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Anti-Counterfeiting and Track & Trace

Pharmaceutical and Medical Packaging

Paul Osborne April 2007

Anti-Counterfeiting

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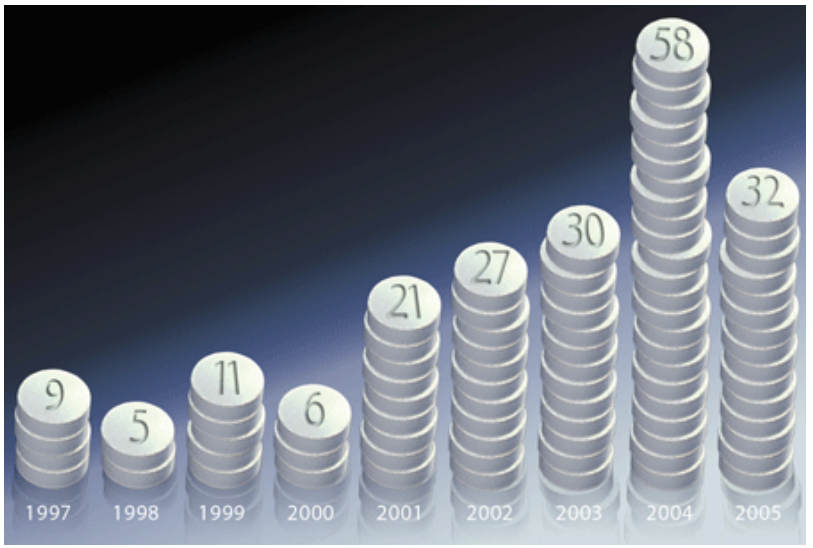
- Within the USA there has been no major breakout of known toxic or contaminated counterfeits in the past year, although the number of investigations opened by the FDA Office of Criminal Investigation (OCI) remains at a high level.
- However outside the USA the picture is more depressing, the number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



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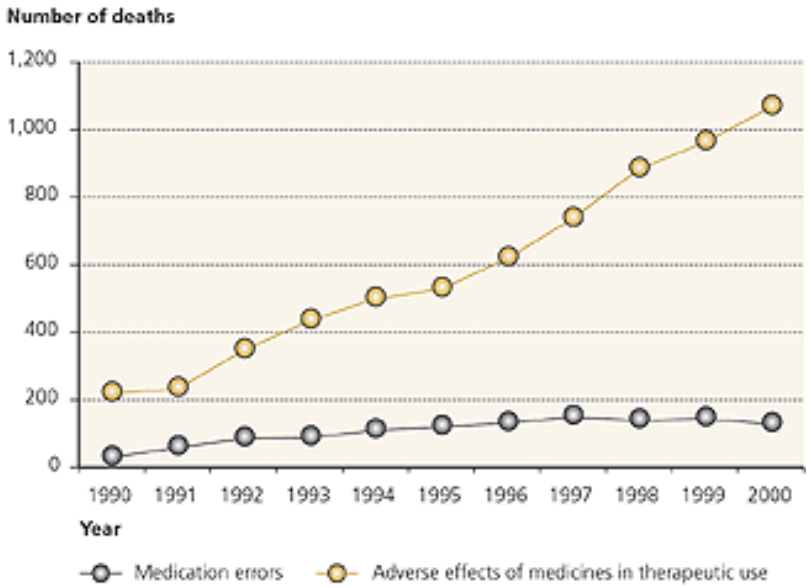
- However, not all threats to patient safety originate from the problem of counterfeit medicines, misadministration also poses a problem.
- The effect of misadministration errors upon the general patient population is profound.
- Patient safety is a key political issue for the UK government. It is known 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.



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- **Overt (open)**
  - Holograms, or more correctly, Optically Variable Devices OVD's.
  - Optically Variable Inks OVI's
  - Microtext
  - Serial data application (Track and Trace) by printing on cartons or by vignette application
  - Flavours (in tablets)
  - Pearlescent coatings (on tablets)
  - Barcodes (on tablets as well as primary, secondary and tertiary packaging)
- **Covert (closed)**
  - Pen reversible inks
  - Encoded serialization data in UV
  - RFID tags
- **Forensic (forensic authentication)**
  - Chemical markers
  - DNA taggants

