


Pharmaceutical Solutions Update

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Athens
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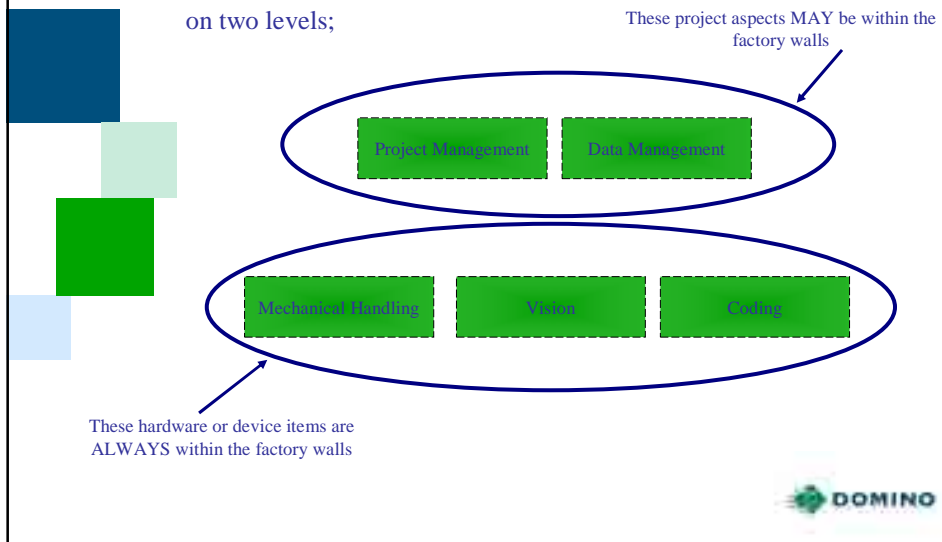
Agenda

- Components Overview
- Terminology
- Current Solutions
- Security Layers
- Requirements



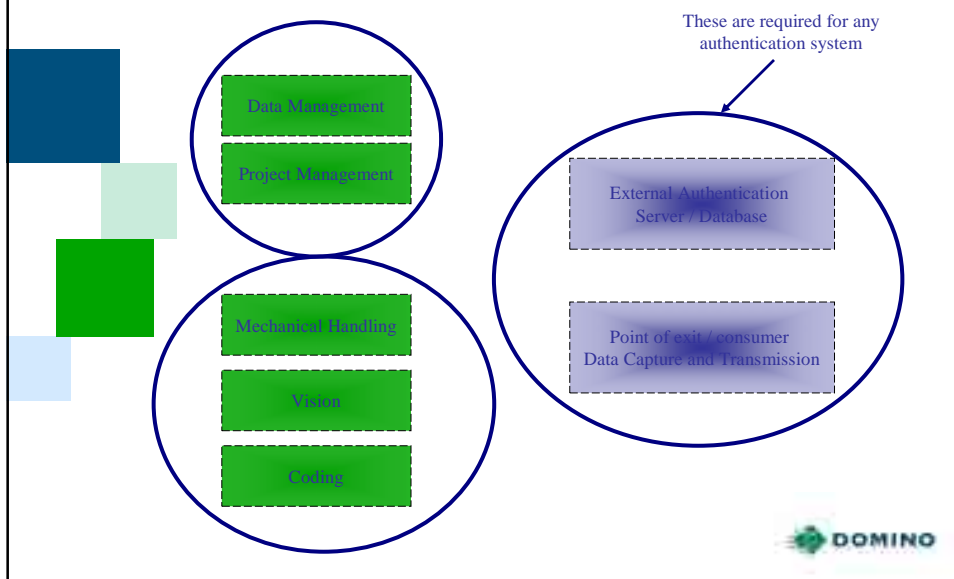
Components Overview

Due to legislative and potential requirements we find new projects within the pharmaceutical sector break down into five components on two levels;



Components Overview

There are often two additional components that are required;



