Anti Counterfeiting and Mass Serialisation of Pharmaceutical products

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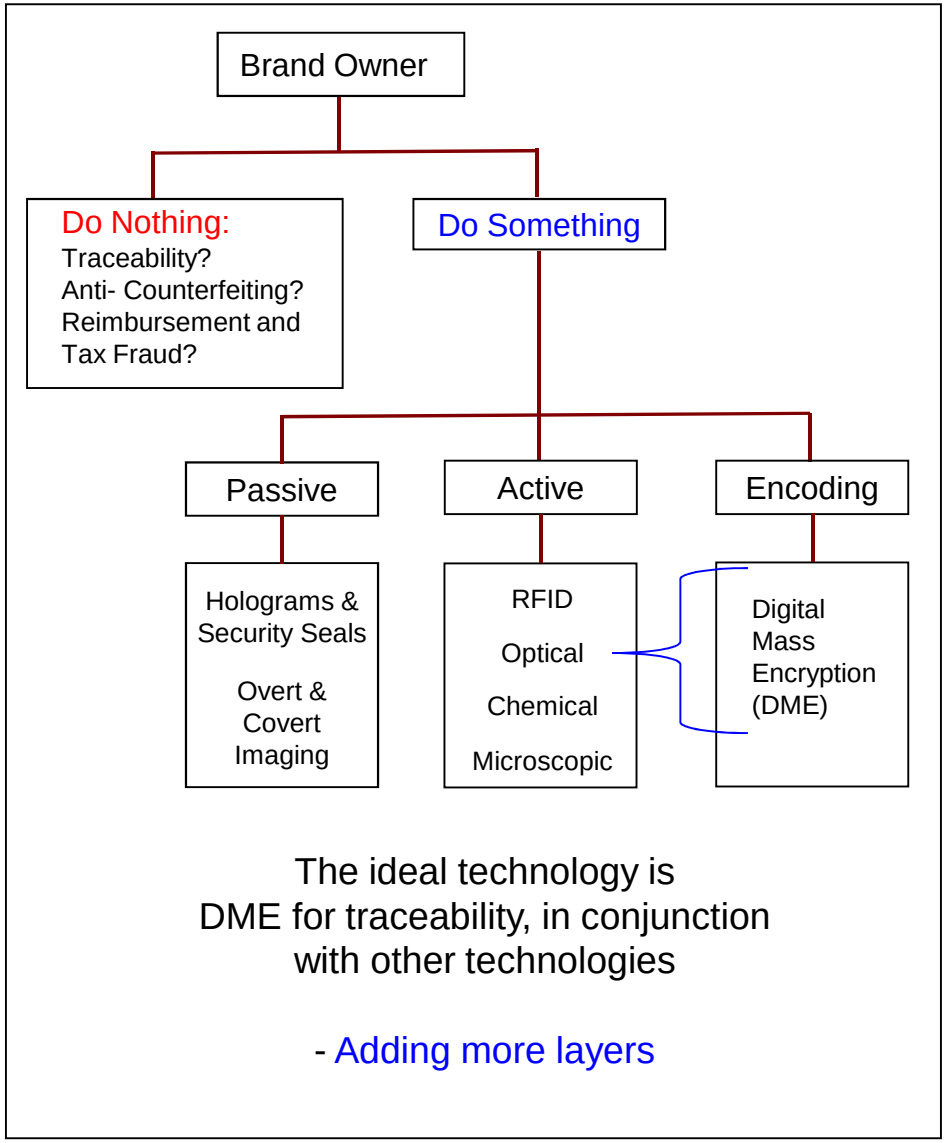
The Threat

Counterfeiting of pharmaceutical products is not often discussed, for obvious reasons, but currently it is:

- Increasing at an alarming rate
- Very lucrative, with low penalties
- A significant danger to patients worldwide
- Difficult to control (and sometimes to detect), and is growing increasingly sophisticated.

WHO estimates that at present, 8% of drugs globally are counterfeit, with this percentage rising to 65% in developing countries. The international drug counterfeiting market is currently at valued at $40bn, estimated to rise to $75bn by the end of 2010.

