



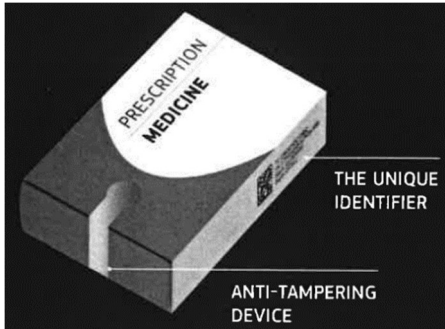
Anti-tampering device



Safety features

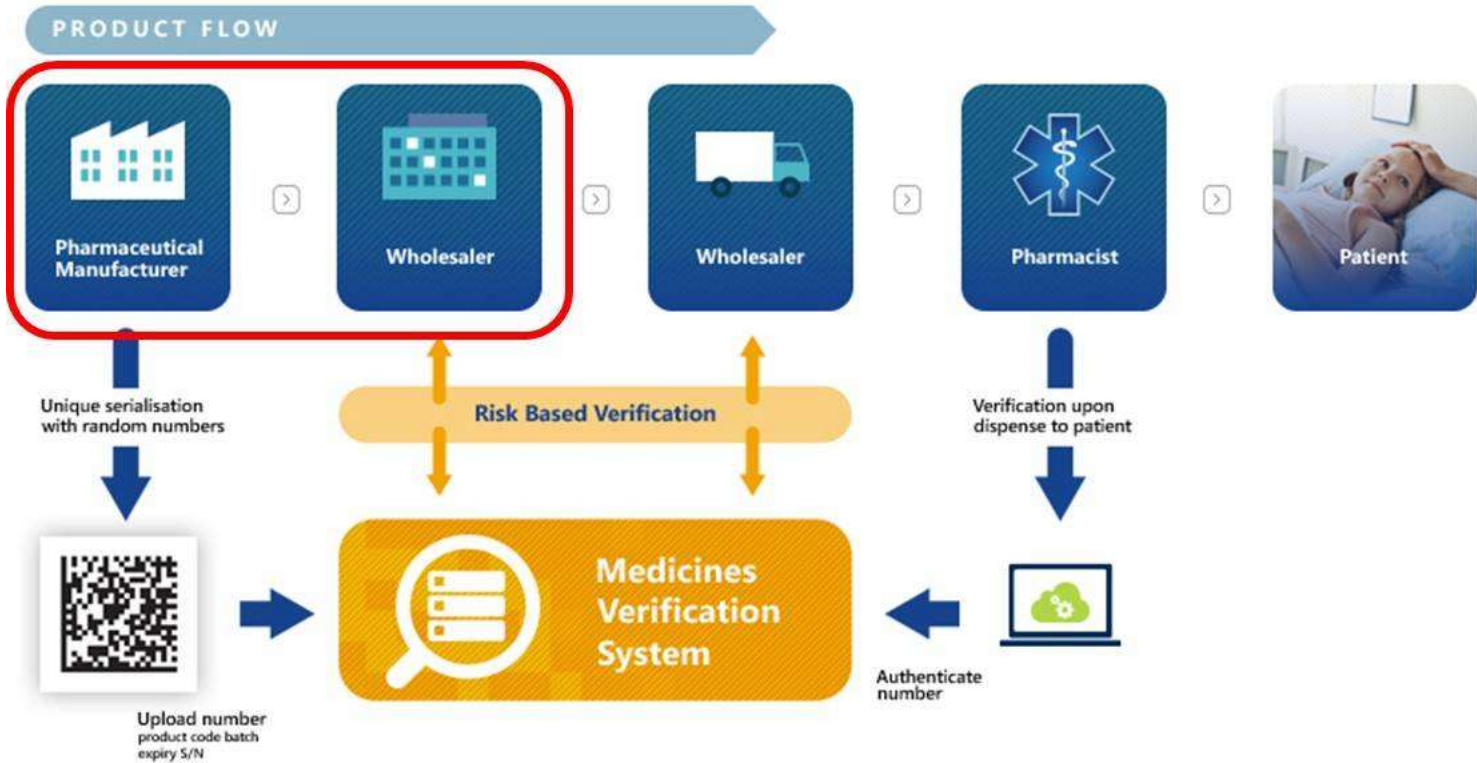


Unique Identifier



THE UNIQUE IDENTIFIER

ANTI-TAMPERING DEVICE



4. Technical on-boarding

Q4.01 What is a registered Connection Provider (Gateway Provider)?

