

SUPPLY CHAIN INTEGRITY

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Supply Chain Integrity

1. Pharmaceutical Supply Chain in Europe
2. Identification and Coding of Medicines

1. Pharmaceutical Supply Chain in Europe

- Complex and fragmented
- No consensus on approach
- Not transparent or consistent
 - Difficulties track and trace
 - Safety concerns: Counterfeiting, issues arising from parallel trade, batch recall capability

2. Identification and Coding of Medicines

Current Environment

Issue: Threat of fraud
Threat of counterfeiting

Reaction: Increase control of transactions



Result: MS each developing national coding initiatives, i.e.:

- Italy - Bollini Decree
- Belgium – Random id (EAN 128)
- France – CIP number (EAN 13)
- Portugal – Barcode (code 39)
- Netherlands – EAN solutions
- Others under review

Identification and Coding of Medicines

EFPIA Rational for Action

- Most MS implementing or planning reforms
- Lack of a clear position from European industry
- Increasing concern about patient safety
- RFID position

Identification and Coding of Medicines

EFPIA Objective

“ to better understand the issue of identification of pharmaceutical products and coding systems, review ongoing initiatives at European level and it’s implications for the industry and other key stakeholders, evaluate the need as well as pros and cons of a possible harmonisation at European level, and, if possible/appropriate, make a recommendation on next steps”

Identification and Coding of Medicines

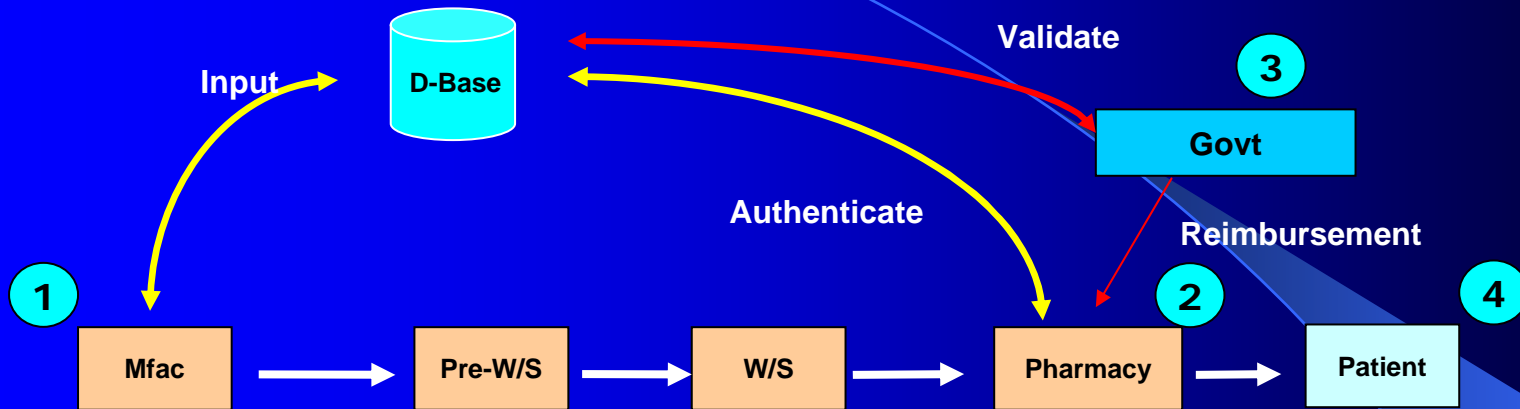
EFPIA Activity

- Coding Task Force created
- Reviewed European situation
- Looked at stakeholders needs
- Identified process to meet those needs
- Determined most appropriate technology

European Coding Solution

- Harmonised EU coding system could offer a more secure, effective and efficient supply chain:
 - Help in detection and prevention of counterfeit drugs
 - Facilitate authentication and avoid human errors
 - Improve supply chain performance
 - Improve patient confidence
- Key factors:
 - Investment needed, but better than 25 different systems + future cost efficiency gains
 - Establishment and ownership of European database
 - Need to authenticate at pharmacy

How will it Work?



1	2	3	4
Manufacturer	Pharmacy	Government	Patient
<p>Apply 2D barcode with mass serialised unique ID number.</p> <p>Pack read at end of line and information transferred to common secure database.</p>	<p>Read pack at point of dispense. Database accessed and pack validated. Other flags as required: recall, compliance message etc.</p>	<p>Immediate flag that pack has been dispensed by pharmacy. Can initiate reimbursement for specific pack, reduced risk of fraud.</p>	<p>Confidence in product, reduced risk of counterfeit.</p> <p>Transparency will improve supply availability</p>

Identification and Coding of Medicines

EFPIA Recommendation

Adoption of a 2D (Data matrix) barcode to be introduced across Europe

- Easiest solution for entire supply chain.
- Meets basic safety, tracking and logistic needs
- Technology is available, can be implemented at MS/EU/Global level
- Ensure process works
- Demonstrate commitment to patient safety

Recommendation approved by the EFPIA Board

Distribution Group currently working on implementation guidelines



BACK UP



Identification Code

Definition of “code”.

“The application of a product identifier unique for a specific pack”.

Comparisons Completed

Solution	2D	EAN 128	EAN 13	RFID
Fraud	✓	✓	✗	✓
Counterfeit	✓	✓	✗	✓
Authenticate	✓	✓	✗	✓
Track & trace	✓	✓	✗	✓
Size	✓ ✓	✗	✗	✓
Implement Now	✓	✓	✓	✗
Cost	Medium	Low	Low	Very High

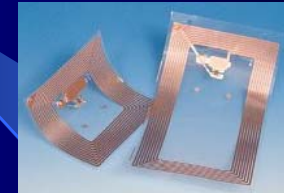
Coding Examples



EAN 13 Code



2D Code



TAG RF ID