



EMVO Gateway User Manual

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EMVO Gateway User Manual

for MAH

(without parallel distribution activity)

and

Parallel Distributors

(MAH with parallel distribution activity)



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1 Background

The European Medicines Verification System (EMVS) is designed to facilitate medicines verification across multiple European markets and prevent counterfeit medicines being introduced into the supply chain. It consists of a central European Hub which has the responsibility for distribution and synchronisation of data across Europe and a series of National Systems, ostensibly one national system for each member state. Medicine verification is achieved by securing all packs, (currently prescription only) with a unique serial number and by logging the entry and exit of each pack to and from the supply chain. Stakeholders are then warned, for example, if more than one instance of the same pack of medicine is detected or the serial number of a given pack is unknown.

The EMVS Gateway is a web-based portal that provides a single web entry point for OBP's (On-boarding Partners) to interface with the European Hub; adhering to the stringent security protocols and technical requirements which must be met for compliance. The EMVO Gateway offers a reliable, flexible organisational architecture and extends the functionality of the core services to unburden companies of the considerable cost of developing, securing and maintaining their own services.

The web-based nature of the EMVO Gateway allows earlier adoption of the EMVS by permitting OBP access to the EMVS prior to an integrated system to system interface being developed. The EMVO Gateway, by virtue of the security system and role provision system employed, can in some cases provide some useful enhancements over the standard system to system interface capabilities. For example being able to utilise the construct of a CMO (Contract Manufacturing Organisation) as a user role and restrict the activities of this user type to only those appropriate for a 3rd party source of product.

The EMVO Gateway is a very secure connection. It can only be accessed using an SSL connection and each user account is accessed using a username and password combination that is managed by the provision of an industry standard, but private to this system, identity server using the principles of the OAuth 2 / OpenID connect standard (but specifically limited to a non-public identity service). The connection between the EMVO Gateway and the EMVS European Hub uses the same digital certificate based connection that is described within the EMVS SDK and used for direct system to system connections.

The EMVO Gateway is, in the same way as the EMVS European Hub, based in the cloud and uses the same cloud technology as the Hub, namely Microsoft Windows Azure.



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2 Introduction

The EMVS European Hub serves three distinct types of organisation;

- MAH without parallel distribution activity (aka Manufacturers).
- MAH with parallel distribution activity (aka Parallel Distributors).
- National Systems being run by a stakeholder body (NMVO).

The EMVO Gateway will interface with the EMVS European Hub as a proxy for Manufacturers and Parallel Distributors i.e. OBP's. This system is NOT able to be used as a proxy for a National System.

As part of the on-boarding process for the EMVS European Hub, each OBP will be issued with a unique Organisation ID. Each organisation will then be split into Clients (a minimum of 1, current maximum of 2) which have their own unique Client ID and digital certificate. The precise details of this on-boarding process are fully detailed on the EMVO website www.emvo-medicines.eu.

The implementation of the EMVO Gateway consists of two major components:

- 1) An Identity service that is used to manage users, assign roles and rights to each user and also to map users with sources of manufactured product.
- 2) A web-based user interface that allows the logged in user to work with products within the organisation he/she is associated subject to any restrictions provided by the access roles and rights.

Both components are significant applications in their own right and are described within the document at hand in two separate major sections.

The EMVO Gateway is hosted in three environments to permit access to resp. the EMVS European Hub Development (ITE), Quality (IQE) and Productive (PRD) environment. Each of the three environments have an independent url for access and each environment is provided with independent identity service provision meaning that user accounts have to be created for each separate environment and are no longer shared across environments.

2.1 Browser Support

We recommend using a fully updated HTML5 CSS3 compliant web browser to get the best experience from the EMVO Gateway, older non-HTML5 browsers or versions will not work correctly. We recommend only the latest versions of:

- Microsoft Edge
- Internet Explorer
- Google Chrome
- Firefox



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➤ Safari

Experiences with mobile versions will vary. No support can/will be provided for unlisted versions and file transfer requires a browser capable of using the file transfer protocols.

All web browsers are subject to the same technical restrictions:

- The web browser must support Javascript; it must be enabled and must have permission to run it.
- The web browser must support Cookies; they must be enabled and the site must have permission to read/write them.
- File uploads are restricted to web browsers that support XMLHttpRequest Level 2. This is an unofficial part of the HTML5 spec.



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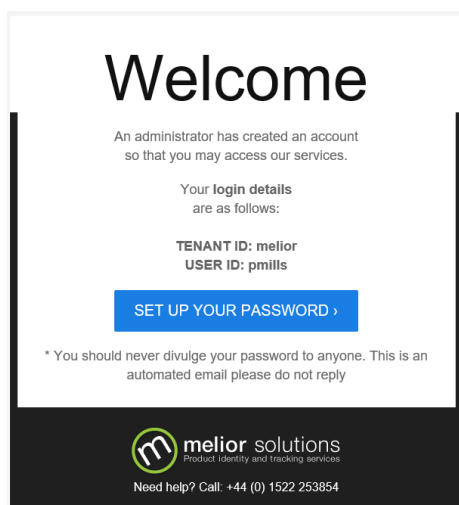
3 EMVO Gateway

Accessed by means of individual url's the EMVO Gateway can be found here:

- ITE: <https://emvo-ite.meliorsolutions.eu>
- IQE: <https://emvo-iqe.meliorsolutions.eu>
- Production: <https://emvo.meliorsolutions.eu>

Please note that during the on-boarding process for the EMVO Gateway, emails will be sent to new users informing them of their account and requesting them to activate the account using a one-time link. These emails will be sent from the meliorsolutions.com domain and not the EMVO domain. Please ensure you add this domain to your "safe senders" list.

The emails will look like this:



Before discussing and documenting the functionality of the EMVO Gateway there are a few basic concepts that need to be clarified and understood.

The EMVO Gateway has the concept of OBP's having manufacturing sources (where the product is made) and each manufacturing source has products allocated to it. Thus, a given OBP may e.g. have two internal manufacturing sites and use three CMO's (Contract Manufacturing Organisations).

The OBP can then define which of the products in the overall product catalogue are to be manufactured at which site (by which source). A product can be assigned (made by) multiple sources however if a product isn't assigned to a source – no interactions may be undertaken for that product.



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In addition, users can be assigned to one or more sources and users can be assigned multiple roles (the rights of use for the system). Some terms used during this guide are:


Products are the master data records for the physical items distributed by the Organisation. Products are obtained from Sources.

Batches are created by Sources and associated with Products. Batches are simply used by the EMVO Gateway as a container into which the Source will create Packs. Batches will have a Batch ID, and Expiry Date. They will contain a list of pack serial numbers and will reference a specific product and from the master data.

Packs are the data associated with the individual sales unit. Each pack will have a serial number and an initial status associated with it. Pack data is uploaded to the European Hub which in turn distributes it to the EMVS connected National Systems (as defined by the product master data). The pack data and any subsequent pack state is retained and maintained by the respective National Systems and not by the European Hub or EMVO Gateway.

