

European Falsified Medicines Directive

Mike Rose GS1 Global Healthcare – Bogota 11 April 2018



לענות על צורכיהם, כל שאנו עושים חייב להיות באיכות מעולה. עלינו לשאוף באופן מתמיד להפחית את העלויות במטרה לשמור על מחירים סבירים. בהזמנות הלקוח יש לטפל באופן מדויק ומהיר. לספקים ולמפיצים שלנו חייבת להיות הזדמנות להרוויח רווח נאה.

ח והנשים העובדים עמנו ברחבי העולם. כל אחד לינו לכבד את כבודם העצמי ולהכיר בערכם.

18 8 NOTE 7 80 4 915 8 3 ARE 4 84 4 2012 3 我們的信條

我們相信我們首先要對醫生、護士和商人負責,對父母親以及 產品和接受我們服務的人具實。為了滿足他們的需求,我們的 是高品質的。我們必須不斷地致力於降低我們的成本,以保 的訂與必須迅速而準確的供應。我們的供應商和經銷商應該

我們要對世界各地和我們一起共事的男女同仁負責。每 利潤。 的個體。我們必須追還他們的尊嚴,還質他們的優點。 種安全感。餅蒔必須公平合理、工作環境必須清潔、 法幫助員工履行他們對家庭的責任。必須讓員工在提 言。對於合格的人、必須給予平等的聘用、發展和升 價稱戰的管理人員,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 支援對社會有益的活動和慈善事業。撤納我們應 社會環境,促進健康和教育事業。我們必須普加 環境和天然資源。 最後,我們要對全體股東負責。企業促著必 嘗試新的構想。必須堅持研究工作,研發個新 正。必須購買新設備,提供新設施,推出新 時之需。如果我們依照這些原則進行經營

alamson alfohnson

Unser Credo

Allem voran steht unsere Vore

Our Credo

services. In meeting their needs everything we do must be of high quality. reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

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. responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment,

to the world community as well. We must be good citizens - support encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use

a sound profit. We must experiment with new ideas. Research must be 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 realize a fair return.

Johnson-Johnson

जिम्मेदार हैं जो हमारे साथ जे पहचानना चाहिए। हमें उनकी ॥ चाहिए। उनमें अपनी नौकरी की ार पर्याप्त होना चाहिए, तथा कार्य त होनी चाहिए। हमें अपने गहिए ताकि वे अपने परिवार के प्रति सुझाव और शिकायत करने में संकोच हास, तथा उन्नति के समान अवसर े चाहिए तथा उनकी कार्यवाहियाँ

Наше Кредо

rcias y quejas. De

ibles anto las comunidades en las que v

n de impuestos. Debe

ентами, перед отцами и матерлам, перед ест такаланталана ставана полагорона, порац особа вшой продукциой и услугама. В соответствии с их

mon

ины обеспечнаать высокие стандарты нач

проиностлин мы должны осослочивать высокно станцарты наче з осох, что мы долаом. Мы должны постоянно стремиться и сен

аланы на алынын на алынын на алынын на алынын каланын каланын каланын каланын каланын каланын каланын каланын к л. чтобы поддержнаать приемпемый уровень цен: Заказы илиенто зна выполняться точно и в срок. Наши поставщики и дистрибьюто

Ны кимоть возможность получать достойную прибыль.

ля и везопасность, пам валого, чтогов соткрытта полото возмать и Пося о семье. Сотрудники должны чувствовать, что они могут

увство уверенности в завтрашном дне. Вознаграждон

в работы, развития и продакжения. Мы должи

бедлярым и соразмортым, а условия труда обеспом праведливым и соразмерным, а условил труда оовслочнать чистоту. Порядок и безопасность. Нам важно, чтобы сотрудники имоли возможи

видинами, которые расотают у нас по всему миру, мы должны лить нисилендуальность в каждом на них. Мы должны уважать на

лициналадального в а палодом на так на должна замения ИСТВО И ПРИЗНАВАТЬ ИХ ВАСПУТИ: НАМ ВАНКО ПОЛДООНИАТЬ В НАК О

