Top 15 Questions and Answers

EU FMD Safety Features and Verification

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Now set for early 2019, the Delegated Act on safety features for the European Union (EU) Falsified Medicines Directive (FMD) has pharmaceutical companies, parallel importers, wholesalers, and pharmacies facing a tight timeline to address extensive serialisation, compliance reporting, and verification requirements. The Delegated Act includes several unexpected rules that add complexity to FMD planning and preparation.

Many supply chain companies have raised questions related to the impending Delegated Act requirements. Read on for some of the most common queries, plus answers from TraceLink experts.

Questions

1. What is the likelihood that all supply-chain organisations will be prepared by the February 9, 2019, deadline? What is the sense of readiness within the pharmaceutical industry?

2. Could you elaborate on the “reporting” in “compliance reporting”?

3. What are the safety features and how are they supposed to be verified?

4. Do all medicinal products require a serial number and other safety features?

5. Do the EU FMD regulations cover only European Union member states? If I’m selling into a specific country, how do I know if that country is covered or not?

6. Can anybody submit compliance reporting to the European hub?

7. The European Federation of Pharmaceutical Industries and Associations (EFPIA) model explains that wholesalers may perform “voluntary” verification, but there are certain situations where a wholesaler is required to verify product identity. Why is there a difference?

8. If a distribution warehouse drops a shipper case of product that must be destroyed, who decommissions the serial number on the product units in that shipper case—the MAH or the warehouse?

9. Suppose I buy products from a wholesaler in Country A, store them in Country B, with plans to resell them later to Country C for repackaging or relabeling. Where does decommissioning of the original barcode take place?

10. When a wholesaler is expected to perform risk-based verification of products against a national repository, are they expected to scan and verify each and every package? Does this thereby present an argument for aggregation in these instances?

11. The EU reporting and verification model requires that parallel distributors must verify against national repositories. Shouldn’t it be possible to do this verification using the European hub?

12. What is the regulatory view for track and trace for medical devices?

13. Do veterinary medicinal products require safety features?

14. How can TraceLink help my company meet the EU FMD requirements?

15. What enterprise resource planning (ERP) systems does TraceLink already support?

Question 1: What is the likelihood that all supply-chain organisations will be prepared by the February 9, 2019, deadline? What is the sense of readiness within the pharmaceutical industry?

Answer: There is a lot to do for the hundreds of thousands of supply chain members serving the EU market in order to be ready within the next three years. Each company faces considerable work both internally and across their supply network to prepare, and the decisions that you make will be dependent on the decisions that others in your supply network make. But there are clear ways of reducing time, cost, and risk during this period. Many companies are already in the process of developing a clear strategy for surveying product lines, internal packaging sites, and external supply partners to determine the data management and network connectivity scope they need to master.

Three years may seem like a lot of preparation time. But if you wait to create a full serialisation and compliance plan with resource requirements and realistic timelines, you introduce significant risk. Use the lead time you have to your advantage in order to determine the full scale and scope of your business requirements and the key solution capabilities and resources that you'll need for success.

Question 2: Could you elaborate on the "reporting" in "compliance reporting"?

Answer: Full compliance with any track and trace regulation typically has many parts. Depending on the regulation, this may include activities such as serialisation, verification, supply chain traceability and government reporting.

"Reporting" in terms of EU FMD compliance for a marketing authorisation holder (MAH) goes well beyond simply executing a file submission to a governmental system. For the EU, compliance reporting involves a multitude of activities including:

- The collection and preparation of product master data
- The collection and preparation of serialised product pack data
- An understanding of the business rules governing each target market for each product shipped into the market

- Generation and submission of the appropriate product master data and pack data transactions through an approved communication link to the European hub
- Management of product status with the European hub as that status changes throughout the lifecycle of the product (such as decommission or recall)
- Management of exceptions as they may occur (such as submission errors)

Secure regulatory compliance with the EU FMD demands a complete compliance management solution that supports all facets of compliance reporting to the European hub.

Question 3 : What are the safety features and how are they supposed to be verified?

Answer: Safety features contain two parts related to the packaging and identification of a medicinal product:

1. A unique identifier encoded in a two-dimensional barcode, which enables the identification and verification of each pack. The unique identifier contains multiple data elements, including a product code and unique serial number.

