



The Global Language of Business

Traceability: How to choose a traceability model? Learnings from the APEC toolkit

African GS1 Healthcare Conference 2018
Breakout Panel II @ 16:15 – 17:30hrs - Tuesday 09 May 2018
Addis Ababa, Ethiopia



Your Panelists



Ulrike Kreysa
Senior Vice-President
Healthcare
GS1 Global Office



Francoise Hirth
Serialisation
Coordinator for Europe
and EEMEA, Roche,
Switzerland



Dirk Van Den Wouwer
Serialisation and End-
to-end traceability
leader EMEA, Johnson
& Johnson, Belgium



The Global Language of Business

Traceability models

Ulrike Kreysa - Senior Vice-President Healthcare - GS1 Global Office

Traceability in Healthcare



A key driver in the Healthcare sector for

- Patient Safety
- Preventing counterfeiting
- Enabling correct patient records
- Enabling effective product recalls
- Traceability down to the patient
- Enabling regulatory compliance
- Enhancing business processes (e.g. inventory management, optimized supply chain efficiency, eProcurement)



APEC Roadmap for Global Medical Product Integrity and Supply Chain Security



- 5 year project (Jan. 2013 - Dec. 2017)
- APEC sponsors:
 - APEC Life Sciences Innovation Forum
 - APEC Regulatory Harmonization Steering Committee
- Objective:
 - examine current practices and regulatory requirements
 - develop **recommendations** to regulators
 - develop **training programs** which will be made publically available through the APEC website
- Track & Trace Work Group (TTWG) with 10 work streams
- Published by APEC Harmonization Center at http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf



TTWG - members



GE Healthcare



Traceability – definition



- Traceability is the ability to identify and trace the history, distribution, location, and use of products. **A traceability system records and follows the trail as products come from suppliers and are processed and ultimately distributed/dispensed as final products.**
- Fundamental to traceability: In parallel with the flow of product there **has to be** a flow of information about the product
- Throughout the entire supply chain:
 - There is Internal and External Traceability
 - Inputs (e.g. receipt) must be linked to outputs (e.g. shipments / dispensing)
 - Stakeholders can have varying roles



The traceability system – important decisions



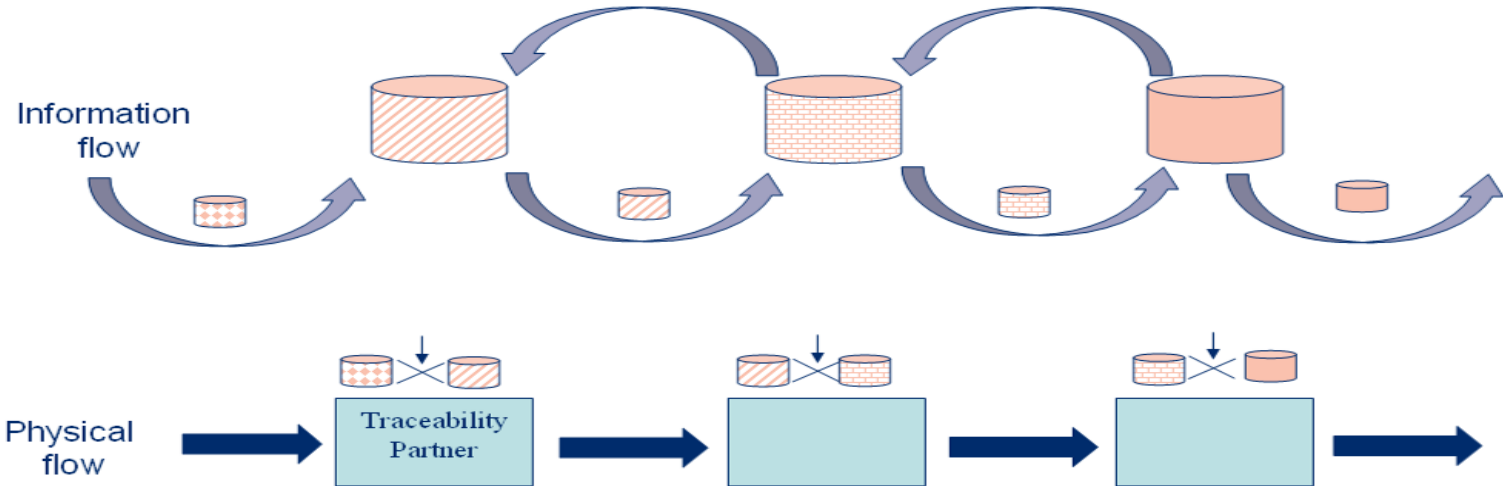
- Where to collect and hold the data from the traceability system?
- Where physically hosted?
- Traceability data are critical, important and sensitive
- Data security
- Access to data? Patients?
- Efficiency of the system
- Dependencies on solution provider?
- End-to-end verification or full traceability?



One up, one down



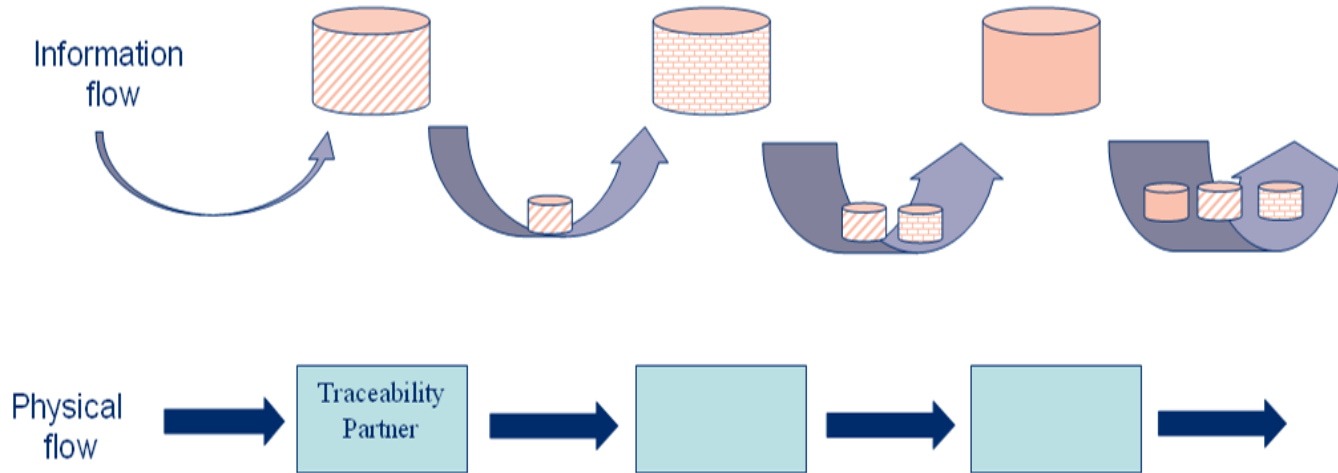
- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor
- The « traditional » concept - simple, but disadvantages



Cumulative Tracking (e.g. California ePedigree)