Overview

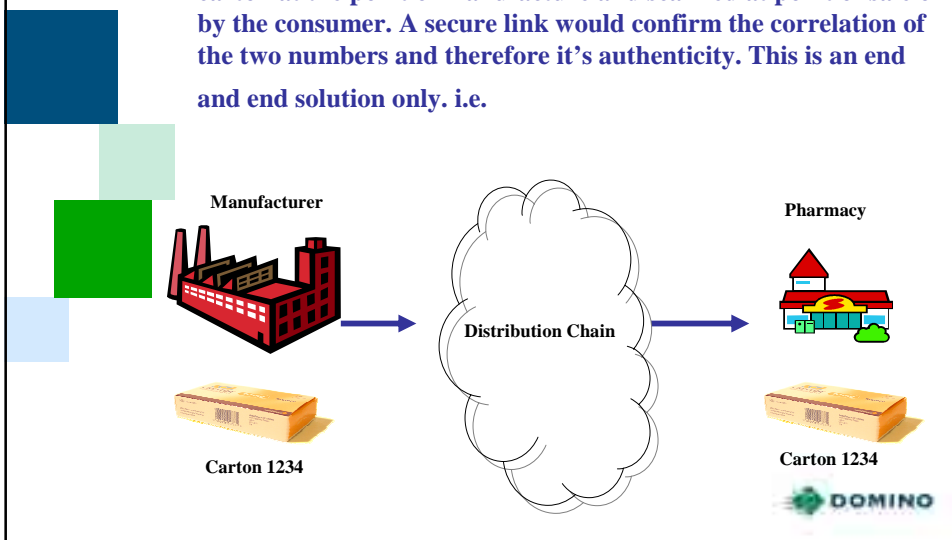
These slides are intended as a brief overview of some current terminology being used within the pharmaceutical sector, these terms are;

- Authentication / Mass Serialisation
- Security / Layering
- Aggregation
- (E) Pedigree
- Track and Trace



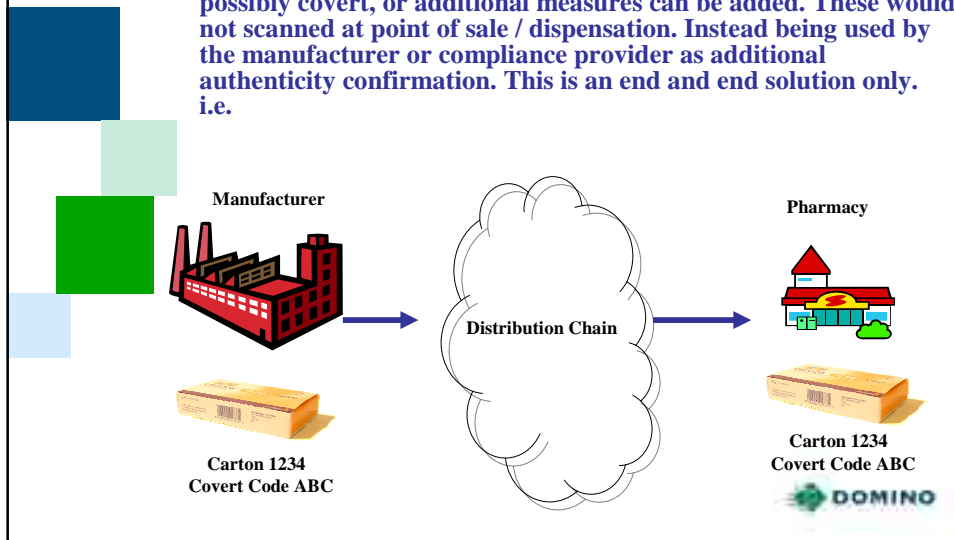
Authentication / Mass Serialisation

A unique and non predictive series of characters is printed on the carton at the point of manufacture and scanned at point of sale or by the consumer. A secure link would confirm the correlation of the two numbers and therefore it's authenticity. This is an end and end solution only. i.e.



