



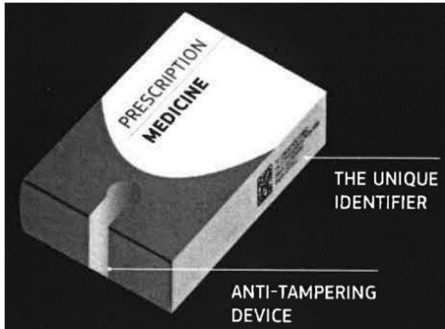
Anti-tampering device



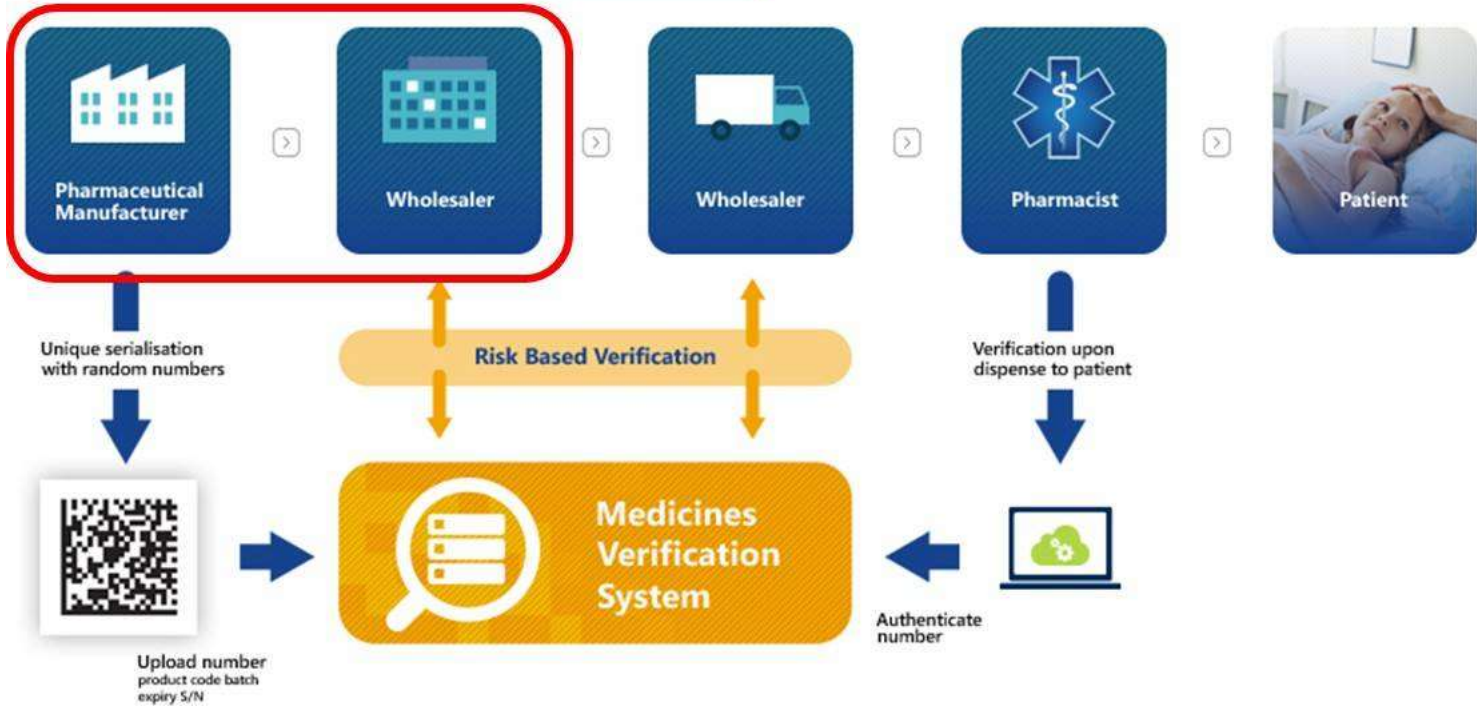
Safety features



Unique Identifier



PRODUCT FLOW



## 5. Maintenance

**Q5.01** What is the Maintenance mode? Who can proceed to the modifications in that step?

**A5.01** The Step 5. “Maintenance” has to be used by the SPOC and the SPOC Assistant to keep updated all relevant information filled-in during the Contractual On-Boarding (company information, SPOC and SPOC Assistant contact details, MAH information, etc.)