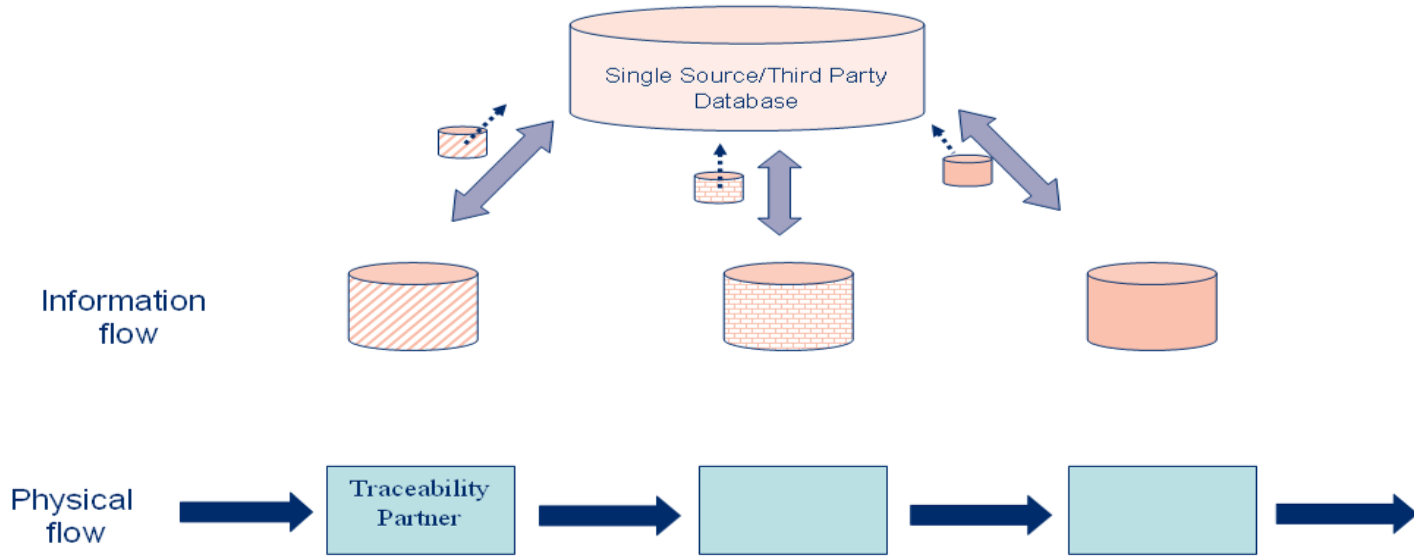
Traceability data received from all previous upstream chain sources **plus** its additional traceability data, available to the next downstream supply partner.
Very “heavy solution” not recommended anymore in “cloud age”



Central Database



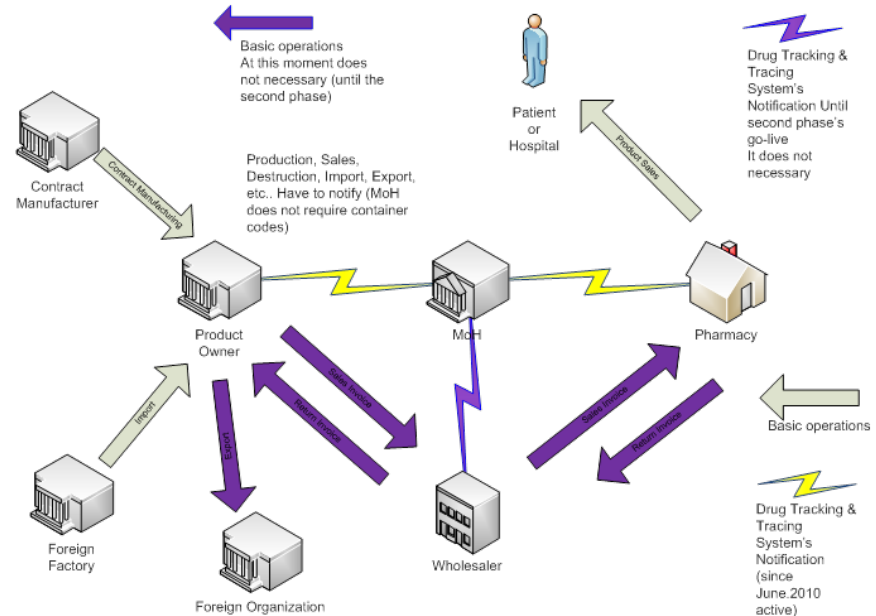
The traceable item source makes its traceability data available (e.g. publishes the data) to a central repository/database maintained by a third party/regulatory body.



Centralised model - Example: Turkey



- The first country which implemented full traceability with GS1 standards was Turkey - did overcome all issues
- Government hold database
- Great success beyond expectations
- ROI after only few years
- Full visibility of drug supply chain



Many achievements and benefits

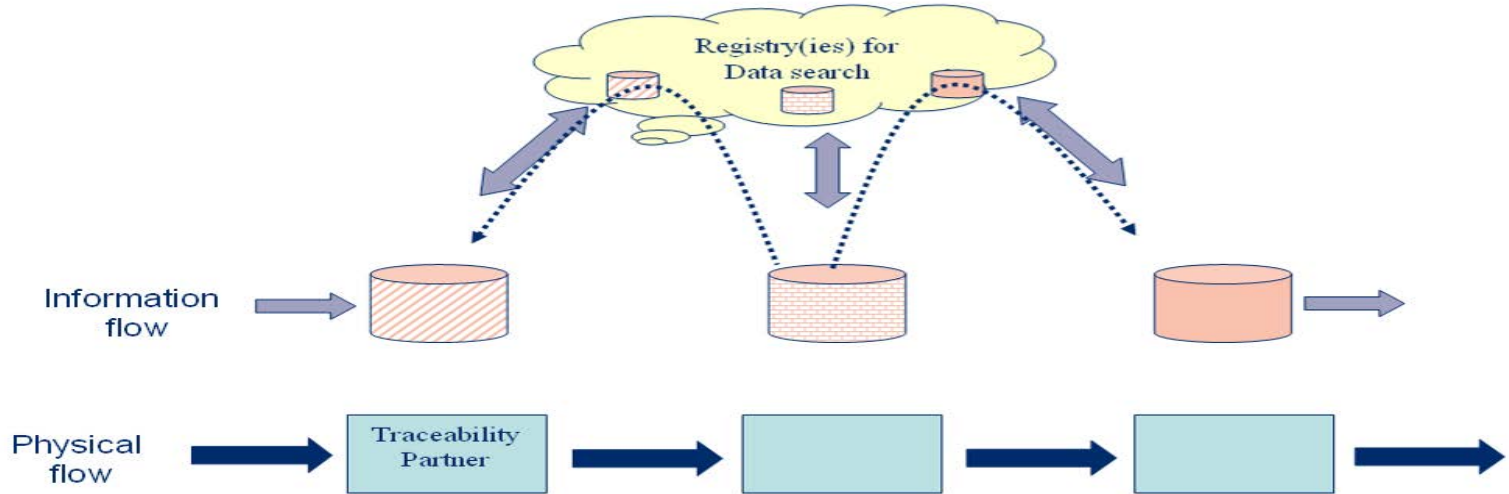


- Safe medicines, prevents counterfeiting
- Prevents resale of medicine
- Expedites recalling of medicine
- Prevents sale of expired medicine
- Preventing drug shortages
- Quality data for insurances
- Provides statistics to develop policies on Rational Medicine Use
- Enables pharmacovigilance and strategic planning

Distributed Model(s)



Traceability identification keys available in a registry to enable traceability data search - information can be stored anywhere as the registry provides the link and data search mechanism. Semi-distributed, full-distributed...



Distributed Model – cloud enabled



- The stakeholders in the USA would like to see this model implemented for the DSCSA (Drug Supply Chain Security Act)
- Broad agreement to use **GS1 EPCIS** standard – supported by US FDA
- Discussions ongoing – also if and how to use **blockchain**

EPCIS – sharing information on events



WHAT objects are the subject of event?