Some of the above will become more completely understood as the operation of the EMVO Gateway is described below.

When a user logs in, they will be taken to an environment specific landing page similar to that shown below:

			
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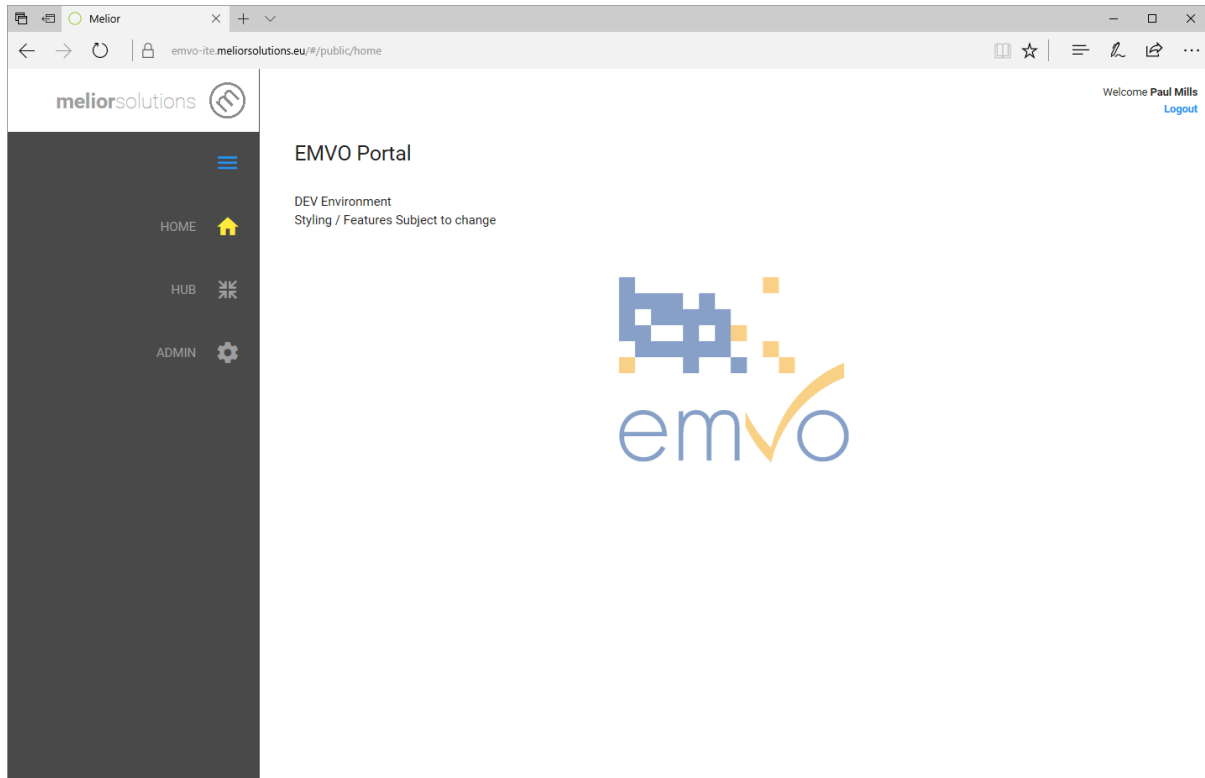



Figure 1 – EMVO Gateway Landing Page

The left hand menu bar can be collapsed and expanded by clicking/pressing the  symbol.

The menu options are:

- Home – takes you back to the landing page.
- Hub – takes you to the page dealing with Hub data interactions
- Admin – takes you to the section where product codes are linked with sources and to the place where user groups can be assigned to organisational based activities (Roles) and then onto Source-based Role assignment.



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3.1 Organisations

The following section describes how products, batches and packs are managed within and organisation. Most of this section is from the perspective of an Organisational Administrator unless otherwise stated.

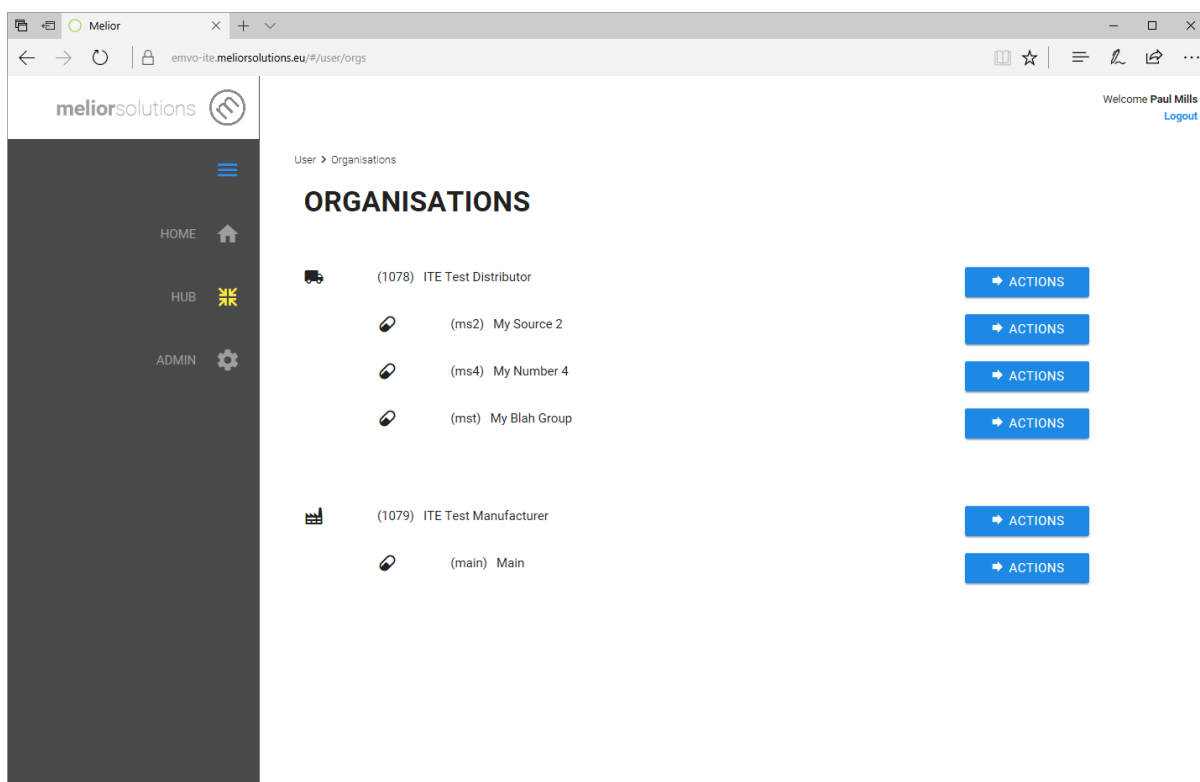
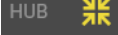
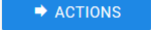


Figure 2 - Organisations View

The screen above is accessed by clicking/pressing the  option from the menu bar. The screen above shows a user with access to two organisations, a Parallel Distributor with three defined manufacturing sources and a Manufacturer with a single defined manufacturing source. Depending on whether you are an OBP who represents parallel distributors or manufacturers, you will only see one of the above section.