Anti Counterfeiting strategies



Anti Counterfeiting strategies

‘Overt’ involves forms of packaging elements that are visible to the naked eye. Some examples include

- Holograms, colour-shifting inks, decorative fonts, specific types of watermarks
- Guilloche - elaborate borders that are also often found on currency

‘Covert’ uses forms of packaging elements that are incorporated into the product and not visible to the naked eye and requires special equipment for visualization. Some examples include specific types of:

- Watermarks or invisible inks that are detected only under ultraviolet or other fluorescent light
- Invisible bar codes, which require specific readers

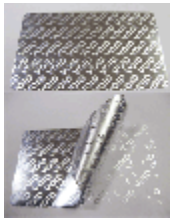
Anti Counterfeiting strategies

Passive technologies

(authenticate by visual inspection)

Holograms

Security seals



Color-shifting inks

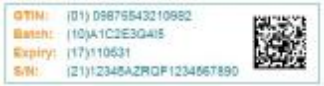
Watermarks

Active technologies

(authenticate with special readers)

Electromagnetic (RFID)

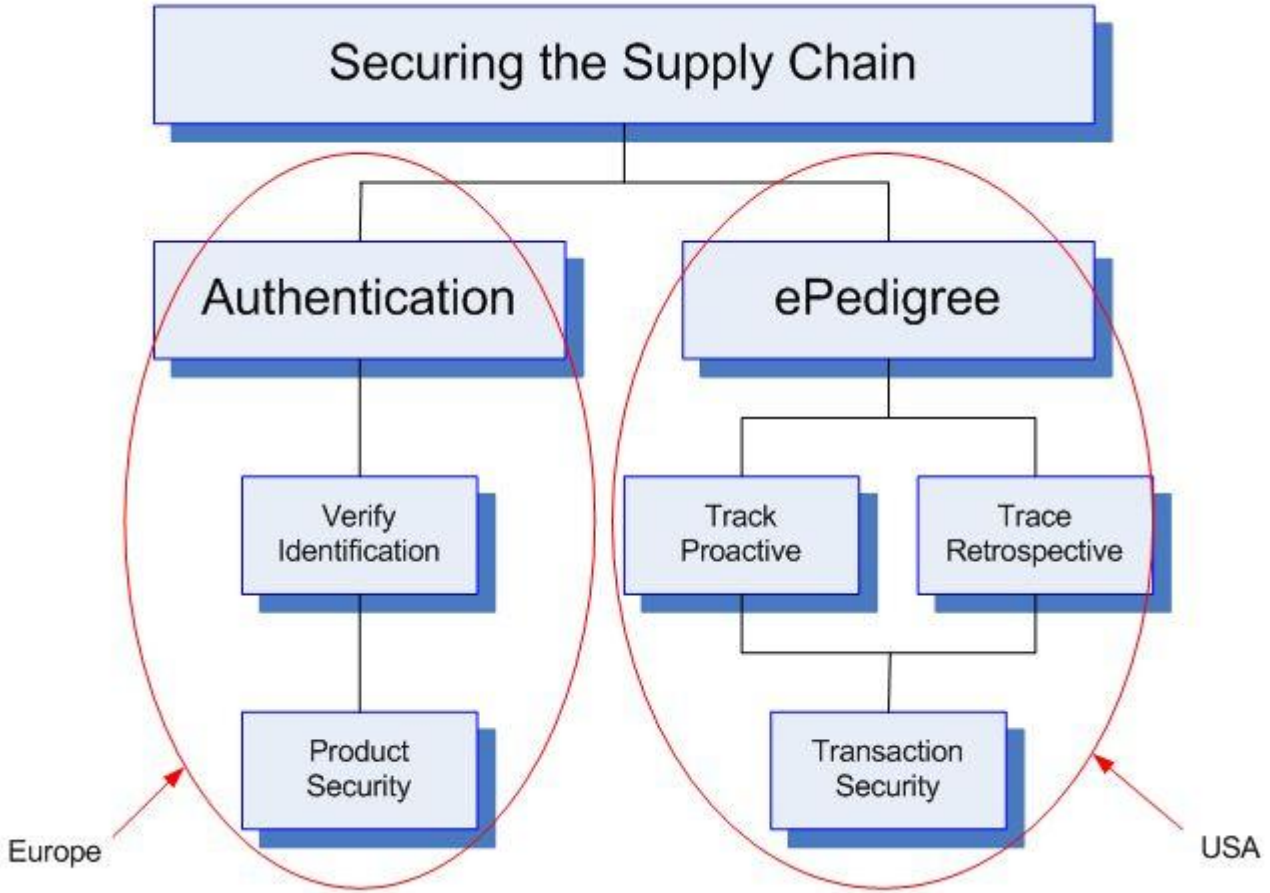
Optical (Camera)



