Safety Features EMVO Q&As









SN: 100000000001 EXP: AUG 22 2015 Lot: AB100613

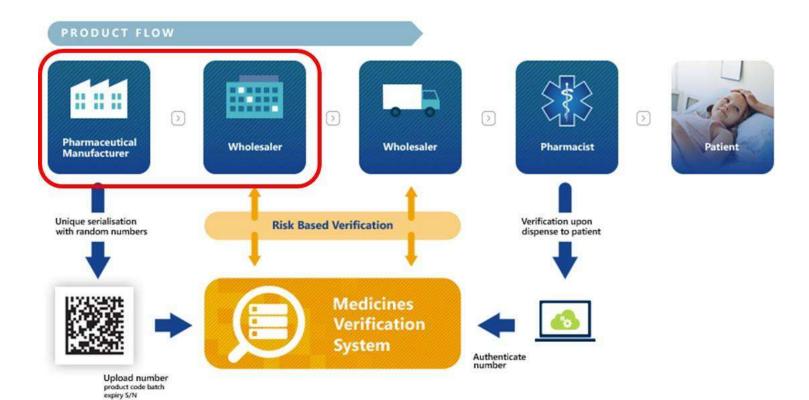
THE UNIQUE IDENTIFIER

ANTI-TAMPERING DEVICE

Anti-tampering device

Safety features

Unique Identifier





7. CMO and 3PL Connection

Q7.01 Can a CMO connect directly to the EMVS?

A7.01 No, CMO's have no contractual relationship with the EMVS and thus are not permitted to upload data. Uploaded data is also always attributed to the party who uploads it and for a CMO the data they produce will need to be attributed to the party employing them – aka the OBP. Thus, a direct connection for a CMO will not function technically or contractually.

Q7.02 How does a CMO get serialisation data into the EMVS?

A7.02 There are **two options** to fix this.

- The CMO can send the data to the OBP and let the OBP upload it directly.
- The OBP can create an account for the CMO using a Gateway provider (e.g. the EMVO-Gateway).

The Master Data Guide, is available in our Documents Overview.

Q7.03 Who is legally responsible for data placed into the system that was initially generated by a CMO?

A7.03 The OBP who owns the account under which the data was uploaded. Data upload is always the responsibility of the connection owner (OBP).

Q7.04 Should serialization data be uploaded by the Marketing Authorization Holder (MAH) or could be uploaded by a Contract Manufacturing Organization (CMO) delegated by MAH?

A7.04 Each On-boarding Partner gets one connection to the EU Hub so there will be no connection of CMOs to the EU Hub. Delegation under certain circumstances is possible but only when delegated under the full control of the On-boarding Partner, EMVO does not grant access for 3rd parties acting as delegates.

Q7.05 How can a 3PL connect to the NMVS?

A7.05 Every 3PL can connect to the national repository system in the countries in which the 3PL hold a wholesale distribution authorization. If this is not the case, the 3PL can only operate through the credentials of the MAH it represents and only for the products the 3PL holds the contract with the MAH.

Q7.06Can a 3PL connect directly to the European Hub?

A7.06 No, not currently. However, a 3PL could use facilities provided by the OBP and upload data via the OBP — e.g. a gateway connection.

Q7.07 Can a 3PL connect directly to multiple national systems where they operate as a multi-national distribution center?

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A7.07 Technically yes, however this will potentially involve the development of multiple interfaces (for the different technical implementations of national system) however this is likely to be entirely dependent on whether the 3PL has a wholesaler license in each of the markets they wish to connect with.

Q7.08 Can a 3PL use the EPCIS standard to upload data to the EMVS?

A7.08 No, not directly however if the OBP has internal systems that support EPCIS and that are also connected with the EMVS, it would be possible for the OBP to support this.

Reference: Knowledge DB: EMVO (emvo-medicines.eu)

Remark: light gray areas and red line are related with CMO.