The adjacent  buttons allow the user to undertake operations that are specific to the organisation or source.



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If the user logged in had been supplied with account credentials for limited access (say the OBP had a single manufacturing source that was a CMO) the screen might look more like that shown below.

Had the logged in user been the CMO defined earlier, the view presented would look like this.

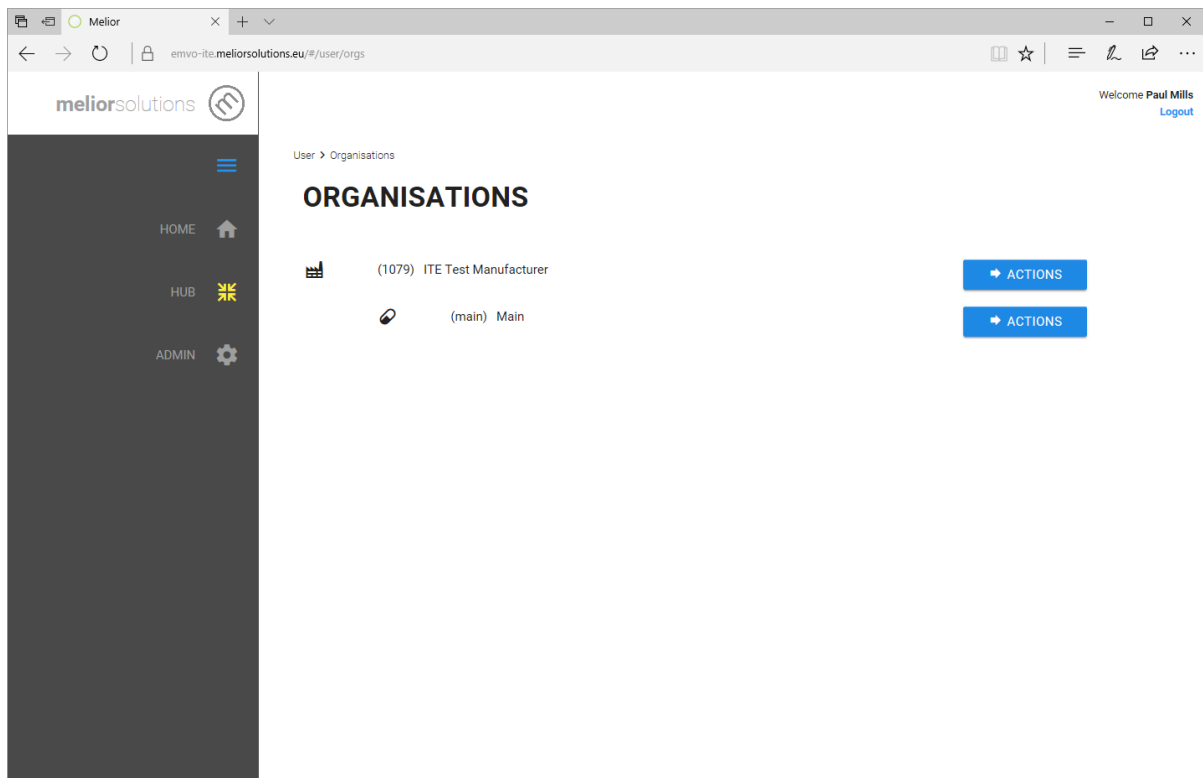


Figure 3 - Organisations View - CMO

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3.2 Organisational Activities

Pressing the **ACTIONS** button adjacent to the organisation entry on the screen shown above renders the following options:

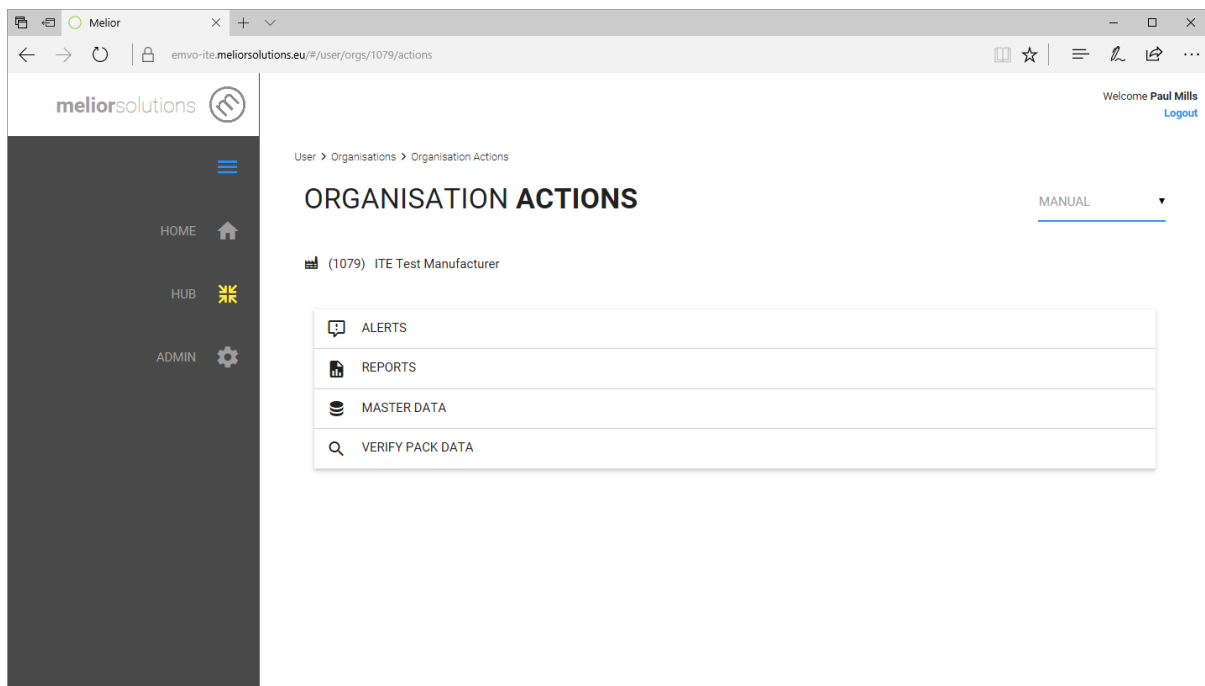


Figure 4 - Organisational Activities

From here it can be seen that the user can access pages to view/manage:

- Alerts – the information sent back from the European Hub when an activity occurs that requires an event to be notified to the OBP.
- Reports – the means by which the OBP can access the available reports from the European Hub.
- Master Data – the means by which the OBP product portfolio of master data can be managed/added.
- Verify Pack Data – the means by which one of more packs in hand may be verified.

