ANSWERS TO YOUR TOP QUESTIONS

Compliance Reporting, The European Hub and National Systems

tracelink
Life Sciences Cloud

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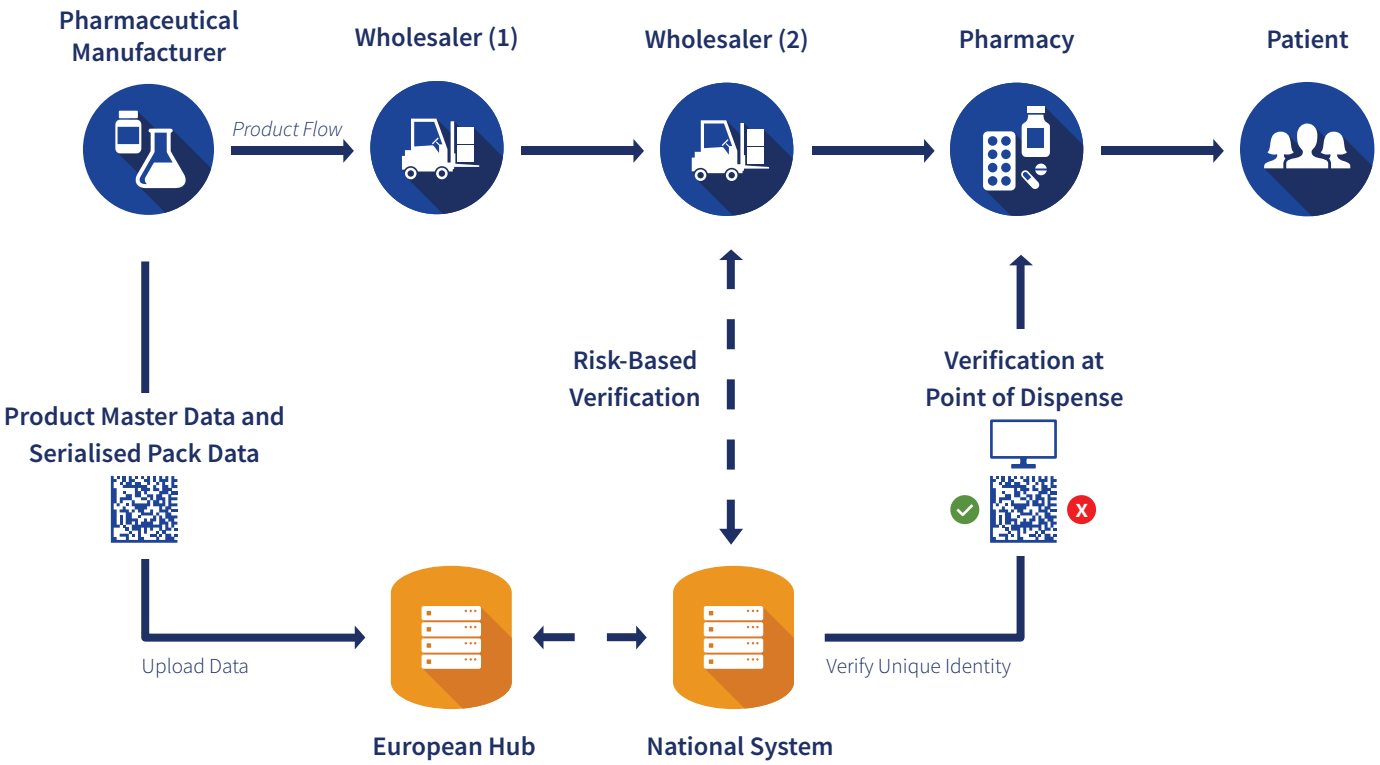
Introduction

The EU Falsified Medicines Directive (FMD) is changing the way the pharmaceutical supply chain will operate in Europe. In addition to introducing new serialisation, verification and safety feature requirements for pharmaceutical companies, parallel importers, wholesale distributors and pharmacies, EU FMD is also introducing new compliance reporting requirements.

Under EU FMD, Marketing Authorisation Holders (MAHs) will need to upload product data to the European Hub, and also register with the National Systems in the EU Member States where their medicines are sold. Wholesalers and pharmacies, meanwhile, must connect to the National Systems in which they operate.

