RESOURCES

What is Article 23 and What Does it Mean for Wholesalers?



EU FMD is intended to define and enforce a safe supply chain where the safety features of a product are verified and decommissioned by a hospital or pharmacy before it is dispensed to the patient. If a product leaves the supply chain prior to being dispensed through a hospital or pharmacy, EU FMD requires that it still must be verified and decommissioned.

Chapter V, Article 23 of the Delegated Regulation states that Member States may require, where necessary, that a wholesaler verifies the safety features and decommissions a medicinal product before it supplies that product to an institution other than a dispensing hospital or pharmacy. Examples of those institutions include universities, veterinary surgeons, and government bodies. You can read the full Delegated Regulation here.

How Article 23 is implemented is open to interpretation by each Member State's national healthcare authority. For example:

- A government may purchase medicines in order to stockpile them in the event of a national emergency. The national authority could decide to exercise Article 23 to require the wholesaler that sells those products to the government to first verify and decommission them.
- In the UK, the MHRA (the UK healthcare authority) could decide to implement Article 23 to require hospitals with a wholesaler license to decommission

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medicines it provides to non-healthcare institutions, such as social care and charitable organizations.

Discussions are ongoing with national authorities to define how each will implement Article 23. The recommendation to wholesalers is to register with their National Medicines Verification Organization (NMVO) in advance of the February 2019 deadline, as verification and decommissioning happens through the National System. The NMVO and national authorities will also provide updates on the implementation of Article 23.

How TraceLink helps

TraceLink's Edge Track can help wholesalers capture, process and exchange serialized product data, and effectively manage product decommissioning. Establishing one connection to the TraceLink network also allows wholesalers to exchange product data with upstream and downstream partners, drastically reducing connection and integration costs while ensuring that they remain in compliance with national systems. The ability to connect quickly with partners will be even more important to help manage product recalls and returns.

European Union
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Learn more about TraceLink's solutions for EU FMD compliance.
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