European Union (EU) Falsified Medicines Directive

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Johnson & Johnson

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The Promise of Serialization
EU Falsified Medicines Directive (FMD)

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Chairman, EFPIA Supply Chain Workgroup
Co-Chair, EFPIA-Medicines for Europe FMD Workgroup
Johnson & Johnson

- World’s largest science & technology company focused solely on healthcare
- More than 275 operating companies in 60 countries
- Selling products in more than 175 countries
- Approximately 128,000 employees worldwide
Johnson & Johnson Portfolio

**Consumer**
- Baby Care
- Body Care
- Facial Skin Care
- Sun Care
- Feminine Personal Care
- Allergy Care
- Compromised Skin Care
- Cough and Cold Care
- Digestive Health
- Oral Care
- Pain Care

**Medical Devices**
- Wound Closure & Surgical Devices
- Minimally Invasive Surgery
- Joint Replacement
- Sterilization
- Eye Health
- Diabetes Care

**Pharmaceuticals**
- Oncology
- Infectious Diseases & Vaccines
- Immunology
- Cardiovascular & Metabolism
- Neuroscience & Pain
Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens - support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should reap a fair return.

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Serialization and Traceability

A unique identification number assigned to each item identifying it with a product number and associated serial number.

It’s applied at every package level - bottle, case, pallet.

These unique numbers are uploaded into a database and can provide actionable product intelligence.
EU Falsified Medicines Directive

Product Safety Features
- Authenticity
- Pack identity
- Tamper evidence

Good Distribution
- Wholesalers & Brokers
- GDP

Active Substances
- GMPs for excipients
- Jan 2, 2013
- Registration API activities
- July 2, 2013

Internet Sales
- Community logo
- 2015
European Stakeholder Model
Aligned on common goal to protect patients

- Secure the legitimate supply chain
- Be proactive as market partners
- Stakeholder-governed model
  - Functioning
  - Harmonised
  - Cost-effective
  - Inter-operable
- Established the European Medicines Verification Organization (EMVO)
- Local governance through National Medicines Verification Organizations
EU Hub and National Medicines Verification Systems (NMVS)
COUNTRY READINESS

[Bar chart showing data for different months from Oct-16 to Sep-17, with categories: rest, Late, Main, and Early. Specific values are not provided in the image.]
EXECUTIVE SUMMARY COUNTRY READINESS
Pack coding harmonisation has increased, but . . .

- To date there have been a number of important decisions made which help harmonise the FMD implementation across Europe:
  - Choice of data carrier (2D DataMatrix)
  - Choice of coding scheme (ability to use International standards such as GS1)

**GS1 - GTIN**
Austria*, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark**, Estonia, Finland**, Germany*, Hungary, Iceland**, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway**, Poland**, Portugal, Romania, Slovakia, Slovenia, Spain**, Sweden, Switzerland, UK

  * GTIN for multi country - shared packs
  ** Some countries will allow GTIN or NTIN

**GS1 - NTIN**
Austria*, France, Germany*

  * For market specific packs

**TBC**
Italy and Greece (coding requirements under discussion)

Some countries (outlined in red) also require a national number in the 2D Barcode when using GTIN
But there are still coding/labeling challenges

- However there are other factors which will drive *unnecessary complexity* and cause issues with FMD implementation if not avoided:
  - Human readable text order
  - Prefix (heading) location
  - Use of labels to apply coding
  - Barcode transition requirements
  - Encoded data order
  - Application identifier use
  - Printed format of the 2D Data Matrix
  - Inclusion of the national number in the 2D Data Matrix
### Complexity Drivers

<table>
<thead>
<tr>
<th>Complexity Driver</th>
<th>Overview</th>
<th>Position Table</th>
<th>Advocacy Doc</th>
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<tbody>
<tr>
<td>Human readable text order</td>
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<td>Final Draft</td>
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<tr>
<td>Prefix (heading) location</td>
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<td>Transition requirements</td>
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</tbody>
</table>
J&J Supply Chain Experience

German securPharm Pilot - pharmacy point of dispense verification

• Approximately 400 pharmacies
• Partnership between pharmacies and manufacturers
• Receive scan confirmation
Serialization is Data Driven

- GS1 standards based
- Digital thread connecting stakeholders
- Embedding uniqueness into business events
- Building digital foundation for IoT, Blockchain, etc.
- Enabling real-time decisions
- Bridging supply chain platforms
Collaboration Identifies Additional Business Value Opportunities

- Strengthens supply chain integrity
- Higher fidelity visibility enables efficiency improvements
  - Reducing counts and checks
  - Reducing claims and credits
  - Enhancing returns verification
- Communal standardizing of “best practices”
Serialization Data Driven Insights Emerging in Manufacturing MAKE and PLAN

- Manual work reduction
- Deviation investigation
- Product issue resolution
- Connecting plant to shelf – Digital Thread
- Unlocking visibility further into supply chain
- Real product flow and movement
- Creating “win-win” for suppliers and customers
Healthcare Commercial Use Cases will Benefit as Well

- Pricing and reimbursement
- Pharmacovigilance
- Pharmacoconomics
- Indication-based pricing
- Patient compliance
Our Actions on Serialization and Track & Trace
Securing the supply chain and driving end-to-end innovation

• 3500+ SKUs in scope
• End-to-end impact
• Customer collaboration and joint value creation
• Recognized by Council for Supply Chain Management Professionals with their 2016 Innovation Award
7 Billion Reasons to Care

Serialization and Traceability Will Benefit Patients and Consumers Everywhere