The European Medicines Verification System



As companies prepare for the February 2019 deadline, they have an increasing number of questions about compliance reporting requirements and how they will interact with the critical systems, the central European Hub and National Systems. To help you understand exactly how they will work and what your responsibilities are, we have compiled answers to frequent questions.

QUESTION 1

How much does it cost to register for EU FMD?

The European Hub

If you are the Marketing Authorisation Holder (MAH) of an in-scope medicine sold in the EU, you will need to connect to the European Hub, which is managed by the European Medicines Verification Organisation (EMVO), to upload product and serialisation data.

EMVO charges an onboarding fee to each Onboarding Partner (OBP) for connecting to the European Hub. If your company is the MAH for multiple products, these can be managed in one OBP Portal.

Up until the 15th of June 2018, the pricing ranges from €4,500 - €30,000, depending on the number of MAHs managed in one OBP Portal. After that, it will increase by 50%.

	Until 15th June 2018	**After 15th June 2018**
OBPs with > 12 MAHs	€30,000	€45,000
OBPs with 6-12 MAHs	€15,000	€22,500
OBPs with 3-5 MAHs	€12,000	€18,000
OBPs with 2 MAHs	€9,000	€13,500
OBPs with 1 MAH	€4,500	€6,750

This is a clear incentive for companies to sign up as soon as possible. Time is fast running out to the deadline of February 2019, and lead times will inevitably increase as it looms closer. To sign up, the MAH does not need to provide details of how they will connect to the Hub or upload serial numbers. EMVO just requires the brand details and the signature of the MAH's Authorised Representative.

To start uploading data to the European Hub, the MAH will either need to develop or purchase software to do so. The software facilitating the connection must meet certain criteria established by EMVO.

National Systems

Each National System is maintained by a National Medicines Verification Organisation (NMVO), who will levy fees. An MAH does not technically connect to the National Systems, but must pay a one-time registration and annual recurring fee to each NMVO where their products are on the market. This fee varies by Member State, number of MAHs, and in some cases by product volume or annual revenue. NMVOs are offering early-bird discounts of up to 50% off the onboarding fee.

If you will be involved in verifying or decommissioning medicines, for example as a wholesaler or dispenser, you will need to connect to the National System of every Member State in which that activity will take place, but there are no fees for establishing these connections.

Companies are advised to make contact with the NMVO of each applicable National System to find out how to register and the associated costs. TraceLink works closely with a number of NMVOs, and we will keep you updated on the latest developments in the run-up to February 2019.

QUESTION 2

How do I upload aggregated data to the European Hub?

The European Hub, to which all Marketing Authorisation Holders (MAHs) of in-scope medicines must upload their product data as part of EU FMD, requires the data to be uploaded in a very specific format. This is leading MAHs to question how the new requirement will tie in with their existing processes, such as aggregation.

Aggregation is not mandated under EU FMD; however, you may already be aggregating due to requirements in other markets that you supply, or simply out of choice for operational reasons.

Uploading Data

Aggregation data such as pallet ID is not a field that is accepted by the European Hub, meaning that it cannot be uploaded. You either need to delete it from your data set before performing a bulk upload, or manually enter your product data for every item. While the former could lead to data discrepancies, the latter is time-consuming and leads to operational inefficiencies.

Companies who work with TraceLink have another option. The TraceLink solution is configured to automatically exclude aggregation data from the upload to the European Hub, without manual manipulation by the Onboarding Partner (OBP). It does this by storing all of your serialisation data in the TraceLink repository including aggregation data, so that updates can be performed at the highest level for operational efficiencies. TraceLink can automatically send this data to the European Hub from your repository. You also have the option to select the pallet ID and TraceLink will upload just the serial numbers contained within that pallet. Our solution finds the relevant data, configures it to the correct format and uploads it to the Hub. Aggregation information can also be exchanged with your trade partners, such as 3PLs, so that they can achieve operational efficiencies by utilising your aggregated information.

With the TraceLink solution, your business can continue aggregating without having to alter your processes or spend time on administrative tasks in order to achieve EU FMD compliance.

QUESTION 3

Can my CMO upload product data to the European Hub?

Many pharma companies in Europe rely on contract manufacturing or packaging organisations (CMOs/CPOs). As those pharma companies prepare for EU FMD, they are asking if their CMOs or CPOs can manage the requirement to upload their product data to the European Hub. For pharma companies that also act as CMOs to other pharma companies, the question takes on deeper meaning.