Individual objects (SGTIN) or groupings (GTIN + Lot/batch)

WHEN did this event take place?

Date, time, time zone

WHERE did this event take place?

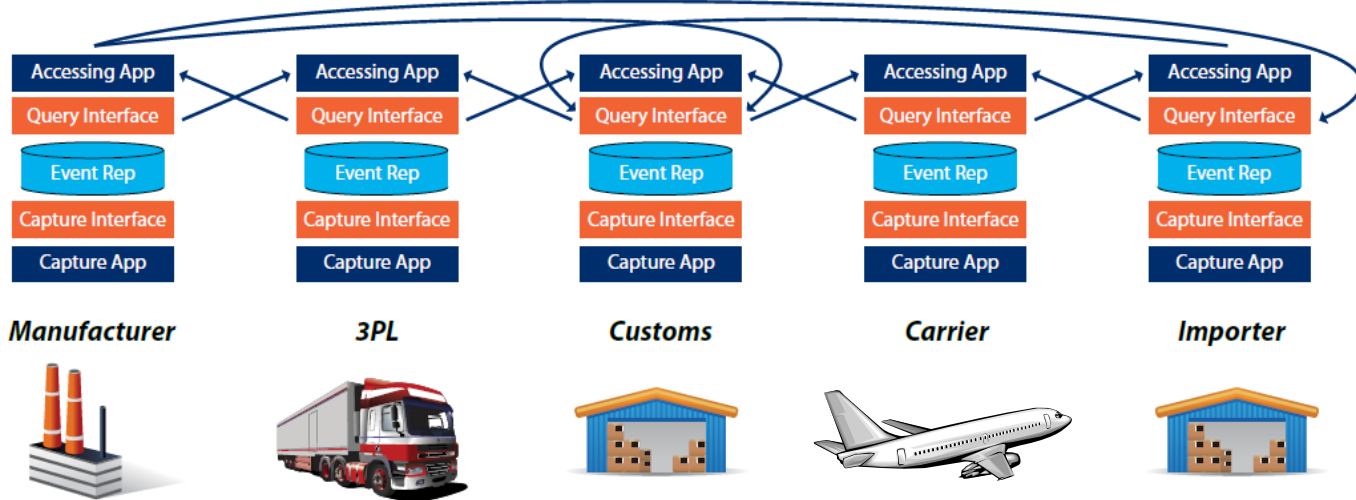
GLN of physical location & object's subsequent whereabouts

WHY did this event take place?

Business step, Disposition, Source/Destination info

All captured in an EPCIS repository

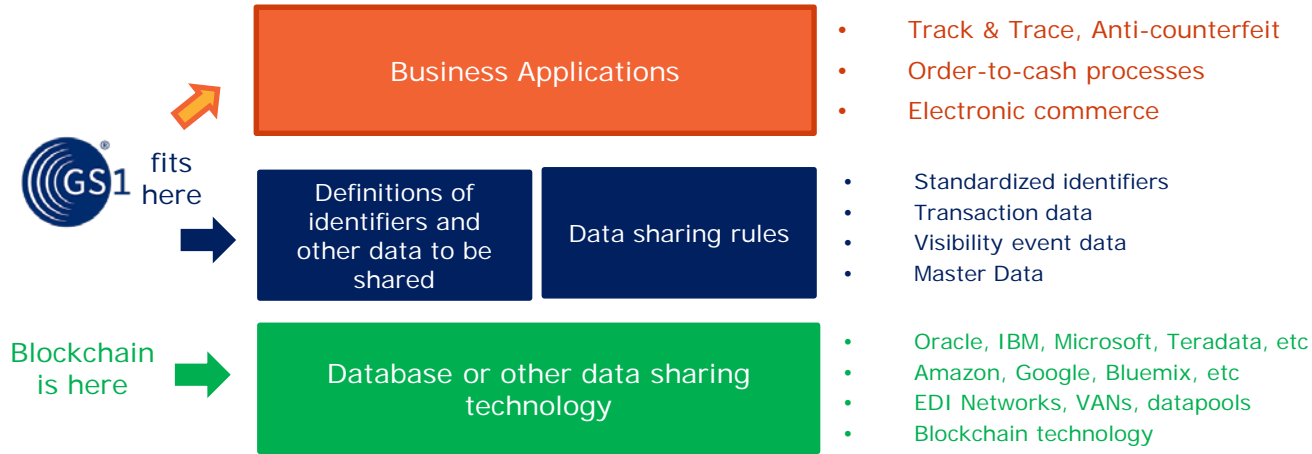
EPCIS end-to-end Visibility



EPCIS enables tracking and tracing AND easy sharing of event data in real-time among trading partners up and downstream

<https://www.youtube.com/watch?v=2aIAV88U6F4>

Blockchain and GS1



Blockchain is a shared, secure, distributed ledger;
GS1 facilitates standards for data and some business applications

GS1 Standards are more important in Blockchain than ever before!
(Jeff Denton, AmerisourceBergen)





Traceability: How to choose a traceability model

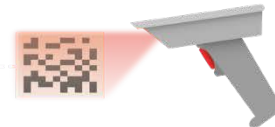
Francoise Hirth, Roche

Traceability: how to choose a model?

Françoise Hirth

F.Hoffmann-La Roche Ltd

*Serialization Coordinator EU &
EEMEA*



Roche's objectives with Supply Chain Safety Measures

Patients



Improve patient care and safety

- Ensure drugs are authentic
- Reduce medication errors

Safety

Trading partners



- Improve collaboration
- Enhance activities and processes

Reliability

Roche



- Increase supply chain efficiency, thus reducing costs
- Support introduction of and comply with non-negotiable regulations for supply chain standardization
- Protect and improve brand position

Reputation

Different measures for different purposes

PRIMARY



GTIN: 07680569220038
EXP: 12 2016
Lot: H0179B03



GTIN + required variable data

SECONDARY



GTIN: 07680569220038
EXP: 12 2016
Lot: H0179B03



GTIN + required variable data



GTIN: 07680569220038
SN: 09000000000000000000000000000000
EXP: 12 2016
Lot: H0179B03



GTIN + Serial Nr + required variable data

TERTIARY



SSCC

Serial Shipping Container Code



SSCC

1. Codification

2. Serialization

3. Aggregation



Which measures when ?

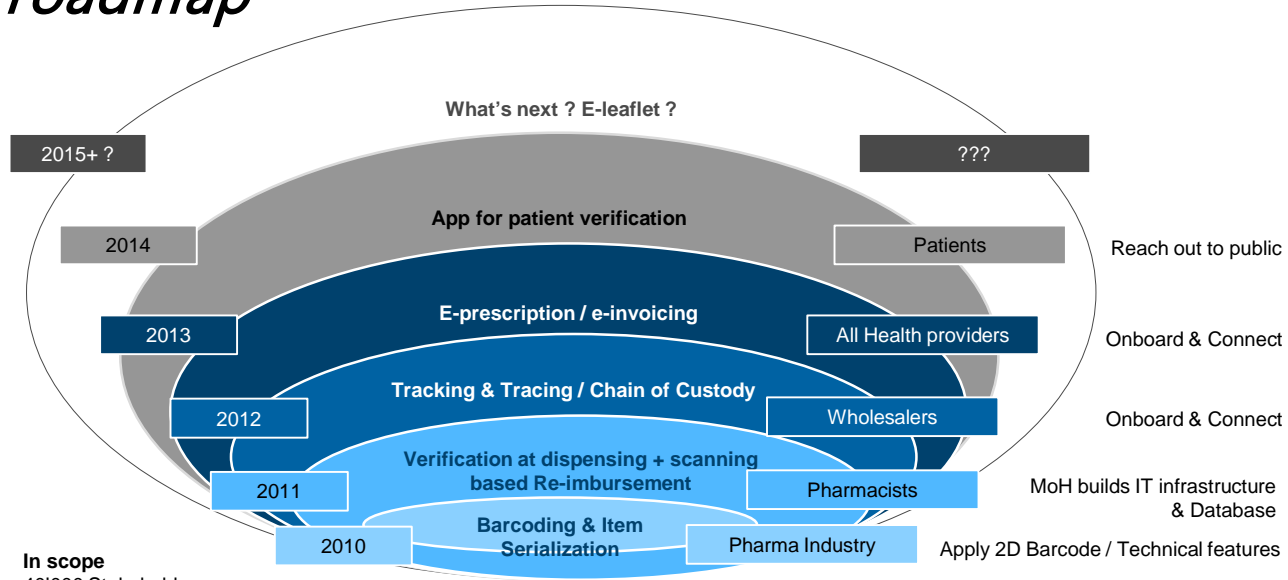
- ❖ **Codification** ; allows to identify the product; GTIN + lot no. + Expiry date
 - First step to go towards traceability (Jordan, Qatar)