As more functionality is added to the European Hub and wider EMVS, this list of options will be enhanced in future releases of the EMVO Gateway. E.g. Product withdrawal.



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3.2.1 Master Data

Each Organisation has a Master Product Portfolio and each product entry in the portfolio can be assigned to one or more manufacturing 'Sources'. In this version of the EMVO Gateway we have divorced the process of generating master data from assigning master data to 'Sources'.

Please note that the term 'Form Type' = 'Pharmaceutical Form'

The screenshot shows a web browser window with the URL emvo-its.meliorolutions.eu/#/user/orgu/1079/actions. The page title is 'MASTER DATA'. The main heading is 'MANUAL REQUEST'. Below this is a 'Product Details' section with the following fields: 'Scan Barcode' (with a red 'X' icon and a blue 'i' icon), 'Code scheme required' (with a dropdown arrow), 'Name', 'Common Name', 'Strength', 'Pack Size', 'Form Type', and 'Pack Type'. Each field has a corresponding input line. Below the 'Product Details' section is a 'Markets' section with three checkboxes: '[GB] Great Britain', '[DE] Germany', and '[AT] Austria'. At the bottom of the form is a blue button labeled 'SEND REQUEST'.

Figure 5 – Manual Master Data Entry 1

Under the page shown above is a small transaction history/log. The details within the transaction history are only maintained for a period of 30 days after which they are deleted from the EMVO Gateway – the information however remains in the audit trails maintained by the European Hub.



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TRANSACTIONS

✓	GTIN 82348293048229	18/08/2017
✓	GTIN 08726387398302	18/08/2017
✓	GTIN 08872384324896	18/08/2017
✓	GTIN 09828372837236	17/08/2017
✓	GTIN 09828372837236	17/08/2017

Figure 6 - Transactions Log View

The master data content shown above is part of the list of data required by the Delegated Regulation. As shown, no market data has been allocated. Selecting a market from the list provided (the list will be amended as more National Systems will be connected are added to the system), the following extra master data fields are shown.



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✓ [GB] Great Britain

National Code required

Article 57 Code required

MAH

MAH ID

Name required

Street 1 required

Street 2 required

City required

Postcode required

Country Code required

Contracted Wholesalers

+ ADD WHOLESALER

Figure 7 – Manual Master Data Entry 2

The MAH details (the licence holder for the product) requires either an ID (if one exists for the selected market) or an address. The MAH 'name' is mandatory and when an address is selected, all of the fields should be completed. It is acceptable to include an ID and address.

Contracted wholesalers, as defined by Article 33(2) h, can be added by clicking/pressing the

+ ADD WHOLESALER

button. As with the MAH details, each wholesaler entry (there may be many) can use either an ID and/or an address. The wholesaler name is mandatory.



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Some details for the master data can be scanned in, e.g. when adding a new master data entry the product code e.g. GTIN can be captured from the pack barcode or when an existing master data entry exists it can be quickly located by scanning the code – which locates the product code and searches the database for the correct entry.

The barcode should be scanned using a HID/Keyboard wedge style of scanner having first placed the cursor in this on-screen element.


MANUAL REQUEST

Product Details

Scan Barcode



Figure 8 - Manually Scan Product Code

Before first use of a scanner, the red  symbol should be clicked/pressed and the two codes shown on screen scanned to calibrate the system to the specific scanner in use. This allows the system to determine the delimiter characters used by the scanner.

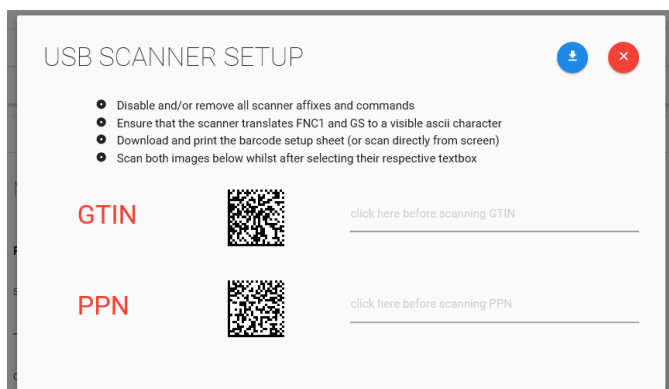




Figure 9 - HID/Keyboard Wedge Scanner Setup

The  symbol allows the codes shown on screen to be downloaded as a PDF file for scanning where the scanner is unable to scan directly from the screen.

Returning to the master data scan element entry, clicking or pressing the  symbol opens a new window that allows the user to search for an existing product code entry.



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Scheme	Value	Name
GTIN	08726387398302	Biologics Something
GTIN	09828372837236	DE PRODUCKT
GTIN	08872384324896	Testinium
GTIN	82348293048229	XL

Figure 10 - Query Master Data

Product codes can be found by typing part of the code value into the search box at the top e.g.

Scheme	Value	Name
GTIN	09828372837236	DE PRODUCKT

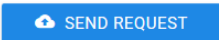
Figure 11 - Query Master Data Filtered

And is subsequently selected by clicking/pressing the  symbol adjacent to the entry required.



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When a master data entry for a product code has been entered or amended, clicking/pressing the  button will transmit the data to the European Hub and from there onward to the specified markets. The result of the send request can then be seen in the transaction log at the bottom of the page.

TRANSACTIONS

✓ GTIN 82348293048229

18/08/2017

➤ REQUEST

9:41:16 am

👁 JSON

📄

👁 XML

📄

⇓

🔍 VALIDATION

9:41:17 am

⇓

📦 LOADED

9:41:17 am

⇓

➦ DISTRIBUTION

9:41:18 am

✓ GTIN 08726387398302

18/08/2017



Figure 12 - Transaction Log Entry - Expanded

The 'JSON' and 'XML' links shown under the request element in the transaction log allow the data sent to the European Hub to be inspected e.g.



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The  symbol views the data using your local text editor, the  symbol allows the data to be downloaded to a local file (in XML or JSON format)

```
{
  "ProductCode": {
    "scheme": "GTIN",
    "Value": "82348293848229"
  },
  "Name": "XL",
  "CommonName": "XL UPD",
  "Form": "CAPSULE",
  "Strength": "31mg",
  "PackSize": "25",
  "PackType": "BAG",
  "TargetMarket": [
    {
      "Market": "GB",
      "SerializationFlag": true,
      "NationalCode": "NC3",
      "Article57Code": {
        "Value": "Ac573"
      },
      "MAH": {
        "ID": "MAHID3",
        "Name": "MAHName3",
        "Street": "MahStreet13",
        "Street2": "MahStreet23",
        "City": "City3",
        "Postcode": "POSTCODE3",
        "CountryCode": "GB"
      },
      "Wholesaler": [
        {
          "ID": "WSID4",
          "Name": "WSName4",
          "Street": "STREET14",
          "Street2": "STREET24",
          "City": "CITY4",
          "Postcode": "POSTCODE4",
          "CountryCode": "GB"
        }
      ]
    }
  ]
}
```

Figure 13 - Example File Format

All of the above processes may seem too 'manual' for many. All processes available on the EMVO Gateway can also be undertaken by means of uploading pre-formatted XML or JSON files. To switch the EMVO Gateway into 'File' mode, the top right of each screen has the following option.

