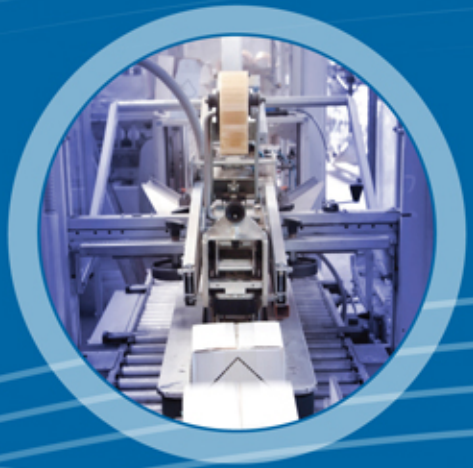
Connecting People, Science and Regulation

Serialisation and Track & Trace regulations on pharma packaging



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Agenda

1) Brief introduction of Edelmann Group

2) Drivers for serialisation and track & trace requirements on pharma packaging

3) Market requirements – Overview over country specific requirements for barcoding and serialisation

4) Closer look at Brazil and at the European Union

5) Case study CFDA China Barcoding – Code 128 C

6) Effects and consequences for the pharmaceutical and packaging industries

7) Conclusions / recommendations for the practice

1) Brief introduction of Edelmann Group
Facts and figures 2014

- Turnover: 238 Mio. € in 2014
- 3,5 billion folding cartons per year
- 1 billion package leaflets per year
- 2.200 staff members
- 7 National plants in Germany
- 6 International plants in France, Poland, Hungary, Mexico, China, India
- Family owned company

2) What are the drivers for serialisation and track & trace requirements on pharma packaging

Main drivers: Counterfeit of medicines, theft, diverted products, fragmented supply chain, reimbursement control

1) Need to improve patient safety – fight counterfeit of medicines - global
Reduce the risk of counterfeit products being dispensed
Detect expired products automatically
Perform product recalls more effectively and efficiently
Deliver the right product to the right patient
Same applies to stolen and diverted products

2) Fragmented supply chain, e. g. in Europe with different coding schemes implemented or proposed by different EU-Member States
Increase manufacturing complexity, production costs and supply chain differentiation across the European market

3) Reimbursement control, e. g. Turkey
Support governments with their reimbursement processes

Projection: 70% of all pharma packages will be serialized by 2020

2) What is the regulatory impact on operations? – Some definitions

Serialization

ØApplying a **unique** identification code to the retail unit of sale

Authentication

ØConfirming the authenticity of the unique identification code, typically at the point of dispense

Track and Trace

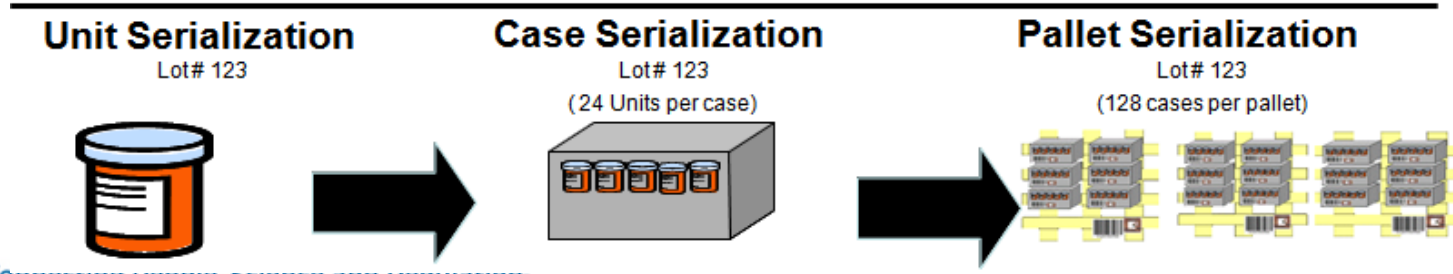
ØDetermining the location of product as it moves through the supply chain

ePedigree

ØDocumenting the chain of ownership of the product as it moves through the supply chain

