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EU Falsified Medicines Directive
Getting Started

A guide to the upcoming mandates affecting the European pharmaceutical supply chain.

WHY WAS EU FMD DEVELOPED?

The regulation aims to prevent illegitimate medications from:

- Entering the supply chain
- Threatening patients
- Moving around the world

WHEN DOES IT BEGIN?

EU FMD became law in 2013, and the compliance deadline is approaching:

February 2016	February 2019	February 2025
The Delegated Act on safety features was published, detailing serialization, reporting, and verification.	Compliance deadline for EU member states, EEA members, and Switzerland.	Compliance deadline for countries with an existing serialization regulation in force (Belgium, Greece, Italy)*. *Note: Check when your market intends to implement EU FMD.*

A NOTE ON GRANDFATHERING
What is grandfathering?: Grandfathering is a provision in which some pre-existing situations are not subject to a new rule or regulation.

Grandfathering for EU FMD requirements: Products packed and released for sale before the law takes effect may be distributed and sold until their expiry date, if they are not repackaged or relabeled.

WHO DOES IT AFFECT?

Everyone in the pharmaceutical supply chain is involved:

Pharmaceutical Manufacturers/MAH*

SERIALIZE
Drug product at the smallest saleable unit

REPORT
1. Product master data
2. Product pack data
3. Recall notifications
4. Status updates

**Note: CMOs, distributors or dispensers could be a marketing authorization holder (MAH).*

Parallel Importers

VERIFY
Unique identifier, prior to relabeling and repackaging product

SERIALIZE
Drug product that has been relabeled and repackaged

REPORT
1. Product master data
2. Product pack data
3. Recall notifications
4. Status updates

Wholesale Distributors

VERIFY
Unique identifier, prior to resale

Serial number of returned products prior to re-entry into the supply chain

Dispensers

VERIFY
Unique identifier, prior to dispensation

Decommission product identifier

A NOTE ON CMOs
CMOs will be required to exchange product and serialization data with their MAH customers to enable the CMO to serialize drug product at the smallest saleable unit - however, the legal responsibility is with the MAH.

A NOTE ON CODE FORMAT
Medications must include a 2D DataMatrix with:
- GTIN / NTIN / National code
- Serial number
- Batch number
- Expiry date
- National reimbursement number (if required)

WHICH PRODUCTS ARE INCLUDED?

Prescription and some OTC drugs are subject to EU FMD requirements:

- Prescription drug products
- Certain OTC drugs at risk of falsification (blacklist products)

A NOTE ON WHITELIST AND BLACKLIST PRODUCTS
Medications with special handling under EU FMD are listed in Annexes I to IV of the Delegated Act on safety features.

WHERE IS IT MANDATORY?

All countries in the European Economic Area* are subject to EU FMD requirements:

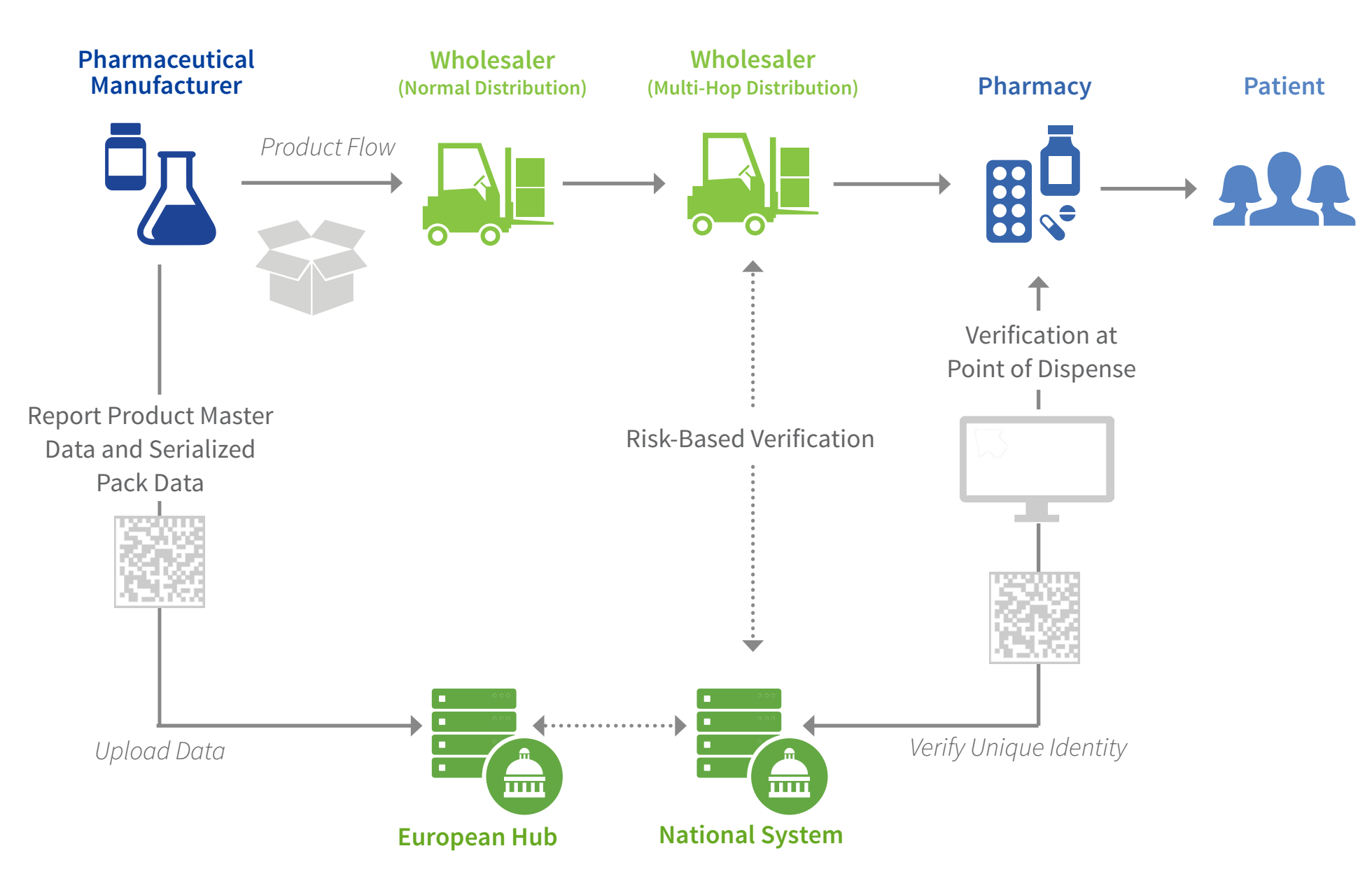
**Note: Switzerland is not part of the EEA but has chosen to adhere to EU FMD.*

A NOTE ON COUNTRIES WITH DEFERRED DEADLINES
Belgium, Italy, and Greece have an additional 6 years to comply.

HOW DOES IT WORK?

The European Medicines Verification System:

Note: Represents one of many potential compliance information flows.



A NOTE ON COMPLIANCE REPORTING
Data that is uploaded and maintained must include:
- Data elements from the 2D barcode
- Code scheme used
- Name of medication
- Common name
- Form and strength
- Package size and type
- Member state(s) for distribution
- Manufacturer name and address
- Marketing authorization holder (MAH) name and address
- List of wholesalers, designated by the MAH through contract, to distribute products on MAH's behalf

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THE MOST PROVEN TRACK AND TRACE SOLUTION FOR EU FMD

TraceLink is already helping more than 700 customers across the supply chain achieve compliance in the U.S., EU, and other markets around the world.

- Completed product master data and product pack data upload certification tests with the EMVO, for connection to the European hub, nearly three years in advance of the deadline.
- **260,000+** Serial numbers already commissioned for live customers to upload to the EU hub.
- Country-specific compliance software for **more** regulated geographies **than any other** provider.
- **69%** Current TraceLink pharma and CMO customers that must comply with EU FMD requirements.
- TraceLink was the first external OBP connection provider to be certified by the EMVO.

BENEFITS

Reduce the time, cost, and risk of achieving compliance

- An out-of-the-box, integrated suite of comprehensive solutions.
- Elastic scalability to meet massive transaction processing required for serialization.
- Tested integration with the European hub.
- Continuous compliance monitoring and updates.
- No need to verify and certify point-to-point connections to each government system.

LOCAL SUPPORT

Located near you, speaking your language

- **80** Team members in the EU - with 400 **worldwide** - dedicated to track and trace.
- **20** Languages spoken by our service specialists.
- European data residency will be hosted by Amazon Web Services and deployed in Germany across multiple availability zones.

PARTNERS

Our partnerships with industry leaders extend the value of the solutions we provide

- **Services:** altran, Excellis Health Solutions, Epista Life Science, ep, Vimachem Industrial Solutions, LifeBee
- **Line Management:** Antares Vision, werum Software & Systems, Sea Vision, Uhlmann, Laetus, OCS Checkweighers, Mettler Toledo PCE Track & Trace
- **Solutions:** advanco