

Verify Brand Serialisation FAQs

WHAT IS EPCIS?

- EPCIS is the common standard messaging language adopted by the pharma industry to address the sharing, passing and management of serialised data required for compliance with the EU Falsified Medicines Directive (FMD) and U.S. Drug Quality and Security Act (DQSA).

DOES THE EU HUB RECEIVE AND STORE ALL OUR COMMISSIONED SERIAL NUMBERS?

- The European Hub serves as the principle place for the storage of master data and as a gateway for the transmission of manufacturer data to the national systems (e.g., Germany). The national systems serve as the verification platforms that pharmacies or other registered parties, such as wholesalers, self-dispensing doctors or hospital pharmacies, can use to check a product's "authenticity."

CAN MY CPO/CMO PARTNER SEND/REGISTER MY DATA WITH THE EU HUB?

- No, the brand owner or Marketing Authorization Holder (MAH) must be the party that registers all the commissioned data with the European Hub.

ARE THERE FEES ASSOCIATED WITH THE EU AND NATIONAL SYSTEMS?

- Yes. Please see the European Medicines Verification Organisation (EMVO) for details about a one-time fee for the European Hub and the annual fee for national systems.

ARE REGULATORY REQUIREMENTS THE SAME IN THE US AND EU?

- No, but there are many commonalities. For example, EPCIS is not prescribed in either regulation, even though using a standardized messaging format is beneficial in both cases.
- The U.S. uses a track and trace model (i.e., data is passed throughout the supply chain). The EU uses a verification model (i.e., data is passed to the central European Hub and authenticated at the market/national level).
- The EU FMD requires tamper-evident packaging; the U.S. DQSA does not.

WHAT IS THE DEADLINE FOR COMPLIANCE IN THE EU?

- February 9, 2019 is the deadline, with exemptions for Belgium, Italy and Greece, which allow a 6-year delay.

HOW LONG MUST WE STORE THE DATA?

- FMD mandates that data must be retained in the European Hub for a period of batch expiry date plus 1 year or 5 years, whichever is the longest.

WHAT IS THE ENCODING REQUIREMENT?

- The data carrier is a 2D data matrix and a human readable unique serial number, combined with the manufacturer product code, batch number and expiration date. A fifth element, such as national reimbursement code, may be required in certain markets.

IS AGGREGATION REQUIRED?

- Aggregation is not required under law, but industry participants have discussed including it to gain a business benefit.

WHEN DOES THE VERIFICATION TAKE PLACE?

- At least once at the point of dispensation
- Risk-based at the wholesale level
- Upon returns to wholesalers

WILL GLOBAL TRADE ITEM NUMBERS (GTINS)/ SERIALIZED GLOBAL TRADE IDENTIFICATION NUMBERS (SGTINS) BE USED?

- Yes, GTINs will be used, but some national systems may require an additional national code.

WHAT IS THE REQUIREMENT FOR SERIAL NUMBERS?

- Alpha numeric and randomized
- Sparsity rule 1:10,000