification and verification across the entire supply chain, therefore improving transparency and patient safety, and helping fight serious problems like counterfeiting
- The adoption of a 2D system does not prevent the adoption of an RFID system at a latter stage nor does it represent a double cost. Experience has shown that RFID technology is not workable at present but would certainly be a natural progression of the system

  - EFPIA position paper, identification and coding of Pharmaceutical products in Europe, November 2006

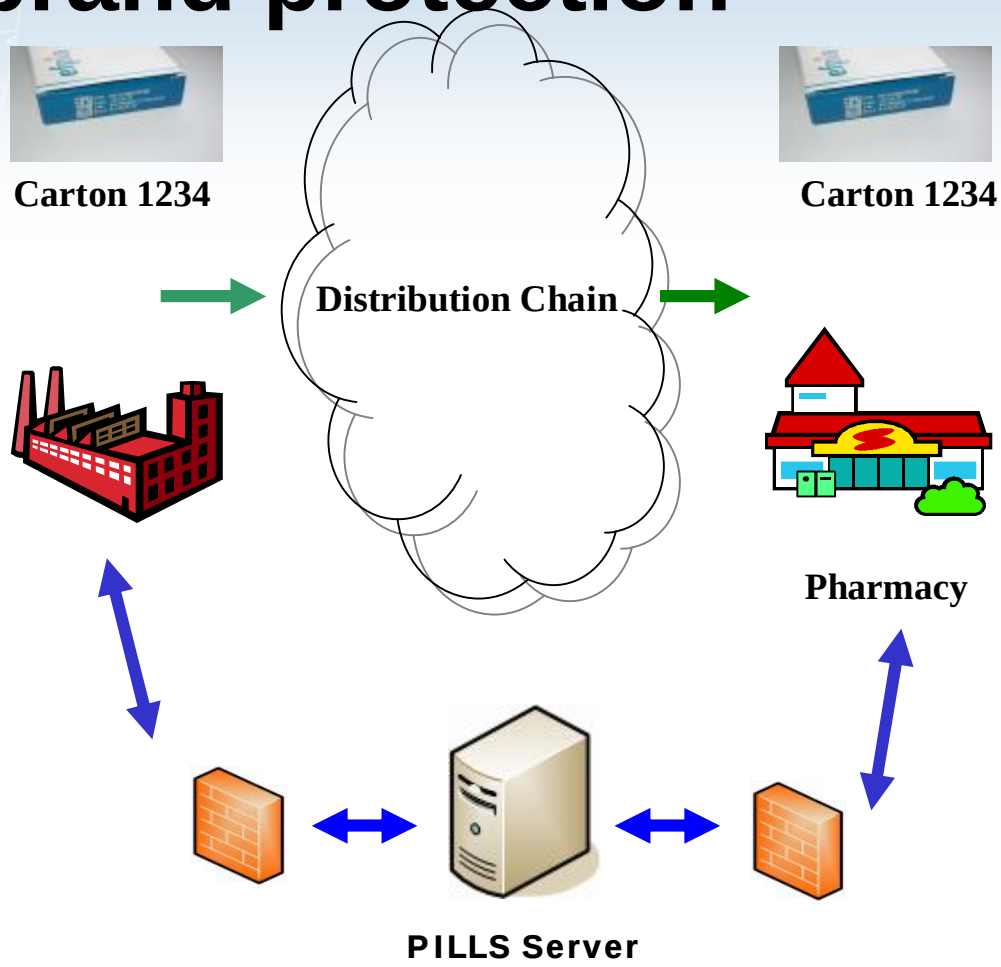


Authentication

Supply chain and brand protection

- A unique and non predictive number is printed on the carton at the point of manufacture and scanned at point of sale / dispensation
- A secure link confirms the correlation of the two numbers and therefore it's authenticity. This is an 'end to end' solution only
- This is authentication by mass serialisation, not 'track and trace'
- The 'coordinated exchange' of uniquely identified products using the concept of pedigree transactions can result in improved supply chain safety and security

  - EPCglobal

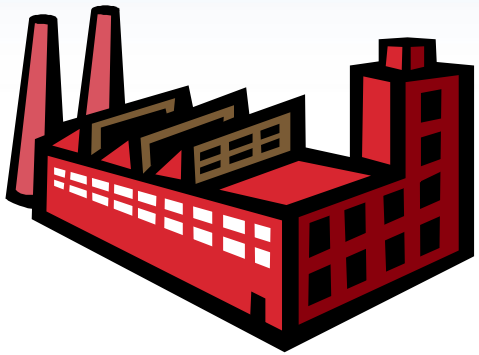


Picture courtesy of Domino Ltd

Aggregation

Supply chain and brand protection

- Unique characters are printed at each packaging step, these numbers are then related by generation or associated by the manufacturing process
- This solution refers only within the factory walls though the numbers used on each pack can also be used for an authentication solution