- ❖ **Serialization** ; allows to capture and share data: GTIN + lot no. + Expiry date + Serial Number
 - End to End verification system in Europe

- ❖ **Aggregation**; allows traceability, only possible when all stakeholders come to common solution
 - Turkey implementation

Onboarding of HC Actors by Continuous Scope Extension

See the example of Turkey's implementation roadmap



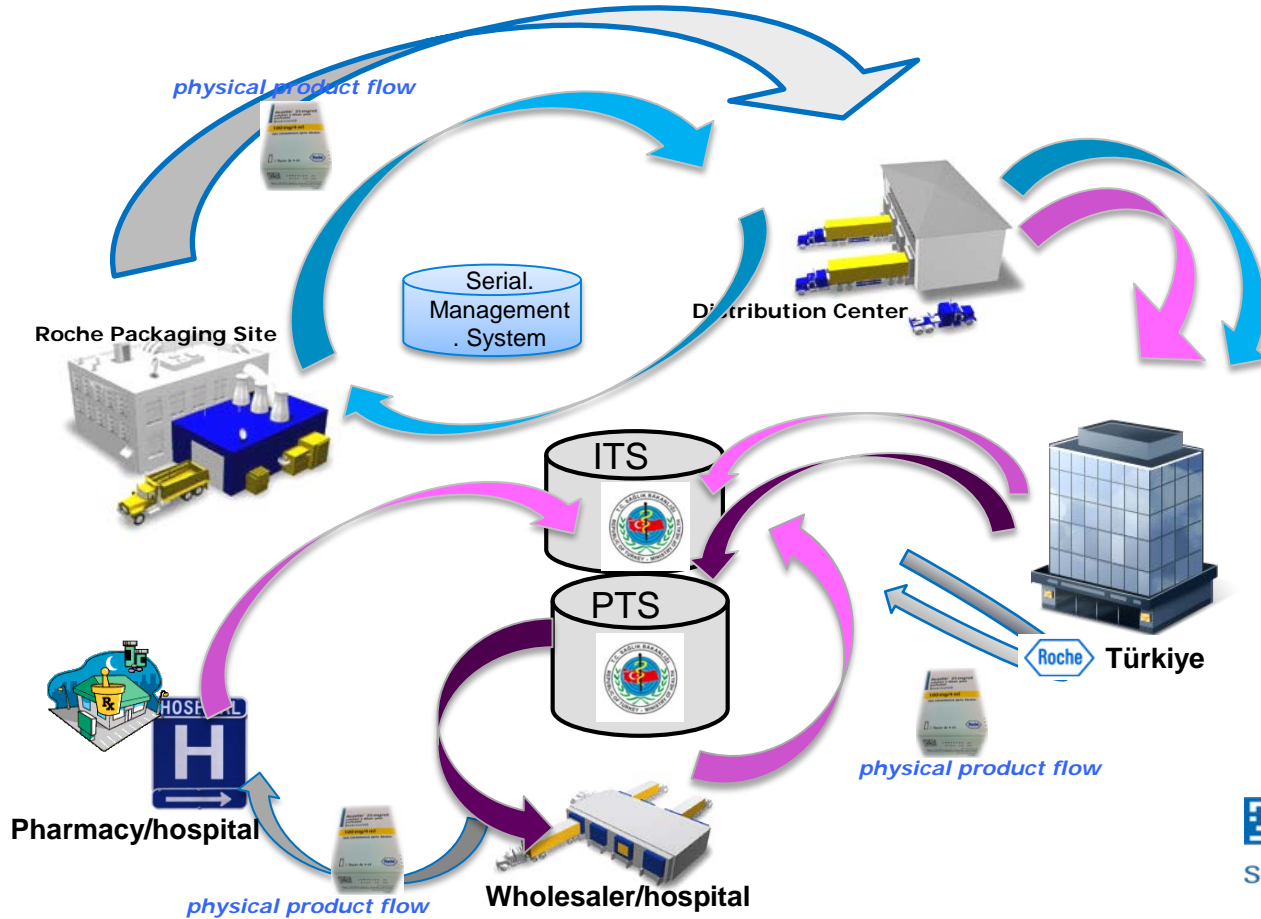
- In scope**
40'000 Stakeholders
- Hospitals
 - Health Centers
 - Family Physician Centers
 - Pharmacies and Pharmacy Warehouses
 - Manufacturers
 - Importers
 - Reimbursement Institutions

Figures & Facts today

- Number of drug types in ITS: 18 900
- Number of drug units in ITS: 7 000 000 000
- Number of daily operations in ITS: 45 000 000
- Number of operations per second in ITS: 520
- Response time of system: < 1 sec
- ROI in ONE YEAR!



Product and Data Flow



Proactive measures

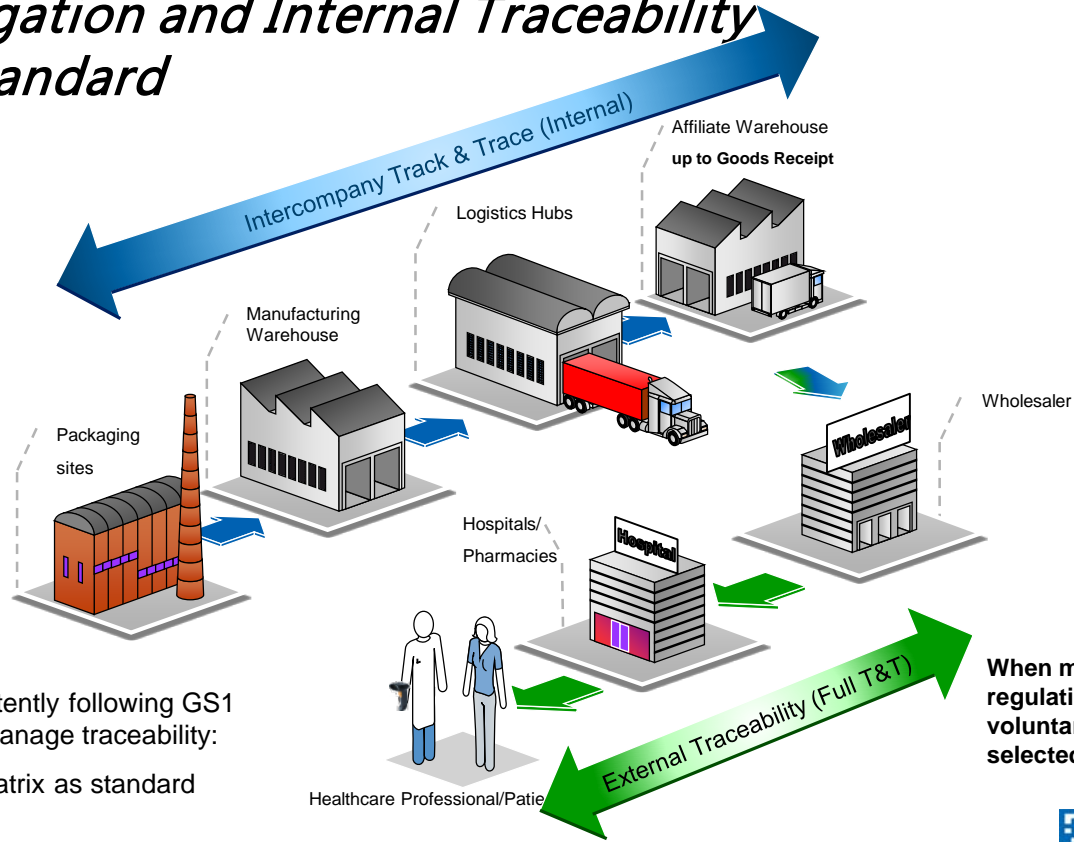
- ❖ Based on our strategy to fight against counterfeits and to ensure a safe supply chain, we proactively implement safety measures:
 - **Codification in Africa**
 - Ensure product identification