Chemical (isotope, DNA)

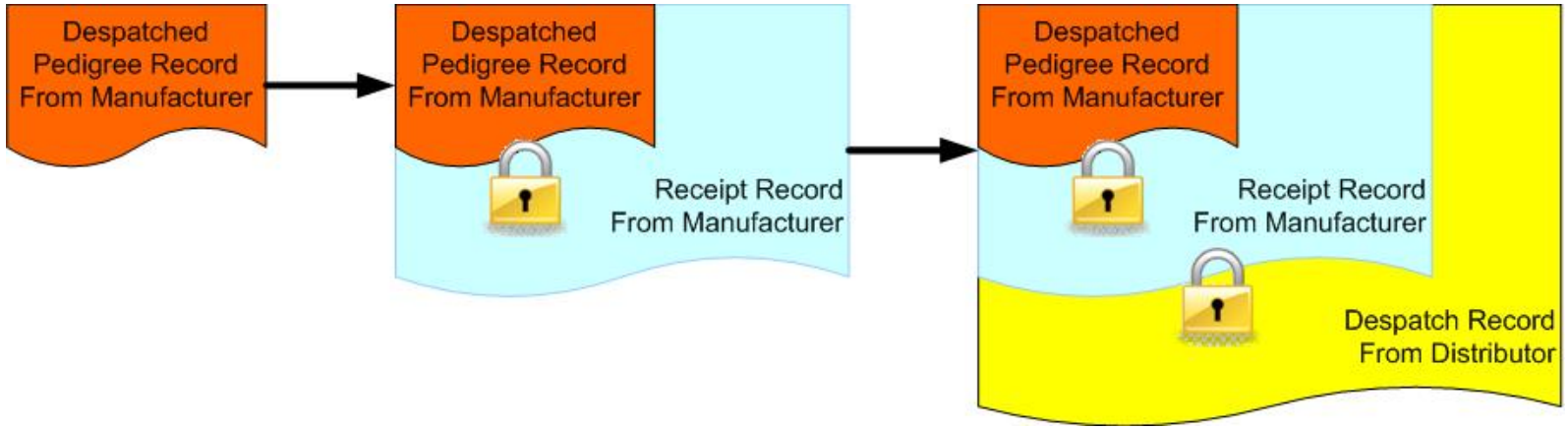
Microtaggants (nanotechnology)

Anti Counterfeiting strategies



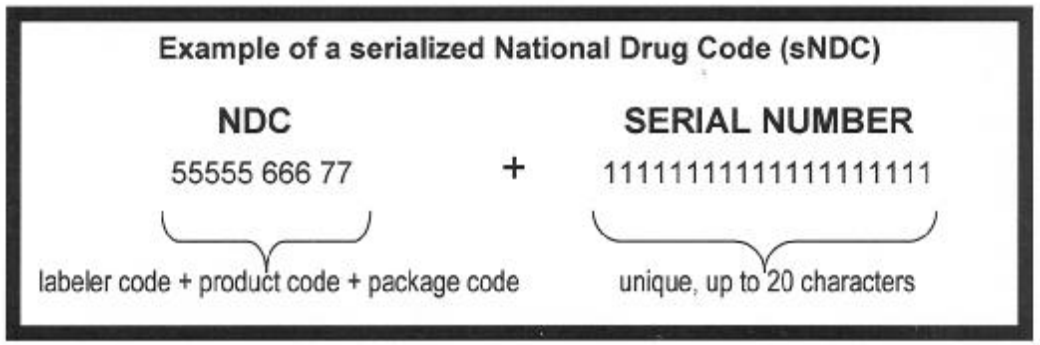
Pedigree

The USA are therefore planning for a fully electronic version of the pedigree standards which are being enforced today in some States by paper versions