Manufacturer

Carton 1234

Case ABCD

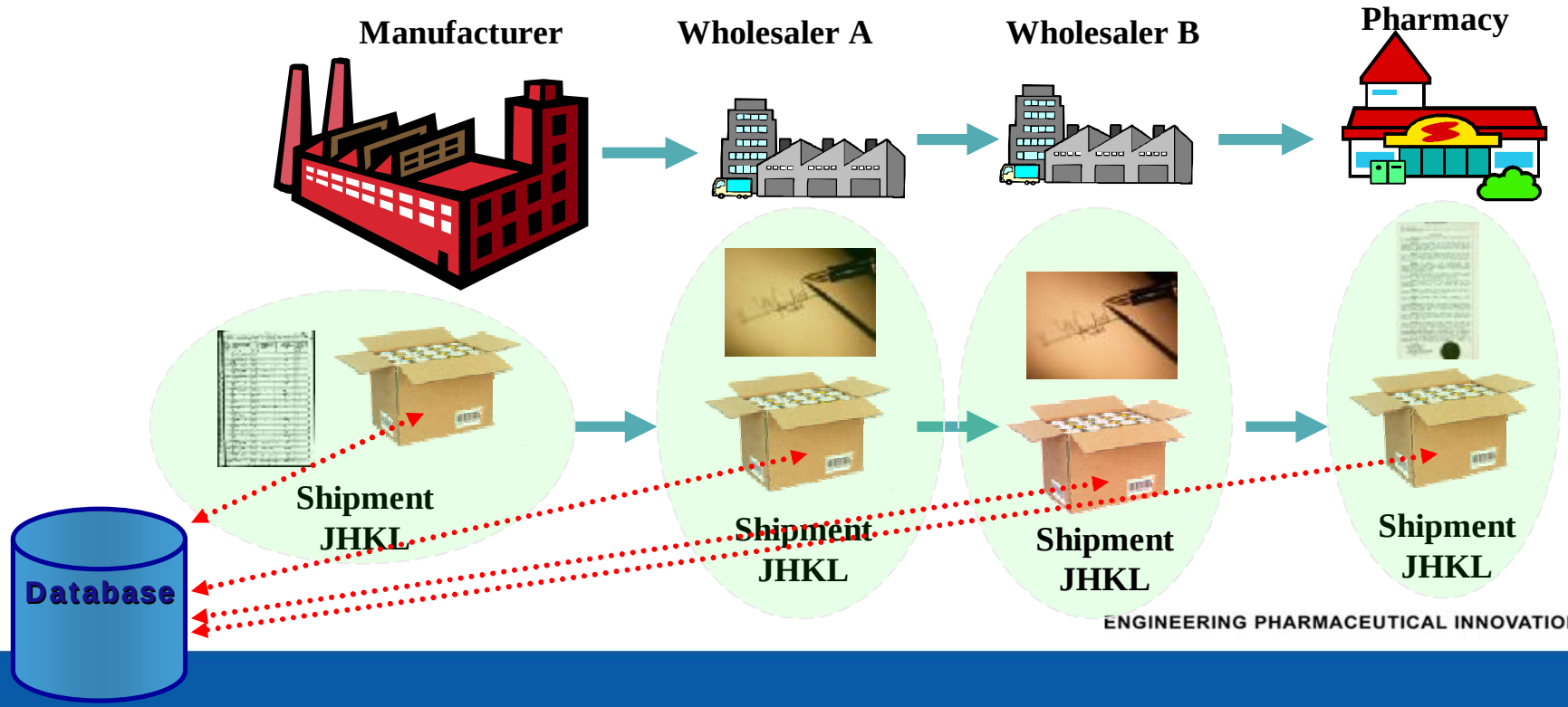
Pallet K6J7

These details are all linked

Track and Trace

Supply chain and brand protection

- A unique identification number will track the prescription drug throughout the distribution chain in real time, this is the most difficult. The supply chain must be both technologically enabled and co-operative in the capturing of these numbers. Depending on the sector this can either be real time or as a historical (pedigree) document. This can be in partnership to both aggregation, authentication and a form of an E-pedigree solution