Anne anto la comunidad mundial. Dobe

uestro Credo

amos que nuestra primera responsabilidad es con los médicos, millos que musarra primera responsacionada es com los meconos meras y pacientes, con las madres y padres y todos los demás itilizan nuestros productos y servicios. Para responder a sus sidades, todo lo que hagamos debe ser de primera calidad. mos luchar constantemente por reducir nuestros costos a fin intener precios razonables. Los pedidos de los clientes deben andidos rápidamente y con precisión. Nuestros proveedores dores deben tener la oportunidad de conseguir una 7 VINnsables ante nuestros empleados, los hombres y mujeres on nosotros en todo el mundo. Cada uno de ellos debe o como persona. Hemos de respetar su dignidad

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Nosso Credo

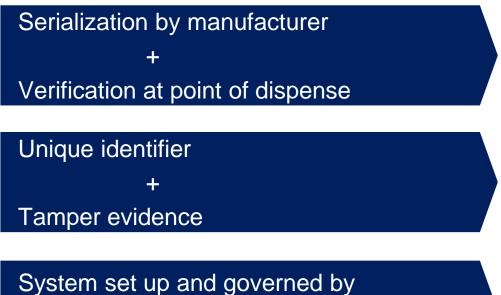
EU Falsified Medicines Directive

Serialization is only one part of the directive



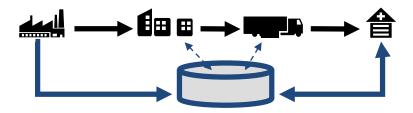
Delegated Act Mandates Rules For Medicines Verification

Key pillars of serialization and verification

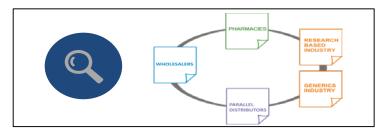


stakeholders under supervision of authorities

Manufacturers pay for the system



PC:	07323281004905	LAUGER CE
SN:	105453778604	NASS -
NN:	If requested by member state	
Expiry:	02-2019	
Lot:	HCZS500	

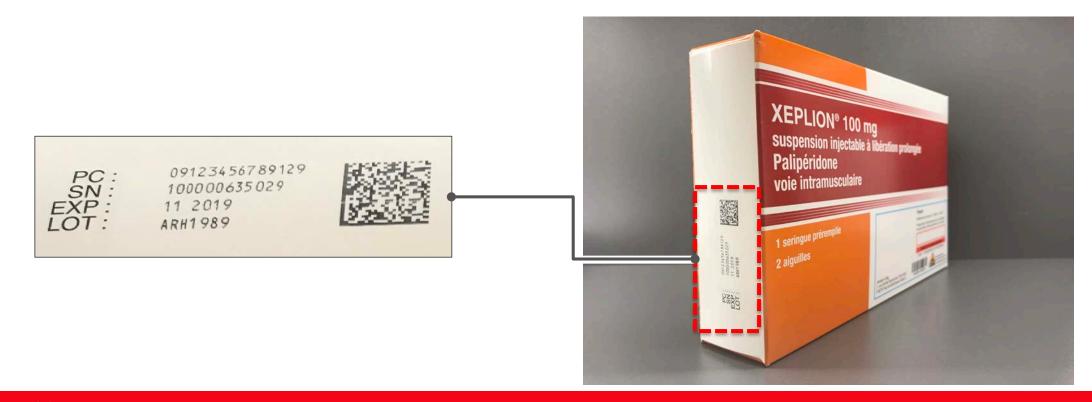




Serialization in the EU

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

Utilizes GS1 standards for Product Code (PC), that is, the GTIN and the other identifiers – serial number, expiration date and lot



European Stakeholder Model

Aligned on common goal to protect patients



Healthcare Federation

- 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 (NMVO)

European Medicines Verification Organization (EMVO)

System management and governance by not-for-profit organization under supervision of relevant competent authority



EU LEVEL

- Governance model includes EU industry associations with supervision by EC
- Oversees
 - ✓ EU Hub
 - ✓ Blueprint template
 - ✓ Service providers
 - ✓ Service agreements

NATIONAL LEVEL

- National Medicines Verification Organisations (NMVO), e.g. in Germany: securPharm e.V.
- Governed by national stakeholders with supervision by competent authorities

EMVO and National Organisations (NMVOs) cooperate on the basis of service level agreements

