Johnson & Johnson SUPPLY CHAIN

European Falsified Medicines Directive

Mike Rose
GS1 Global Healthcare – Bogota
11 April 2018


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 realize a fair return.
Johnson & Johnson
Unser Credo
我們的信條
Наше Кредо
Nuestro Credo
Nosso Credo

EU Falsified Medicines Directive

Serialization is only one part of the directive

Product Safety Features

- Authenticity
- Pack Identity
- Tamper evidence
- End-to-End Verification Model
- EU Hub and National Verification Systems

Feb 9, 2019

Good Distribution

- Wholesalers & Brokers
- GDP

2014-Q1

Active Substances

- GMP for Excipients

Jan 2, 2013

- Registration API activities

July 2, 2013

Internet Sales

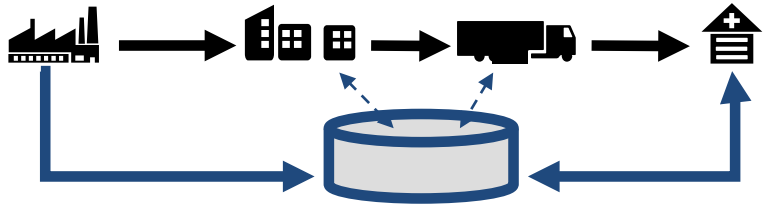
- Community logo

2015

Delegated Act Mandates Rules For Medicines Verification

Key pillars of serialization and verification

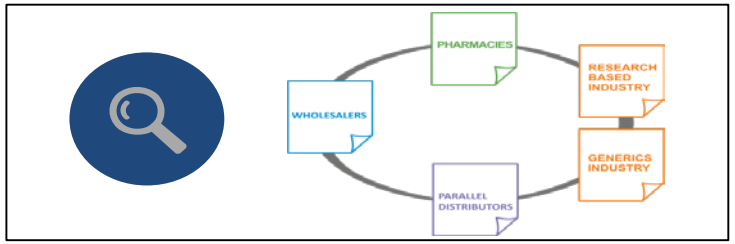
Serialization by manufacturer
+
Verification at point of dispense



