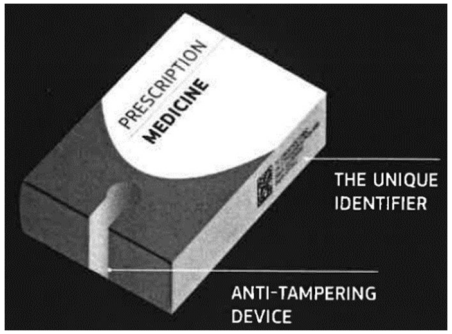
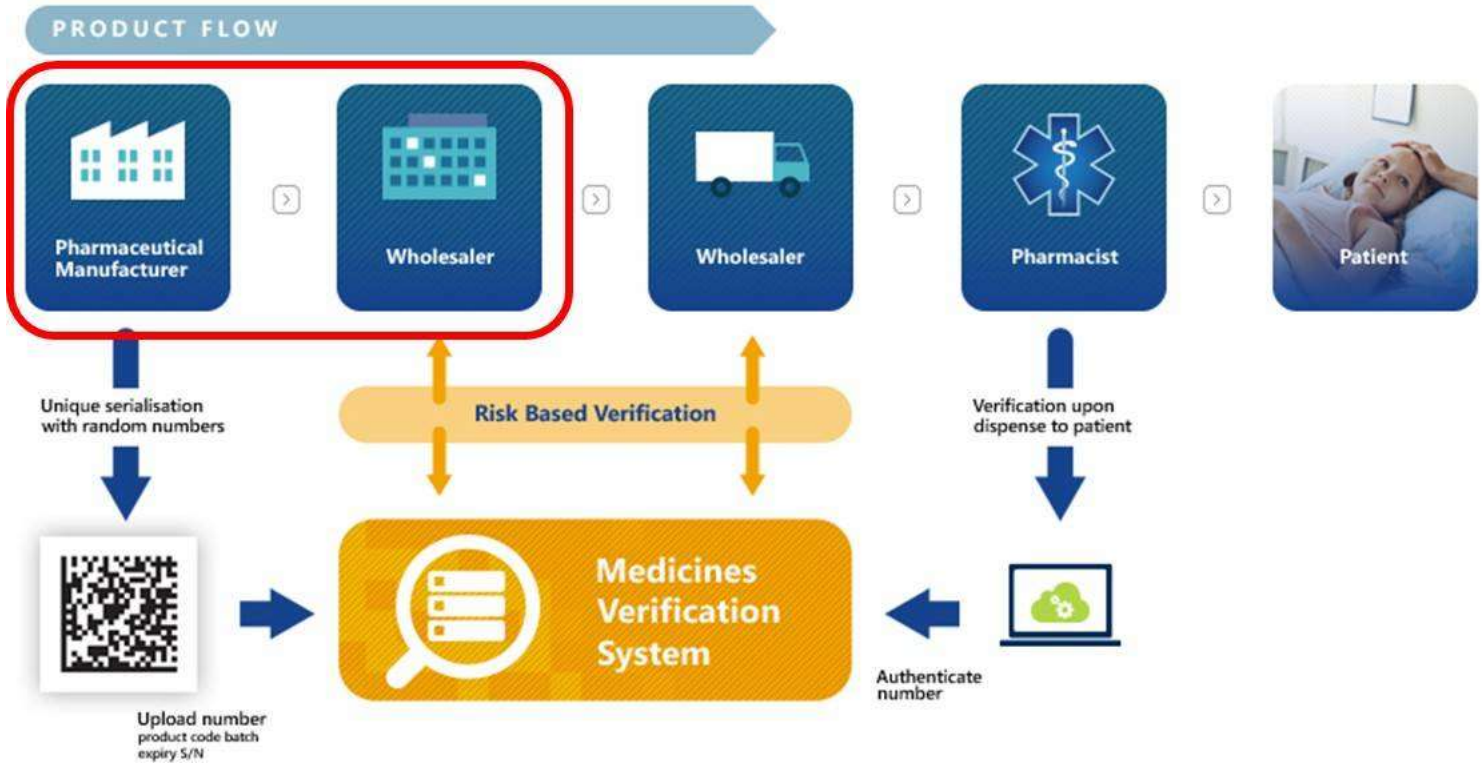
Anti-tampering device

Safety features

Unique Identifier





6. Data Upload

Q6.01 Do you provide the EMVS Master Data Guide as download?

A6.01 Yes. Master Data Guide, is available in our Documents Overview

Q6.02 How codes will be uploaded when multi-market packs are destined for two markets – one of which does not yet have an operational Repository?

A6.02 A use case for a product destined for Belgium and Germany (Germany is active, Belgium is inactive):

1. - Product Master Data with Market Data uploaded for Germany only
2. - Product Master data and Pack data sent to German Repository
3. - Belgium comes online
4. - Product Master Data is updated to include Belgium
5. - Product Master Data pushed to EU Hub
6. - EU Hub loads Product Master Data to Belgium and updates Germany
7. - Pack data resent, loaded to both markets

The Master Data Guide, is available in our Documents Overview. The Questions and Answers Document, published by the European Commission, also gives a helpful answer to this topic.

Regarding this, we would like to refer to question 1.12 (*Would it be possible to place a unique identifier on the packaging of a medicinal product during the 3 years period between the publication of Regulation (EU) No 2016/161 and its application?)* of this FAQ from the European Commission.

Q6.03 Is it possible to deliver a serialized product from country A to country B when this product is not registered in country B?