Governance Structure

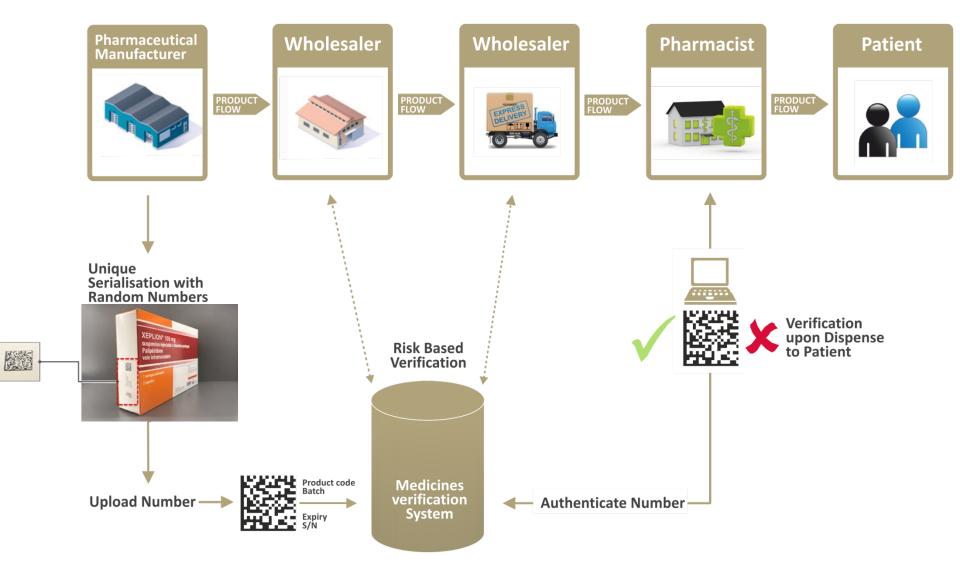
Allows for Effective Management of Verification System

Basic Principles

- Basic concept: "Point-of-Dispense Verification"
- All verification activities are performed in national systems of the EU member states
- Interoperability between the different national systems through European Hub
- Data are owned by party that generates it
- Data of other parties cannot be accessed except:
 ✓ For verification purposes
 - ✓ If specifically agreed between partners
- Supervision by relevant competent authorities
 - ✓ For reimbursement / pharmacovigilance purposes

Common Basic Concept

Point of dispense verification

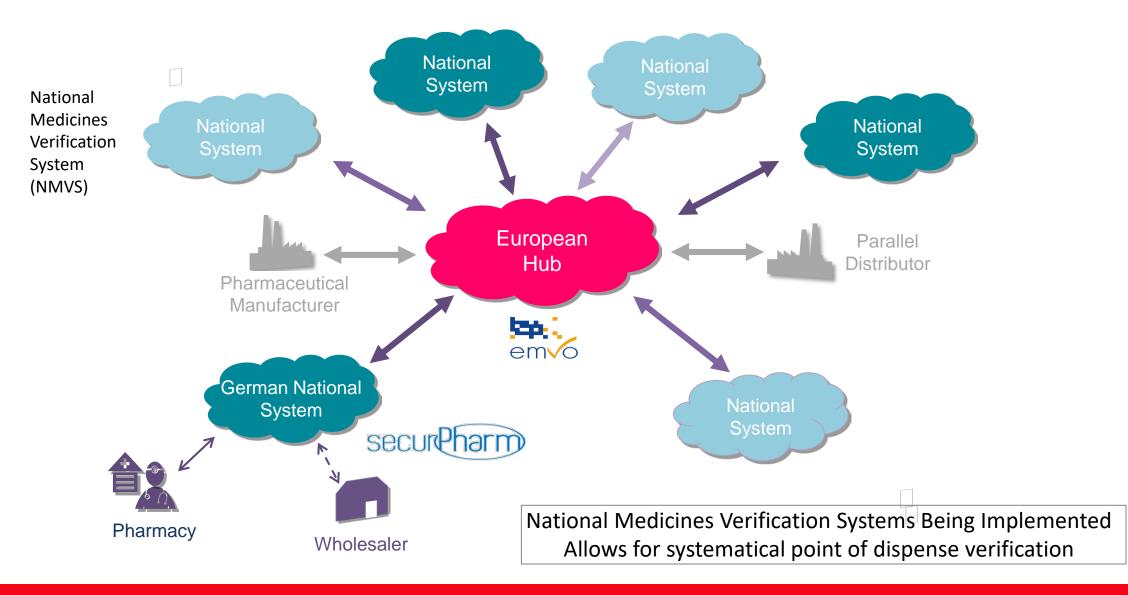


PC SN EXP LOT 09123456789129 100000635029 11 2019 4RH1989

Pan European Architecture



Designed for interoperability and efficiency



Global GS1 Standards Benefit ...