The short answer to the question is a resounding no.

Only the Marketing Authorisation Holder (MAH) of a product can register with the EMVO as an Onboarding Partner (OBP) to upload product data to the European Hub. A CMO is not permitted to be an OBP nor to connect directly to the European Hub. The MAH is only authorised to upload the data for the products it manufactures under its own brand names.

Once the MAH has connected to the European Hub, it may create a gateway account within its portal for a CMO to upload product data on its behalf. In this case, the data is still being uploaded under the MAH authorisation, after the MAH has initially developed the connection to the European Hub.

The MAH also has the regulatory obligation to report product updates to the European Hub, such as decommissioning and removal from the market. At this stage, the product would already be in the supply chain and not in the CMO's possession – a key reason why CMOs are not authorised to report on the MAH's behalf.

What if my CMO is also an MAH?

When a pharmaceutical company also operates as a CMO or CPO to manufacture or package products for another MAH (its "customer"), it is still not eligible to upload that customer's product data to the European Hub. Once it has applied the safety features to the customer's products, it must send the product data back to that customer (an MAH) who must connect to the Hub as an authorised OBP.

In this instance, the company would need to maintain separate connections: a direct connection to the European Hub for its own products, and one to the customer or the customer's gateway account for the products it manufactures as a CMO.

How TraceLink helps

For pharmaceutical companies, establishing and maintaining multiple connections – to the European Hub and to your supply chain partners – can be a significant technical and administrative challenge. With our network approach, you only have one connection: to TraceLink. As part of its EU compliance solution, TraceLink has developed a standard feature to execute EMVO conformance testing, including product functionality and services optimised to help guide customers through the EMVO approval process for connection to the EU Hub.

The TraceLink Life Sciences Cloud is the only purpose-built solution that digitises the entire pharmaceutical supply chain to help pharma companies and CMOs meet existing and emerging regulations.

QUESTION 4

How do I prepare product master data for EU FMD?

Product master data is a single source of the truth, a reliable record of basic information such as product name, identification code, and dosage. In addition to this foundation information, different markets around the world have additional requirements as part of their serialisation or track and trace regulations. For this reason, even if you operate in the USA and have already prepared product master data for DSCSA, you still have work to do for the EU Falsified Medicines Directive (FMD), which requires the Marketing Authorisation Holder to prepare specific product master data for each target market, including:

- Effective date
- Product type (RX/OTC)
- Marketing Authorisation Holder name
- Distribution partner(s)
- EMVS dosage form
- PAC code
- Target market(s)

Target market is critical, as some markets require a product code in a format specific to that market. The European Hub will route these through to the relevant National System so that the product can be sold there.

If you fail to collate and submit an accurate master data set, your product will not be able to be sold in the EU.

Preparing your product master data

The first thing to do is identify all of your products that are subject to EU FMD and their respective target markets, in order to create a list of all of the required information, as the requirements vary by market. Once you have that list, you can involve the necessary personnel in your organisation and define responsibilities for:

- Gathering the data.
- Collating it in the correct format for upload to the European Hub.
- Establishing a process for keeping it up to date.
- Uploading it to the Hub.
- Developing a policy for capturing master data for new products.

If you sell multiple products to multiple markets in the EU, this will be a substantial task and involve a large volume of data.

Simplifying master data upload to the European Hub

Companies who use TraceLink benefit from a master data management solution that automatically routes your product master data to the European Hub, thus reducing implementation time and risk.

The TraceLink solution helps companies consolidate master data in one central area – something many pharma companies have traditionally struggled with, since there is typically no single place within their organisations where master data is stored. Then, to ensure successful compliance reporting, the TraceLink solution has built-in intelligence to manage the mandatory master data for each target market. It automatically populates the necessary master data elements required for each compliance report to the European Hub, which means fewer details need to be manually entered. This reduces time and also the risk of incorrect or incorrectly formatted data being uploaded.

Going forwards, any changes to your master data are automatically communicated to the European Hub.

QUESTION 5

What happens to my product data if a National System isn't ready?

As part of EU FMD, Marketing Authorisation Holders (MAHs) must upload their product master data and product pack data to the European Hub, which routes that data through to the National System of the market in which it will be sold. The product must be scanned and verified against the National System before being dispensed to a patient.