 - **Aggregation in Europe** whereas only serialization is required
 - Ensures a better visibility of the supply chain

 - **Serialization in Ecuador, Australia** whereas there is no Health Authority requirement
 - Known counterfeits cases

Traceability Model at Roche

Aggregation and Internal Traceability as a Standard



We use consistently following GS1 standards to manage traceability:

- GS1 DataMatrix as standard data carrier
- EPCIS as traceability data standard

When mandated by regulations or as voluntary project in selected countries

*Doing now what patients need
next*



The Global Language of Business

Implementing Falsified Medicines Directive (EU) Deployment in a global company

Dirk Van Den Wouwer, Johnson & Johnson

Implementing Falsified Medicines Directive (EU)

Deployment in a global company

Dirk Van den Wouwer
EMEA Serialization & Traceability Leader
Johnson & Johnson Supply Chain

Regional GS1 Healthcare Conference, Addis Ababa, Ethiopia
May 2018

Johnson & Johnson

- Global science & technology company focused solely on healthcare
- More than 275 operating companies in 60 Countries
- Selling products in more than 175 Countries
- Approximately 130,000 employees worldwide



我們的信條

我們相信我們是商業醫生，博士和病人負責，對父母親以及
產品和穩定我們服務的人負責。為了滿足他們的需要，我們
是最高品質的。我們必須不斷地努力於降低我們的成本，以保
持訂貨品質與價格的供應。我們的供應與服務應隨時隨地
可靠。

我們對世界各地和我們一起共事的男女同仁負責。每
個組織，我們必須維護他們的尊嚴，讓其他們的權利，實
現安全。薪酬必須公平合理，工作環境必須清潔，管
理必須公正。我們必須對他們的責任，必須讓員工在任
務。對於工作的人，必須給予公平的待遇，發展和升
職機會的經理人，他們的行為必須公正和合乎倫理。

我們對我們所生活和工作的社會，以及全世界
人類對社會有益活動和慈善事業，應負我們的
社會責任。促進健康和教育事業。我們必須善加
保護和天然資源。

最後，我們對全體股東負責。企業經營必須
嘗試新的模式，必須堅持研究工作，研發新藥
品。必須購買新設備，提供新服務，推出新
藥之案。如果我們按照原則則進行經營

אנו מאמינים כי אנו רופאים, מורים וכל האחרים
המשתמשים בחומרינו ובשירותינו. לכל אחד
מאלה יש צרכים, ולכל אחד מהם יש זכויות. עלינו
לשמור על זכויותיהם, ולעמוד על מחירים סבירים.
באופן תמידי להבטיח את היעילות במחירה לעומת
הצרכים. עלינו לשאוף להגדלת האיכות של
החומרים, ולעמוד על מחירים סבירים. עלינו
להבטיח את היעילות של החומרים, ולעמוד על
מחירים סבירים.

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

Nosso Credo

Unser Credo

Allem voran steht unsere Verantw...

stern und
ste in
ste
ste zu
unseren
in den
den.

st wird
ste
ste
ste
ste
ste
ste
ste
ste

Наше Кредо

Наша основная ответственность — перед врачами и медицинскими сестрами, матерями и отцами и всеми теми, кто пользуется нашими продуктами и услугами. В соответствии с этим мы должны стремиться к высокому качеству всего, что мы делаем. Мы должны постоянно стараться снизить издержки, чтобы обеспечить приемлемые цены. Заказчики должны иметь возможность получить свои заказы быстро и точно. Наши поставщики и дистрибуторы должны иметь возможность получить достойную прибыль.

Мы несем ответственность перед теми, кто работает с нами по всему миру. Каждый человек должен рассматриваться как личность. Мы должны уважать их достоинство и признавать их заслуги. Они должны чувствовать себя в безопасности на своих рабочих местах. Вознаграждение должно быть справедливым и адекватным, а условия работы — чистыми, упорядоченными и безопасными. Мы должны стремиться к способам помочь нашим сотрудникам исполнять свои семейные обязанности. Сотрудники должны чувствовать себя свободными высказывать предложения и жалобы. Должна быть равная возможность для развития и продвижения для всех. Мы должны предоставлять компетентное управление, и наши действия должны быть справедливыми и этичными.

Мы несем ответственность перед теми сообществами, в которых мы живем и работаем, и перед мировым сообществом в целом. Мы должны быть хорошими гражданами — поддерживать добрые дела и благотворительность и нести свою справедливую долю налогов. Мы должны поощрять гражданские улучшения и лучшее здоровье и образование. Мы должны поддерживать в хорошем состоянии имущество, которым мы имеем привилегию пользоваться, защищая окружающую среду и природные ресурсы.

uestro Credo

nos que nuestra primera responsabilidad es con los médicos, enfermeras y pacientes, con las madres y padres y todos los demás usuarios nuestros productos y servicios. Para responder a sus necesidades, todo lo que hagamos debe ser de primera calidad. Debemos luchar constantemente por reducir nuestros costos a fin de obtener precios razonables. Los pedidos de los clientes deben atenderse rápidamente y con precisión. Nuestros proveedores deben tener la oportunidad de conseguir una buena ganancia.

Insalvables ante nuestros empleados, los hombres y mujeres de todo el mundo. Cada uno de ellos debe ser considerado como persona. Debemos respetar su dignidad y reconocer sus méritos. Ellos deben sentirse seguros en sus trabajos. La compensación debe ser justa y adecuada, y las condiciones de trabajo limpias, ordenadas y seguras. Debemos estar conscientes de las maneras de ayudar a nuestros empleados a cumplir sus responsabilidades familiares. Los empleados deben sentirse libres de hacer sugerencias y quejas. Debe haber igualdad de oportunidades para el empleo, desarrollo y avance para los calificados. Debemos proporcionar una administración competente, y sus acciones deben ser justas y éticas.