A4.01 An On-boarding Partner (OBP) Gateway Connection Provider is a third-party contractor engaged by the OBP, who assists in whole or part of with the development, implementation, provision, use and/or operation of the OBP interface to the EU Hub via a Gateway Connection. Every OBP Gateway Connection Provider has to be promoted by at least one OBP in the On-boarding Process. OBPs can choose to connect to the EU Hub via a **direct connection** (data send from OBPs system straight to EU Hub) or a **Gateway Connection** (data sent first to a Gateway Provider. The Gateway Provider sends it through to the EU Hub)

Q4.02 Can I purchase a Direct Connection as a module of my existing IT System?

A4.02

Yes, your IT software supplier may decide to offer a module off-the-shelf to allow your existing IT System to connect with a Direct Connection to the EU Hub.

Q4.03 What should I fill in in the field “Name of Gateway Provider”?

A4.03 The Gateway provider is the provider of a Gateway connection to the EU Hub. **You have to decide with whom you want to connect.** For example, if you choose for the EMVO Gateway connection, you complete this field with “EMVO Gateway”.

Q4.04 Is a regular provision of respective ISO 27001 certificates in place and is this covered by the contract between EMVO and manufacturers?

A4.04 **Solidsoft Reply is ISO 27001 certified.** EMVO does not deem it necessary for each manufacturer to also be ISO 27001 accredited.



Q4.05 Will manufacturers be informed in case of incidents related to their data (network intrusion, loss of data etc.)? If no assessment can be made whose data is affected, will all manufacturer be informed?

A4.05 Yes, **Manufacturers will be informed in both cases.**

Q4.06 Are there requirements to the hardware and the internet connection of the local organization? Do we need to have a static IP address? Is VPN communication with the HUB going to be established?

A4.06 **No**, there are not any hardware requirements in the form of a list. Your chosen service provider will already be aware of the security requirements and the need for a fixed endpoint. VPN is not used.

Q4.07 I have to name the client for the connection details. What information of the client is needed here (e.g. the DNS or the IP address of the server)? Or is it simply our company?

A4.07 **We offer you to define your name for the client.** You should use your company name suffixed by the gateway provider or 3rd party provider name. This allows to easily identify your client connection with the European Hub such that for future maintenance or even disconnection requests, we can be certain that any amendments are made to the correct instance.

Q4.08 In the EMVO connection details, I have to define the connection type – and the connection technology. For both connection types (direct- or gateway), Java or .NET can be chosen. Can we also opt for another technology?

A4.08 EMVO can only provide support for clients using one of the technologies we have specified and any deviation from this may entail additional costs which will have to be borne by either the connection provider or the On-boarding Partner.

Q4.09 Does the connection between EU Hub and a National Repository follows the structure of the three environments? (Test, Quality, Prod)

A4.09 **No.** National Repositories will follow a different path. Your provider (whoever that is) will have a support contract with SolidSoft Reply (EU Hub) and as a result will have a development and test environment all of their own. Integration tests will be performed there and then transit to our IQE for certification testing – then to Production.

Q4.10 Are you planning to migrate data from one to another environment?

A4.10 **No.** We are absolutely not planning any data migration from any environment.

Q4.11 Can a company decide if it prefers to have a separate connection for each of its MAHs to the EU Hub instead of assigning only one connection?

A4.11 In general, **no** . EMVO allow in maximum two connections to the EU Hub per OBP. (i.e., 1 direct + 1 gateway; 2 gateway).

Q4.12 Are GTIN or other standards codes mandatory during the On-boarding procedures?