Unique identifier
+
Tamper evidence

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

System set up and governed by stakeholders under supervision of authorities

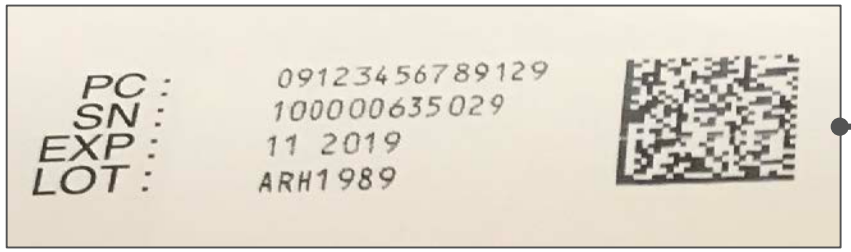


Manufacturers pay for the system

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

- 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

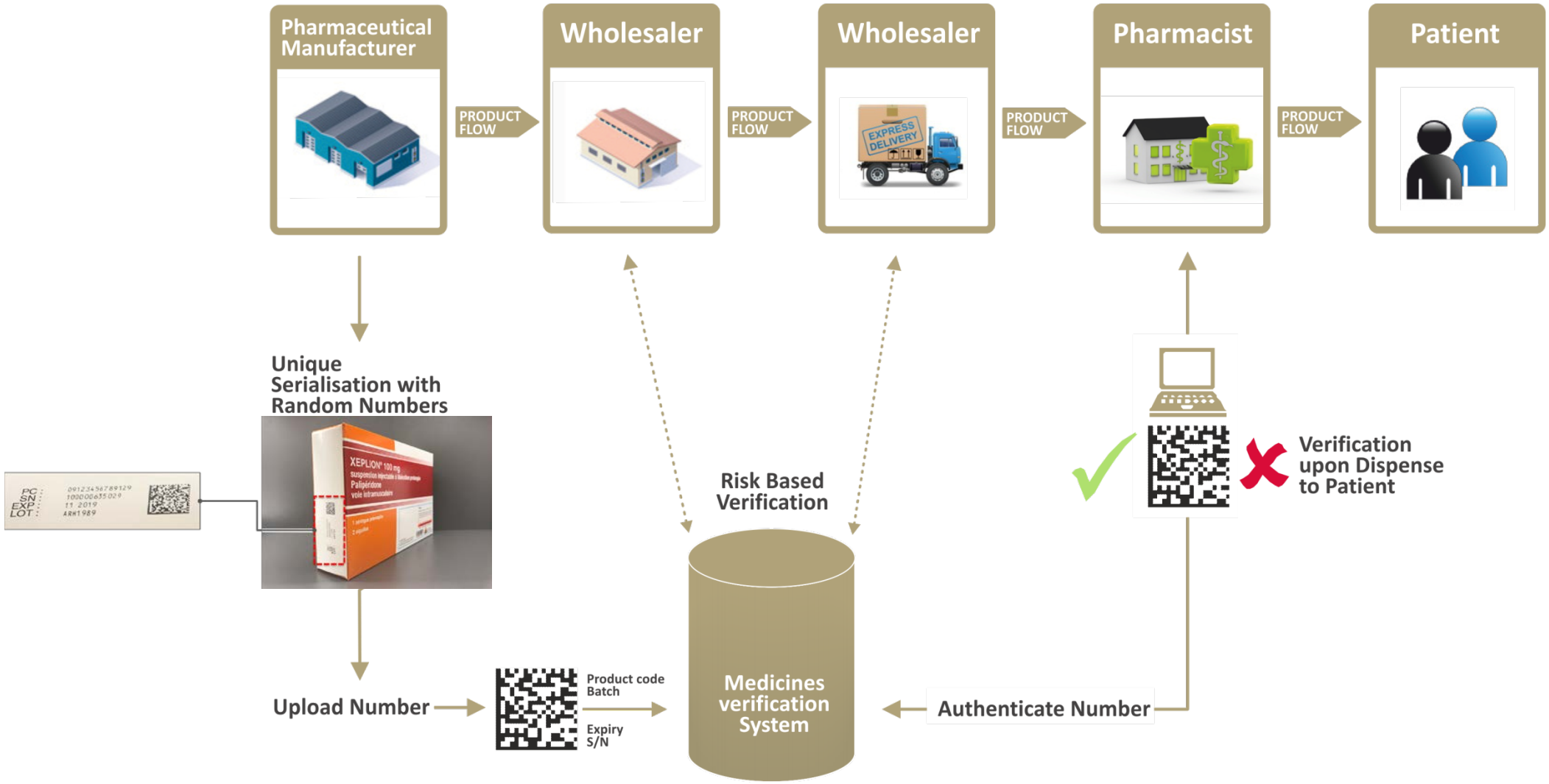
Governance Structure
Allows for Effective Management of Verification System