   To verify the unique identifier, a stakeholder (dispenser or other) in the supply chain scans the barcode and submits the information to the national repository. The national repository responds with information confirming the authenticity of the unique identifier.

2. Anti-tampering technologies that enable the determination of whether the product packaging has been tampered with. There is no mandatory specification for what anti-tampering devices must be included on a pack.

Question 4: Do all medicinal products require a serial number and other safety features?

Answer: Not all medicinal products require safety features. The requirement depends on whether the product is a prescription drug or not, as well as the risk level associated with the product.

In general, all medicines requiring a prescription must carry a serial number and other safety features, with the following exceptions:

- Prescription drugs listed in Annex I of the Delegated Act (the "whitelist") are exempt from this requirement.
- Medicinal products that are not subject to prescription, but are listed in Annex II of the Delegated Act (the "blacklist") because of their risk level, do require safety features applied to each pack.

It is important to note that a product may be considered a prescription medicine in one country but not in another. Thus, in preparing your serialisation and compliance system to manage multi-market products, such a system will need to identify and act appropriately (for example, in applying safety features) depending on the target market.

Question 5: Do the EU FMD regulations cover only European Union member states? If I'm selling into a specific country, how do I know if that country is covered or not?

Answer: The EU FMD and related Delegated Acts were designed by the European Parliament and EU regulators to provide a harmonised European Medicines Verification System (EMVS) for adoption across EU member states. Other countries having extensive trade arrangements with the EU that are expected to align with and follow EU FMD requirements for safety features include Switzerland and the European Economic Area members of Norway, Iceland, and Liechtenstein. It is also important to note that the EU FMD provides considerable flexibility to the individual country to determine if a medicine must contain safety features such as an identifier and on-package features (and thus require serialisation/reporting) or not.

In addition, a given country may add additional data to the on-package and data carrier requirements. So the same drug product may have quite different serialisation and reporting requirements in two different target markets.

Question 6: Can anybody submit compliance reporting to the European hub?

Answer: Connections to the European hub are managed by the European Medicines Verification Organisation (EMVO). The EMVO have very specific criteria for how a connection is developed and proven.

Question 7: The European Federation of Pharmaceutical Industries and Associations (EFPIA) model explains that wholesalers may perform "voluntary" verification, but there are certain situations where a wholesaler is required to verify product identity. Why is there a difference?

Answer: Early on, the EFPIA took the lead in coming up with a model for a repositories system of drug product information and serialisation data coupled with verification of drug products in the EU, which then became the European Stakeholder Model (ESM). In this original design, it stipulated that while pharmacy dispensers would be required to verify drug product identity, wholesalers in the middle of the supply chain would also be able to verify identity of drug products using similar mechanisms—if so desired and on a voluntary basis. With the publication of the final Delegated Act related to safety features and the repositories system, however, several supply chain transactions were identified as areas where potential risk was introduced into the supply chain. These included sales between wholesale distributors in the supply chain and resale of returned product. As a result, certain supply-chain scenarios involving wholesale distributors now trigger required risk-based verification procedures.

For example, if a wholesale distributor purchased drug product from another wholesale distributor that is not the original manufacturer—a wholesaler holding market authorisation or a wholesaler that is essentially designated as an agent of the MAH—this second wholesale distributor is required to verify the authenticity of the unique identifier prior to resale.

Question 8: If a distribution warehouse drops a shipper case of product that must be destroyed, who decommissions the serial number on the product units in that shipper case—the MAH or the warehouse?

Answer: If a case of product is dropped and it is determined that all units in the case must be destroyed, then the serial numbers assigned to it must be destroyed. But whether the case must be decommissioned or not depends on whether the unsaleable product has been commissioned and reported to the EMVS.

If the MAH owns the product, then it has already been commissioned and the serial number will need to be decommissioned. If the distribution warehouse has not reported product master data to the EMVS, however, then decommissioning is not required since no original commission report was generated. The warehouse may still want to report it for internal bookkeeping purposes, though.

Question 9 : Suppose I buy products from a wholesaler in Country A, store them in Country B, with plans to resell them later to Country C for repackaging or relabeling. Where does decommissioning of the original barcode take place?

Answer: If the repackaging and relabeling occurs in Country C, then the decommissioning would occur in Country C prior to the repackaging or relabeling of the original pack. The key point is determining when the repackaging or relabeling occurs—not necessarily where it occurs.