Pedigree

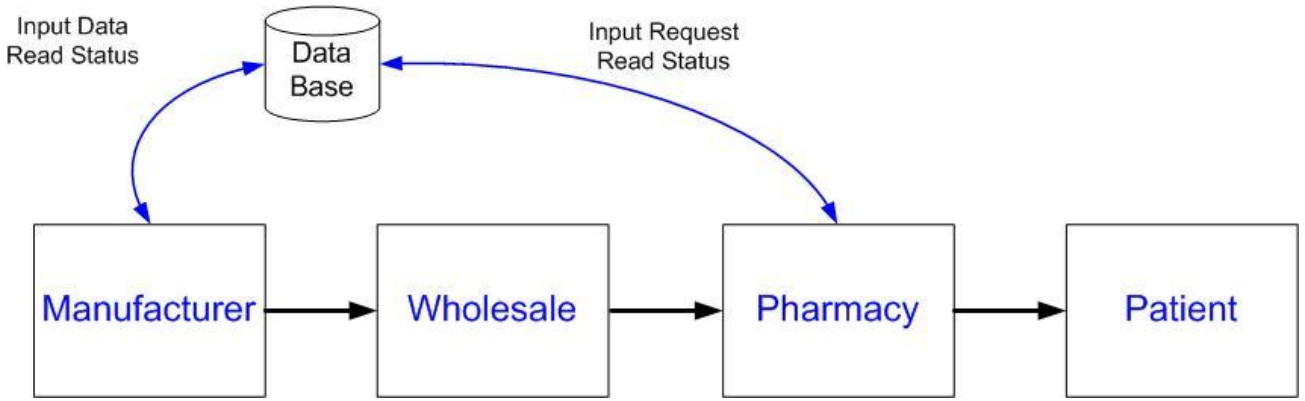
- On March 29th 2010 the FDA published the final version of the ‘Guidance for Industry Standards for Securing the Drug Supply Chain - Standardised Numerical Identification for Prescription Drug Packages’
- It describes the following procedure for item-level serialization
- The SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC)



Pack Serialisation

The EFPIA concept on coding and identification of Pharmaceutical products consists in two parts:

- The harmonization of pharmaceutical products codification throughout Europe via the implementation of a **serialized Data Matrix** (ECC200) on secondary packaging of all products sold in Europe
- The **verification** of pharmaceutical products at their point of dispensing (by the application of unique and non-predictive serial codes - USC's)



Pack Serialisation

USC's are produced and placed on products in two ways

Script form		2-D barcode
HK2IWF0HU20KA8M7	→	
253FIAEUGU2MMK7W	→	
WQ2HKAU1QE2X7GIF	→	

Human readable form

- human readable alphanumeric code
- easily readable by consumers
- each and every item has its own unique code

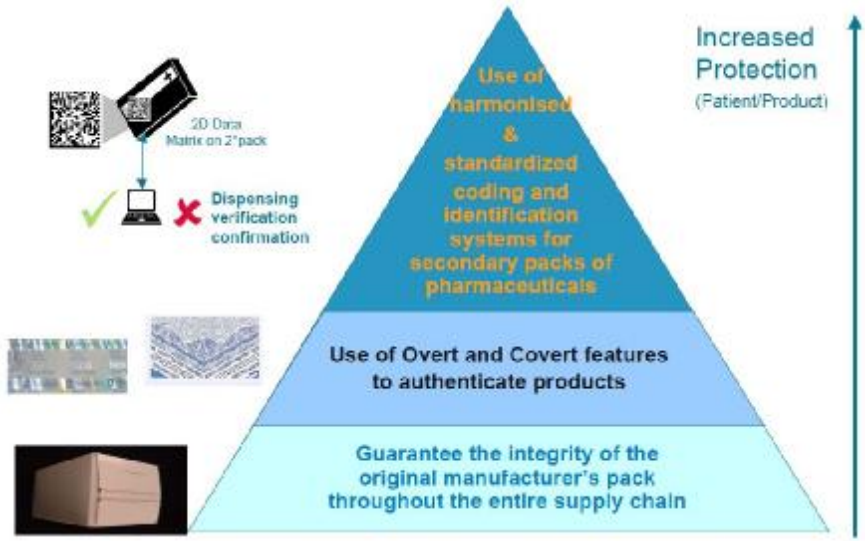
2D DataMatrix barcode

- international standard (widely in use now)
- new standard barcode readers capture the code
- new mobile phones can also read 2D barcodes!