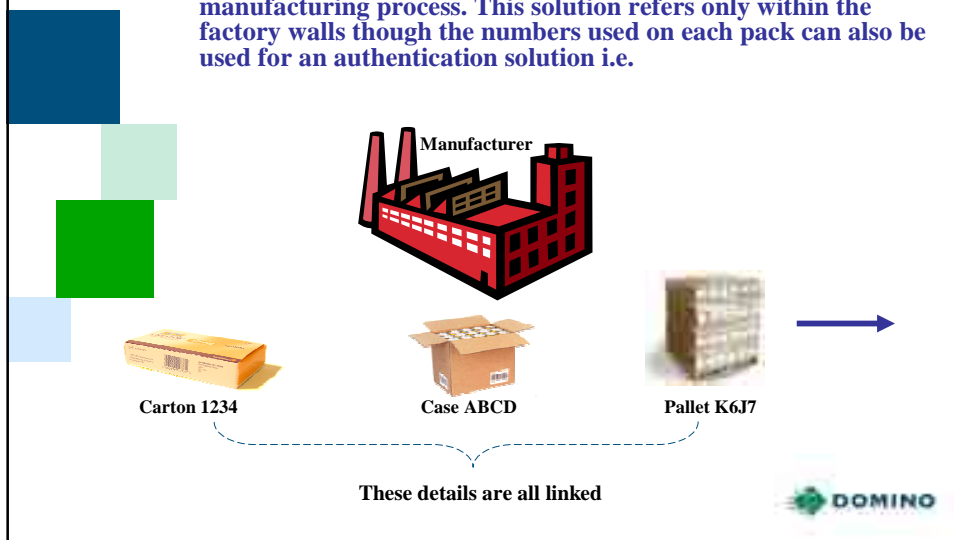
Security / Layering

As well as a unique and non predictive series of characters printed on the carton at the point of manufacture a second number, possibly covert, or additional measures can be added. These would not be scanned at point of sale / dispensation. Instead being used by the manufacturer or compliance provider as additional authenticity confirmation. This is an end to end solution only. i.e.



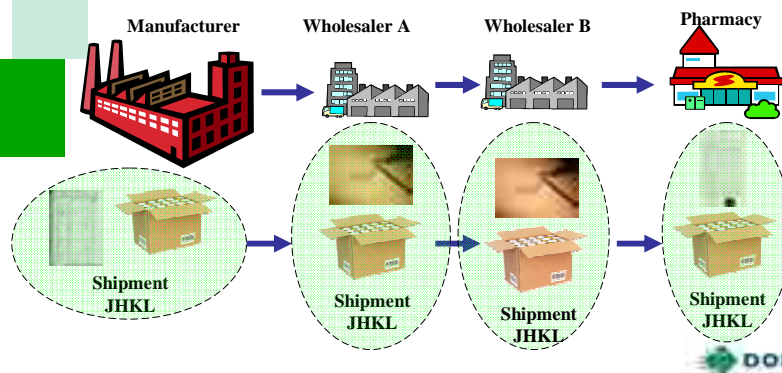
Aggregation

Unique character sets 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 i.e.



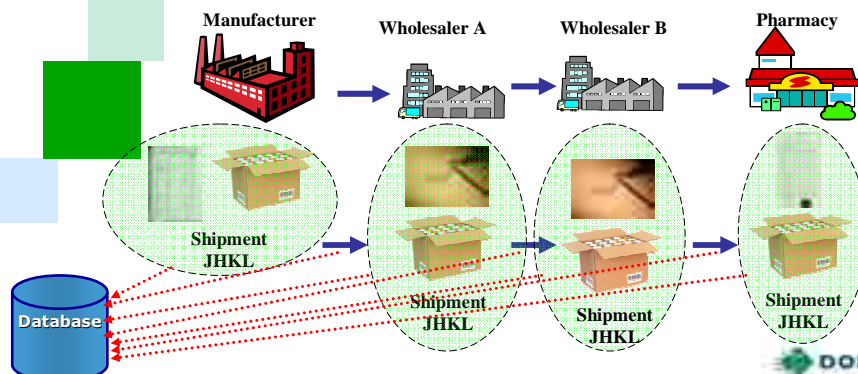
(E) Pedigree (Provenance)

- A unique identification number will track the prescription drug at the smallest package or immediate container distributed and is noted as received by each person in the distribution chain up to sale or dispensation.
- The pedigree is added to and allows each person to show a continuous chain of custody back to the original manufacturer with E signifying electronic.
- This is an end and end solution and can be in partnership to both aggregation and authentication solutions i.e.