EFPIA Standard

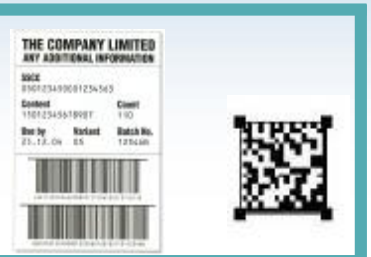
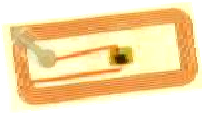
Supply chain and brand protection

- Product Code – which has an application identifier of (01) and contains the article number and the manufacturer company prefix 14 digit GTIN (Global Trade Identity Number) or other country codes, possibly CIP (Club Inter Pharmaceutique) in France
- Expiry Date – which has an application identifier of (17) and is a fixed length, 6 digit field of the form YYMMDD (as GS1)
- Unique Serial Number – which has an application identifier of (21) is 20 characters long, this may be modified to 16 digits
- Batch Code – which has an application identifier of (10) and is a variable length field, alphanumeric in style and can be up to 10 characters long (Alphanumeric)

20-digit Unique serialised number in Data matrix ECC200

(01)05000328751207 (17)080228 (21)98765432109876543219 (10)1234567ABC = 58 A/N Characters

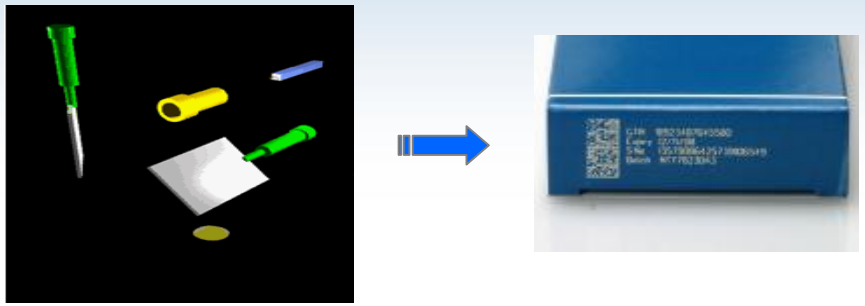
Supply chain and brand protection

PRINTED OPTION				
				
	u Unit Dose	u Item	u Case	u Pallet
RFID OPTION				

Picture courtesy of Domino Ltd

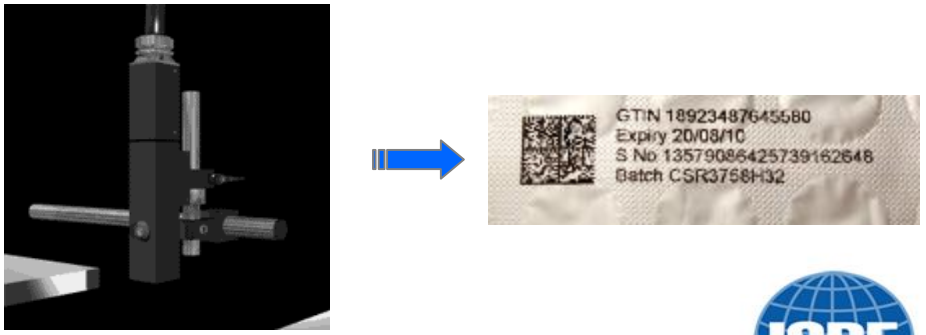
Supply chain and brand protection

- Scribe (or ‘Vector’) Laser creates Human and Machine Readable Codes (MRC’s) including Data Matrix



- Drop On Demand (DOD) Inkjet printing uses multiple print heads to print blank Blisters and Cartons to enable just-in–time customisation including Human and MRC’s including Data Matrix

- Continuous Inkjet (CIJ) printing uses a continuous stream of ink to print Human and MRC’s including Data Matrix