Pack Serialisation

Mass serialization in Europe should be a reality over the next 4-5 years:

- Reinforcing the need for a unique standard for adoption in Europe in order to ensure the introduction of an efficient and cost effective system
- By: Data Matrix Barcode and human readable having unique non-predictive USC identity and other relevant data on each carton

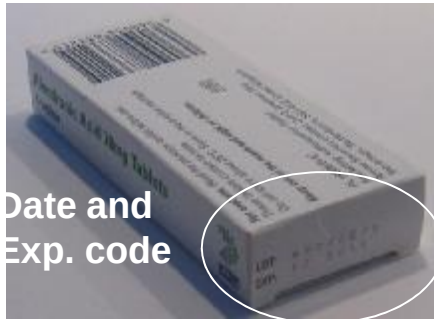


GTIN:	(01) 09876543210982
Batch:	(10)A1C2E3G4I5
Expiry:	(17)110531
S/N:	(21)12345AZRQF1234567890

Pack Serialisation

Traceability – the existing picture:

- Traceability is a requirement for both anti-counterfeiting and tax reimbursement
- Only at batch level
- Linear barcode including product code read automatically with a barcode reader at pharmacy level (best case and not in all countries)
- Batch number and expiry date usually written clearly



Pack Serialisation

Traceability - tomorrow:

- At unit of sales level (i.e. at carton level in Europe)

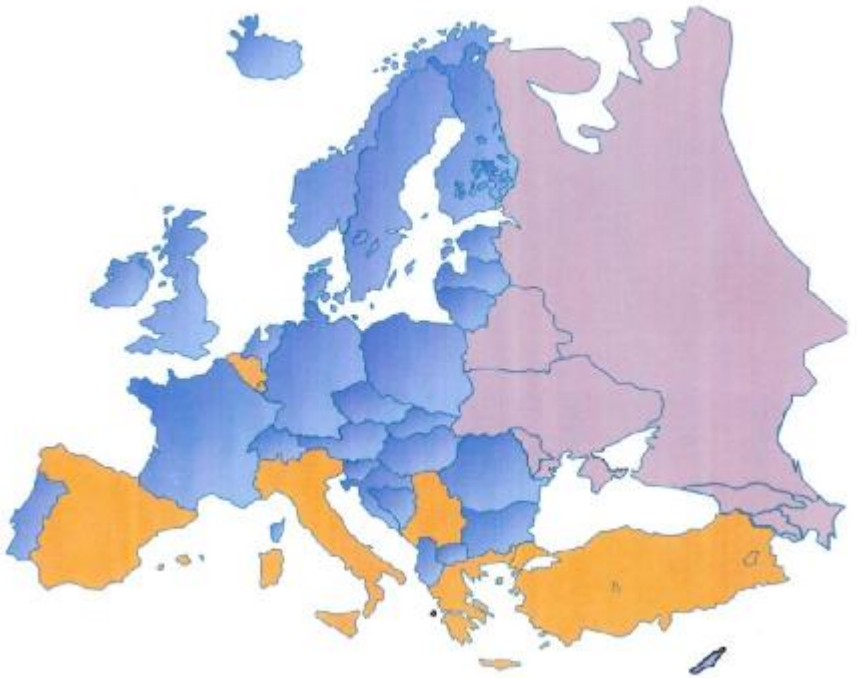
Product code (GTIN), batch number additional random, non-sequential code and expiry date will need to be included in a Barcode in order to be read automatically and avoid dispensing errors:

- Allow automatic detection of expired products
- Prevent counterfeits
- Fight reimbursement and tax fraud

Pack Serialisation - Geography

Traceability – today by geography:

- 4 countries (Belgium, Italy, Greece & Turkey) are already requesting a serial number for each pack (in addition to the national product code)
- Turkey is proceeding, having gone live in Jan 2010 with the EFPIA scheme
- 2 countries (Spain and Serbia) are currently working on new legislation mandating the use of a serial number



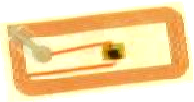
Picture courtesy of EFPIA

Pack Serialisation – RFID and Barcodes

Much has been written about the relative merits of RFID and Barcodes as data carriers for the new implementation of pharmaceutical pack serialisation

- While bar code labels are inexpensive, widely used, and based on open standards, they have disadvantages, but are the choice of the moment

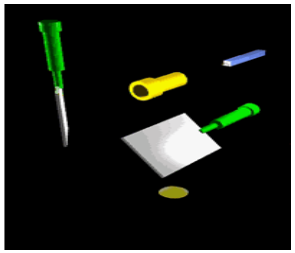
- RFID is more expensive than bar code technology, RFID standards are still evolving and physical limitations such as interference can affect RFID performance