Question 10: When a wholesaler is expected to perform risk-based verification of products against a national repository, are they expected to scan and verify each and every package? Does this thereby present an argument for aggregation in these instances?

Answer: Unique identity is defined at the package level under the EU FMD. Since the risk-based verification requirement specifies that the wholesaler shall verify the authenticity of the unique identifier of the medicinal product, the common industry interpretation we hear is that the wholesaler will need to verify each package.

If you receive a case of 50 packages in a scenario that triggers the verification requirement, then you will need to perform verification on those individual packs regardless of the case packing that they were sent in.

What is unclear is any specific requirement that determines the precise method that a company may use to perform that verification. The Delegated Act on safety features does not specifically state that each individual barcode of a pack must be physically scanned as part of the verification process for each unique identifier. This may open the door for the use of inference and aggregation to improve the speed of the verification process.

If the packages are contained in a closed case for which a case identifier has been created and aggregation relationships generated between the case identifier and the identifiers of each of the packs within the case, then there are potential benefits in being able to infer the contents of that closed case using aggregation data to retrieve the unique serial numbers needed for verification. This would allow the wholesaler to avoid having to open the case, extract each pack, and then individually scan each pack for verification against the repositories system. Note that case-level serialisation and aggregation are not required by law under the EU FMD and associated Delegated Act on safety features—and aggregation itself is the subject of considerable industry debate. These are just potential operational enhancements that the industry may consider during implementation of solutions to efficiently manage EU FMD compliance across the supply network.

Question 11: The EU reporting and verification model requires that parallel distributors must verify against national repositories. Shouldn't it be possible to do this verification using the European hub?

Answer: The EMVS, which includes the European hub and a series of national repositories, is structured such that when an MAH reports product master data and pack data to the European hub, it passes the pack and unique identifier information straight through to the national repositories. The national repositories are the actual repositories containing the required package data and unique identifier for verification within member states.

The European hub is not a repository in this sense. You can think of the European hub more like a switch or central information and data router. The system was really designed for stakeholders to query against the local system that actually has the information needed for verification.

Question 12: What is the regulatory view for track and trace for medical devices?

Answer: The EU FMD only covers medicinal products for human use and doesn't address the identification and traceability of medical devices. Globally, regulations concerning unique device identity (UDI) have been considered or adopted across several countries. Countries such as the U.S., Argentina, and Turkey already have regulations concerning UDI while places such as the EU and China are considering them. Because we've seen serialisation regulations and the track and trace of prescription medicines grow so quickly in this decade, it wouldn't be surprising to witness significant growth in similar requirements for medical devices in the future. Probably the biggest difference is that medical device regulations tend to focus on UDI and not on supply-chain traceability.

Question 13: Do veterinary medicinal products require safety features?

Answer: No. Safety features are only required for products intended for human use.

Question 14: How can TraceLink help my company meet the EU FMD requirements?

Answer: It is crucial to start planning for the extensive new serialisation requirements in order to meet the 2019 deadline for EU FMD compliance. This is where TraceLink can help. Working with our proven, global network-tenant solution allows you to leverage an end-to-end compliance platform that is already commercially deployed to meet EU FMD serialisation and compliance reporting requirements, while simplifying the overall management of your supply network.

The TraceLink EU Compliance solution was designed to provide exactly that—a complete compliance management solution, including:

- Preparation and submission of required product master data and serialised pack data
- Management and updating of product status
- Automated report triggering based on master data and operational workflow triggers
- Full exception management and alerting
- Full search capabilities based on flexible criteria
- Report drilldown for targeted data retrieval