Finalmente, nosotros tenemos la responsabilidad con los accionistas. El negocio debe producir una ganancia sólida. Debemos experimentar con nuevas ideas. La investigación debe ser llevada a cabo, se deben desarrollar programas innovadores y pagar los errores. Se debe comprar nuevo equipo, se deben proporcionar nuevas facilidades y se deben lanzar nuevos productos. Se deben crear reservas para tiempos difíciles. Cuando operamos de acuerdo a estos principios, los accionistas deben obtener un buen retorno.

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



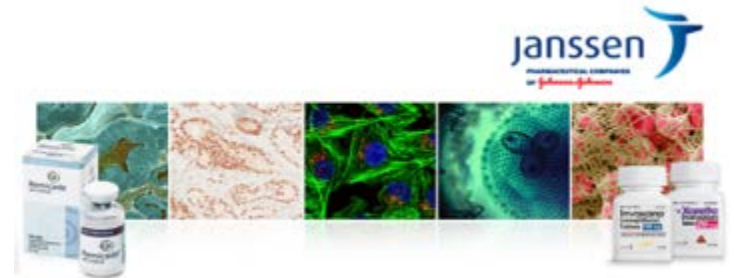
Medical Devices

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



Pharmaceuticals

- Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension



EU Falsified Medicines Directive

Serialization is only one part of the directive

Product Safety Features

Authenticity
Pack Identity
Tamper Evidence

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

European Economic Area

Diverse country approaches



Confirmed RA Requirements



Pending RA Requirements

European Economic Area

- **Feb 9 2019:**
 - Serialization
 - Falsified Medicines Directive
 - All countries except...

Switzerland

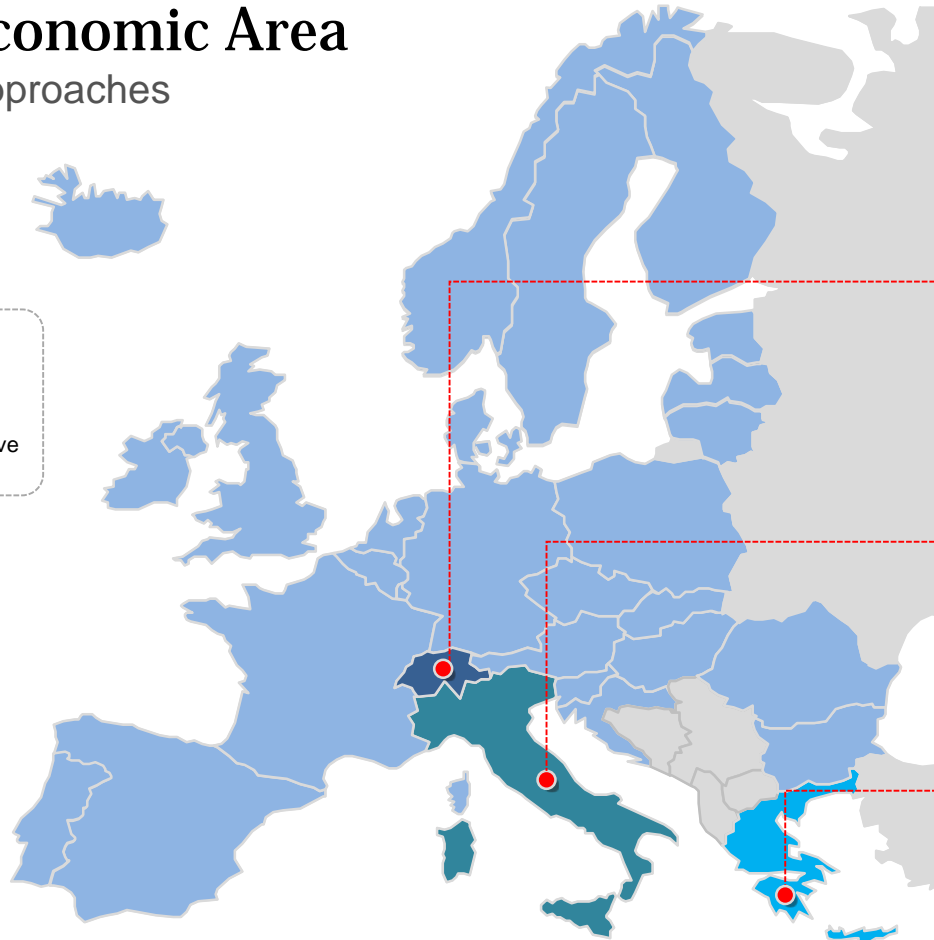
- **Voluntary Adoption:**
 - Serialization
 - Falsified Medicines Directive

Italy

- **Feb 9 2025:**
 - Serialization
 - Falsified Medicines Directive

Greece

- **Feb 9 2025:**
 - Serialization
 - Falsified Medicines Directive



Delegated Act Mandates Rules for End-to-End Verification

Key pillars of serialization and verification

Serialization by manufacturer

+

Verification at point of dispense

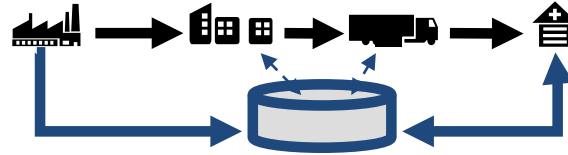
Unique identifier

+

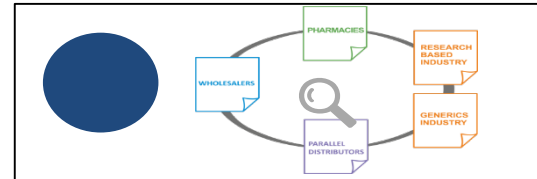
Tamper evidence

System set up and governed by stakeholders under supervision of local authorities

Manufacturers pay for the system



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



Who Will Have to Pay?

Installations for
pack coding



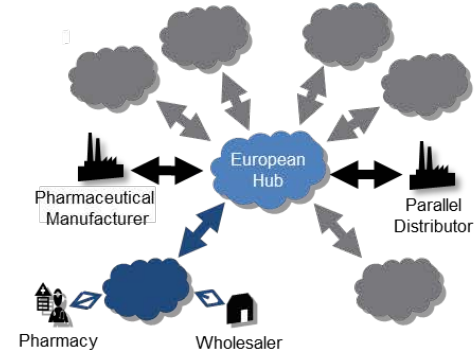
**Marketing Authorisation
Holders**

Installations for
pack verification



**Pharmacists, wholesalers,
...**

Repository system
(Hub & national systems)