Pack Serialisation - Technology

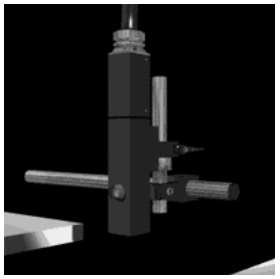
The Technology of pack marking:

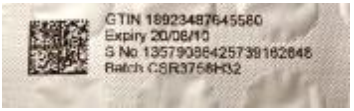
- Scribe (or ‘Vector’) Laser burns away upper layer (ablation) to leave white background, can provide codes of grades A, B and C



- Thermal Inkjet (TIJ) printing uses multiple print jets to print cartons in motion, can provide codes of grades A, B and C

- Continuous Inkjet (CIJ) printing uses a continuous stream of ink to print carton in motion, has attracted less attention due to perceptions of ‘mess’





Pack Serialisation - Technology

The Technology of pack marking:

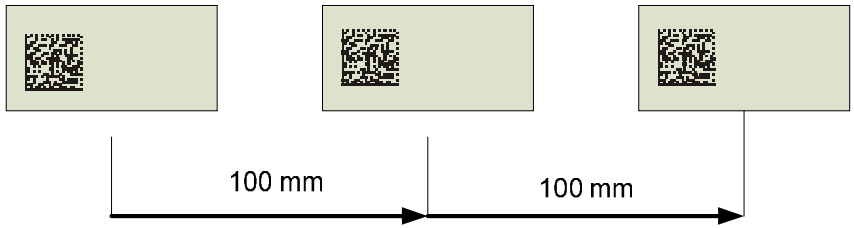
- Labelling – Unique pre-numbered labels applied to cartons or containers. Here print quality of grade A barcodes can be continuously supplied

- Labels or cartons may be printed locally off line or even have the printing ‘in line’ complete with serialisation. Here again print quality of grade A barcodes can be continuously manufactured

Pack Serialisation - Technology

The Technology of pack marking:

- Speed of marking



Pitch mm	100	100	100	100	100	100	100
cartons / minute	50	100	200	300	400	500	600
Linear speed m/min	**5**	**10**	**20**	**30**	**40**	**50**	**60**

Pack Serialisation - Technology

The Technology of pack marking

		L = < 20 metres per min M = 20-50 metres per min H = > 50 metres per min	Technology										
Material	**Example**	**Code Format**	**Continuous Ink Jet (Single jet)**			**Continuous Ink Jet (Duo jet)**			**Thermal Ink Jet**			**Laser**		
Medical Devices		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H
Tablets		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats	L	M	H	L	M	H	L	M	H	L	M	H
White Cartons (Porous / Varnish Free)		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H
White Cartons (Varnished)		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H
Coloured Panel / End / Carton (Porous / Varnish Free)		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H
Coloured Panel / End / Carton (Varnished)		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H
Plastic Pill Bottles		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H
Blister Foil		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H
I V Bags and Blood Products		Human Readable and DM up to 16 high (e.g. 2 lines of text)	L	M	H	L	M	H	L	M	H	L	M	H
		Large DM Formats (e.g. 3 lines of text or greater)	L	M	H	L	M	H	L	M	H	L	M	H