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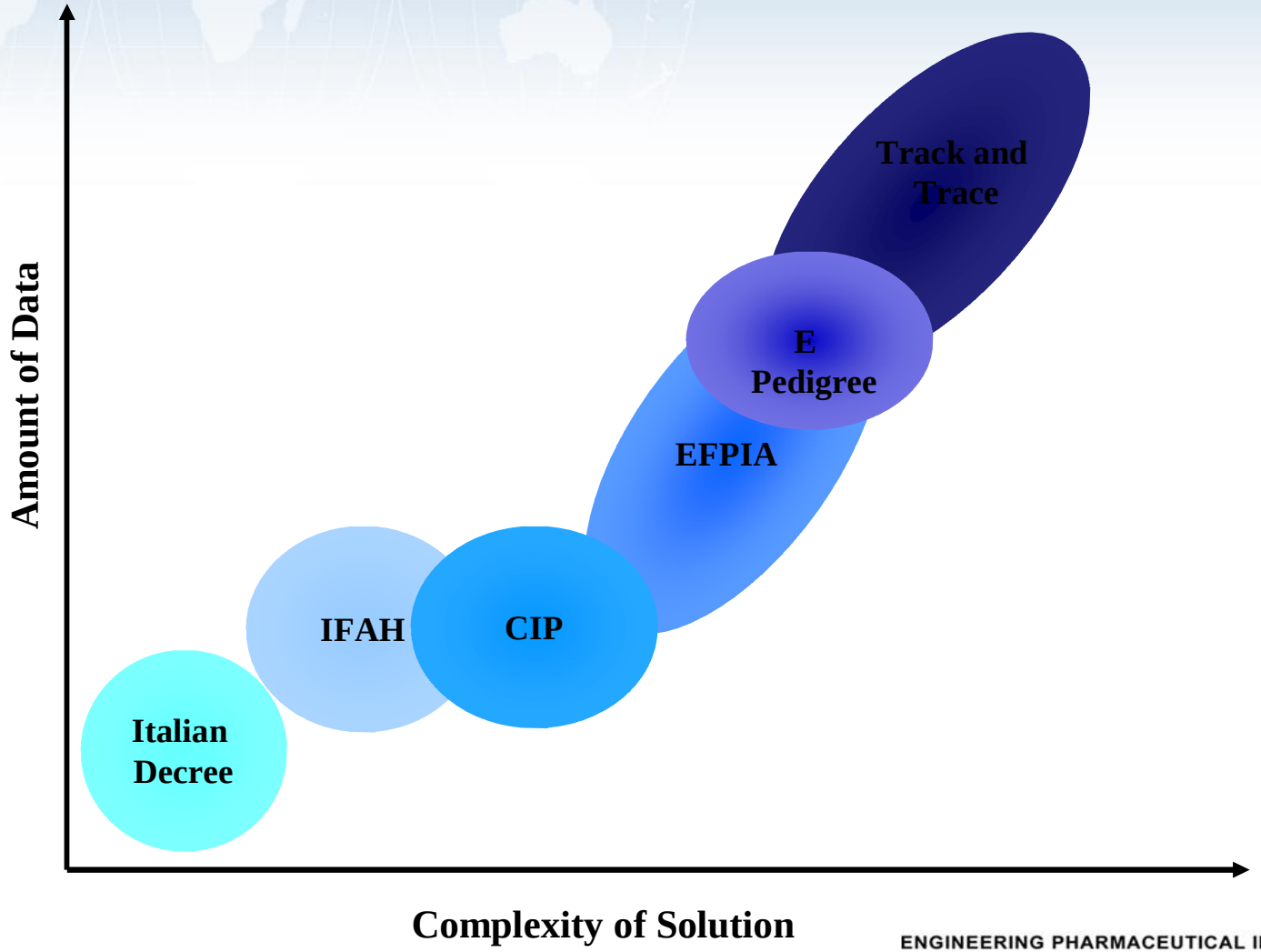
- The promise of increased functionality in RFID systems created in compliance with the new EPCglobal Generation 2 (Gen 2) standard creates a foundation for a new era of RFID use in the pharmaceutical supply chain
- Global: 860 - 960 Mhz UHF tags
- Maximum read and write cycle 300 / 350 minute in the USA, around 250 in Europe today. New standards in Europe in 2008 gives 300 / 350 minute.
- Tags will be in packaging, including labels and cartons

