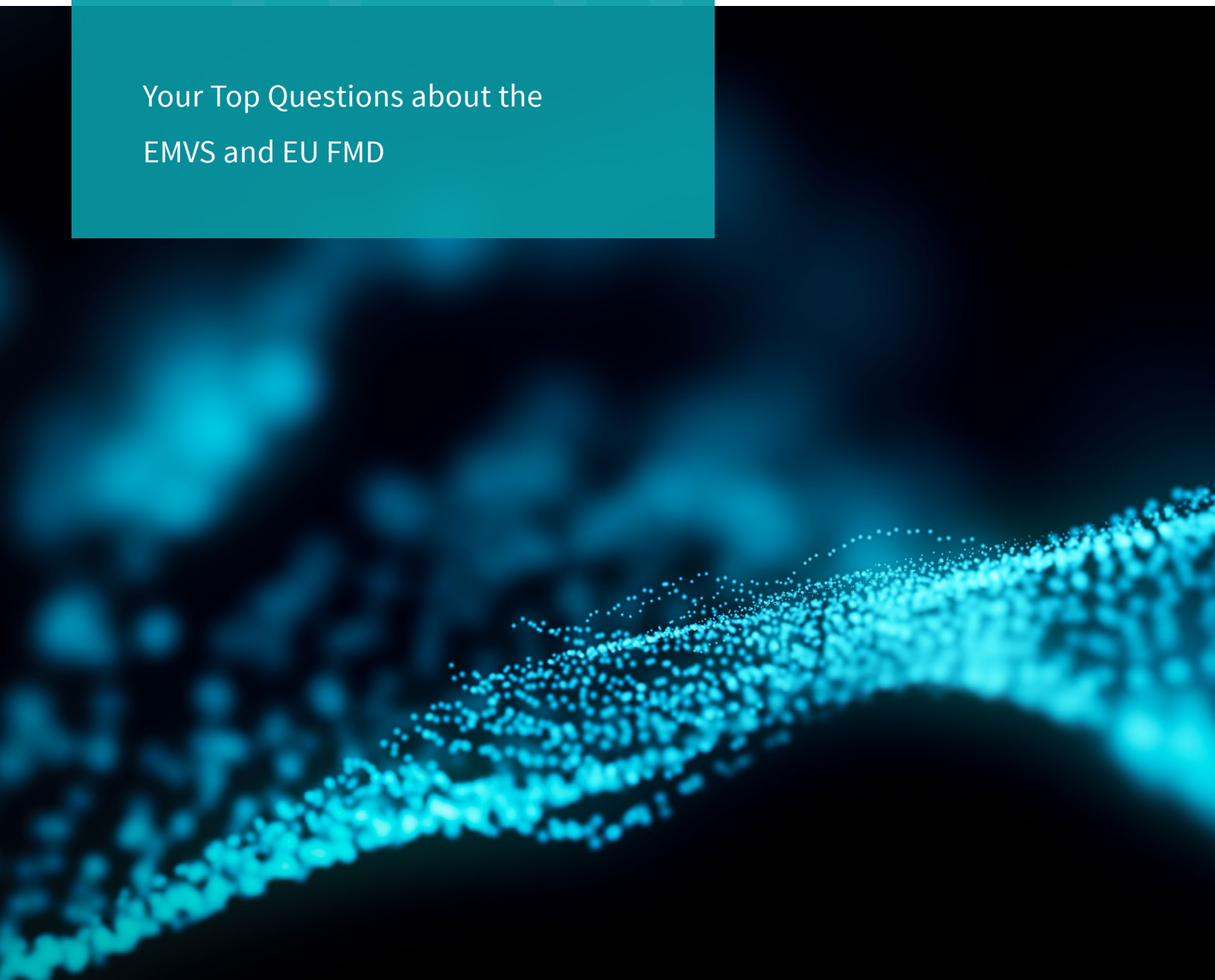
# SERIALIZATION, ONBOARDING PARTNERSHIPS, AND THE EUROPEAN HUB

Your Top Questions about the EMVS and EU FMD

tracelink
Life Sciences Cloud



# 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 first requirement: serialization. Learn more from use cases that explore European hub connectivity, onboarding partnerships, and implementation timelines.

