COMPLIANCE REPORTING, COUNTRY REQUIREMENTS, AND MULTIMARKET TRADE

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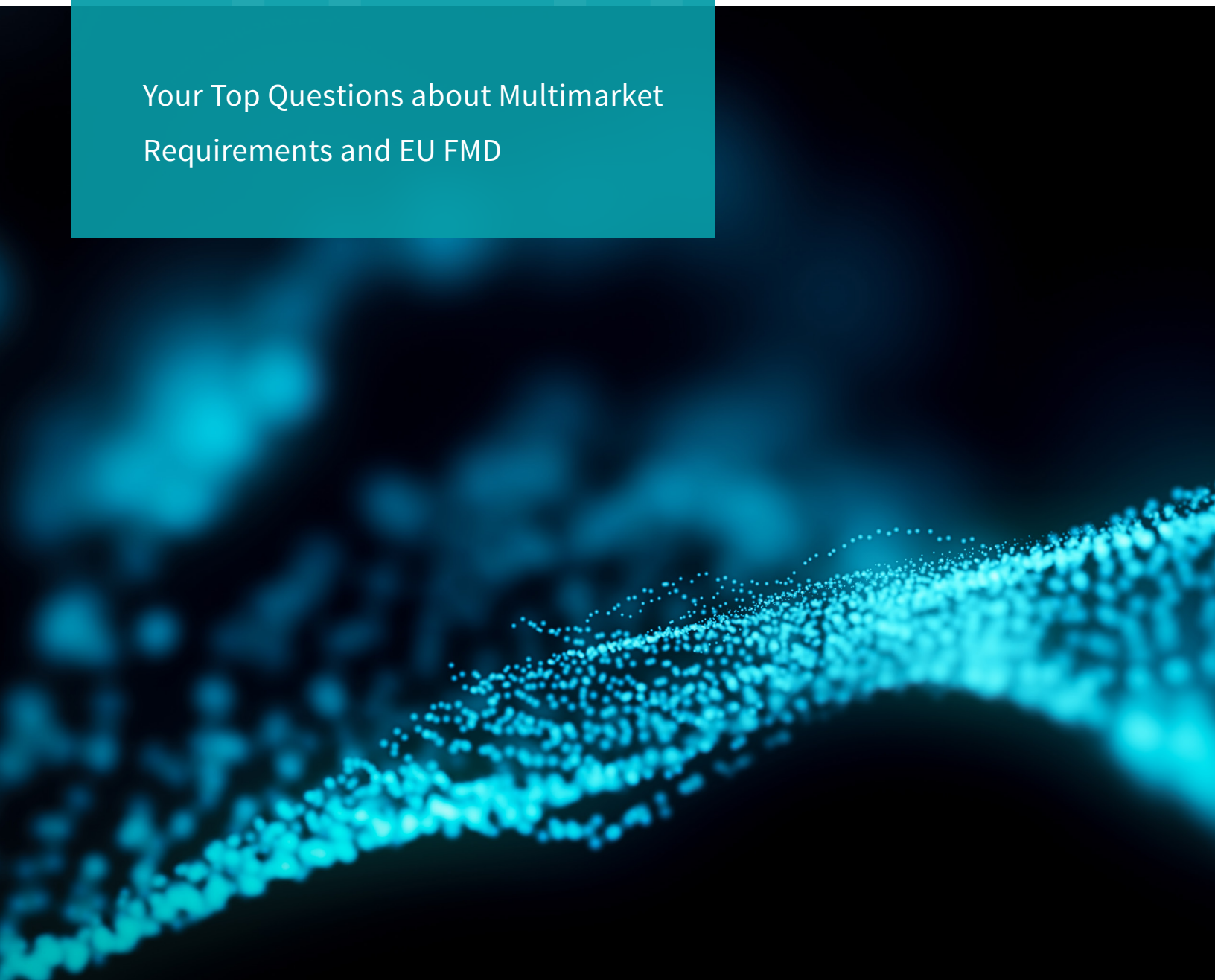
Your Top Questions about Multimarket Requirements and EU FMD



INTRODUCTION

Companies selling medicines in the EU now have less than two years to comply with the comprehensive regulations of the EU Falsified Medicines Directive (EU FMD). The Delegated Regulation of 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 and Safety Features
3. Compliance Reporting

In this eBook, TraceLink experts answer questions about the third requirement: country compliance reporting and multimarket trade considerations. Learn more from use cases that explore country-specific considerations for France, Belgium, Germany, Switzerland, the U.K., India, and the U.S.

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1. How do serialization and traceability requirements under EU FMD overlap with regulations outside of the EU?

No other country in the world has the same regulatory requirements as those imposed by the Delegated Regulation under EU FMD. Just because you meet serialization and traceability requirements for EU FMD does not guarantee you are meeting any other country's regulatory requirements. Still, there are many commonalities—and differences—between EU FMD and other countries.

European Union

Commonalities

- **DataMatrix** – the GS1 DataMatrix barcode is used as the standard data carrier in the EU, which is also the case in the U.S. and South Korea. (China, on the other hand, uses a linear barcode today.)
- **GTIN** – most EU countries will accept the GS1 GTIN.
- **Secondary level** – serialization is required at the secondary saleable-unit level, which is the most common scheme across global regions.
- **Aggregation** – not required under EU FMD, which is also the scenario in the U.S.
- **Halting counterfeit medicine** – a common goal of any traceability scheme is to halt the movement of counterfeit drugs through the supply chain.
- **Product integrity** – EU FMD, like other countries, governs packaging and labeling operations to address product integrity.

