

# VERIFICATION, DISTRIBUTION, AND DATA MANAGEMENT



Your Top Questions about Verifying  
Product and EU FMD

# INTRODUCTION

In 2016, the Delegated Act on safety features was published, introducing tough laws that enable harmonized, European-wide measures to rigorously control the safety and supply of medicines for human use. This part of the EU Falsified Medicines Directive (EU FMD) specifically outlines how pharmaceutical companies, parallel importers, wholesalers, and pharmacies must all address—and meet—three extensive requirements by February 9, 2019:

1. Serialization
2. Verification
3. Compliance Reporting

In this eBook, TraceLink experts answer questions about the second requirement: verification. Learn more from use cases that explore risk-based verification, parallel distribution, aggregation, grandfathering, and more.



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# VERIFICATION, DISTRIBUTION, AND DATA MANAGEMENT

## 1. Initially, verification was to be voluntary but there is now an EU FMD requirement for risk-based verification. What changed?

The original recommendation of the European Federation of Pharmaceutical Industries and Associations (EFPIA) was that wholesalers could perform verification on a voluntary basis. Upon further consideration, however, the industry and regulators identified multiple scenarios in which verification of product identity prior to resale would be necessary.

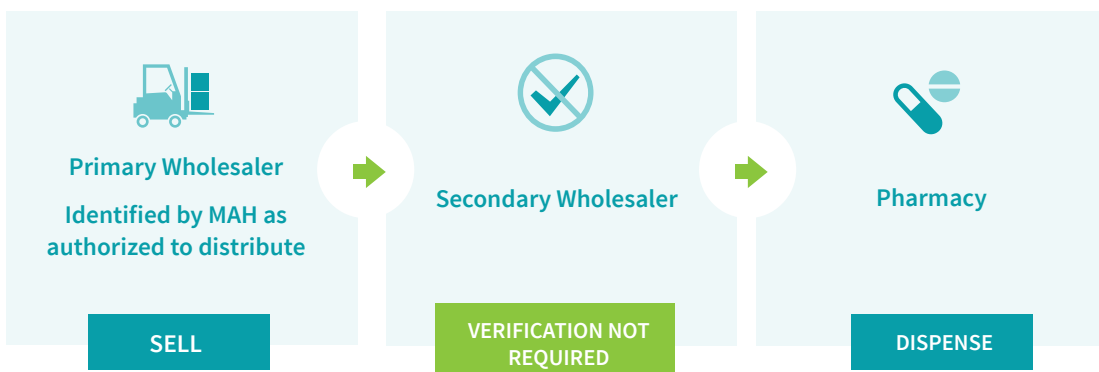
The final Delegated Regulation—published in 2016—identifies specific scenarios where risk for a product is increased in the supply chain, requiring risk-based verification. Wholesalers and parallel distributors must perform risk-based verification against a national system by rescanning product to verify its identity and isolate any potential risk as much as possible.

## 2. If a primary wholesaler has an agreement to distribute product as an appointed supplier of the MAH, does a secondary wholesaler need to perform risk-based verification of that product?

One data element that must be submitted to the EMVS is a list of wholesale distributors appointed by an MAH under contractual agreement to resell product into the supply chain.

When a secondary wholesaler buys product from an MAH-appointed primary wholesaler, the risk is reduced. As a result, the common interpretation in this scenario is that risk-based verification of the product identifier is not required under EU FMD. (Figure A).

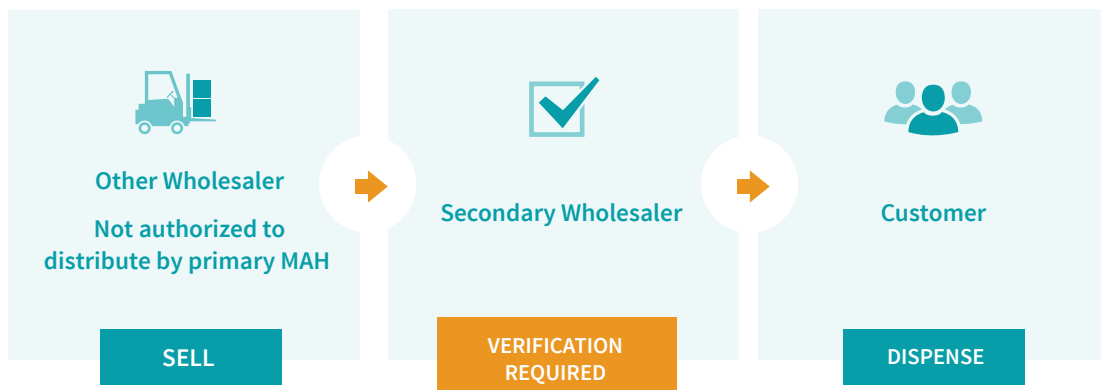
Figure A



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But if a secondary wholesaler buys product from a wholesaler that does not have a primary agreement with the original MAH for that specific product pack, the secondary wholesaler is required to perform risk-based verification (Figure B).