# TABLE OF CONTENTS

# SERIALIZATION, ONBOARDING PARTNERSHIPS, AND THE EUROPEAN HUB

## 1. What is the European hub and who is responsible for transmitting data to and from national systems and the hub?

The European hub operates as a router or switch to exchange data between an Onboarding Partner (OBP) and a National Medicines Verification System (NMVS). The hub is managed by the European Medicines Verification Organization (EMVO), while national repository systems serve the EU member states and other European countries that follow EU FMD regulations.

Together, the European hub and the NMVS repositories comprise the European Medicines Verification System (EMVS), which was created to provide a comprehensive, efficient mechanism for pharmacy dispensers and other supply chain stakeholders to verify the product identity of medicines introduced into the supply chain by pharmaceutical companies and parallel importers.

*The EMVS was created to provide a comprehensive, efficient mechanism for pharmacy dispensers and other supply chain stakeholders to verify the product identity of medicines.*

## 2. When is the deadline to connect to the European hub?

The Delegated Regulation on safety features requires a marketing authorization holder (MAH) or parallel importer (PI)/distributor to have product serialized—with product and serialization data uploaded to the European hub—on or before February 9, 2019.

Your company's timeframe to connect to the hub will be determined by how much time you will need to:

- Execute an OBP agreement with the EMVO.
- Establish the technical connection to the hub.
- Test and troubleshoot your integrated connection.
- Execute the required product master and product pack data transactions for all products you've serialized for the market.

## 3. What will happen after the February 2019 EU FMD deadline if a country's NMVO isn't fully operational?

Every country following EU FMD is supposed to establish and connect to the European hub and national repository system by 2019, whether operating their own repository or sharing one. At this point, it's not clear what the roles and responsibilities will be for an MAH or PI with a product that's approved for a particular country that doesn't have an operational national repository system, nor for a pharmacy dispenser operating in such a country.

We expect more details to be published in the coming months on the processes to follow should a specific country and its National Medicines Verification Organization (NMVO)/repository system not be ready by the EU FMD deadline in 2019.

## 4. We are a group of companies with multiple MAHs. Which one will serve as the OBP?

A corporation that consists of multiple MAHs/PIs must decide which legal entity will act as the OBP as part of the signup and agreement process with the EMVO. The OBP is then legally authorized to sign on behalf of all listed MAHs.

## 5. Can an OBP be from a non-EU country?

Yes. An OBP can be a registered company headquartered or domiciled in any country.

## 6. If we are an MAH, and we contract with 2 CMOs, who will be the OBP?

As the MAH, you or your organization's designated legal entity will serve as the OBP, and will be authorized to sign on behalf of your MAHs/PIs. The OBP combines the serialization data and all common MAH connections, along with any CMOs those MAHs may be using. A CMO cannot directly connect to the European hub.

## 7. If a CMO is listed as the official manufacturer, can they connect to the EMVS to upload on behalf of their MAH customer?

No, a CMO cannot technically or contractually connect directly to the EMVS to upload data on behalf of an MAH. The data uploaded is always attributed to the party that uploads it, so the MAH serving as the OBP must own the account and connection with the European hub.

There are two options for a CMO to get data into the EMVS:

1. The CMO can send compliance data to the OBP for the OBP to upload directly.
2. The OBP can create an account for the CMO on the OBP system. This enables the CMO to upload to the hub on behalf of the MAH.

*A CMO cannot technically or contractually connect directly to the EMVS to upload data on behalf of an MAH.*

## 8. How is a 3PL comparable to a CMO or wholesale distributor in regards to connecting to the European hub or national systems?

The EMVO stipulates that, like a CMO, a 3PL may not connect directly to the European hub, and thus must send any required information for upload to the OBP to enable the OBP to upload the data to the European hub. The OBP could optionally grant an account on their system for such upload.

A 3PL may connect to a national system to perform updates to information about medicines in the system, such as product status. In this scenario, they would connect under a Wholesaler profile.