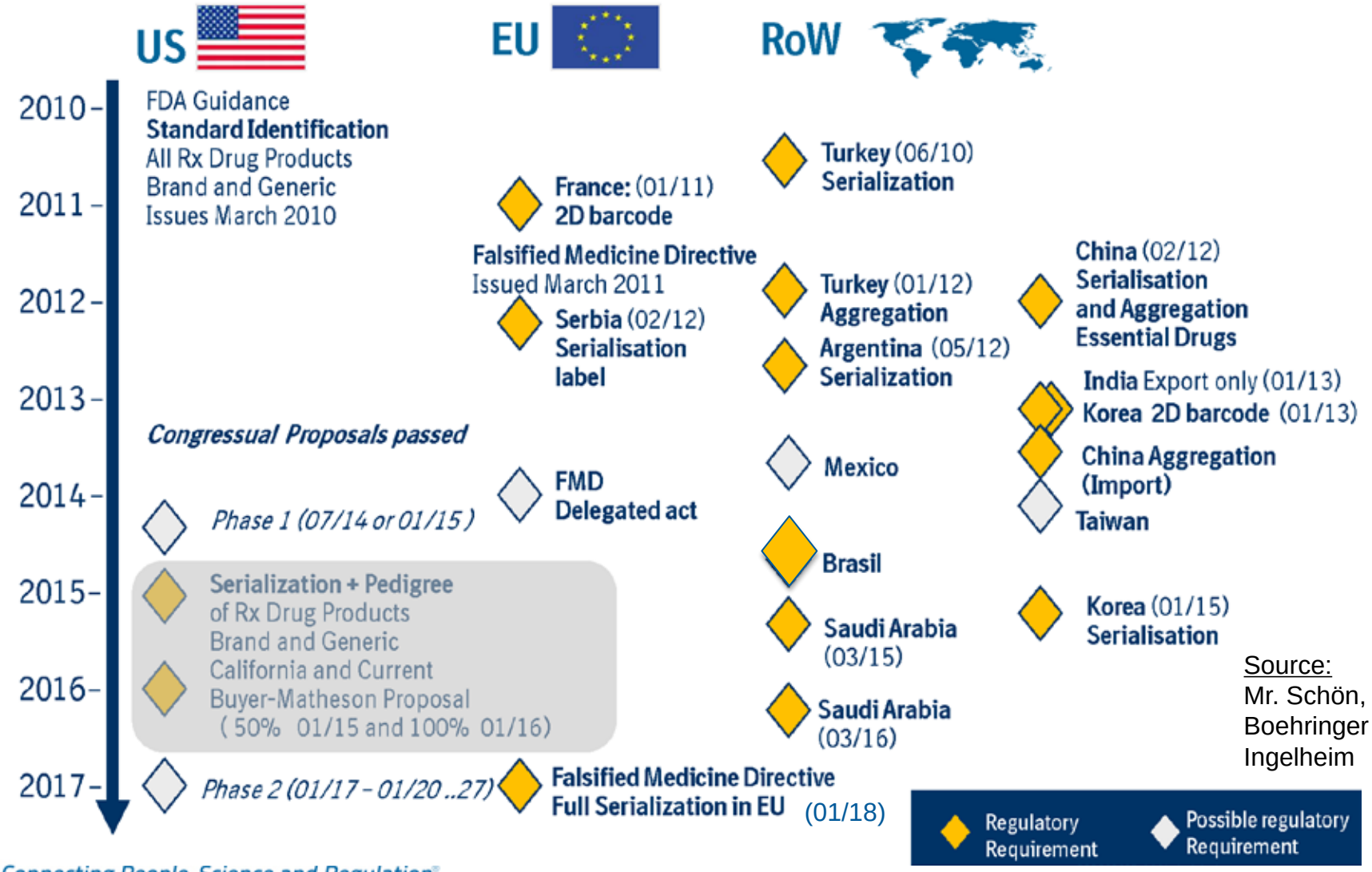
Aggregation and Inference (required for Track & Trace)

ØEvery item, case and pallet is assigned a serial number
ØItems are aggregated to cases (parent / child relationship)
ØCases are aggregated to pallets
ØUnit level serial numbers can be “inferred” by reading the case or pallet serial number



Source:
Pfizer

3) Market requirements – Overview over country specific requirements for barcoding and serialisation



Source:
Mr. Schön,
Boehringer
Ingelheim

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3) Market requirements – Overview over country specific requirements for barcoding and serialisation

Country	Level	Data	Format	Timing	Code
India	Sales Pack	GTIN, Serial No., Batch No. & Exp. Date	GS1 128 (linear) or GS1 2D – outer packaging. GS1 2D - immediate packaging	Current	1D or 2D
China	Sales Pack	Manufacturer Code, Serial No. & Check Digit	6 Digit Numeric, 9 Digit Serial No., 4 Digit Check No. (EAN/ UCC-128-C 20)	Current	1D
Korea	Sales Pack	Product Identifier, Serial No., Batch No. & Exp. Date	GS1	2015	2D
Japan	Biologicals - Unit	Batch No.		Current	2D QR Code
Brazil	Sales Pack (primary pack suspended)	Serialised Unique Identifier Medicines (IUM), GTIN, Reg.No., Batch No. & Exp. Date	GS1, 2D Data Matrix 9 mm x 9 mm, security seals	Current	2D
Argentina	Sales pack	Product Identifier, Serial No.	1D or 2D Matrix	Current	2D
Canada	Sales Pack	Product Identifier	GS1, Safety Seal	Current	2D
US	Saleable item	Serial No., GTIN, Batch No. & Exp. Date	GS1	2017	2D

Source: Mr. Kastrup, Meda

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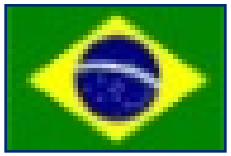
4) Market requirements - Closer look at Brazil and at the European Union - Brazil



ANVISA Published Resolution – RDC 54/2013 - Dec 11, 2013
Manufacturer to apply a Unique Identifier of Medicines (IUM)

IUM to include: - 13 –digit ANVISA Registration Number (NHRN)
- 13-digit Serial Number (Randomization Required)
- Serial number must be unique across all products not per GTIN
- Lot
- Exp

GS1 Standards Not Specified but May be Used

2D Data Matrix Bar Code
- Track-and-Trace Solution
- Aggregation Required
- “Real Time” Feed of Data to Database
- Third Party to Administer Database

Common Carriers included in track-and-trace requirements

This means: Track & Trace (central database); 3 batches must be done by 2015-12-10. All products must be serialized by 2016-12-10.