Track and Trace

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. i.e.



Overview

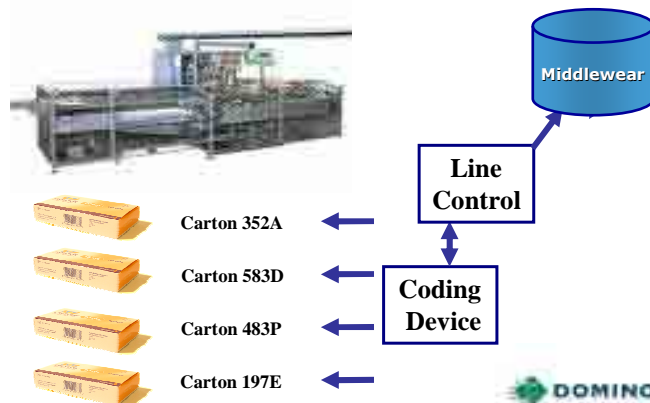
The next slides are a brief overview of some current solutions being used including;

- Mass Serialisation at Line
- Activation / Data Capture
- Middleware
- External Authentication



Mass Serialisation (at Line)

The generation and application of unique, non predictive numbers onto product (usually primary) at point of packaging. This can be done either individually or by a buffer method. Generally there is no relationship between any number and any specific carton until activation (see next slide).