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

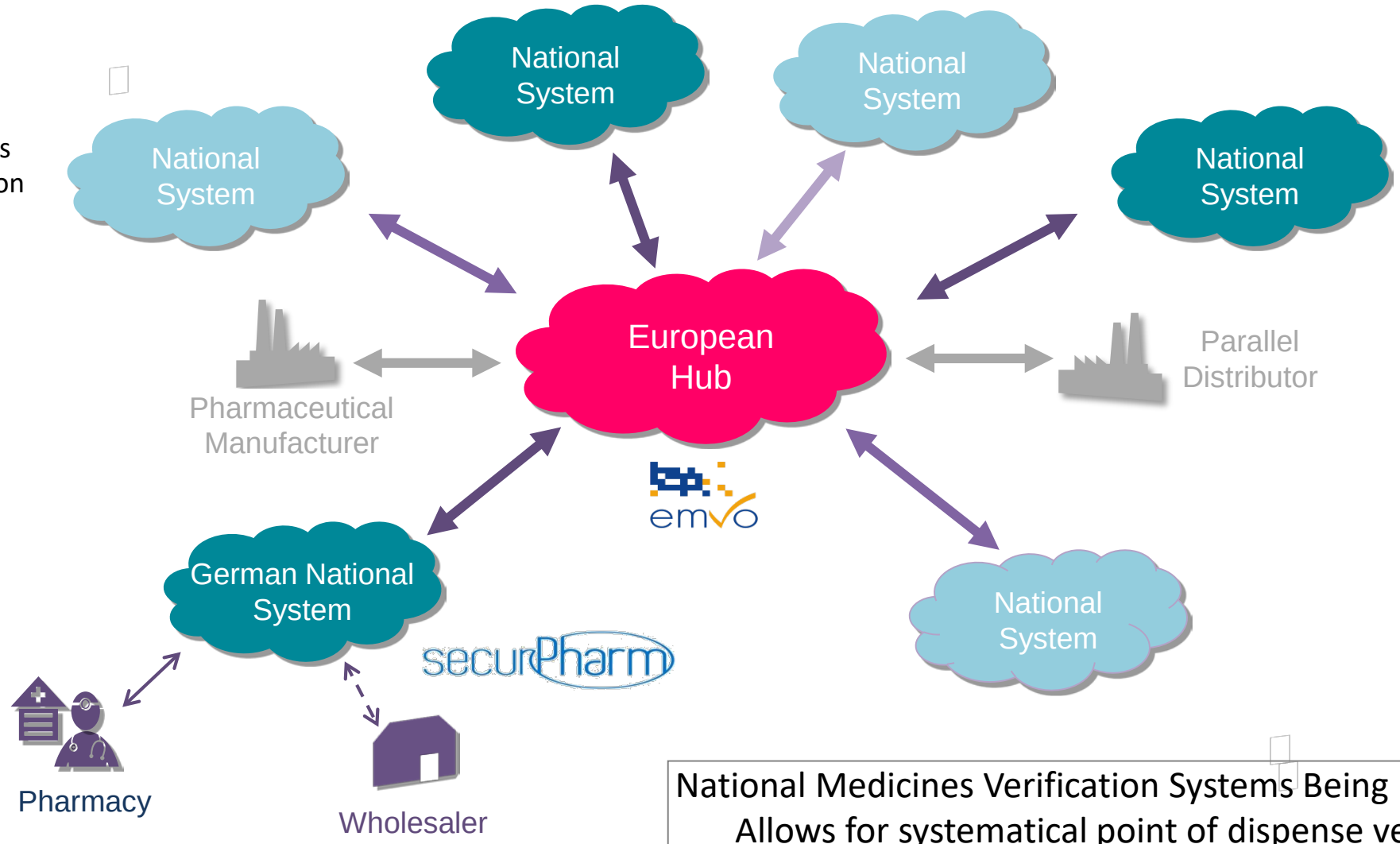
Point of dispense verification



Pan European Architecture

Designed for interoperability and efficiency

National Medicines Verification System (NMVS)



National Medicines Verification Systems Being Implemented
Allows for systematical point of dispense verification