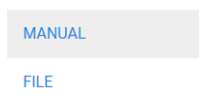


Figure 14 - File/Manual Operations Toggle

The default is 'Manual' and by changing to 'File' the options on screen change dramatically. Master data management in 'File' mode becomes the following:



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MASTER DATA

FILE REQUEST

File (.json / .xml)

SEND REQUEST

TEMPLATES

TRANSACTIONS

✓	GTIN 82348293048229	18/08/2017
✓	GTIN 08726387398302	18/08/2017
✓	GTIN 08872384324896	18/08/2017
✓	GTIN 09828372837236	17/08/2017
✓	GTIN 09828372837236	17/08/2017

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Figure 15 - Master Data Entry - File Mode



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3.2.2 Alerts

This is a very simple dashboard/display window that allows alerts sent from the European Hub to be viewed/inspected.

ORGANISATION ACTIONS

FILE

(1079) ITE Test Manufacturer

ALERTS

No Alerts

Figure 16 - Alerts View

3.2.3 Reports

As with 'Master Data' this can be invoked by manual request or a file-based request. The manual screen options are shown below:

TRANSACTIONS		
✓	PMR - GTIN 82348293048229	18/08/2017
✗	PMR - GTIN 02094782893477	10/08/2017

Figure 17 - Manual Reports Request

The report type is selected in the first element, the product code (by means of scanning, selecting from the product catalogue or manually typing the value) is entered in the 'code' box and the

SEND REQUEST

button sends the request to the European Hub. When the report is ready, the transactions log will contain a new entry with a green 'tick' symbol against it. Expanding this log

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entry will allow the report to be fetched from the system using the  PDF  symbols which will either view or download the PDF file from the European Hub.

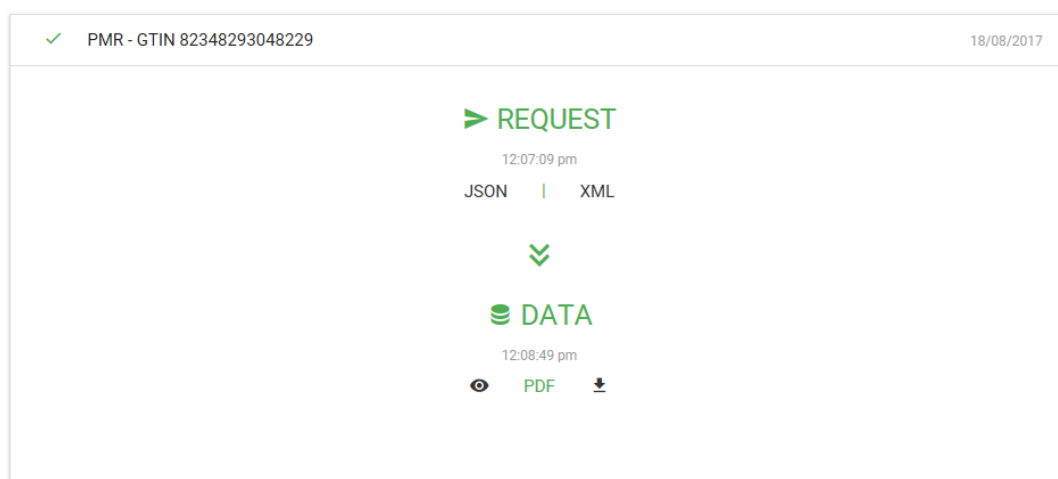


Figure 18 - Transaction Log Entry Expanded

An example file is shown here:

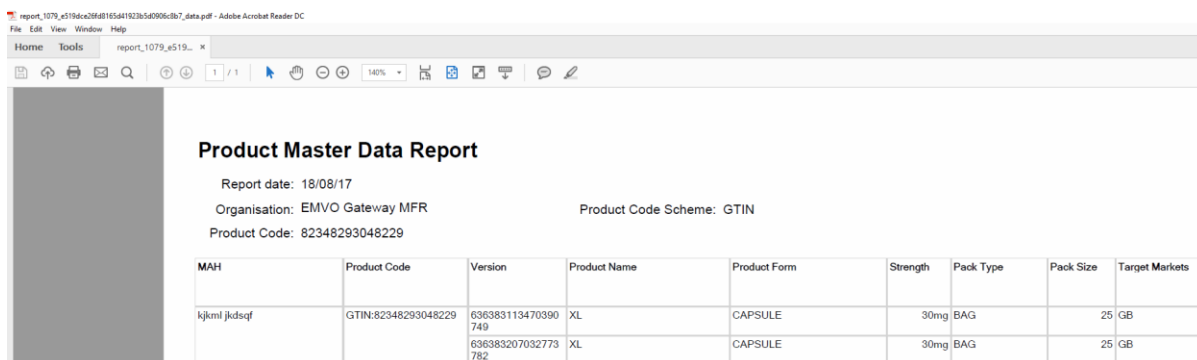


Figure 19 - Sample Report

The file-based screen options are now shown below with the same operational requirement as above except that the product code can be specified within a file e.g.

```
{
  "CodeScheme": "GTIN",
  "CodeValue": "01112223334448"
},
```




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REPORTS

FILE REQUEST

Report Type
PMR - Master Data Report

File (.json / .xml)

SEND REQUEST

TEMPLATES

TRANSACTIONS

✓	PMR - GTIN 82348293048229	18/08/2017
✗	PMR - GTIN 02094782893477	18/08/2017

Figure 20 - Sample File Format

Figure 21 - File Based Report Request

3.2.4 Verify Pack Data

This option allows the OBP to verify the status of a given pack. In accordance with the stakeholder agreements enshrined in the EMVO Foundation Documents, the pack(s) must be under the control of the OBP and not in the open market. This is the 'pack in hand' concept.

To manually verify a pack or packs the manual screen is selected to 'Verify Pack Data'.