Source:
Pfizer, Optelvision

4) Market requirements – Focus on the European Union – safety features of the EU-falsified medicines directive

Directive 2011/62/EU amending Directive 2001/83/EC ~ EU-falsified medicines directive (FMD):

The outer packaging of a medicine must contain the following information:

***1. „Safety features**, that enable distributors and persons, that are allowed to give out medicines to the public, to*

– ***verify the authenticity of the medicine***
– ***identify individual pack***

European stake-holder model (ESM)

Product #: (01)09876543210982
Batch: (10)A1C2E3G4I5
Expiry: (17)140531
S/N: (21)12345AZRQF1234567890

→ securPharm

ESM
A MEDICINES VERIFICATION SYSTEM FOR EUROPE

2.** as well as a **device**, that allows to verify, **if the outer packaging has been manipulated ("tampered with").

→ ***European Standard EN 16679 "Tamper Verification features"***

4) Market requirements – Focus on the European Union – safety features of the EU-falsified medicines directive

2 Safety Features

Individual identification feature
"unique identifier"
Serial number (2 D Data-Matrix-Code)
Precision in "delegated acts"
Testing via securPharm / ESM
Base: EFPIA-Data matrix Project

Anti-Manipulation feature
„tamper proof evidence", better: „tamper verification feature"
Several possibilities: Glue points, gluing seal, cellophane wrapping, specially constructed folding cartons, emerging technologies;
Decision by the manufacturer

What will the Delegated Acts contain?

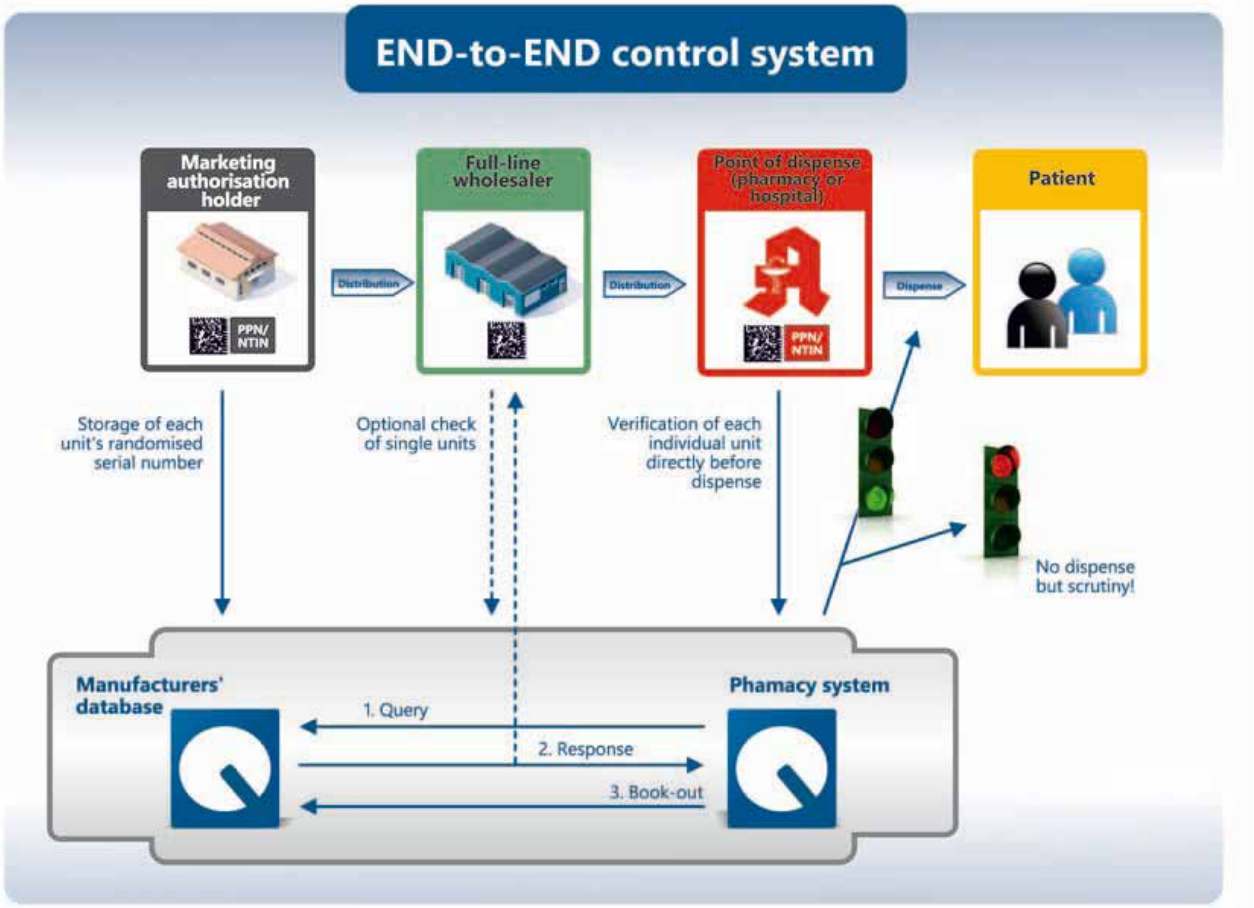
- Technical specification of the data carrier: 2D-Datamatrix
- Mode of verification of the safety features: End to end
- Requirements for the data base systems: Stakeholder Model
- Exceptions to apply the safety features for Rx-medicines / requirements to apply for OTC