A4.12 The EMVS supports both the GS1 standard and the IFA PPN standard and doesn't provide benefit either way. However, the GS1 standard does provide measurable supply chain benefit for all stakeholders and is much the preferred option.

Q4.13 I have issues to access the OBP portal. What should I do?

A4.13 If you receive the following error messages access denied or request access, you are most likely using either a wrong account or the wrong link to the OBP Portal. For this reason, we recommend that you always refer to the login information you received in the e-

mails sent by noreply@emvs.com to access your OBP Portal account. If you still receive an error message of that kind, please try to access your account through a *Private/Incognito window* before contacting the Helpdesk. This could solve the issue since it is related with the cache stored in your browser. Please make sure that you key in your OBP Portal account **with the right credentials (received from noreply@emvs.com) for the first time**. This will prevent many possible issues related to your connection to the OBP Portal in the future.

Q4.14 I have continuous problems with Product Data upload to the EU Hub. What should I do?

A4.14 EMVO wants to ensure that all OBPs receive the most accurate and up to date information in the most efficient way. To receive the information with regards to all known problems within the EMVS, EMVO strongly recommends to subscribe to the [EVI \(European Medicines Verification System Information\)](#) Alerts for the specific systems you are interested in.

In case your incident does not seem to be one of the ones described, we kindly request that you fill in the following form and send your request to our helpdesk (helpdesk@emvo-medicines.eu). Please ensure that you send us the failed call-back (if available), as well as the Correlation ID and Timestamps written, rather than attaching screenshots.

- OBP Name -
- Environment Name - *(EMVO ITE, IQE or Production or ISV Sandbox)*
- Schema used - *(2016/2018)*
- Connection Type - *(Gateway/Direct)*
- Middleware (other systems) - *(e.g. SAP)*
- Common Name or Client ID - *(e.g. M.1104.6/1104.6)*
- Target Market -
- SDK used - *(Java/.NET)*
- Timestamps (UTC) - *(ideally within 24 hours)*
- Correlation ID - *(from message sent to the EU Hub)*
- Request Type - *(e.g. Product Master Data Upload, Session Token Refresh, Report Request, Product Pack Data Upload)*

- Error Message -
- Description of the Issue -

Q4.15 What is Retrospective Upload and when should I use it?

A4.15 In order to have the Product data properly linked to the Master Data, the OBPs have to use 'Retrospective Upload' functionality. The 'Retrospective Upload' functionality is only relevant for multi-market products where not all associated National Medicines Verification Systems (NMVS) are live yet. In this way, OBPs will be able to upload their serialized data to all National Medicines Verification Systems where their products are marketed.

