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What are the Language Requirements for EU FMD Safety Features?

Under the new EU FMD requirements, every pack of in-scope medicines will have to bear safety features in the form of an anti-tamper device and a unique identifier. The unique identifier must be encoded in a machine-readable 2D Data Matrix and also appear in human-readable form.

In general, the human-readable information must be in the official language of the EU Member State in which it will be dispensed. A Marketing Authorization Holder (MAH) in France, for example, will need to apply safety features to their products in German if the target market is Germany.

The unique identifier comprises four mandatory data elements. A fifth element—a National Reimbursement Number—is only required in markets with reimbursement policies.

Data Label	Standard Abbreviation	Data Element
Product Code	PC	Max. 50 characters, ISO-c
Serial Number	SN	Max. 20 characters, rando
Batch Number	LOT	Alphanumeric
Expiry Date	EXP	Standard six-digit format:
National Reimbursement Number	NN	Determined by target mark

Labels must be in the language authorized by the EU Member State in which the pack will be dispensed, and must precede the actual data element. Abbreviations are allowed when there is insufficient space to print the full label, such as on vials. MAHs who supply in-scope medicines to a range of markets will have to customize their packaging and configure the new safety features as required by each market.

EU FMD will also have an impact on “multi-market” packs. Companies currently have the flexibility of including the information required for multiple markets—in multiple languages—on one pack so it can be shipped to any of those markets. Under EU FMD, each pack may only bear one unique identifier—but in which language? Discussions are ongoing between the relevant National Authorities to agree on ways to enable all of the required information to be included in one code, in an agreed language or languages.

What this means for MAHs is that their EU FMD compliance solution needs to be able to handle all of the requirements—language, coding and serialization—for each market and for any combination of markets. Not meeting the requirements for product identifiers creates a risk that the product will be rejected by the European Hub or by a National

System and that pharmacists won’t be able to verify and dispense it.

How TraceLink helps

The TraceLink Life Sciences Cloud is a purpose-built serialization solution, engineered to respond to new and emerging regulations. Your product pack data is configured to meet the requirements of each target market and auto-populate the appropriate fields from your product master data. As the details of the regulations are firmed up—such as language requirements for multi-market packs—the TraceLink solution will continue to evolve to ensure that our customers have the most up-to-date configurations to achieve continuous compliance across markets and languages.

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