Source: Mr. Brückner, BPI

But: Regulations, which medicines are for prescriptions, are nationally different
Shall bear (= Must) for Rx vs. shall not (= forbidden) for OTC
National regulations may go beyond the FMD / delegated acts
Publication Delegated Acts: 2015, safety features required in 2018

4) Market requirements - Closer look at the European Union - German Organisation securPharm - End-to-end

German system securPharm, ongoing since test start January 2013, linked to European-Stakeholder-Model, www.securpharm.de



Data:
Product Number
Serial number
Lot.-Nr.
Expiry date;
8,8 Mio. packs in the test system,
88.600 verifications

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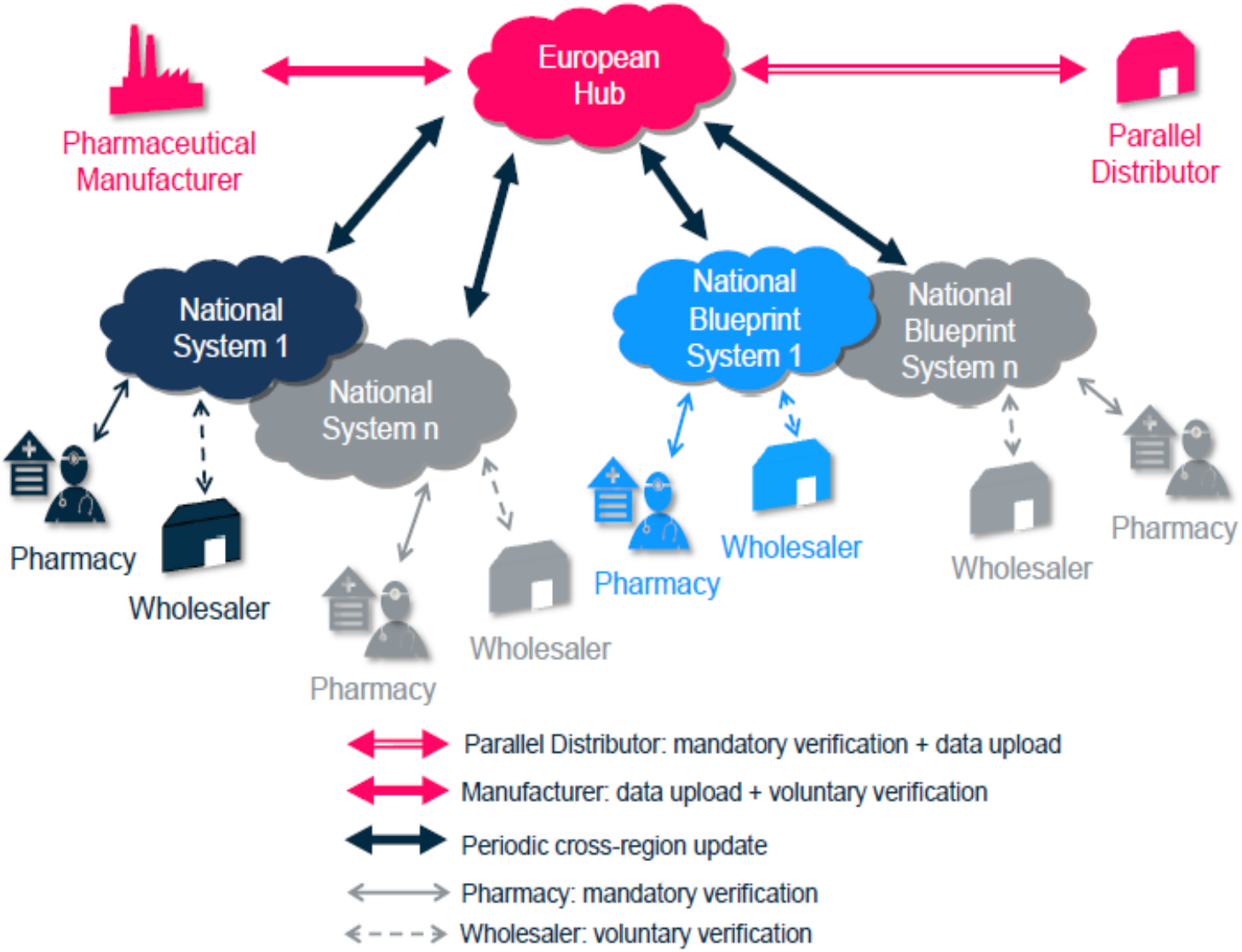
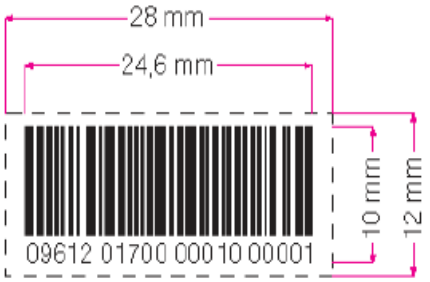
4) Market requirements - Closer look at the European Union - European Stakeholder Model (ESM)



