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 serialized 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 Organization (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, lot number, expiry, and any

© TraceLink Inc. 2009 - 2025 All Rights Reserved

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?

Whilst 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 program needs to be:

1. **Fast.** Pharmacists will not want the process of performing serialization 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 resynchronizing 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 serialized 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

© TraceLink Inc. 2009 - 2025 All Rights Reserved

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. Contact us to learn more about our solution for pharmacies.

BlogEuropean Union Falsified Medicines DirectiveGlobal Track & TraceRegulatory/ComplianceEuropean Union
Contact Us
Learn more about TraceLink's solutions for EU FMD compliance.
CONTACT US
Contact Us
Learn more about TraceLink's solutions for EU FMD compliance.

Thank you for contacting us; we’ll be in touch shortly.

© TraceLink Inc. 2009 - 2025 All Rights Reserved