## 9. Can a CMO generate serial numbers under EU FMD?

As long as a CMO follows the legal requirements of EU FMD—including randomization of serial numbers and ensuring the correct product codes are applied to the right product packs—it is certainly possible for that company to generate serial numbers for product packs under EU FMD.

TraceLink does have customers that are set up this way, though in helping hundreds of companies with serialization, we've seen that it's not necessarily simpler for a CMO to be managing serialization and then sending data back to the original manufacturer.

Particularly under EU FMD, which has requirements for traceability and government compliance reporting, it is difficult for an MAH to manage serialization—with numerous types of master data and status information to manage internally—unless the MAH owns the serialization repository itself. The MAH must also have the ability to officially prepare the compliance reports and status updates to the European hub, adding even greater complexity.

## 10. Is it the responsibility of the MAH to ensure the manufacturer doesn't release product before the product pack data has been successfully uploaded into the European hub and national systems?

Our interpretation of the Delegated Act is that the regulation is clear about the information and status of product pack introduced into the supply chain: it is the responsibility of the MAH or PI, not of any manufacturing partner or facility. If you're unsure about the timing or triggers signaling that you've successfully submitted information into the European hub prior to a CMO shipping directly to a 3PL and then out to the marketplace, there are facilities to query the hub for status information about your own products.

You may consider using an operational trigger that would check whether a product pack has been successfully uploaded into the EMVS, thereby ensuring no packs get into the supply chain that aren't appropriately identified.

*You may consider using an operational trigger that would check whether a product pack has been successfully uploaded into the EMVS.*

## 11. Can a wholesaler use the European hub's verification request capabilities as a way to control serial numbers instead of building a connection with a national system?

The European hub's verification request capabilities are designed to be used by an OBP submitting product pack data to the hub, and not by other stakeholders in the supply chain. In general, wholesale distributors that need to perform a risk-based verification request must do so by submitting queries against the national system that serves their market.

# SERIALIZATION, ONBOARDING PARTNERSHIPS, AND THE EUROPEAN HUB

## 12. Is the connection to the European hub performed through a third-party system like TraceLink?

Yes. An authorized third-party solution such as TraceLink can connect to and manage all compliance data exchanges between the European hub, an OBP, and its MAHs/PIs/CMOs.

*TraceLink can connect to and manage all compliance data exchanges between the European hub, an OBP, and its MAHs/PIs/CMOs.*

## 13. How long does it take to connect to the European hub—from signing the NDA to being live in production and performing validation?

Due to the highly variable size and scope of serialization and traceability operations, there is no set time for how long this overall process of connecting to the hub will take. To avoid risk, many companies are giving themselves at least several months of buffer time between the legal deadline and their operational readiness deadline for connection to the hub.

*Companies are giving themselves at least several months of buffer time between the legal deadline and their operational readiness deadline for connection to the hub.*

Part of the complexity involves working with the EMVO's commercial and partner management team to execute the participation request, perform legitimacy checks of your company's application, and to complete the contractual and commercial onboarding processes.

The other major factor comes from managing the technical onboarding of EMVO connections across the EMVO, OBP, and solution teams. TraceLink is at a distinct advantage by being one of just two solution providers with a certified connection to the European hub. The fulfillment of these extensive testing and certification processes benefits customers by enabling them to use a connection that's already tested and operating with the EMVO and with other OBPs.

# SERIALIZATION, ONBOARDING PARTNERSHIPS, AND THE EUROPEAN HUB

*TraceLink is at a distinct advantage by being one of just two solution providers with a certified connection to the European hub.*

## 14. What documentation is needed to begin planning for implementation of a serialization solution?

In working with pilot partners and hundreds of other serialization and traceability projects across the globe, TraceLink has developed a series of project documentation deliverables for use with any implementation. We understand the different components you need to account for during implementation, so we provide all of this as part of the implementation service. Your implementation will include project plans, design templates, and other documentation so you don't have to build your serialization program from scratch.

*TraceLink has developed a series of project documentation deliverables for use with any implementation.*

## 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.

# REQUEST AN EU SERIALIZATION SOLUTIONS DEMO

tracelink
Life Sciences Cloud