5) Case study CFDA China Barcoding Code 128 C

- With effect from 31st Dec. 2015 all pharmaceutical products situated in Chinese market must have a serial CFDA barcode!
- CFDA-Barcode quality specifications / requirements
- Print specifications

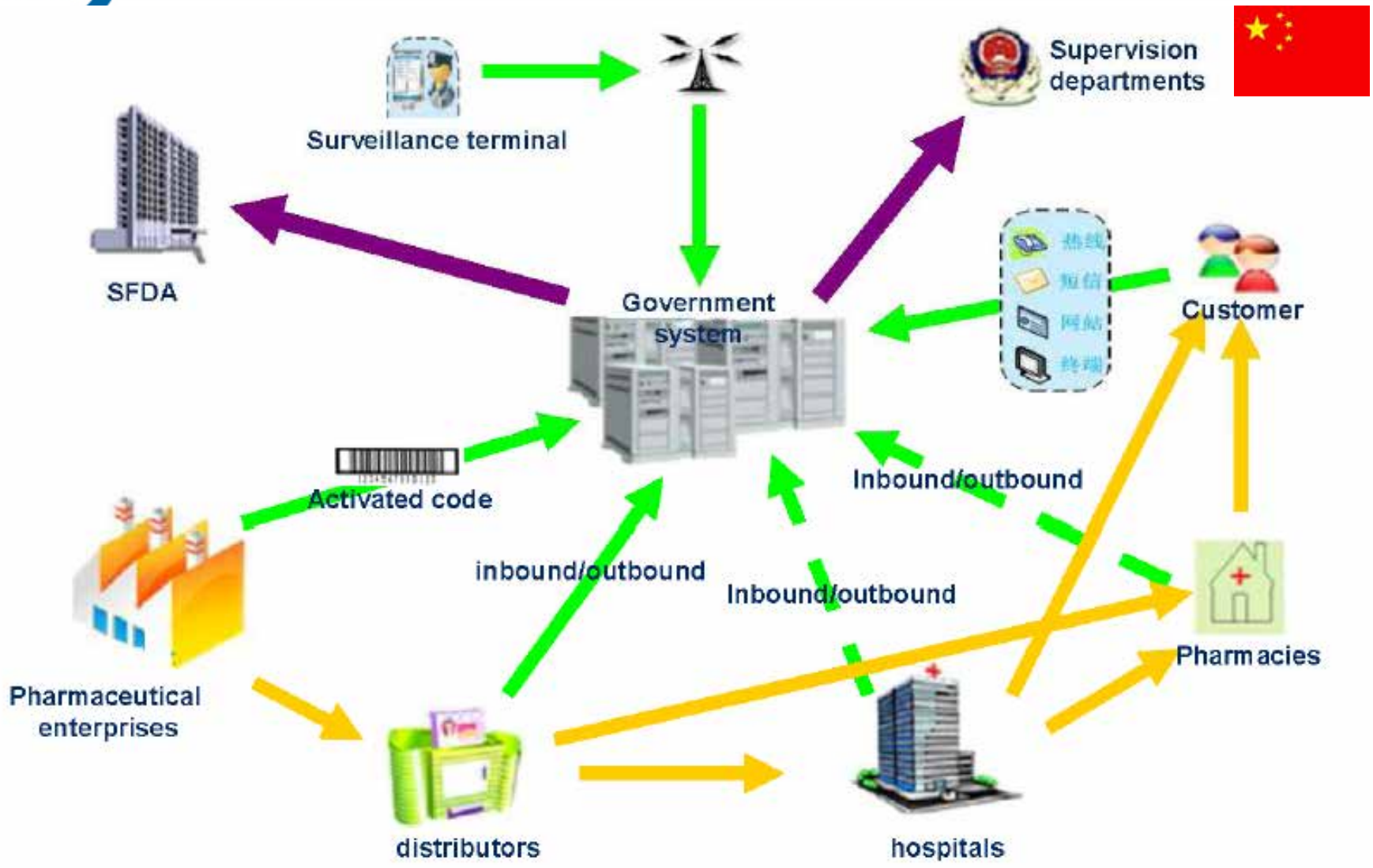


Minimum barcode dimensions at 7mils !