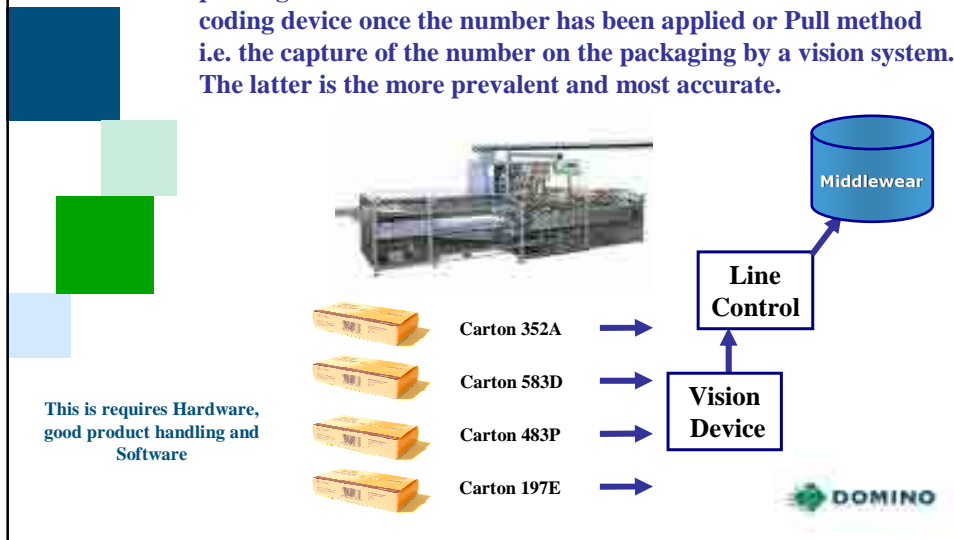


This requires Hardware,
good product handling and
Software



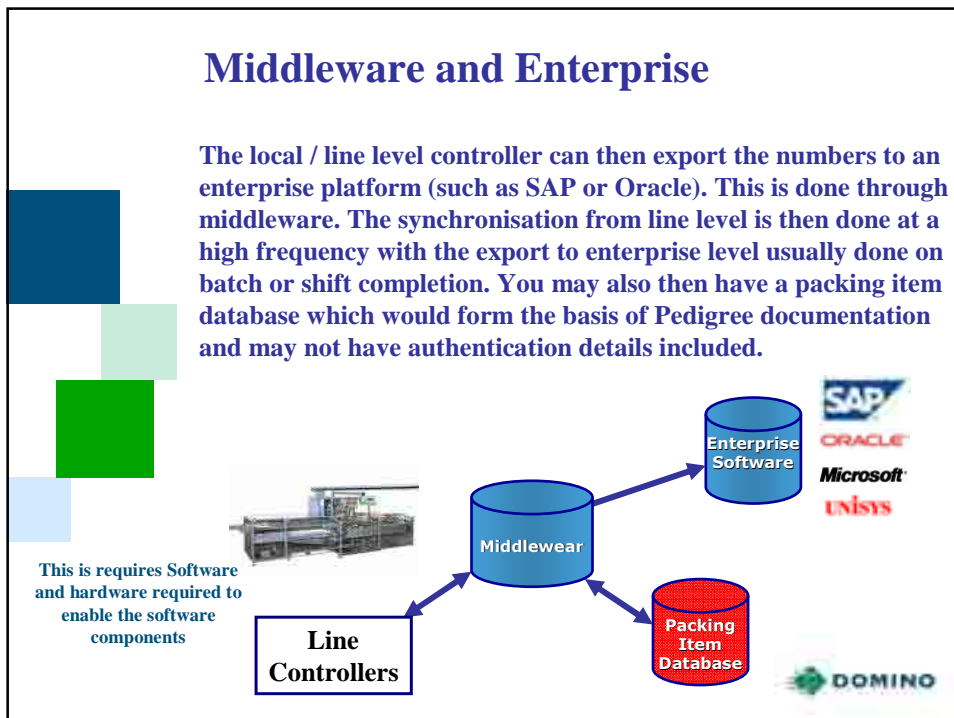
Activation / Data Capture

There are two methods to activate a unique number within the packing item database. The Push method i.e. Handshake from the coding device once the number has been applied or Pull method i.e. the capture of the number on the packaging by a vision system. The latter is the more prevalent and most accurate.



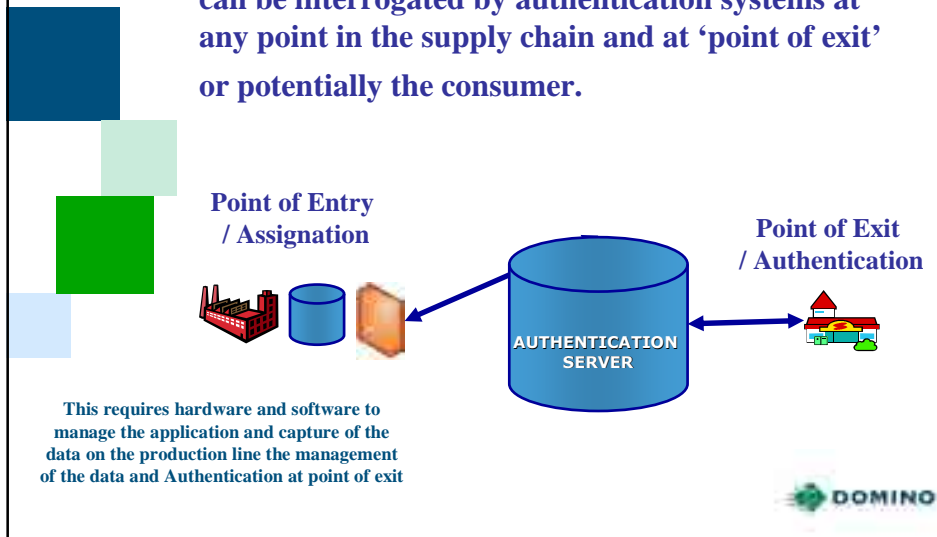
Middleware and Enterprise

The local / line level controller can then export the numbers to an enterprise platform (such as SAP or Oracle). This is done through middleware. The synchronisation from line level is then done at a high frequency with the export to enterprise level usually done on batch or shift completion. You may also then have a packing item database which would form the basis of Pedigree documentation and may not have authentication details included.



External Authentication

The data applied at 'point of entry' is managed and can be interrogated by authentication systems at any point in the supply chain and at 'point of exit' or potentially the consumer.