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Q VERIFY PACK DATA

MANUAL REQUEST

Product Details

Scan Barcode

ψ ⓘ

Code scheme required

▼

Batch Details

Batch ID

Batch Expiry

📅

Pack Details

Type Serial ID

+

Scan Barcode

ψ

Serial Ids

None

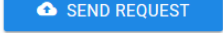


📤 SEND REQUEST

TRANSACTIONS

✓ GTIN 08726387398302 - BH712637 18/08/2017

Figure 22 - Manual Pack Verification

The easiest way to interact with this screen is to use a barcode scanner and scan the packs into the screen. First by scanning any pack into the 'product details' element (or selecting it manually from the database), then by scanning packs into the 'Pack Details – Scan Barcode' section. Alternatively, pack serial numbers may also be added manually.

When the packs and serial numbers have been entered, clicking/pressing the  button will send the request to the European Hub which in turn will forward it to the appropriate market and await the result. The result when it arrives will be shown in the transactions log and the results can be viewed or downloaded in either JSON or XML format using the  or  buttons following the 'Distribution' section of the log entry. The source data sent to the Hub to instigate the



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request can also be inspected using the same buttons but those shown under the 'Request' section of the log entry.

TRANSACTIONS

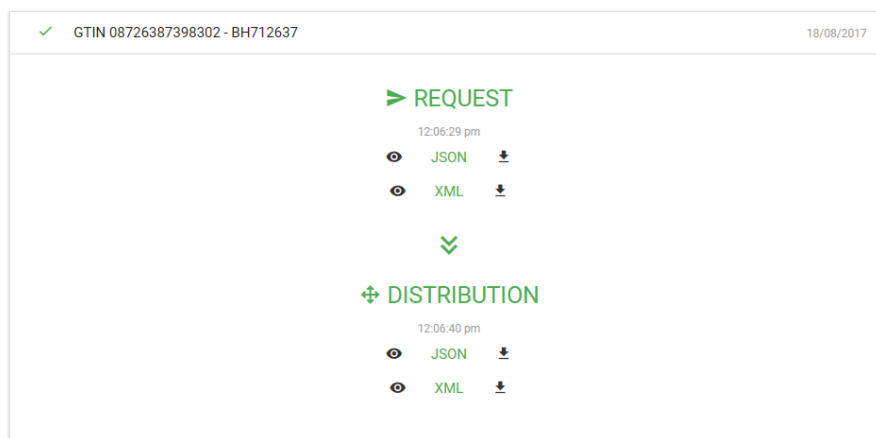


Figure 23 - Transaction Log Entry Expanded

Packs can also be verified by sending a pre-populated XML or JSON file containing the pack data for the request using the 'File' option for Verify Pack Data.

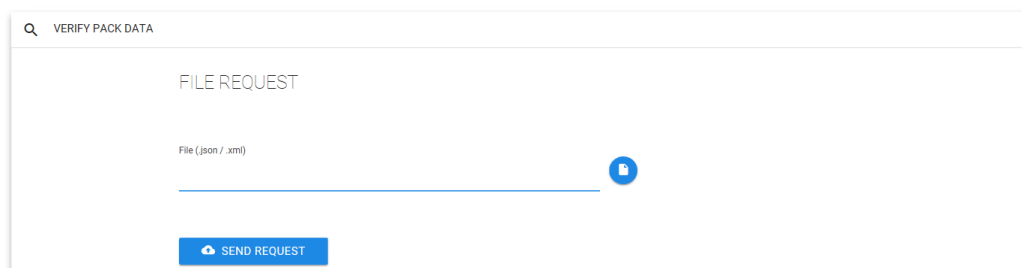


Figure 24 - File Based Verification Request

A sample file is shown below in JSON format.