Will product pack data be stored in the European Hub?

National Medicines Verification Organisations (NMVOs) are at different stages of readiness. This has led some to question what will happen if MAHs are ready to upload product pack data to the European Hub, but the relevant National System is not ready to receive it. Do you wait until the National System is ready? Or will the data be stored in the European Hub in the interim?

The European Medicines Verification Organisation (EMVO) has said that the European Hub is built to route product pack data, not to store it. However, the Falsified Medicines Directive is an EU-wide regulation: in order to comply with it, you must apply the mandatory information to all of your products, even if the National System in question is not yet operational.

Should a National System come online after the February 2019 deadline, EMVO's current stance is that MAHs would have to retrospectively upload their product pack data once the relevant National System is ready to receive it. MAHs in this situation are obligated to store this data, keep track of when the National System goes live, and then upload it. This could have a large operational impact on your business if you sell into multiple markets.

Precisely what happens to products destined for a market without an operational National System as of the 9th of February 2019 would have to be agreed to between the EMVO and NMVO.

How TraceLink helps

If you are using the cloud-based TraceLink EU FMD compliance solution, all your product pack data can be stored in your TraceLink repository. This eliminates the need to store and manage potentially vast amounts of product pack data on your servers and mitigates the risk of the data being lost or corrupted during downtime or system migration.

Once the National System is live, you can upload it to the European Hub from your TraceLink repository:

- The mandatory data elements for each market are automatically populated from your repository to ensure compliance.
- Data can upload quickly using bulk functionality.
- If you are aware that products have been decommissioned or removed from the market before that time, you can update their status in your repository before performing the upload.

Using our purpose-built compliance solution, you can follow your standard serialisation processes regardless of the status of the individual EU markets, and be ready and up-to-date as each NMVO is ready to accept product data.

QUESTION 6

How should my pharmacy connect to a National System?

When the new EU FMD regulations come into effect on the 9th of February 2019, pharmacists will have to check the safety features of in-scope medicines before dispensing to a patient. This includes scanning a unique serialised 2D code to verify it against the local National System to ensure it is genuine.

This means that all pharmacies – retail, hospital and internet – must establish a digital connection to the National System in the country where they dispense products.

To establish the connection, pharmacies need to register with their country's National Medicines Verification Organisation (NMVO), which governs the National System. However, the responsibility of how to connect is down to the individual pharmacist as the 'system owner'.

What technology will I need to connect to a National System?

In order to verify products against a National System, pharmacies will require:

1. Software that can connect to the National System and exchange data with it.
2. Scanning equipment that can read the 2D Data Matrix code containing the product data (GTIN/NTIN, serial number, batch number, expiry date and any additional country-specific fields).
3. An on-site internet connection with sufficient bandwidth to send and receive that data without causing delays to patients.

What are key considerations when selecting software?

While there is no specification as to whether the software must be a standalone application, a browser-based extension or a plug-in to existing software, the programme needs to be:

1. **Fast.** Pharmacists will not want the process of performing serialisation decommissioning to slow down their ability to dispense medicines.
2. **Resilient.** The solution must be able to deal with interruption to the internet connectivity, accurately re-synchronising transactions to the National System in the event of the internet being down.

For pharmacies, the choice is between adapting an existing system that was not designed to meet these new requirements; selecting, installing and testing new software; or using a cloud-based software-as-a-service (SaaS) solution that was purpose-built to meet the challenges of EU FMD.

How TraceLink helps

Using TraceLink's Life Sciences Cloud and EU FMD Compliance solution, pharmacists will simply scan the medicine. The submission of the serialised product data and subsequent status return from the National System will all be handled through a single connection to the TraceLink network. The purpose-built, GxP-compliant and GAMP-aligned solution offers pharmacies a secure, robust connection and multiple service options:

1. A standalone service;
2. A service integrated with pharmacists' existing PMR or inventory management software, or;
3. A mobile service.

Whichever option is chosen, TraceLink ensures that the pharmacy's connection to the National System will be updated when regulatory changes require software updates, and our European services team provides expert local support.

For answers to more questions about EU FMD, visit **www.tracelink.com/insights**

Contact us for more information or to arrange a serialisation demo.