Security Layers

- There is a hierarchy of security being used by customers to protect their products;

1 st Level -	Overt
2 nd Level -	Covert
3 rd Level -	Forensic

Overt

- This is normally a secure and encrypted numbering system. There are different variants of these, predictive, non predictive, pseudo random and fully random.
- The number can be easily seen and is in human readable format to allow the consumer to easily authenticate via telephone or web system.
- OVD (optical variable devices), TEL (tamper evident labels) and colour shift technologies also fit into this category.



Covert

- This is normally an invisible or hard to detect method of marking. These can be used by Government Inspectors or Customs posts. Variants include;
 - Micro printing
 - UV / Fluorescence Marking

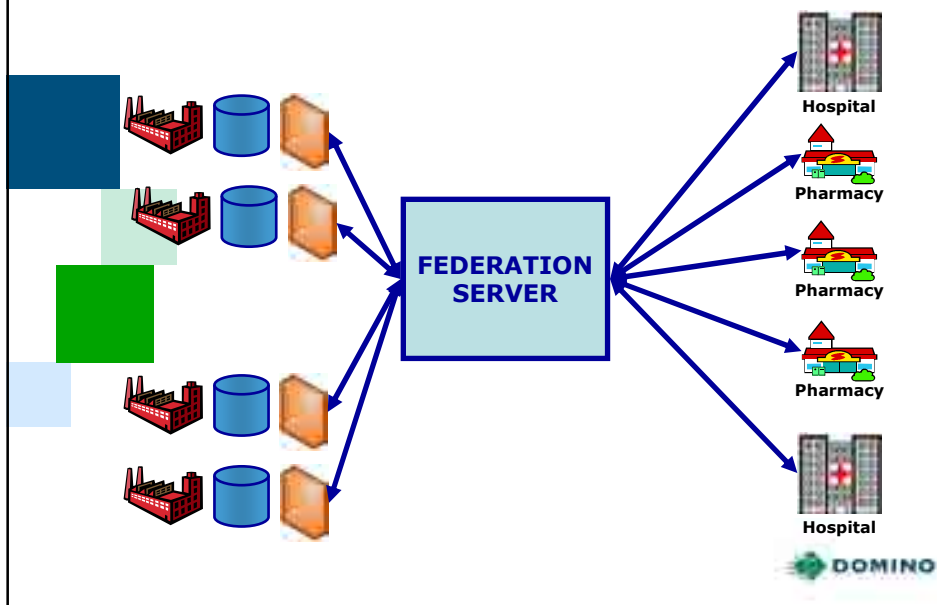


Forensic

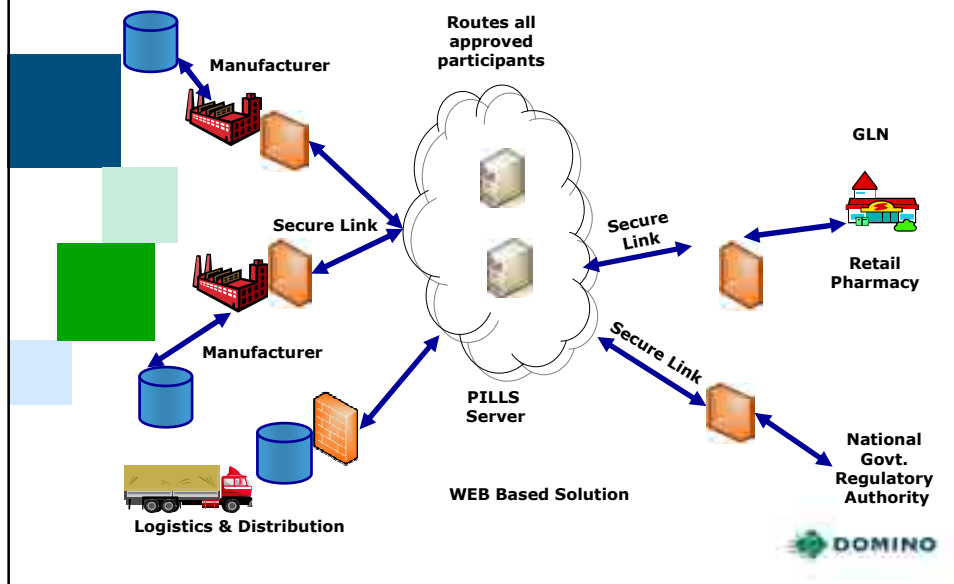
- The most secure method available and normally only used by the manufacturer for authentication, variants include.
 - Packaging Fingerprinting
 - Taggants
 - DNA Markers
 - Additives