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```
[
  {
    "CodeScheme": "GTIN",
    "CodeValue": "01112223334448",
    "BatchId": "test123",
    "BatchExpiry": "170810",
    "SerialIds": [
      "0973485738947843",
      "9082737298047329",
      "0927376237187817",
      "0238583950605940"
    ]
  }
]
```

Figure 25 - Sample File Format

3.3 Manufacturing Sources

The most frequent operation will be to create new packs (and by association the batch information). All operations associated with a manufacturing source can be accessed by clicking/pressing the

➔ ACTIONS

button adjacent to the manufacturing source entry shown on the main 'Hub Organisations' screen.



(1079) ITE Test Manufacturer

➔ ACTIONS



(main) Main

➔ ACTIONS

Figure 26 - Organisation Selection

The screen presents the following options:

- Create Packs
- Update Packs
- Update Batch
- Recall Batch

As more functionality is added to the European Hub and wider EMVS, this list of options will be enhanced in future releases of the EMVO Gateway.



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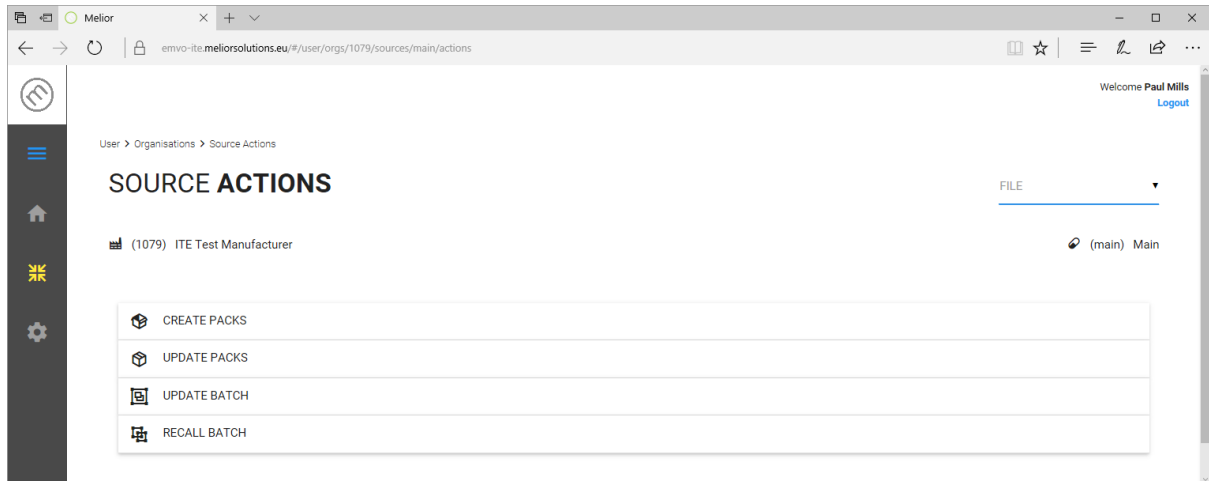


Figure 27 - Manufacturing Sources Activities

The options all follow a similar pattern to those already described for the organisational functions.



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3.3.1 Create Packs

The screen shows a high degree of similarity with that of the master data entry/amend screen.

CREATE PACKS

MANUAL REQUEST

Product Details

Scan Barcode

Code scheme required

Batch Details

Batch ID

Batch Expiry

Manufacturer

Manufacturer ID

Name

Street 1

Street 2

City

Postcode

Country Code

Pack Details

Type Serial ID

Scan Barcode

Serial lots

None


SEND REQUEST

Figure 28 - Manual Create Packs Request



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As with previous similar screens, the product code is scanned in or selected, the batch and expiry information entered, the details of the physical manufacturer (of the batch) are entered and finally the list of serial numbers entered. The  button then sends the batch and pack information to the European Hub which in turn forwards it to the markets previously defined for the given product code within the master data definition. When the data has been distributed successfully, the transaction log will contain an entry with a green tick which, when expanded, will show the success of the request.

TRANSACTIONS

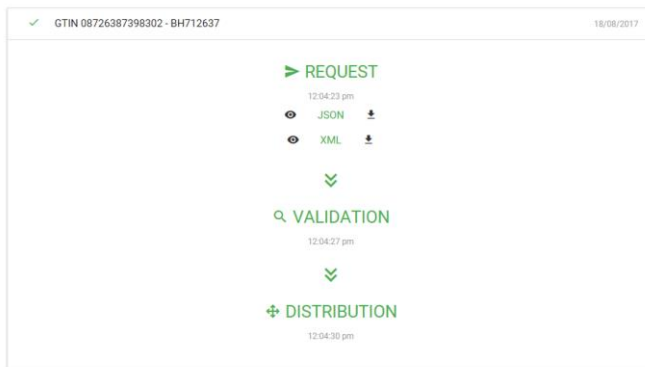




Figure 29 - Transaction Log Expanded

As with all transaction log entries, the request data can be viewed or downloaded using the  or  buttons.

The same functionality can be invoked by means of a pre-filled file. The screen options become much simpler.



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CREATE PACKS

FILE REQUEST

File (.json / .xml)

SEND REQUEST

TEMPLATES

TRANSACTIONS

✓ GTIN 08726387398302 - BH712637 18/08/2017

Figure 30 - File Based Create Packs

A pre-filled file in either JSON or XML format is selected and the request sent. The transaction log is updated in the same way as for a manual upload.

3.3.2 Update Packs

The following screen shows the information page associated with the 'Update Packs' functionality. This functionality is used, primarily to bulk-decommission packs from the market.

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UPDATE PACKS

MANUAL REQUEST

Product Details

Scan Barcode

Code scheme required

Batch Details

Batch ID

Batch Expiry

Pack Details

Current Status required

New Status required

Type Serial ID

Scan Barcode

Serial Ids

None

Figure 31 - Manual Request Update Packs

As with other functionality, this can also be displayed and operated as a file-based capability using the file/manual toggle selection in the upper right of the screen.

The selection requires that the user select the product code, batch ID and expiry date for the packs in question. Once selected the current status of the packs should be selected (it should be known and if not can be resolved by means of a verification activity) and then the status the packs should be transformed into. Clearly not all transformations are permitted (e.g. Recalled to Active), the system will respond appropriately if an illegal transformation is selected once the request has been sent.



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Packs are then added by adding serial ID's using a scanner or hand entry. For multiples of packs, the file-based operation is easily more efficient.



3.3.3 Update Batch


Available as a file-based operation or manual, the update batch capability allows the batch ID and/or expiry date to be amended post initial upload. This is expected to be an extremely rare occurrence as the batch ID and expiry date also need to be contained within the datamatrix code on the pack therefore use of this function assumes that the initial upload was incorrect.

UPDATE BATCH

MANUAL REQUEST


Product Details

Scan Barcode  


Code scheme required 

Batch Details

Current Batch ID

Current Batch Expiry 

New Batch ID

New Batch Expiry 

Manufacturer

Manufacturer ID

Name

Street 1

Street 2

City

Figure 32- Manual Request Update Batch



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As with all batch uploads, the manufacturer details for the batch need to be entered as well as the existing batch ID and expiry date (the existing values are required to prevent inadvertent updating of batch details).

3.3.4 Recall Batch

Used as the name implies, to initiate a batch recall.

RECALL BATCH

MANUAL REQUEST

Product Details

Scan Barcode

Code scheme required

Batch Details

Batch ID

Batch Expiry

Recall Details

Effective From

Markets

☐ [GB] Great Britain ☐ [DE] Germany ☐ [AT] Austria

Description

SEND REQUEST

Figure 33 - Manual Request Recall Batch

The operation requires details of the product and batch, the date from which the recall will be effective, the details why the recall is being initiated (this will be propagated to the NMVS's to aide recall execution) and finally the markets in which the recall should be undertaken, which can be either:



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- equal to the markets of initial sale
- less than the markets of sale (e.g. where the issue is text based on the pack or patient leaflet thus not affecting all markets)
- greater than the markets of original sale when it is known that packs may have circulated more widely and may have been injected locally.



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4 User Accounts, Roles and Associations.