Global GS1 Standards Benefit …

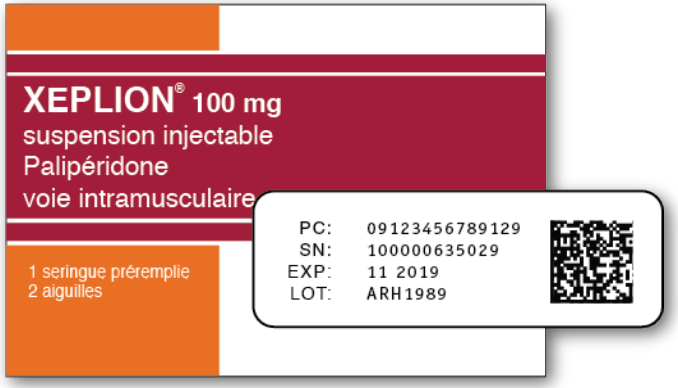
Patient Safety

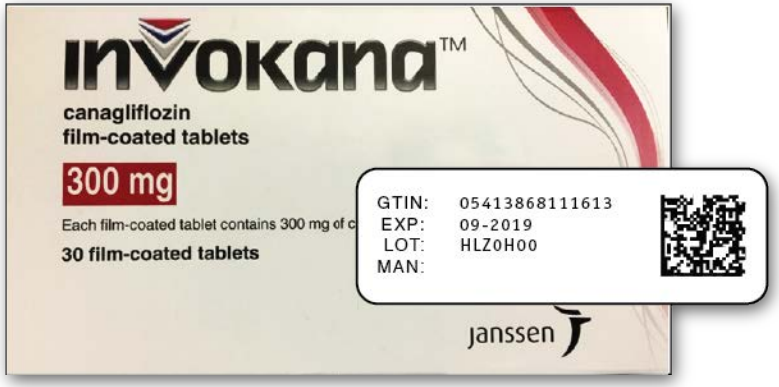
Supply Chain Efficiency

Product Intelligence

Serialization and Traceability

Standards drive supply chain performance





Pharmacy Point of Dispense Verification

German securPharm Pilot

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 & Johnson's business segments—from planning and sourcing to manufacturing, logistics and deployment. When delivering medicines to healthcare providers and patients around the world, 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. Using 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.

Global compliance strategy

Dirk Van den Wouwer, EMEA End-to-End Traceability Leader with JJSC, is responsible for the serialisation 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 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 Falsified 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 GTINs (GS1 Global Trade Item Numbers) in barcodes to uniquely identify each product," says Van den Wouwer. "This allows us to track and trace the packaged product, from our manufacturing site to any patient, in any country across the globe."

Simplifying complexity

Van den Wouwer explains why JJSC has chosen to use GS1 standards globally. "In the healthcare industry, supply chains have become increasingly complex and vulnerable to falsified 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 standards."

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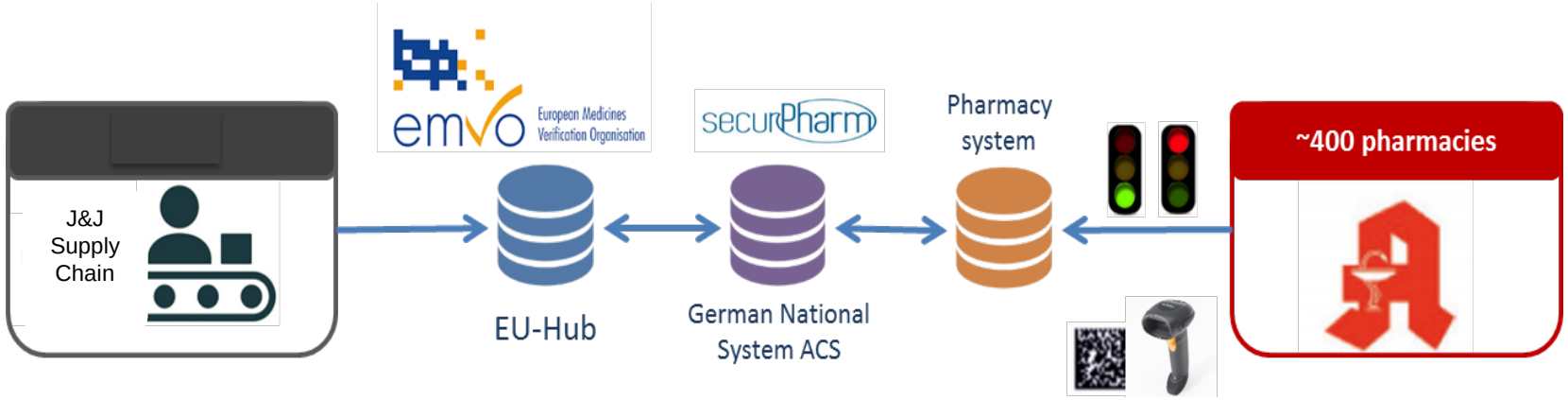
Dirk Van den Wouwer
EMEA End-to-End Traceability Leader
Johnson & Johnson Supply Chain

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



Selected National Medicines Verification Systems

Slovenia

Ireland

Sweden

Finland

Bulgaria

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