Pharmaceutical Serialization

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Topics

- Pharmaceutical counterfeiting – a global pandemic
- Serialization – another tool in the toolbox to fight fake medicines
- Regulatory environment – serialization and Track & Trace regulations around the world
- Other business values beyond compliance
Counterfeiting – How bad is it?

- In some developing areas of Asia, Africa and Latin America up-to 30% of retail sales are counterfeit.
- 50% of sales on the internet are illegal.
Impact of counterfeit drugs

According to Interpol more than 1 million people die each year from counterfeit drugs.

Comparing with other causes of death:

- The mortality of HIV/AIDS in 2016 was 1 million people (WHO, The Top 10 causes of death, Jan. 2017)
- Road injuries killed 1.4 million people in 2016 and this is the 8th leading cause of death (WHO, The Top 10 causes of death, Jan. 2017)
SERIALIZATION – ANOTHER TOOL IN THE TOOLBOX TO FIGHT FAKE MEDICINES
What is serialization?

• Serialization adds a unique identifier (serial number) to the finished pack, typically the outer carton.

• In addition to the serial number, other key data elements such as the batch number and expiry date, and product identification number are printed on the packaging.

• This information is also included in a 2-dimensional barcode for more efficient use in processing.

• This information is used throughout the supply chain to track or verify authenticity.
**Identify:**
This requirement specifies the information that need to be printed on the saleable unit, case and pallet and the standard that need to be followed. It includes information such as GTIN, serial number, batch, expiration date, etc. GS1 is the most widely adopted standard.

**Capture:**
This requirement defines how the data needs to be encoded. (i.e. barcodes) so that it can be captured by scanning technologies. This requirement includes the standard and symbology (2D GS1 Datamatrix, GS1-128 linear) for the barcodes.

**Share:**
The sharing requirements specifies how the serialization and relevant context data need to be shared externally. This requirement defines the file layout with data elements and business events that need to be shared. The sharing could be done by uploading the data to the Ministry of Health database or to the customer receiving the product and it differs for each market with no single global standard.
Common Identify and Capture requirements

Packaging Level where serialization is applied

- Serialization starts at the “smallest saleable unit”. This is usually the carton that holds the primary package (or it could be the primary package if that is the smallest saleable unit). Smallest saleable unit is the lowest packaging unit that a manufacturer can sell to a pharmacy.

- Serialization needs to be applied to primary package only if the primary package is sold as the smallest saleable unit.
Traceability of product packages are achieved by using the captured serial number and product identification information to track the movement of the product in the supply chain. The following are the two most popular traceability models:

1. **Point of Dispensing Verification**

2. **Full Track and Trace**
Point of Dispensing Verification

Manufacturers | Wholesalers | Distributors | Pharmacists | Patients

Product Movement

Data Movement
1) MAH reports commissioned serial numbers to the EU hub
2) EU Hub Routes Data to the National Databases

Note: There is no reporting or tracing of movement throughout the supply chain in this model.

Authenticate Number at Dispensing

Successfully authenticated serial numbers are then flagged as dispensed (decommissioned)

This model has been adopted in EU, implemented via the Falsified Medicines Directive Delegated Regulation
Full Track and Trace

1) Manufacturer reports commissioned serial numbers to the national system
2) Each downstream supply chain entity reports their movement of serial numbers

1) Pharmacies report serial numbers received
2) Patients may (country dependent) self-verify serial numbers

This model has been adopted in Turkey, Argentina, South Korea, China, Saudi Arabia and Russia.
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**Important:** Primary package serialization is extremely complex and expensive to implement and does not add much benefit to protect the product.
REGULATORY ENVIRONMENT – SERIALIZATION AND TRACK & TRACE REGULATIONS AROUND THE WORLD
OTHER BUSINESS VALUES
BEYOND COMPLIANCE
Value of serialization beyond compliance

What some of the business drivers for serialization?

- **Product Protection & Patient Safety**
- **Reimbursement:** Improve payment monitoring and prevent reimbursement fraud
- **Supply Chain Visibility and Efficiency**
- **Recall Improvement**
- **Returns, Shipment accuracy and efficiency**

The serialization coding and the data sharing infrastructure could be leverage to achieve business benefits beyond compliance. Some of these business use cases are at an early stage of discussion and will evolve in the coming years.
THANK YOU!