Print quality shall be 2,5 or better, statutory requirement is at least level C.

parameters	value
Bar code type	Code 128C
Bar code density	≥7mils
Bar code height	≥8mm
Data type	digital
Length	20 digitals
Bar code printing color	black
Readability	>C class
The minimum width of margin above or beneath of bar code	≥1mm
The minimum width of margin beside bar code	≥10X, X ≥ 0.17mm X mens module width

5) Case Study CFDA China Barcoding CFDA-System



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5) Case Study CFDA China Barcoding Effects

- Packaging machines must be equipped for reading the CFDA-barcode and aggregation of the folding cartons to the outer boxes (level 1).
- Change of the folding carton layout is required: text- & varnish-free area.
- China-barcode should be part of the packaging specification/artwork.
- Tbd: How to call off the EPC-numbers from the CFDA, how to transmit them (read them into the ERP-System and export them), how to check?
- The EPC-codes can be printed and verified at the folding cartons producer. This reduces complexity.

- Which random samples and controls before, during and after coding?
- Which products, formats, volumes are affected? -> Subcontractors?
- Need for an interdisciplinary team, resources, management commitment, test runs and pilot tests

Internal team members should include someone representing the following departments within the organization:

- Engineering
- Operations
- Scheduling
- Validation
- Label/Package Design
- Sourcing
- Information Technology
- Quality
- Supply Chain/Logistics
- Regulatory/Legal
- Client Services

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7) Conclusions / recommendations for the practice

6) Effects and consequences for the pharmaceutical and packaging industries

a) A layered approach towards packs protection

b) Combination of tamper verification features with anti-counterfeit features

c) Higher security by tamper verification features on product packaging and transport packaging

d) Need for Comprehensive IT / Printing / Reading systems

e) Plan for serialisation and for tamper verification features

f) Additional benefit via mobile / internet based Track & Trace Solutions

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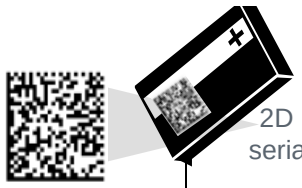
6a) A layered approach towards packs protection



2D Data Matrix / serialized code on 2 ° pack

Dispensing verification confirmation

Increased Protection (Patient/Product)

Use of harmonised coding and identification systems for secondary packs of pharmaceuticals

Product Identification

Use of overt and covert features to authenticate products

Product Authentication

Guarantee the integrity of the original manufacturer's pack throughout the entire supply chain

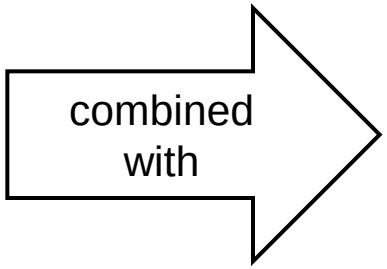
Product Integrity

Source: EFPIA

6b) Combination of tamper verification features with anti-counterfeit features

Closure possibilities

- Gluing
- Originality labels
- Film wrapping
- unglued/by design



ACF-features

- Varnish free areas
- Security labels
- Holograms
- Single station coding

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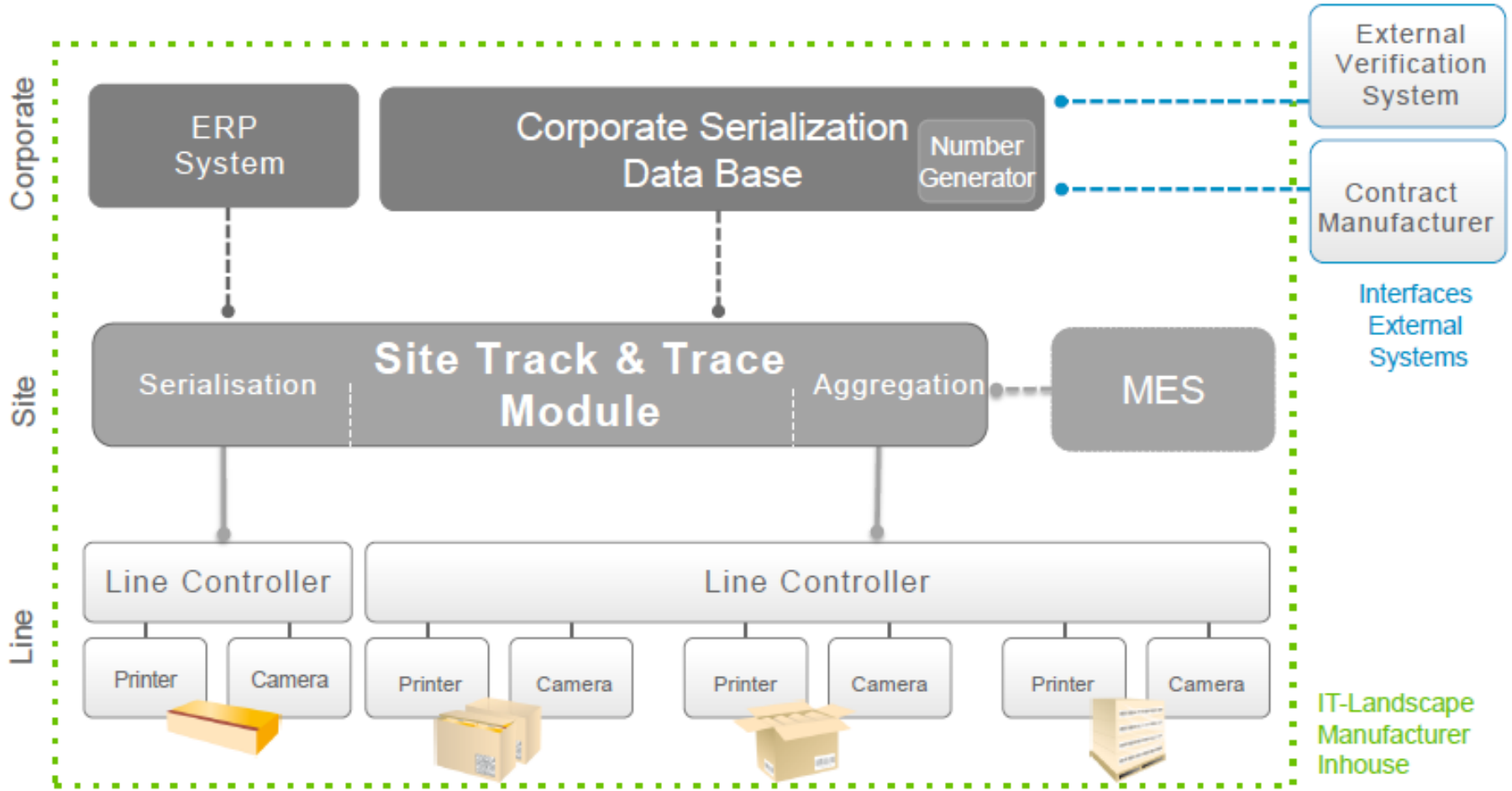
6c) Higher security by tamper verification features on product and transport packaging