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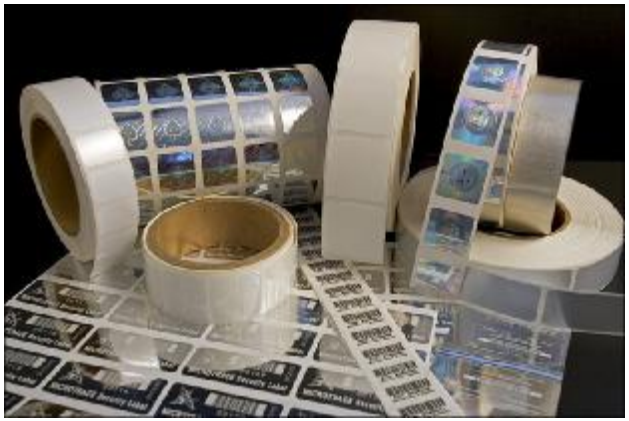
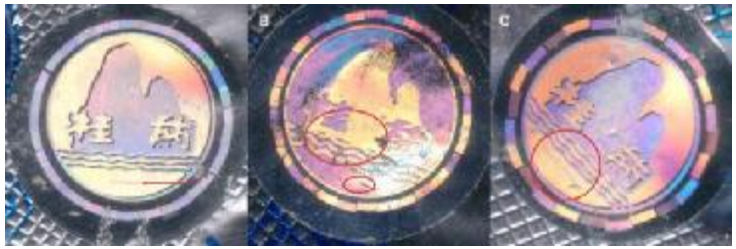
- Optically variable devices (OVD) are becoming ever more popular as tools to provide security for documents and products subject to counterfeiting. Issues faced during the design and implementation of OVD's for a specific security application include matching the proper security feature for its intended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





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- 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 sometimes printed using the silk screen process.
- They do however offer excellent protection against all counterfeiting methods.

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- Perhaps the oldest example of printing as an anti-counterfeiting device is intaglio printing. The process involves high-pressure printing of documents to create an embossed, tactile structure of ink and paper. Intaglio printing can be used to create "latent images," having horizontal lines in the background to form the structure and vertical raised lines in the foreground. When viewed from an angle, the raised lines will shade the background lines, bringing that grid into relief.

- 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.

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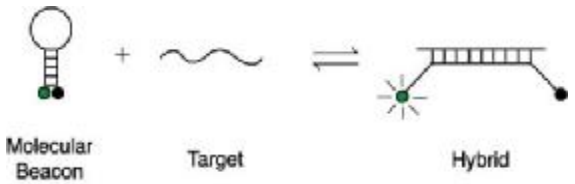
- Security tags that use unique DNA authenticators that can be used as labels, or actually built into a product along with a logo. A strand of DNA from twenty to tens of thousands of base pairs long is synthesized or extracted from a plant genome. This DNA strand is assigned a unique product name, and 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.



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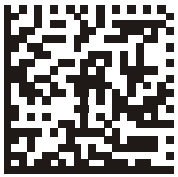
- When discussing either bar code or RFID utilisation as a control in the supply chain additional facts must be considered regarding using such data carriers as part of a ‘track and trace system’.
- The pharmaceutical supply chain in Europe and the US is a complex industry with many millions of medicinal packs in free flow each year, becoming more and more fragmented, leading in turn to a decrease in the ability to track and trace 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



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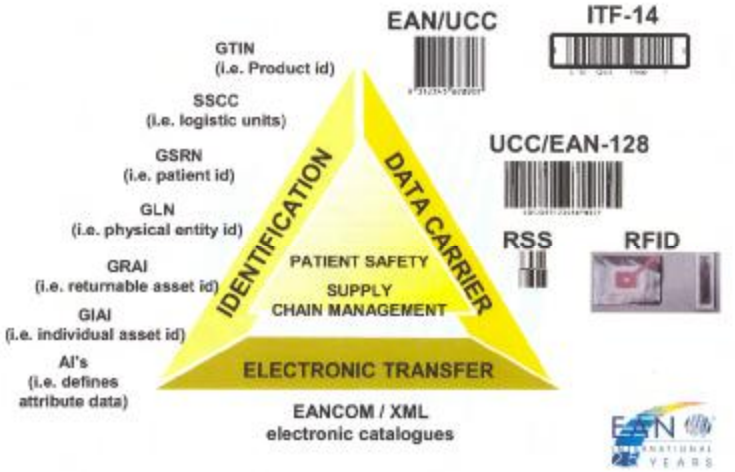
- The GS1 group has made strong recommendation for the adoption of the EAN.UCC system for the identification and labelling of all pharmaceutical products marketed throughout Europe, and indeed globally, whether through the use of bar codes or RFID.
- At Patient Pack level, information is encoded primary data identified with the GTIN (Global Trade Identity Number) and Application Identifiers for secondary data like expiry date, batch number. The unique serial identification is a further step.



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- Any technology used with medicines has to be fully reliable and applicable. EFPIA has therefore identified other solutions that could help to improve the coding of medicines:
- EAN 13: Can identify name, company and country
- EAN 128: Can identify name, company, country and around 10 more parameters. The main problem is that it takes a lot of space in the package
- 2D (i.e. Data matrix): Can cover multiple information and does not take much space in the package
- In the US, especially for the Unit Dose initiative and complying with the EAN.UCC system, the preferred barcode configuration is the RSS14 code, now called the GS1 DataBar.

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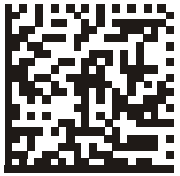

- However it is generally believed that data matrix codes offer advantages over GS1 DataBar;
- Size - Data Matrix symbols as small as 2 mm can be accurately printed and read. GS1 DataBar will not fit on all unit dose packages.
- Print Quality - Data Matrix can be decoded with as little as 20% contrast. GS1 DataBar, like all linear barcodes, requires a higher level of print quality and contrast.
- Readability - Data Matrix can be laser marked directly on any surface including reflective materials such as foil packaging associated with some unit-dose blister packs.
- Error Correction - Data Matrix symbols employ Reed-Solomon error correction. A large proportion of the code (up to 1/3) can be damaged and still decode correctly. GS1 DataBar has no error-correction capability.