**Q5.02** Would I be able to modify all information of the Contractual On-Boarding Part?

**A5.02**

1. The OBP can maintain MAH information already provided in Step 2.7. For the purpose of the Legitimacy Check, the OBP was required to provide MAH and products information in step 2.7. However, in Step 5 – “Maintenance”, information on products is no longer required. Still, the OBP is requested to provide EMVO with the full list of the MAHs it will be willing to upload data for in the EU Hub. This list has to be complete and updated according to any change.
2. All detailed company information, except the company type, can be updated.
3. The OBP can also modify the SPOC and the SPOC assistant contact details.
4. The OBP can view and/or download the latest Participation Agreement applicable. Whenever an updated Participation Agreement will be made available, the OBP will be requested to sign the new version of the contract and follow the procedure accordingly.
5. The Invoicing Information Form can be viewed or downloaded. In case more MAHs are registered in the OBP Portal than mentioned on the already approved Invoicing Information Form, the Invoicing Form will be rejected in order for you to restart the invoicing process.

**Q5.03** Is another Legitimacy check going to be performed on the newly provided information?

**A5.03** **No.** Once the Legitimacy check is passed in Step 3 the modification of information in Step 5. Maintenance will not trigger a new Legitimacy check. Still, all information will be randomly checked in the aftermath in order to ensure that the MAH listed in Step 5 are all affiliated to the OBP company.

**Q5.04** How can I add more recipients to receive the EMVO communication?

**A5.04** In case an OBP would like to increase the number of recipients receiving communication from EMVO besides the SPOC & SPOC Assistant (if applicable), EMVO recommends to use a dedicated mailing list/inbox e.g., “serialisation@emvo.eu”, as the e-mail address of the SPOC Assistant account. However please note that the e-mail address needs to be linked to a registration of a contact person

(forename & last name). Furthermore, to receive the information with regards to all known problems within the EMVS, EMVO strongly recommends subscribing to the EVI (European Medicines Verification System Information) Alerts for the specific systems of interest.

**Q5.05** What is Product Code (PC) ownership transfer and what is the underlying process?

**A5.05** Once uploaded to the EU Hub, PCs are technically linked to the OBP which initially uploaded the PC. This can lead to:

1. Technical blockage for the legitimate owner of a PC in case of an incorrectly uploaded PC by another party.
2. A technical blockage for the new owner of a PC in case of Divestitures and Acquisitions (D&A) activities, such as Mergers, Acquisitions or MAH transfers. Consequently, a Data upload correction/PC ownership change can be performed, respectively.

However, EMVO reserves the right to apply and invoice the resulting costs. Please click [here](#) to consult the costs related to the Data upload correction/PC ownership transfer. The fee model is effective as of 1st October 2019. For additional information, please contact the EMVO Helpdesk.

**Q5.06** What should I do in case my OBP/MAH is facing MAH transfer or D&A/M&A activities?

**A5.06** Please notify EMVO in good time as soon as your OBP, Company or MAH(s) face(s) one of the following scenarios. **1.**MA transfers **2.**MAH transfers **3.**D&A/M&A activities Please do so by contacting the EMVO Helpdesk ([helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)), providing the following information (if applicable).

- Which scenario do you face?
- How many entities are involved and which?
- Who is the Acquirer/New Owner & who is the Transferor/Old Owner?
- How many OBPs are involved and which?
- What is the planned timeframe? / When is the action taking place?
- How many SKUs/Product Codes (PC) are affected?
- Was data uploaded for the affected SKUs/Product Codes (PC)?
  1. If yes, for which SKUs/PC?
  2. If yes, Product Master Data (PMD) and Product Pack Data (PPD)?
- Who will be the responsible contact person(s)/representative(s) of both parties?

Reference: [Knowledge DB : EMVO \(emvo-medicines.eu\)](#)