Tamper verification features on product and transport packaging

Source: Mr. Kastrup, Meda

6d) Need for Comprehensive IT / Printing / Reading systems - Corporate, site and line levels



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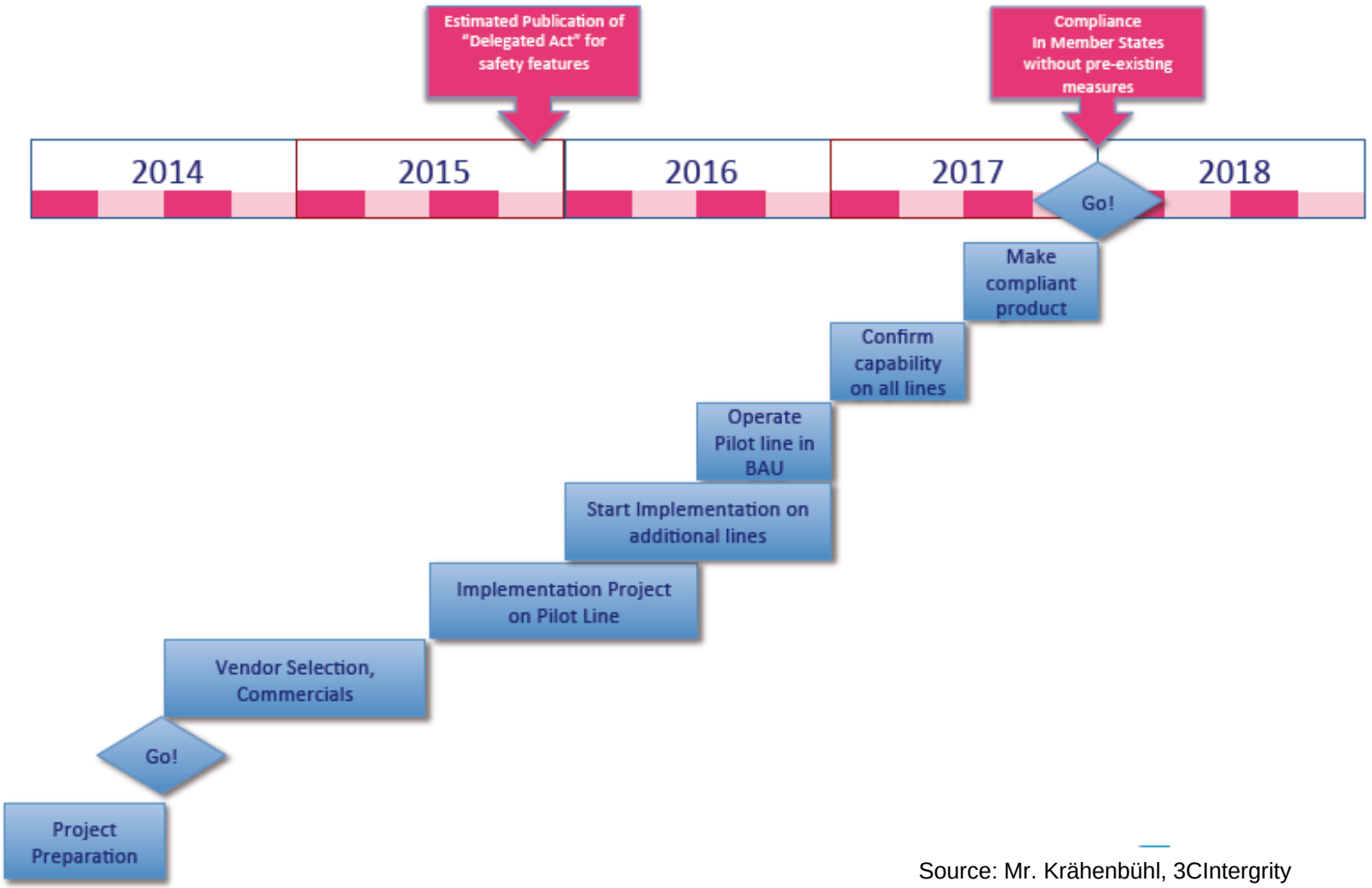
6e) Plan for serialisation and for tamper verification features