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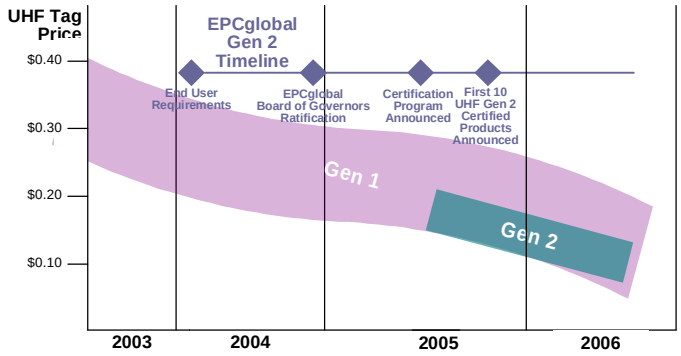
- The adoption of a 2D system does not prevent the adoption of an RFID system at a latter stage nor does it represent a double cost.
- Experience has shown that RFID technology is not workable at present but would certainly be a natural progression of the system.
- Certainly the next generation of RFID tags the so called ‘Gen 2’ units will reduce costs significantly.



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- The importance of securing physically the primary container or secondary packaging cannot be understated in the fight against counterfeiting.
- Without tamper evidence on say the carton, any additional security or anti-counterfeiting measure is only securing the cardboard container.
- The labeling must also include a description of the safety feature. For blister packaging, each tablet or capsule is individually sealed, so any form of tampering is immediately visible.

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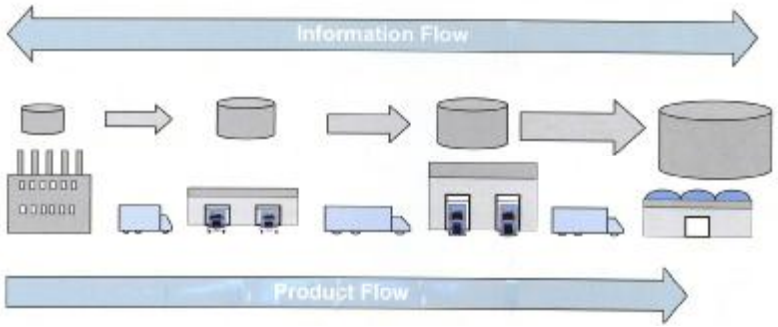
- When FDA first considered a drug product having an electronic pedigree the thinking was of a simple ‘One Way Push / Pedigree Compliance’, where data is pushed from trading partner to trading partner.
- However, this means that even with a relatively simple linear transaction, the data grows as it moves.



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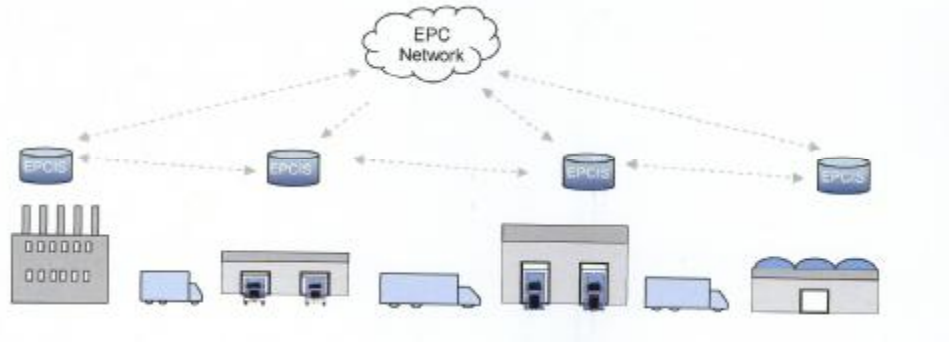
- Electronic Product Code Information Services provides a scheme whereby the EPC naming convention, using the EAN.UCC system and the Information Services provide the IT ‘backbone’ of the system. Transactions are registered with the network, enabling the network to authenticate products or build pedigrees, with local databases providing the information required.



Anti-Counterfeiting - Conclusions

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- Anti-counterfeiting techniques being developed act as a barrier to the counterfeiter, forcing him to look elsewhere for a product to copy. There is no individual ‘silver bullet’ to anti-counterfeiting, but rather a number of techniques built up by so called ‘layering.’
- Tracking and tracing medicinal product through the entire supply chain is feasible and would supply not only a strong anti-counterfeiting technique but also a powerful tool against drug misadministration.
- Further to this the possibility exists to track individual administration doses of drug to the patient.
- Physically securing the container or carton is as important as any other countermeasure being considered.
- Only with the ‘buy in’ of Government, by increasing penalties for such counterfeiting actions and with closer co-operation between manufacturer and the investigating authorities will the counterfeiting threat be met.

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Thank you for your attention!