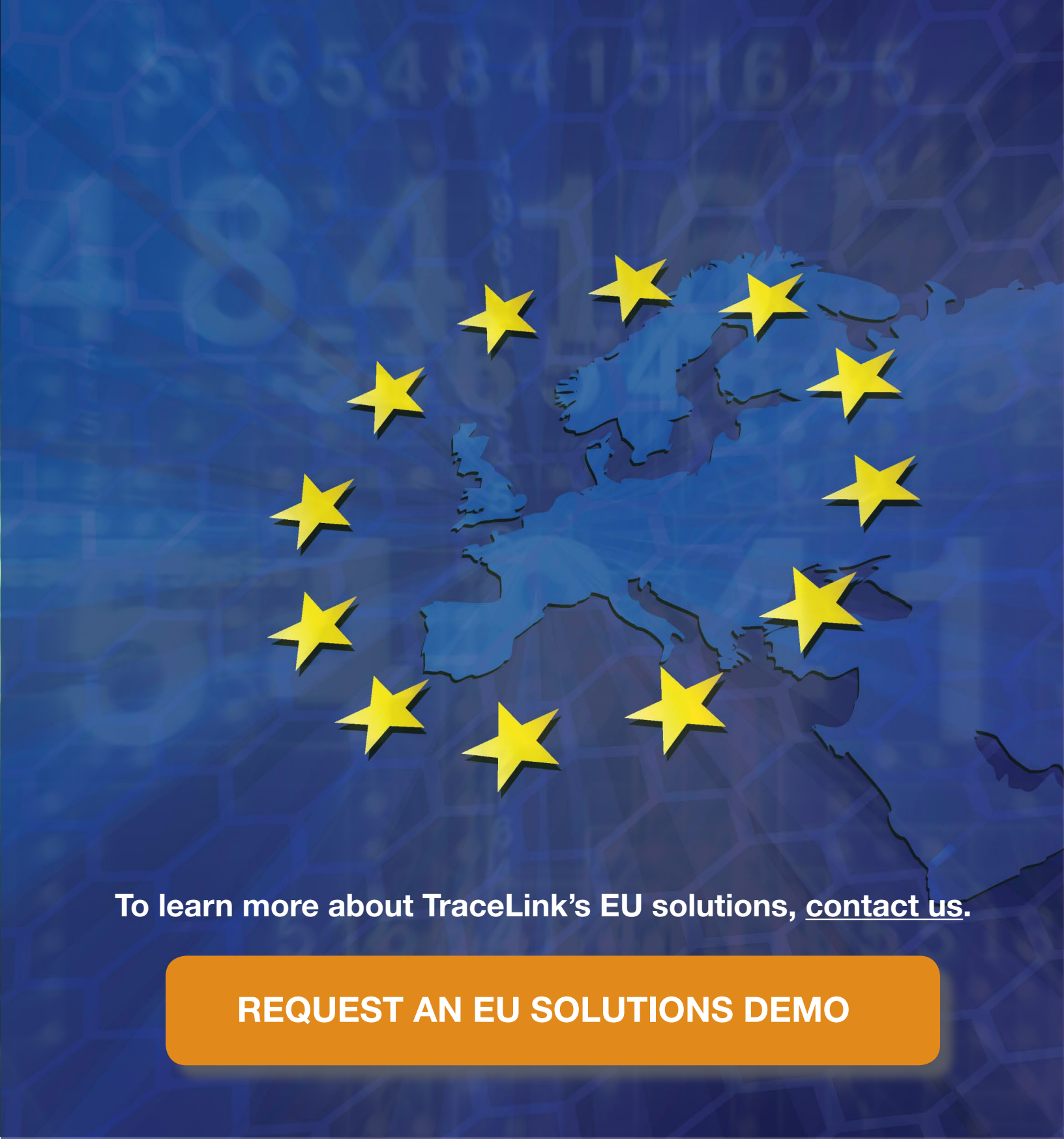
Question 15: What enterprise resource planning (ERP) systems does TraceLink already support?

Answer: TraceLink supports native integration with a broad range of ERP and warehouse management (WMS) systems, including SAP, Oracle, JDE, Microsoft, QAD, Infor, and JDA. In addition, TraceLink has integrations with more than a dozen of the leading line management systems such as Optel Vision, Systech, Laetus, Uhlmann, and MTPCE.

TraceLink also speeds connectivity to any new systems with a well-defined integration interface and transaction mapping process. Finally, solutions on the TraceLink Life Sciences Cloud also support standalone operation using our efficient user interface and manual data import capabilities for those companies not yet ready to implement a fully integrated infrastructure.

Additional Resources

- TraceLink has a very detailed EU FMD educational webinar on the track and trace requirements. Held live on February 3, this webinar is available on-demand. Get help as you begin the detailed planning required for successful EU FMD compliance.
- The Delegated Act 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.
- The European Commission published an additional set of questions and answers on safety features for medicinal products here.



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