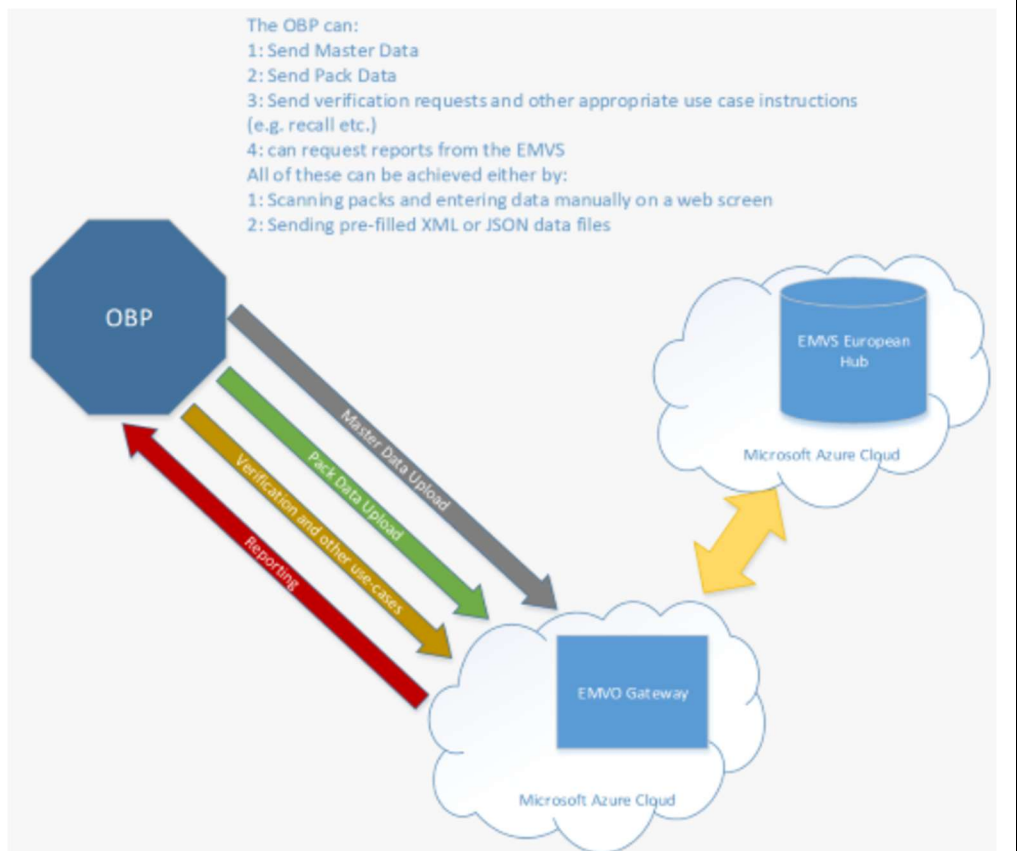
For further details on the 'Retrospective Upload', please consult the document uploaded on the OBP Portal, in the Technical Info Pack section. The document includes questions and answers and describes scenarios of uploads performed before and after the release 1.4 of the EU Hub.

Q4.16 How, as a Parallel Distributor, do I upload Pack Data in the EU Hub when no serial code is available in the physical pack?

A4.16 For the particular case where a Parallel Distributor/Importer uses the EMVO Gateway and buys products which are not yet serialized, EMVO recommends to create a dedicated GTIN/NTIN/PPN owned by your OBP, as a placeholder to fill in the field "Original Product Code" for all Original products which are not yet serialized. Please be aware that this product code should not be used for any product you currently sell or will sell in the future.

Q4.17 What is the EMVO Gateway?

A4.17 Essentially the EMVO Gateway is an alternative means of connecting to the European Hub (alternate to developing a direct connection, or other Gateway Provider solutions). The direct connection will suit many OBP's however it is complex to realize. The EMVO Gateway provides an easier way to connect to the EU Hub using typically understood techniques and is aimed at those OBP's who want to participate in pilot programs but do not yet have a direct connection established or smaller OBP's who have no need for the direct connection because their volumes of batches are much lower. It's highly manual in operation so not well suited to automated processes, however it is a very effective means for connecting easily with the European Hub and wider EMVS.



Q4.18 How to access the EMVO Gateway?

A4.18 In order to access the EMVO Gateway, the OBP will be asked to execute the following 3 steps:

a) After the OBP has decided to connect to the EU Hub via the EMVO Gateway and selected this option in either step 4.2 'Client Connection 1' or in step 4.3 'Client Connection 2' on the OBP Portal, the Single Point of Contact (SPOC) can request access to the EMVO Gateway. To do so, he/she is requested to send an e-mail to the EMVO Helpdesk (helpdesk@emvo-medicines.eu) with following information:

- Company name
- CP Number - the number appearing on the OBP's account and in the Participation Agreement
- SPOC's First Name and Last Name
- SPOC's E-mail address
- Environment (IQE/PRD)

This action should be taken before the OBP reaches the step "Request session token" in IQE or PRD environment in Step 4 of the OBP Portal.

- b) The credentials and URL to the EMVO Gateway portal will be sent to the SPOC through the following email: noreply@meliorsolutions.com (please be aware that it might appear in your Junk folder).
- c) The SPOC receives the information pack to complete the EMVO Gateway connection. The EMVO team generates and uploads a Session Token in the OBP Portal for the requested connection. To be able to access the EMVO Gateway portal properly, the SPOC will be advised, via email, on the next steps to complete the connection.

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