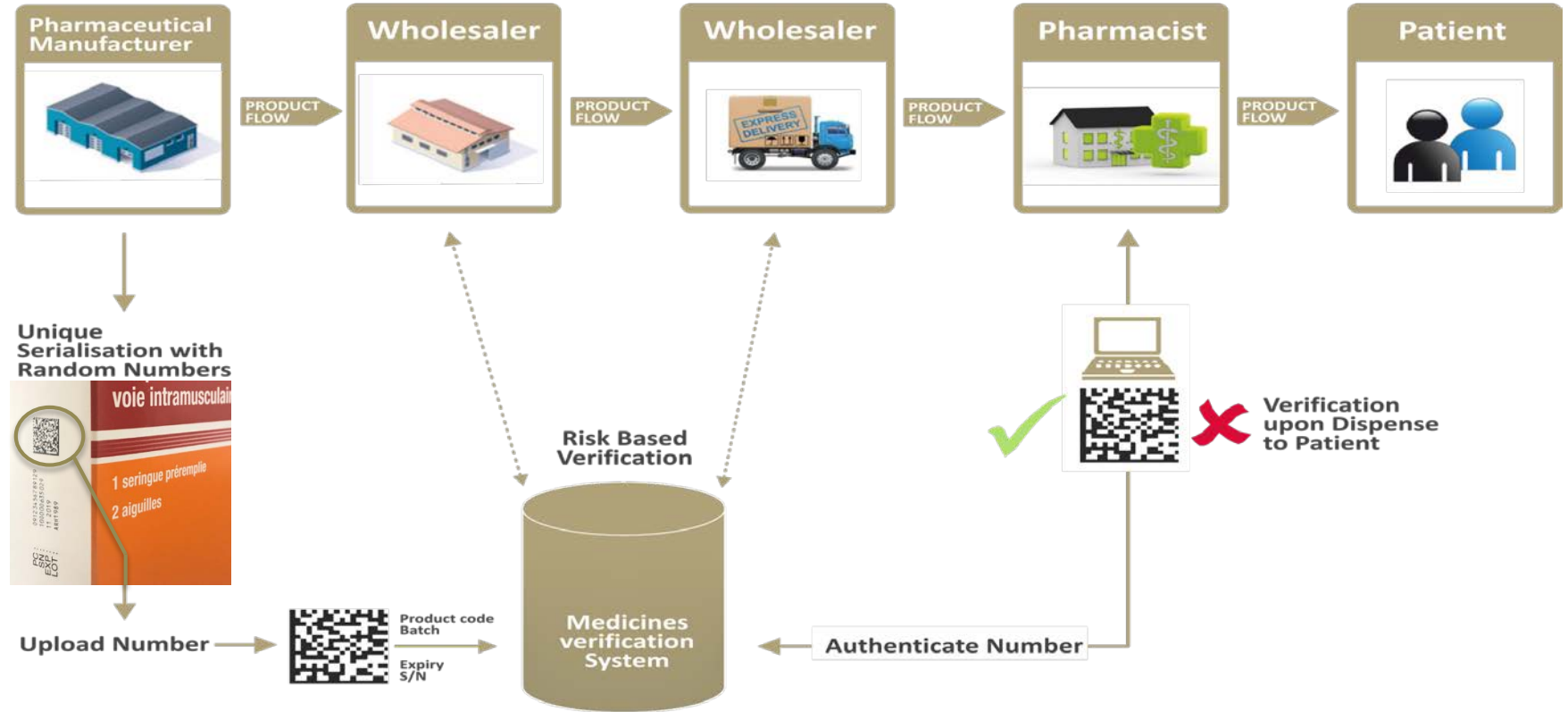
**Marketing Authorisation
Holders**

MAHs selling products in a Member State pay for respective national system and a share of the European Hub



Point of Dispense Verification

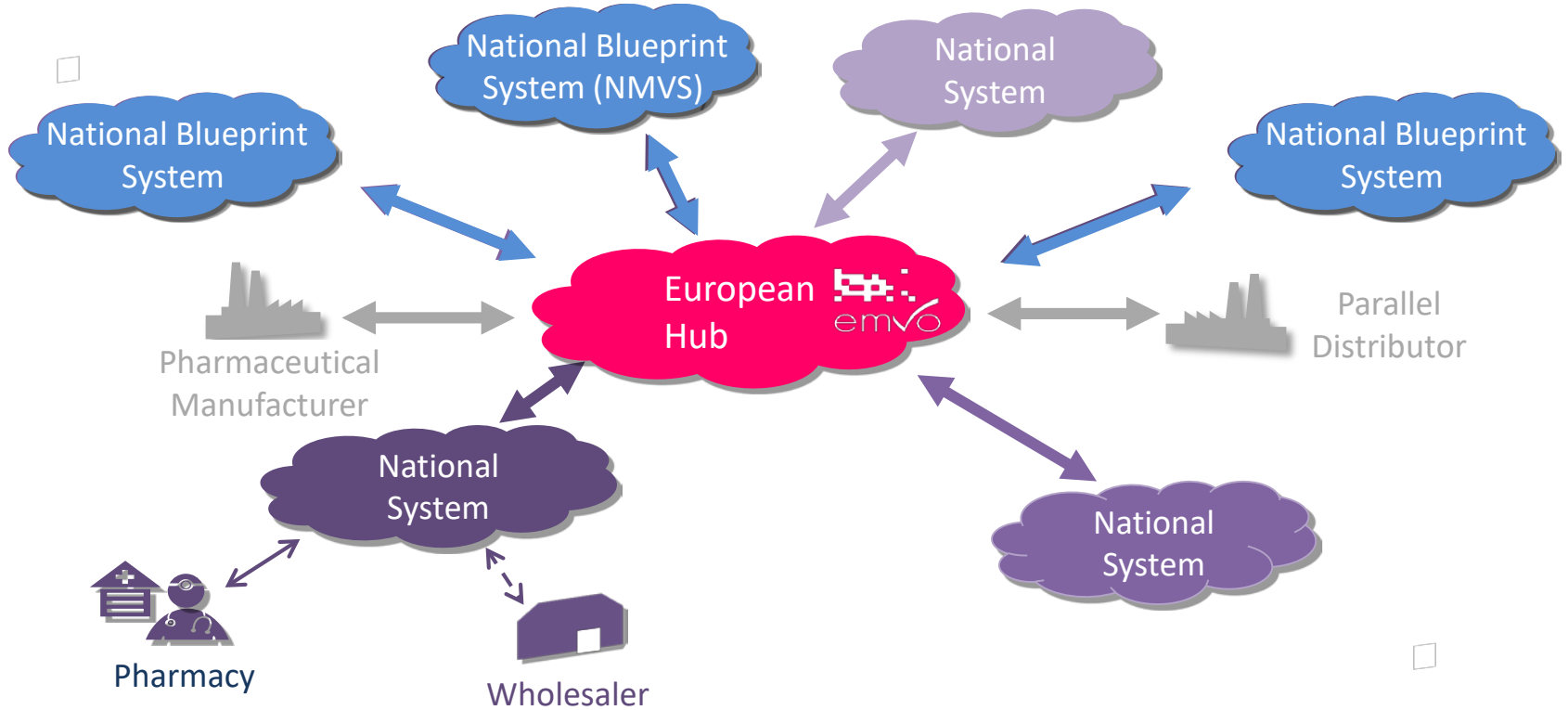
All parties verify against one central system