Differences

- **GTIN** – some EU countries may choose not to accept the GTIN, opting for a unique national identifier instead.
- **Case level** – in the EU, companies do not have to serialize at the homogenous-case level as they do in the U.S.
- **Randomization** – the Delegated Regulation requires randomization coding of serial numbers using a specialized algorithm. This is unlike the U.S., which has no specifications for randomization or rules for ensuring uniqueness of serial numbers.

- **Data elements** – product identifiers may need to be encoded with four, five, or more data elements, depending on the market(s) the product is targeted for.
- **Verification** – EU FMD is focused on point-of-dispense verification in the supply chain, not traceability. This is fairly unique worldwide. Unlike the U.S., South Korea, China, and Brazil, the focus of EU FMD is not to track key events like changes of ownership across the supply chain. Instead, the most important factor is to ensure verification of the medicine pack before it is dispensed to a patient.

Further comparison between EU FMD and other country requirements would warrant considerable discussion. While this eBook seeks to address several country-specific scenarios, you can find more detailed information about EU FMD and country requirements by downloading the eBook, Inside EU FMD and the Delegated Acts: A Compliance Primer.

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2. Will France require safety features for reimbursed product?

In France, the regulatory authorities have discussed applying EU FMD to reimbursed product in addition to prescription products. If these requirements become finalized, then these products would need to have safety features applied to them and follow EU FMD requirements.

France

Under EU FMD, European countries are authorized to determine how the requirements apply to their specific product situations. For example, some products are available by prescription in one market but not in another.

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3. For multimarket product packs, will countries need to include the national code in the 2D DataMatrix, or will they just use the GTIN?

For European countries following EU FMD, the reality is that the product code will be a mixed requirement for the foreseeable future. Some countries accept the GS1 Global Trade Item Number (GTIN) today, while others are transitioning from a National Trade Item Number (NTIN) containing a national code to a GTIN. Still others presently have no plans to transition to a GTIN from the product code.

Germany

Germany, for example, is currently considering the use of a GTIN, plus a National Healthcare Reimbursement Number (NHRN) for multi-market packs, and the use of a national product code or an NTIN for a single-market pack. We expect these decisions to continue evolving between now and February 2019.

For European countries, the reality is that the product code will be a mixed requirement for the foreseeable future.

4. Will Belgium use the GTIN like most countries, or do they plan to use the PPN?

While the GTIN is often used in the Belgian market, Belgium follows a pan-European product coding structure for packaging, using the Pharmacy Product Number (PPN) for its national product code. Today, Belgium is still aligned in using the PPN for product coding under EU FMD, but there are discussions underway between local regulators and the industry about the potential to transition to GTIN for the final regulation.

Belgium

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5. With Switzerland becoming part of the EMVO, will products moving across EU and Swiss borders need to be decommissioned?

The final resolution of this issue is unclear today, but given the volume of cross-border trade between EU countries and Switzerland, it is likely that some regulatory accommodation will be made. If so, then for the purposes of EU FMD regulation, this kind of medicine movement would not be considered an import or export and would therefore product would not need to be decommissioned.

Switzerland

Given the volume of trade between EU countries and Switzerland, it is likely that some regulatory accommodation will be made.

6. If we follow the U.S. DSCSA guidelines for pallet-label logistics, will the same product also be accepted under EU FMD?

Under EU FMD, there are no regulations for the application of safety features at the pallet-label logistics level. Still, the Delegated Regulation services a collection of independent countries, and because drugs are primarily regulated at the country level, one country's labeling and packaging requirements may be different from another.

United States

Whether U.S. DSCSA guidelines for labeling at the pallet-logistics level are okay for products shipped to European countries will depend on the specific country of destination, based on any local labeling requirements that a particular country may have.

Under EU FMD, there are no regulations for the application of safety features at the pallet-label logistics level.

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7. If my company has an exemption from India's export council (Pharmexcil), is it still necessary to follow all of the EU FMD guidelines for safety features?

India

Yes. Your organization must completely follow the guidelines of EU FMD whether you have an exemption or not. Being granted an exemption for India export regulations does not change the requirements an MAH has under the Delegated Regulation.

Serialization at the sales-pack level for India export is quite different from EU FMD requirements. Because India export regulations and EU FMD vary significantly, you may want to consider pursuing an exemption from the secondary (sales pack) serialization requirements. For example, India export requires a GTIN for product, but depending on the European country, your product may need a GTIN, NTIN, or national product code.

In addition, the India exemption also requires that you still barcode product at the tertiary level for transport cases for export. This case-level requirement won't be a factor in the EU, although it will be an issue in other countries such as the U.S.

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8. How does Brexit impact the requirements in the U.K.?

United Kingdom

Even as the U.K. plans their exit from the EU, the expectation is that they will still follow EU FMD with plans to participate in the European Medicines Verification System (EMVS) for pharmaceutical traceability. Our pharmaceutical customers are telling us their intentions today are also to follow EU FMD for the English market. And because other member states will still use the EMVS, you will want a solution that ensures you are fully covered by your provider's integration into the European hub.

Other non-EU countries are also deciding to align with EU FMD (Norway and Switzerland, for example), so you'll also want a serialization solution that can track developments that support compliance reporting specific to their adopted national system.

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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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