„Hope for the Best, Plan for the Worst“



Source: Mr. Krähenbühl, 3CIntergrity

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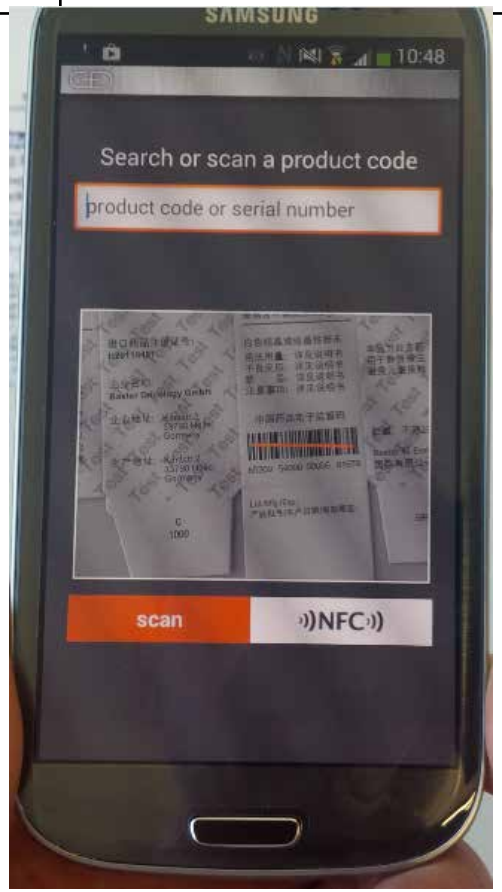
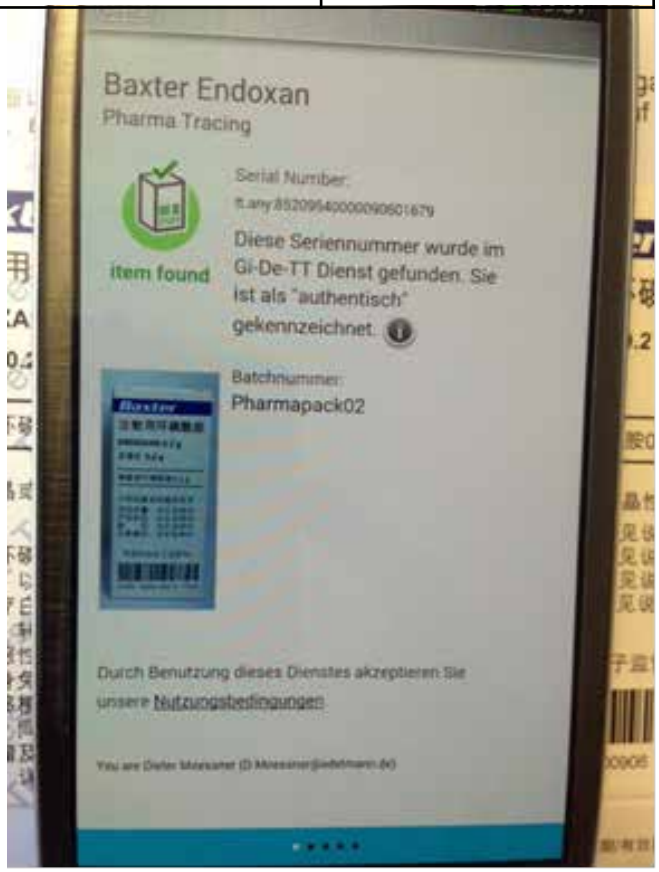
6f) Additional benefit via mobile / internet based Track & Trace Solutions

Switch on mobile phone (button top right), Insert PIN and press “OK”, start TT-Application.	Move the camera over the China-Code of the folding box. The camera automatically detects the China-Code and carries out the authentication.	The result will be displayed.





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7) Conclusions / recommendations for the practice

a) Start, don‘t wait!

b) Which products, markets, volumes are affected (subcontractors?)?

c) Do you need to serialise? If so, then please process the packaging change together with the change of the tamper verification feature.
-> Change of the artworks, provide space for serialisation code, selection of the tamper verification feature, change / notification of regulatory, change of packaging specification.
-> Definition, choice, and validation of the serialisation code and the tamper verification feature (one for all - country-/product specific?)

d) Time plan, release of budget and resource planning

e) Install an interdisciplinary project team: Packaging material, regulatory, purchase, technics, IT, production, logistics, QM, etc.

f) Validate the tamper verification feature: It must survive the supply chain

g) Make test runs and pilot tests, plan the roll-out

Edelmann Group

Thank you very much for your kind attention.

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