A6.03 If products are sold by exceptions in countries where the products are not registered, the EMVS will allow for a verification process though with very slow performance. Therefore we strongly recommend to **use the multimarket pack approach** which means you'll need to upload the Product master data in the NMVSs of country A and country B. The Master Data Guide, is available in our Documents Overview.

Q6.04 How is the EMVS testing the randomness of Serial Numbers (UID)?

A6.04 The EMVS, consisting of the European Hub and the National Systems, implemented a level of testing to check the level of

randomisation of serial numbers supplied by each OBP. The Delegated Regulation (Article 4) clearly states that the serial number has to be random and places some definitions about how random the values should be for a given product code.
To provide a sense-check, the EU Hub implemented some tests on the randomisation of serial numbers for every file of Product Pack Data (PPD) which is uploaded to the EU Hub. This might trigger a warning which is sent to the OBP, informing them that the numbers may not be sufficiently randomised.
At this moment, EMVO plans to adapt the randomisation test algorithm in the next release of the EU Hub and have randomisation tests implemented in the National Systems. This should result in less warnings to OBP's. When the tests are implemented by the National Systems, all serial numbers ever uploaded for a specific product, can be taken into account.
At all times, OBP's should be aware that it is not a warranty that the generation method used is sufficiently robust when no error message has been received. The testing undertaken by the EMVS only 'weeds out' those that fall well below the standard required.
EMVO is not an authority of the use and construction of suitable algorithms to produce serial numbers of a sufficient random nature. OBP should research the recommendations of NIST (National Institute of Standards and Technology).

Q6.05 What is to be done if the original batch number is longer than 20 characters?

A6.05 An inbound product suitably coded for the European market under the terms of the FMD Delegated regulation cannot have a batch ID greater than 20 characters – the coding schemes simply do not support this.

Q6.06 Does the strength and pharmaceutical form need to be added to the Registered Product Name to form the Name of the Medicinal Product?

A6.06 This question is related to one of the common data elements in the EMVS Master Data Guide (Appendix 1), Name of Medicinal Product.

Does the strength and pharmaceutical form need to be added to the Registered Product Name to form the Name of Medicinal Product, if this Registered Trade Name not includes the strength and pharmaceutical form?

This Registered Trade Name is more appropriate for the 'common-name' entry and not for the 'name' field. According to our investigations, the name should be followed by the strength and form information as indicated in the guidance document by reference to SmPC rev.

Ultimately however this is only guidance – you should seek detailed clarification from the regulator responsible for the market(s) on which your product is sold as EMVO is not a regulatory authority and this data is not used within the EMVS (currently) for any other purpose than report content/decoration.
The majority of the master data elements were imposed on the system by the Delegated Regulation (Art. 33(2)) and EMVO does not have the history to know why the master data in that article is so rich in content. Your regulatory authorities should be able to provide the background and guidance. The Master Data Guide, is available in our Documents Overview.

Q6.07 Why not all countries are listed in appendix 4 of the Master Data Guide?
A6.07 Appendix 4 of the Master Data Guide does not cover countries who made the decision of including the reimbursement number into the data matrix code.

Q6.08 Who is a Designated Wholesaler?
A6.08 'Designated Wholesalers' are wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf. Likewise, the parallel importer / parallel distributor may designate a wholesaler, by means of a written contract, to store and distribute on his behalf the products covered by the parallel import authorisations/parallel distribution notices respectively. A detailed presentation related to designated wholesaler is available in our Documents Overview.

Q6.09 Is a designated wholesaler obliged to verify the authenticity of the unique identifier of medicinal products?
A6.09 No, the designated wholesaler is not obliged to verify the authenticity of the unique identifier of medicinal products. The Delegated Regulation sets out in which cases a wholesaler is obliged to verify the authenticity of the unique identifier of medicinal products. Consequently, wholesalers are not obliged to verify the authenticity of the unique identifier of products that they have received from the manufacturer or the MAH or a wholesaler properly designated under Article 20(b) Delegated Regulation ("designated wholesaler"). A detailed presentation related to designated wholesaler is available in our EMVO Master Data Guidance – Designated Wholesalers.

Q6.10 What is a Sales Affiliate of a MAH?
A6.10 A Sales Affiliate of a MAH is a company focussing on sales which is controlled by the MAH or which is a subject to control by the same legal entity as the MAH. Affiliates should be considered as proxies of the MAH and should not be listed as 'Designated Wholesaler'.

'Affiliate' means a company or legal entity that is effectively controlled by another or associated with others under common ownership or control. A detailed presentation related to Sales Affiliate of MAH is available in our EMVO Master Data Guidance – Designated Wholesalers.
Q6.11 What is a Co-Marketer? A6.11 A Co-Marketer is a company commercializing a product under a different trademark. As co-marketers commercialise the product under a different trademark, they have their own marketing authorisation, different from that of the MAH. Therefore, Co-marketers are considered as MAH in their own right and should not be listed as 'Designated Wholesaler'. A detailed presentation related to Co-Marketer is available in our EMVO Master Data Guidance – Designated Wholesalers.
Q6.12 How is the [Strength] field as a common master data element defined? A6.12 In addition to the information from section 4 "Common Master Data Elements" of the EMVS Master Data Guide, please be informed that, when uploading data, there is a character limit on the [Strength] field of 30 characters. As a result, the EU Hub will reject any upload of data when this field is populated with more than 30 characters. The correct population of the [Strength] field as per above sits with is the OBP's exclusive responsibility.
Reference: Knowledge DB : EMVO (emvo-medicines.eu)