Federation Concept for Authentication



Federation Concept – PILLS Server Diagram



EFPIA – Looked at other Globally Successful Structures

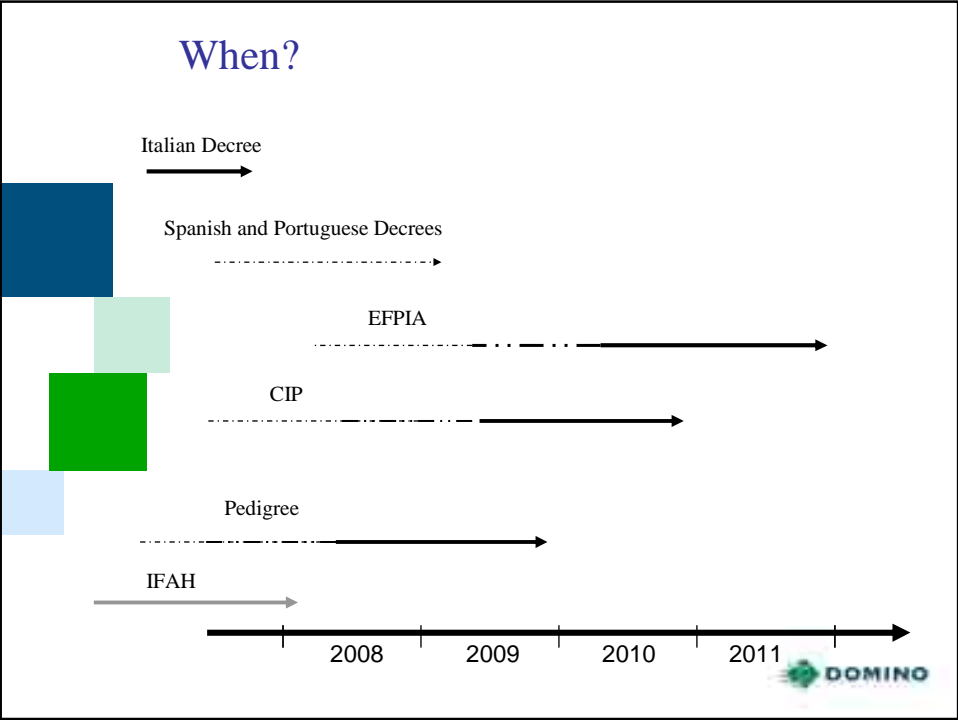
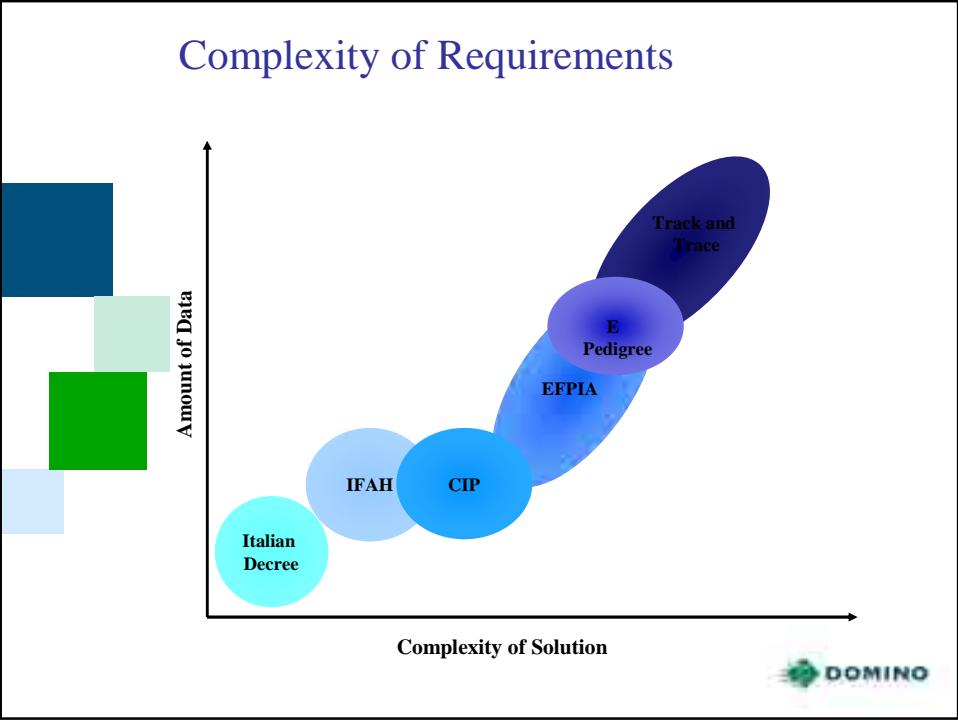
Based on NCHCD Blood Trial Developed by Domino
An SGTIN – Serialised GTIN using Global GS1 Standards and EAN 128 (Application Identifiers) to delineate the key elements