Patient Safety



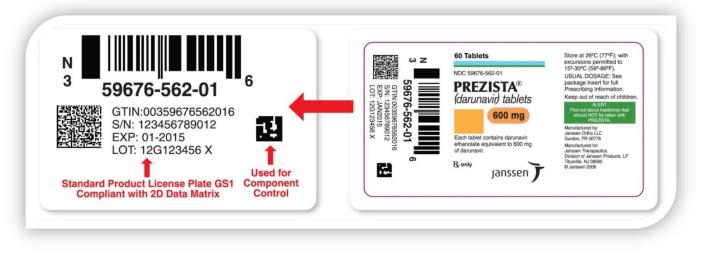
Supply Chain Efficiency



Product Intelligence

Serialization and Traceability

Standards drive supply chain performance









Pharmacy Point of Dispense Verification

German securPharm Pilot

GSI

Johmon-Johmon SUPPLY

Delivering life-saving treatments and end-to-end traceability for patient safety

Johnson & Johnson Supply Chain (JJSC) is comprised of more than 63,000 professionals worldwide who support the global supply chains of Johnson's Johnson's Dusiness segments—from planning and sourcing to manufacturing, logistics and deployment. When delivering medicines to healthcare providers and patients around the word, JJSC in Germany is leading the way to ensure the authenticity and safety of these drugs with its serialisation programme, supporting the European Union (EU) Falsified Medicines Directive. Uning GS1 standards as a foundation, JJSC is confident that compliance can be simplified as more and more European countries adopt the GS1 common language of business.

standards."

with standards."

Dirk Van den Wouwer EHEA Ensi-to-End Traceabili Johnson & Johnson Supply C

Simplifying complexity

Van den Wouwer explains why JJSC has

chosen to use GS1 standards globally. "In the

medicines. We have invested and continue

to invest in standard operating procedures

common platforms and GS1 standards to help

us simplify processes-to speak 'one business

language' in our multi-national environment

The more global the healthcare supply chain

becomes, the more it is a 'must' to work with

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The more global the healthcare supply chain

becomes, the more it is a 'must' to work

healthcare industry, supply chains have become

increasingly complex and vulnerable to falsified

Global compliance strategy

Dirk Van den Wouwer, EMEA End-to-End Traceability Leader with JJSC, is responsible for the serailsation and traceability programme of all products manufactured in the EMEA region (Europe, Middle East and Africa) and distributed throughout the world. "Since we serve the global marketplace,

we must comply with all of the different regulations in the different regions and countries—something that could be quite complex," says Van den Wouwer. As the EMEA regional lead for the olobal

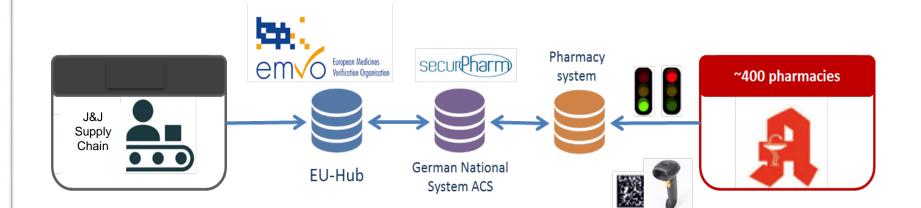
As the PREA regional wald for the global serialisation and traceability programme, Van den Wouwer is making sure that all JJSC production and distribution sites including processes and systems, are ready for the EU Fabilified Medicines Directive (FMD) 2019 deadline.

An integral part of the company's global compliance strategy is GS1 standards.

"We are using GS1 standards, a combination of serial numbers and GTNNs (GS1 Global Trade Item Numbers) in barcodes to uniquely identify each product," says Van den Wouwer. "This allows us to track and frace the packaged product, from our manufacturing site to any patient, in any country across the globe."



Proved J&J Supply Chain systems and GS1 standards worked to provide traceability from manufacturing to the pharmacy



Selected National Medicines Verification Systems



Johnson & Johnson Next Steps

- Continue ramping up production of serialized products
- Participate in NMVS pilots
- Work with all stakeholders to help ensure successful implementation
- Explore secondary uses of the EMVS/NMVS data