Figure B



### 3. I understand there are additional complexities for parallel importers. What are the parallel importer requirements under EU FMD?

To minimize the risk of diversion in Europe, the Delegated Regulation requires parallel importers and parallel distributors to follow a complex set of serialization, risk-based verification, and reporting requirements.

When a parallel importer alters the original safety features of a product with the intention to repackage or relabel it, before introducing it into the market, it must:

- Verify the original product's identity against the national system.
- Decommission the serial number.
- Serialize all repackaged product at the pack level.
- Report the product master data and serialized pack data to the European Medicines Verification System (EMVS).

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## 4. What are the complexities for wholesale distributors and parallel importers that ship product outside of the supply chain?

Wholesale distributors and parallel importers may also need to perform verification and decommissioning of a medicine pack if the company is distributing that medicine to entities typically considered outside of the normal supply chain, such as medical practitioners and optometrists. These requirements will vary on a country-by-country basis.

## 5. What information should product master data contain?

Every serial number must be accompanied by master data, which functions as a single source of truth to build a reliable system of record—no matter where data is encountered in the supply chain. Master data describes elements such as product name, a price list, or a partner shipping address. In the life sciences supply chain, there are three key subsets:

- **Company Master Data** contains a record for each of your company's locations.
- **Partner Master Data** identifies your partners and their locations.
- **Product Master Data** is a list of all your products and their descriptive information.

Product master data is often the most difficult form of master data to manage because its information is complex, changing, and stored across multiple internal systems. For EU FMD, this is particularly complex because the product code, which is used to identify a particular product and packaging form of a medicine, will vary depending upon the ultimate target market for that medicine. Companies may need to configure a GTIN, an NTIN, or a unique national product code as part of their master data for serialization and reporting purposes.

Only after you've entered a product into your master data can you create and manage its serial numbers using your company's serialization solution.

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## 6. Can the EMVS handle aggregation data?

Under EU FMD, unique identity is defined at the package level and aggregation is not required by law. Uploading aggregation data to the European hub is not possible, as the transaction interfaces supporting the EMVS do not currently support handling for aggregated data relationships. Still, some pharma companies are choosing to aggregate product in Europe and other markets for the business enhancements it provides.

*The transaction interfaces supporting the EMVS do not currently support handling for aggregated data relationships.*

## 7. How is grandfathering outlined under EU FMD? Can non-serialized product be put on the market before the EU FMD deadline and remain on sale until the expiry date?

The Delegated Regulation allows you to distribute and sell non-serialized products without a product identifier before the February 9, 2019, deadline, up through the product expiry date. These EU FMD grandfathering provisions apply only if non-serialized products are released for sale or distribution before the deadline, and if they are not repacked or relabeled.

Countries such as Belgium, Greece, and Italy are allowed an additional six years of transition time to meet the EU FMD deadline because they already have serialization and coding schemes in place. These countries have yet to make a decision on whether they will take advantage of this grace period. But multi-market companies will need to manage both their country-specific requirements—such as Italy's Bollino—and serialization as regulated under EU FMD.

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## 8. How does the MAH confirm the uniqueness of serial numbers generated by their serialization solution?

Serial numbers in Europe must be randomized by a specialized algorithm, and the manufacturer must ensure uniqueness for one year after the expiry date of the pack, or five years after the pack has been introduced for sale into the supply chain, whichever is longer.

A global enterprise system like TraceLink enables management of all serialization and regulatory data, and business processes throughout the enterprise—including randomization and commissioning. Such a Level 4 system is necessary to confirm status, manage exceptions, and verify the data that must accompany each serial number.

*TraceLink enables management of all serialization and regulatory data, including randomization and commissioning.*

### Additional Resources

- TraceLink has a detailed [EU FMD webinar](#) to help you build your core understanding of the regulation. Held live on March 22, 2017, this webinar is available on demand. Get help with what implementation looks like, how to manage partner integrations, and tips for creating your serialization timeline.
- The Delegated Regulation on safety features detailing implementation requirements was published in the Official Journal of the European Union on February 9, 2016. The regulation is available [here](#).
- If you're just beginning your EU FMD compliance journey, the [Inside EU FMD and the Delegated Acts: A Compliance Primer](#) guide is for you. Learn essential information about the EMVS, how the regulations impact you, and what the key differences are between EU FMD and U.S. DSCSA.



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