Repositories Systems

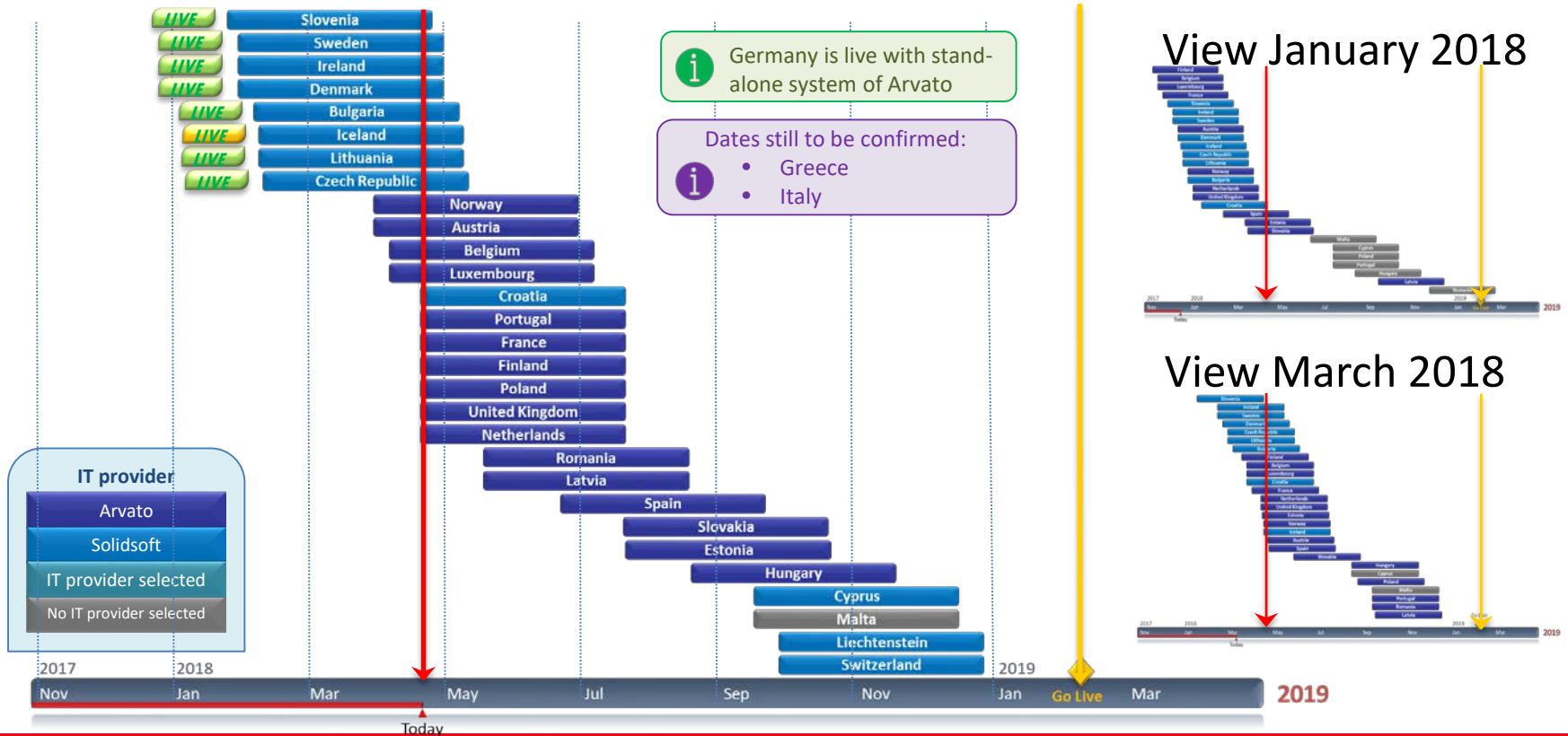
Enable systematic point of dispense verification





Implementation National Systems - View 2 May '18

More go lives expected!





Constant Focus Required on Different Areas

Good progress made, but time is ticking...



**Artwork
started**



**Artwork
Finished**

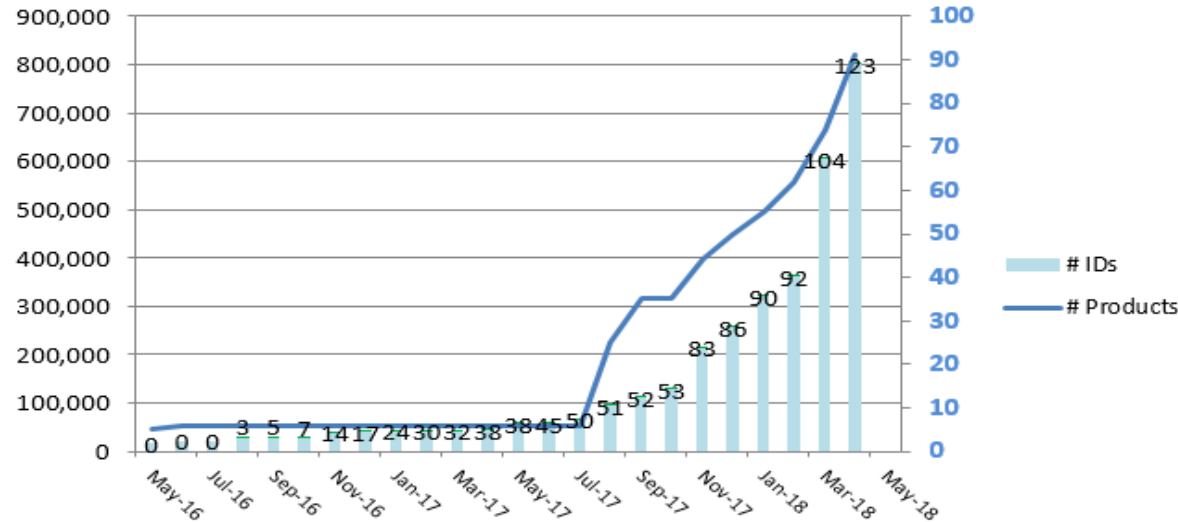
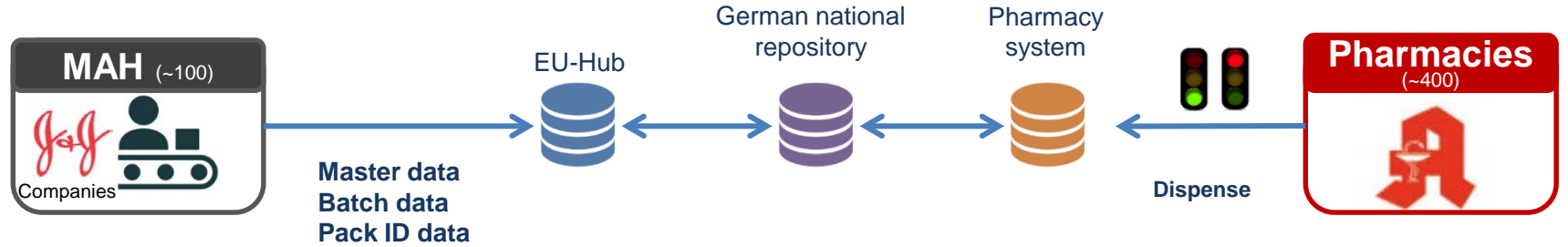


**First
Production**



Piloting the German National System

Proven technology but quite some learning by doing



End-April 2018

- 800K+ packs
- ~400 batches
- ~100 SKUs / products
- 123 dispenses



Key Attention Points

Build on experience gained in other countries



Game Changer

- Full end-to-end process
- Impacting all business units, partners, systems & platforms



Multi-Country Packs

- Refrain from using NTIN
- Alignment on National Reimbursement number



Special Flows

- Marketing Authorization Holder
- Producer
- Distributor



Regulatory Reporting

- Clear specifications needed upfront
- Alignment to industry standards



Know How

- Reuse experience build by stakeholders
- Cost & timings of implementation decreases as capabilities are being deployed

7 Billion Reasons to Care



GS1 Global Standards Will Benefit
Patients and Consumers Everywhere

Audience Q&A time...



...and THIS WEEK do not miss...



...the “Q&A with the Experts” panels related to Traceability:

Thursday – 10 May

- 14:00 to 15:00 hrs

Getting started with traceability – Geraldine Lissalde-Bonnet, Director Public Policy, GS1 GO/Dirk Van Den Wouwer, Johnson & Johnson

Choosing a traceability model – Ulrike Kreysa, SVP Healthcare, GS1 Global Office, Pascal Aulagnet, Pfizer

- 15:00 to 16:00 hrs

GS1 standards for sharing traceability information – Craig Alan Repec, Senior Manager, Supply Chain Visibility, EPCIS & RFID, GS1 GO, Dirk Van Den Wouwer, Johnson & Johnson

Traceability implementation in the hospital – Tania Snioch, Director Healthcare, GS1 GO/Feargal McGroarty, St. James’s Hospital, Ireland