Supply chain and brand protection



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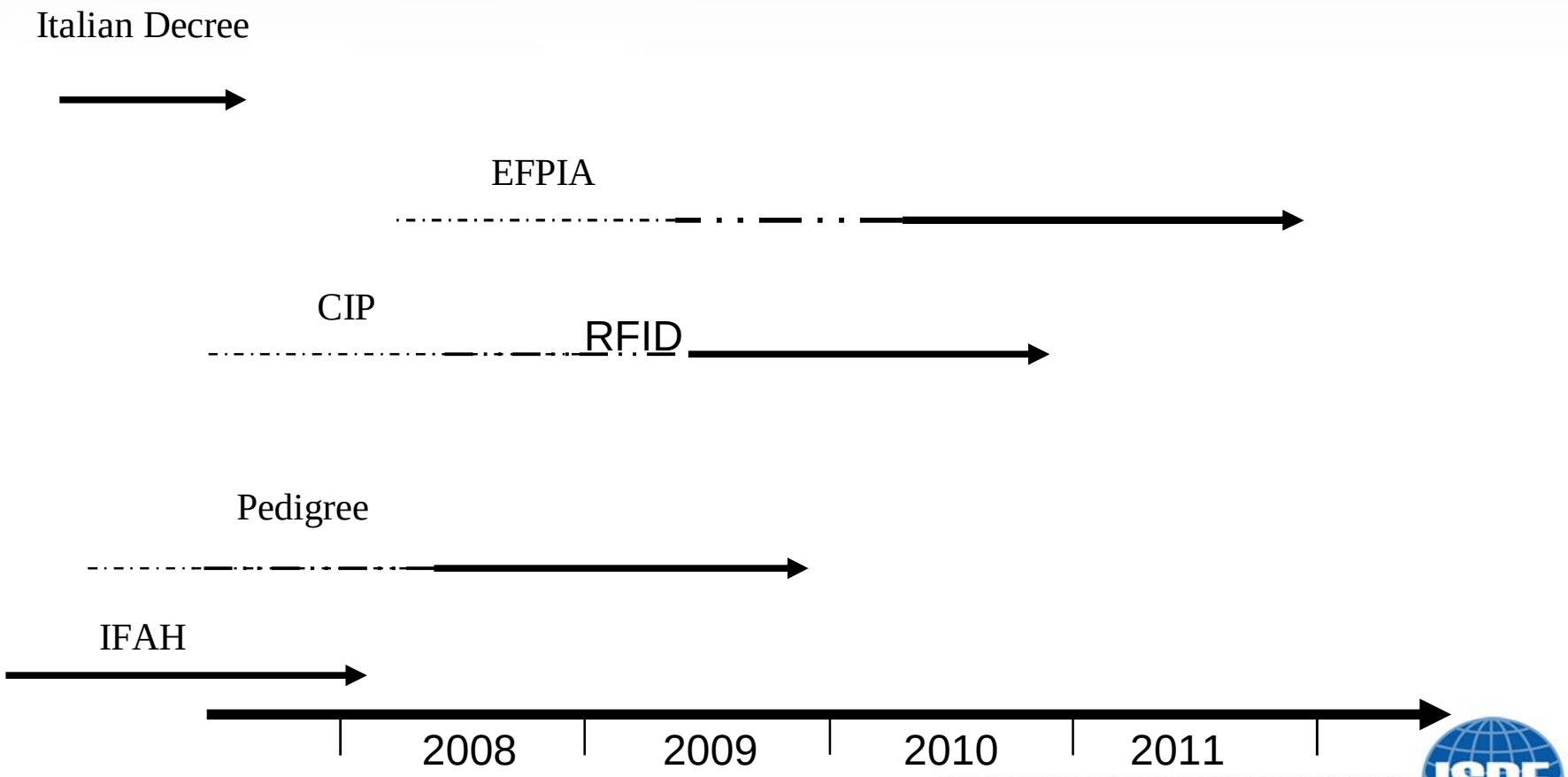
- The Itallian Bollini decree is well know to us
- On October 24th 2004 the Institute For Animal Health (IFAH) endorsed recommendations to adopt the ECC200 Data matrix code as the global standard for the identification of packaging for animal health products
- AFSAPPS (the French Health Products Safety Agency) announced the transposition of the European Directive CE 2004/27: information on the batch numbers and the expiry dates of pharmaceuticals will have to be kept throughout the supply chain. AFSAPPS decided to adapt the national CIP code from 7 to 13 characters, associated with a special prefix in a Data Matrix symbology using the GS1-128 syntax. This must be implemented at the latest on December 31, 2010
- EFPIA is introducing a 2D (2 Dimension Data Matrix) Bar Code system to be introduced across Europe. This mechanism would include the use of unique serialisation numbers for each secondary packaging unit distributed and sold across Europe

Supply chain and brand protection



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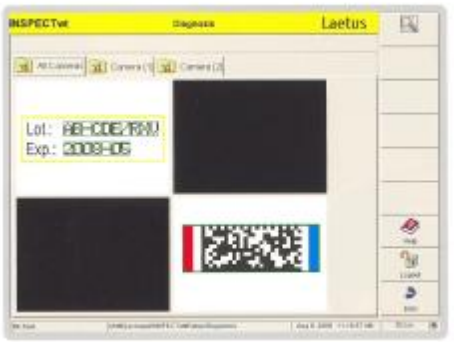
- When we consider the in-line printing and marking of various data, or RFID implementation we must also consider that such data can also be corrupted in the printing, marking or writing process
- So it will be necessary check this data and even to log it in the event of serialisation
- The need therefore is for 100% on-line inspection of this information or 100% inspection of the complete blister or carton printing
- The Laetus Argus Inspect wt range of equipment offers this functionality



Supply chain and brand protection

Thank you
for your attention!