Mass Serialization and Traceability

Implementation in the Pharma Industry

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What drives the industry towards more “traceability”

Strategic thinking & a long-term vision required

Roche's roadmap

A few Take-home messages
An ongoing focus towards more control & security in today’s global Pharma Supply Chains

The Importance of Packaging is Increasing in Pharma

- **Product security**
  - counterfeits
  - diversion
  - theft

- **Patient safety**
  through Barcoding & a safer Product Identification
  - bed-side scanning
  - avoid medication error
  - 5 patient’s rights
  - mobile computing authentication

- **Process integrity & Transaction security**
  with Traceability at Sales Unit level
  - chain of custody / accountability
  - protect industry reputation
  - combat re-imbursement fraud
  - supply chain visibility
  - trust
  - recall effectiveness

- **E-supply-chain & Digitization**
  as a transformational and sustainable trend
  - m-health / e-services
  - e-leaflet
  - mobile computing authentication
  - sales unit level data (payers)
An ongoing focus towards more control & security in today's global Pharma Supply Chains

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**MAH’s responsibility:**

- **Increase Confidence & Demonstrate evidence** that product is safe & secure *from manufacturing till it reaches the patient*

- **Building in intelligence** and **sophisticated features** into primary & secondary packaging
  - “Interactive” packaging
  - “intelligent” packaging
The outcome: the sales units gets unique and tamper-proof
A unique number to identify each single tamper-proof sales pack

Roche is global GS1 member

Level 1: 2D-CODING and Serialization

- **Serial Number**
  - A unique number assigned to a single unit
  - A randomized numeric code

- **Material Number**
  - GTIN / NTIN

- **Data Carrier**
  - Machine readable

- **Human Readable Information**

- **Tamper Evidence**

- **Overt/Covert Anti-Counterfeiting features**
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Roche approach: **Vision + backward** planning

What we didn’t want: «Classical» **Incremental** approach

**Think BIG**  **Start SMALL**  **Scale FAST**

- French Coding
- Korea SER
- Brazil T&T
- E-pedigree
- EU VPD
- TE …
Where do we see this journey going…

Do not focus on one specific requirement; Instead, put in perspective

From Product Security… … to Transaction Security & Digitization

Product & Company specific brand protection measures

Patient verification. Unique IDs & Industry approach given

Safe transactions & trading partners
Co-operation
Industry & National authorities

Intelligent packaging
Packaging gets a vital part of the product offering, for increased patient safety & customer services

Traceability

Secure e-Supply Chain

E-services

M-services

The country maps indicate what the country targets as of today
Strategic thinking & a long-term vision
What our approach is from beginning

- A cross functional global effort
  - ensure standardization, interoperability and integration
  - Strong global drive & close cooperation with local implementation teams / SME’s
  - This is not only a technical project

- Develop and implement an adaptable/scalable technical standard solution
  - Co-develop with vendor
  - A constant mix of prototyping, conceptual design and operational implementation

- Work together with other stakeholders
  - authorities, standard bodies, associations, peers, trading partners, vendors…

Accept the challenge as an opportunity
Success through a collaborative approach
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A few Take-home messages
A long term effort

Phase O
Strategy defined, prepare execution

Phase I
Proof-of-concept, built a working infrastructure (E2E) & fulfill short term requirements

Phase II
Ramp-up & fulfill mid-term requirements

Building the infrastructure while fulfilling regulations

MAXIMIZING BUSINESS VALUE

EU, US timelines known. Define implementation pace

Foundation in place
Prepare implementation roadmap

Packaging line upgrade

Implementation Effort

We are here
As a consequence, we have to upgrade all packaging lines and build a new IT-infrastructure while ensuring continuous supply.

The “PHYSICAL WORLD”

- International standards!

The “DATA WORLD”

- Coordination of various vendors requiring strong and robust planning under consideration of capacity bottleneck at OEM vendors
- Regulatory developments with impact on program timelines
- Roche supply constraints

Consider line/site switches
Build bridging stocks in alignment between supply planning-site planning team
Consider workarounds e.g. offline printing

Roche
It is not only about line upgrades & IT tools!
People & Functions are impacted, requiring a strong change management

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<th>Impacted functions</th>
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<th>Commercial Operations</th>
<th>DC Operator</th>
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**Manage Demand**
- Maintain country/regulatory requirement database in master data / BoM / recipe
- Maintain Product # / GTIN in master data (MDMS, MLS)
- Manage artworks change

**Produce Quality Product**
- Print/verify Product # on pack
- Transmit serial # ranges to MLS, LC
- Print/verify Serial # on pack
- Collect serial # from MLS, LC and transmit to OER
- EDI – interface monitoring

**Assess & Release Material**
- QC-testing & grading acceptance criteria
- Manage serialized samples
- Manage deviations / OoS

**Manage Logistics & Distribution**
- Create ASN to trading partner
- Report data to MoH database
- Manage customer’s authentication request
- Manage delivery of serialized/aggregated products in warehouse
- Transfer serialized products between CoE/CMO and DC’s
- Exception handling in warehouse

**Change management**
the REAL challenge of the implementation of mass serialization
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A few Take-home messages
Onboarding of HC actors by continuous scope extension

See the example of Turkey’s implementation roadmap

What’s next? E-leaflet?

App for patient verification

E-prescription / e-invoicing

Tracking & Tracing

Verification at dispensing + scanning based Re-imbursement

Barcoding & Item Serialization

In scope
40’000 Stakeholders
• Hospitals
• Health Centers
• Family Physician Centers
• Pharmacies and Pharmacy Warehouses
• Manufacturers
• Importers
• Reimbursement Institutions

Figures & Facts today
Number of drug types in ITS: 18 900
Number of drug units in ITS: 7 000 000 000
Number of daily operations in ITS: 45 000 000
Number of operations per second in ITS: 520
Response time of system: < 1 sec
ROI in ONE YEAR!

The same can currently be observed in Argentina & in Korea (live since 2010/2013)

2015+?

2014

2013

2012

2011

2010

Patients

All Health providers

Wholesalers

Pharmacists

Pharma Industry

Onboard & Connect

Onboard & Connect

Reach out to public

MoH builds IT infrastructure & Database

Apply 2D Barcode / Technical features
Applying a 2D Barcode on the packs is just the beginning of the journey… and it’s not only about Traceability.

- **Digitization** of supply chains with efficiency increase
- **Interaction with payers** e.g. by supporting value-based pricing models
- New **e/m-patient behaviors** e.g. mobile computing authentication, e-leaflets
- **Paperless** transactions e.g. prescription, reimbursement and dispensing
- New type of scanning-based **customer services**
- It can support new practices arising from **Personalized Medicine**

A great opportunity for a new kind of **HEALTHCARE INNOVATION**
Doing now what patients need next