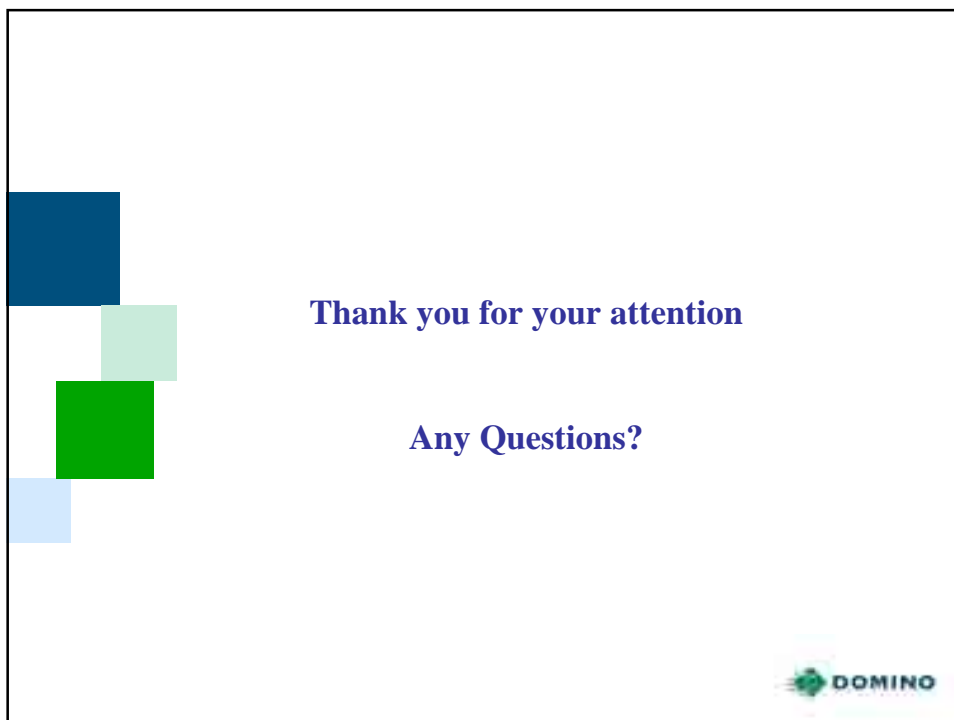
✦ GTIN/Country Code – GTIN has an application identifier of (01) and contains the article number or drug number and the manufacturer company prefix is 14 digits.

✦ Expiry Date – which has an application identifier of (17) and is a fixed length, 6 digit field of the form YYMMDD

✦ Batch Code – which has an application identifier of (10) and is usually a variable length field, alphanumeric in style and can be up to 20 characters long

✦ Serial Number – which has an application identifier of (21) is also variable length, also alpha numeric and can also be up to 20 characters long.





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