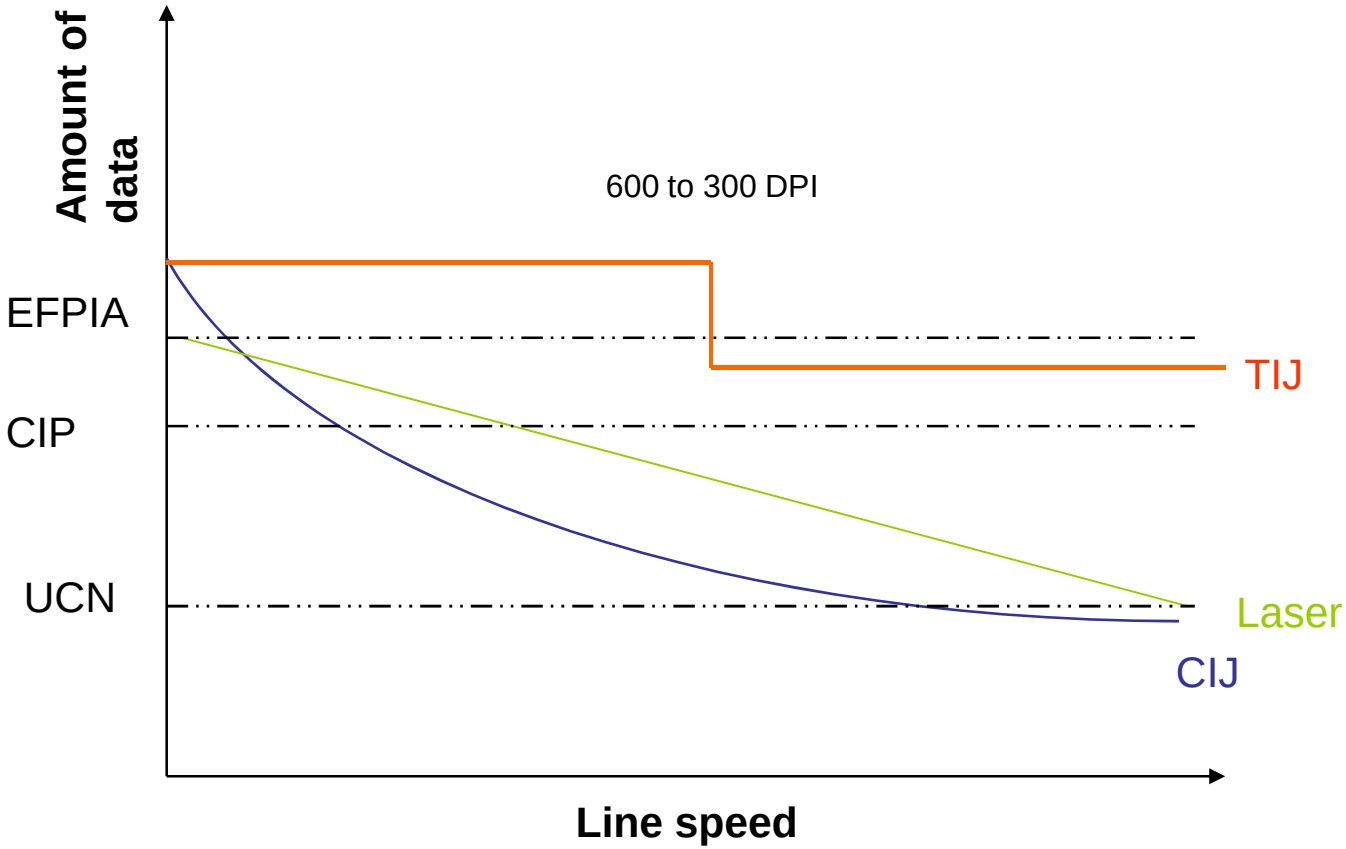
Table courtesy of Domino Ltd.

Pack Serialisation - Technology

The Technology of marking, below is an indication of the marking speeds of the comparative technologies;

3400935974419

ABC123456



Pack Serialisation - Technology

The Technology of marking Inspection:

Barcode reading requirements:

- Small
- Robust
- High speed
- GMP
- Barcode data transmitted over TCP/IP (Ethernet)
- Code grading?

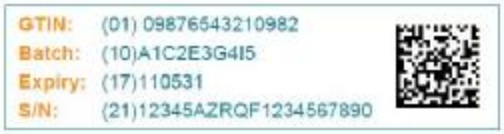
Picture courtesy of Cognex

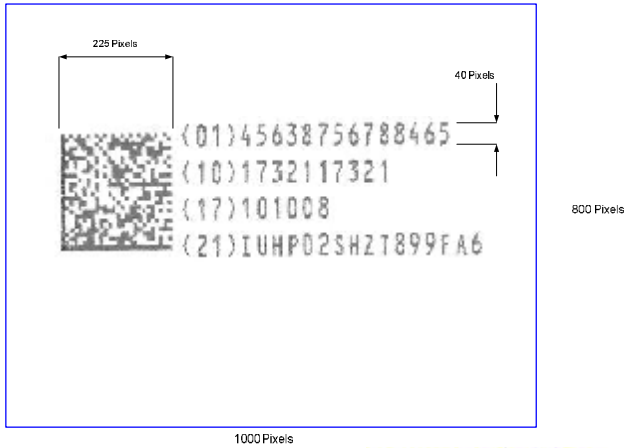
Pack Serialisation - Technology

The Technology of marking Inspection:

Vision system requirements:

- Small
- Robust
- High speed
- GMP
- High Resolution -1000 x 800 pixels minimum
- Powerful OCR capability, print quality as well as identity
- Data transmitted over TCP/IP (Ethernet)





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