

European Union (EU) Falsified Medicines Directive

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Johnson Johnson SUPPLY CHAIN

The Promise of Serialization

EU Falsified Medicines Directive (FMD)

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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



Lubriderm

VRTEC





יי האבות ולכל האחרים המשתמשים בתוצרים ובשירות היוהי שו ייי אשוגה שלנו היא לרופאים, לאחיות ולחולים, לענות על צורכיהם, כל שאנו עושים חייב להיות באיכות מעולה. עלינו לשאוף בהזמנות הלקוח יש לטפל באופן מדויק ומהיר. לספקים ולמפיצים שלנו חייבת להיות הזדמנות להרוויח רווח נאה.

^ם והנשים העובדים עמנו ברחבי העולם. לל אחד ים לכבד את כבודם העצמי ולהכיר בערכם.

我們的信條

我們相信我們當先並對醫生、優士和高人負責、對父母親以為 意品和很受我们因若的人负责。为了满足他们的需求,我们 是高品質的。我們必須不斷地沒力於降低我們的成本,以保 的目前必须出现而非能的供用。我們的供當商和原新商用目

我們與對世界各地和我們一起共事的男女同仁負責。每 **第17**8 * 的個種。我們必須讓餐他們的算服,讓異他們的優點。 種安全意。機器必須公平合理、工作環境必須清潔、 法属防鼻工履行他們對家庭的責任。必須讓員工在國 言。彭於会布的人,必须给不平等的聘用、要原和3 價偏職的管理人員,他們的行為必須公正並符合道

我們要對我們所生活和工作的社會;以及全世界又 支援對社會有益的活動和慈善事業、撤銷我們遵 社會環境、促進健康和飲育事業。我們必須發展 環境和天然資源。

最後,我們要對全體段束負責。企業經營必算 實試驗的構想。必須堅持研究工作、研發個單 正。必須購買新設備,提供新設施,推出和 時之需。如果我們依照這些原則進行接續

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Unser Credo

Allem voran steht unsere V

Our Credo

Johnson-Johnson

Nosso Credo

ते पहचानमा बाहिए। हमें उनकी ॥ चाहिए। उनमें अपनी नौकरी की र पर्याप्त होना चाहिए, तथा कार्य गहिए ताकि वे अपने परिवार के प्रति सुझाव और शिकायत करने में संकोच हास, तथा उन्नति के समान अवसर • वाहिए तथा उनकी कार्यवाहियाँ

Наше Кредо

uestro Credo

imos que nuestra primera responsabilidad es con los médicos. nnos que nuestra primera responsacionad de con los monicos meras y pacientes, con las madres y padres y todos los demás minetas y pauleentes, cum las maures y paules y rotus los dama litican nuestros productos y servicios. Para responder a sus ningan nuestros productos y servicios. Fais realminos a sus sidades, todo lo que hagamos debe ser de primora calídad auauee, tool to que neglerina serve en sur primera servica, mos luchar constantemente por reducir nuestros costos a fin ntes rostar consumemente por reducir nuestros costos a m intener precios razonables. Los pedidos de los clientes deben Intenur precios razonadores: Los pedidos de los cirentes detes indidos rápidamente y con precisión, Nuestros proveedores auces rapioamente y con precision, recesa os provecos dores deben tener la oportunidad de conseguir una nnsables ante nuestros empleados, los hombres y mujeres neerures anno nuesarios empretacios nos nominees y inigenes on nosotros en todo el mundo. Cada uno de ellos debe on nosoiros en rodo er munoo, vaux uno de sous o o como persona. Hemos de respetar su dignidad name

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



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

Healthcare Federation

EU Hub and National Medicines Verification Systems (NMVS)



COUNTRY READINESS



EMVO PMMR SEPTEMBER 2017

emvo Main Upinia

EXECUTIVE SUMMARY BLUEPRINT TENDENCY



- 5 emvo 🎬

- SEL

96

EXECUTIVE SUMMARY COUNTRY READINESS



EMVO PMMR SEPTEMBER 2017

Early Adopter

Main Stream

Late Follower

Non EU Countries

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/ labelling challenges

- However there are other factors which will drive <u>unnecessary complexity</u> 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

efpia

C medicines

• The arms of the best space

Complexity Driver	Overview	Position Table	Advocacy Doc
Human readable text order	Complete	Complete	Final Draft
Prefix (heading) location	Complete	Complete	Final Draft
Use of stickers/labels to apply coding	Complete	Complete	Draft
Transition requirements	Complete	Complete	Under Approval
Encoded data order	Complete	Draft	Draft
Application identifier use	Complete	Draft	Not Started
Printed format of the 2D Data Matrix	Complete	Draft	Not Started

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"

((GS)1 THE GLOBAL LANGUAGE OF BUSINESS CASE STUDY **Piloting Traceability with** GS1 Standards AmerisourceBergen teams with Johnson & Johnson Supply Chain for significant learnings CHALLENGE "The key to success in meeting any instance of regulatory The Food and Drug Administration (FDA) regulation requires that the pharmaceutical industry implement end-to-end traceability by 2023. Trading compliance-really comes partners in the supply chain have chosen to implement and test GS1 Standards down to collaboration. It all based solutions in real-world pilots to meet the deadline for interoperability. rests on the willingness of our SOLUTION dustry partners across the supply chain to work toward While GS1 Standards have created a hierarchy that reaches down to the us and then drive product level for serialization, several industry entities have voluntarily chosen to use GS1 EPCIS even as this standard evolves to fully meet the intent of the to adoption. This pilot with regulation. EPCIS allows trading partners to exchange data, in concert with the JJSC has been a stunning products as they move through the supply chain. An industry pilot between example of true partnership Johnson & Johnson Supply Chain (JJSC) and AmerisourceBergen Corporation as we move to establish a (ABC) did just that with actionable and repeatable results. meaningful standard that RENECITS serves our industry and protects patients." In addition to assuring compliance and continued product access for patients and customers, serialization can potentially enable the investigation of - HEATHER ZENK, Vice President, counterfeit and diverted products, affording brand owners additional supply Secure Supply Chain. chain integrity and security. End-to-end visibility means that recalls, where AmerisourceBergen necessary, can be executed more efficiently. As the foundational standard, the Global Trade Item Number* (GTIN*) helps to automate all processes and minimize errors, ultimately increasing patient safety.

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
- Pharmacoeconomics
- 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

Johnson-Johnson SUPPLY CHAIN