All of the user account specification is undertaken within a separate but private identity service that in turn uses an industry standard. OAUTH 2/OpenID Connect. OAUTH 2 is also used by Google, Facebook, Microsoft and many others and has become the most widely used identity service in use on the internet today. Our implementation uses the principles of the OAuth 2 / OpenID connect standard using a non-public identity service implementation. It is not possible to log into the EMVO Gateway using your Facebook user account for example.

The specification of users and their roles, rights and associations requires that we first understand a few concepts about how the organisations within the EMVS are constructed. The following definitions aim to clarify these concepts.

4.1 Organisation:

An organisation is the overall company wanting the interface with the EMVS.

Organisations have a product portfolio which is essentially the master data for the organisation as a whole. The organisation is also referred to as the OBP of On-Boarding Partner.

4.2 Sources:

Sources is short-form for Manufacturing Sources. A 'Source' is an entity from which a product is provided. This could be an internal manufacturing facility (or one of many) or it could be an external contract manufacturing organisation/facility (CMO).

Sources produce and provide products that form part of the Organisational product portfolio. They cannot provide a product where the master data for the product does not exist in the organisational product portfolio. Sources can provide any number of the products within the Organisational product portfolio. It is the task of the Organisation EMVO Gateway administrator to assign each Source with the product(s) that are appropriate (ranging from one products to all within the portfolio). **The name of a 'Source' is case-sensitive and unique within an organisation.**

4.3 Users:

Users are analogous to people. Users are created within an Organisation and can be assigned to one or more Groups and Groups can be assigned to Sources via attributes called Roles. Thus a user can be created such that they can only undertake specific actions on behalf of one Source which in turn could be a CMO. A user could also be assigned to multiple or even all the Sources defined under the organisation and thus be able to undertake actions for the assigned Sources.



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4.4 Groups:

Groups, which are accessed from the same location as users are created (the identity portal) are essentially just a means to group user accounts together and make the management of activity 'Roles' simpler. For example, instead of assigning 20 users to the task of being able to edit master data, a single group can be assigned to edit master data and the twenty users assigned to the group. Group membership then allows a much simpler means to amend the user scope of interaction with the system. The concept is very similar to the security group's capability within Active Directory.

Thus, 'Users' are assigned to 'Groups' and 'Groups' are assigned to activity 'Roles'.

4.5 Roles:

Roles are activity profiles. The EMVO supports four distinct roles under an Organisation and four further roles under sources.

Organisational Roles.

When an organisation profile is 'viewed' there is a section on the page titled 'ROLES' and this section details the four role profiles that can be applied to an organisation. This page is accessed from 'Admin' > 'Organisations' > 'View Organisation'. (Selecting the 'View' button shown below).

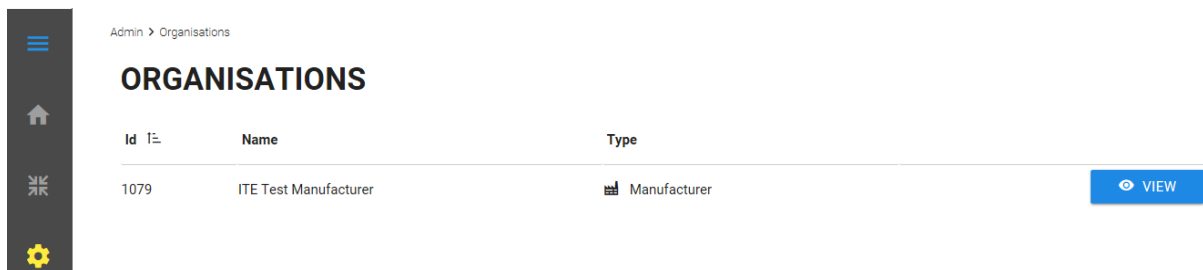


Figure 34 - Admin Organisations

The available Role definitions at the Organisation level are as shown below.

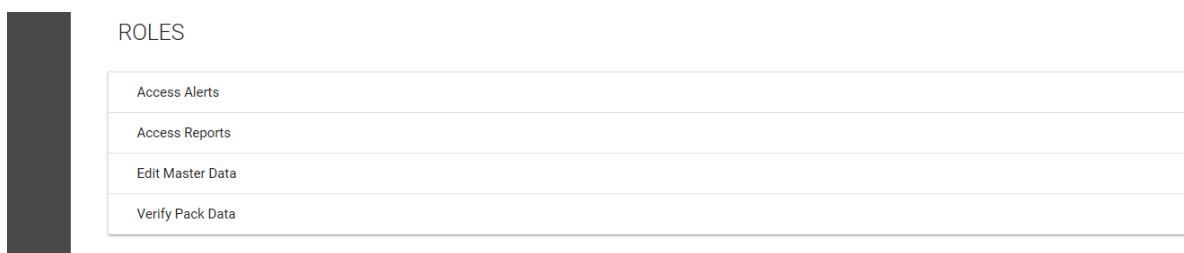


Figure 35 - Organisational Activities



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Under each activity (Role) the administrator can assign groups and is able to assign as many groups as required. Shown below we have the 'supervisor' group assigned to the 'Access Alerts' Role.

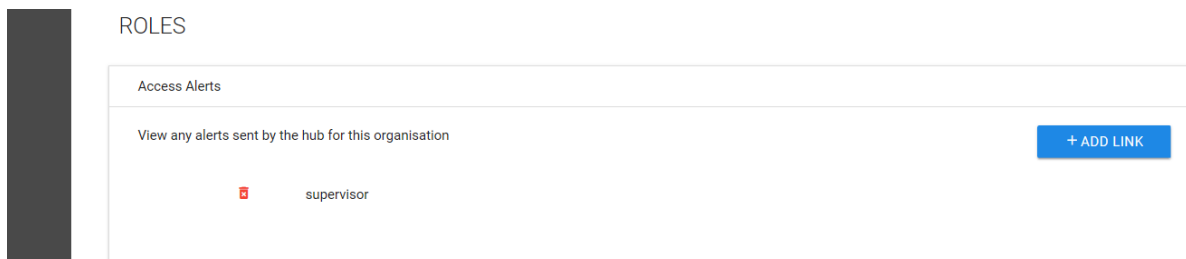


Figure 36 - Organisational Activity Role Assignment

Organisations thus have four roles defined:

- Access Alerts – to define who is able to access the Alerts sections of the EMVO Gateway.
- Access Reports – to define who is able to access the Reporting section of the EMVO Gateway.
- Edit Master Data – to define who can edit the organisational master data and,
- Verify Pack Data – to define who is able to initiate a verification process for pack data.

In addition, the EMVO Gateway supports additional activity 'Roles' at the level of a manufacturing source.

When a manufacturing source is viewed, a new section of 'Roles' is visible.

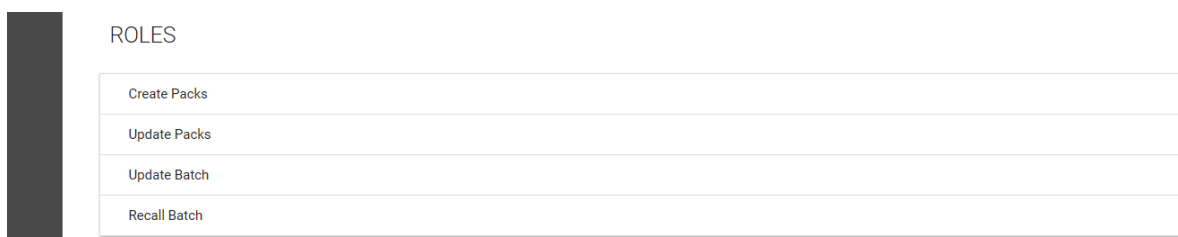


Figure 37 - Manufacturing Sources Activities

Here we can see that groups can be assigned to the activity 'Roles' for:

- Create Packs – this defines who can upload new pack data on behalf of the source. restricting the available options to that user group.
- Update Packs – this defines who is permitted to amend the status of packs (e.g. decommission packs)
- Update Batch - this defines who is permitted to amend the details for a batch, e.g. change the batch ID or expiry date.



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- Recall Batch - this defines who is permitted to recall a batch – thus it is expected that only supervisory or QP level user groups will be added here.


Thus it is possible to have one group (which could be one or more users) able to upload pack data (i.e. create new batches) but perhaps not able to recall batches or indeed perform any operations at the organisational level. When defining a CMO user it is likely that a group will be assigned only to the 'create packs' (batches) at the source level and not to any other activity thus totally

4.6 Initial Setup

When an account is create for a given organisation, an Administrator account is provided together with the basic organisational structure as used by the European Hub. Beyond this, no other users are created and no manufacturing Sources are created.

You will be provided with a url for connection to the environment required and administrator access. You have to activate your administrator account (and any subsequent user accounts created) by accessing the provided link and entering a password of your choosing. The link will be provided by email. Note that the EMVO Gateway support team cannot access your account on your behalf so if you lose or forget the admin password, all the support team can do is reset it for you.

Once you access the given url you will be presented with an environment specific login page (here shown as the dev/test environment)

			
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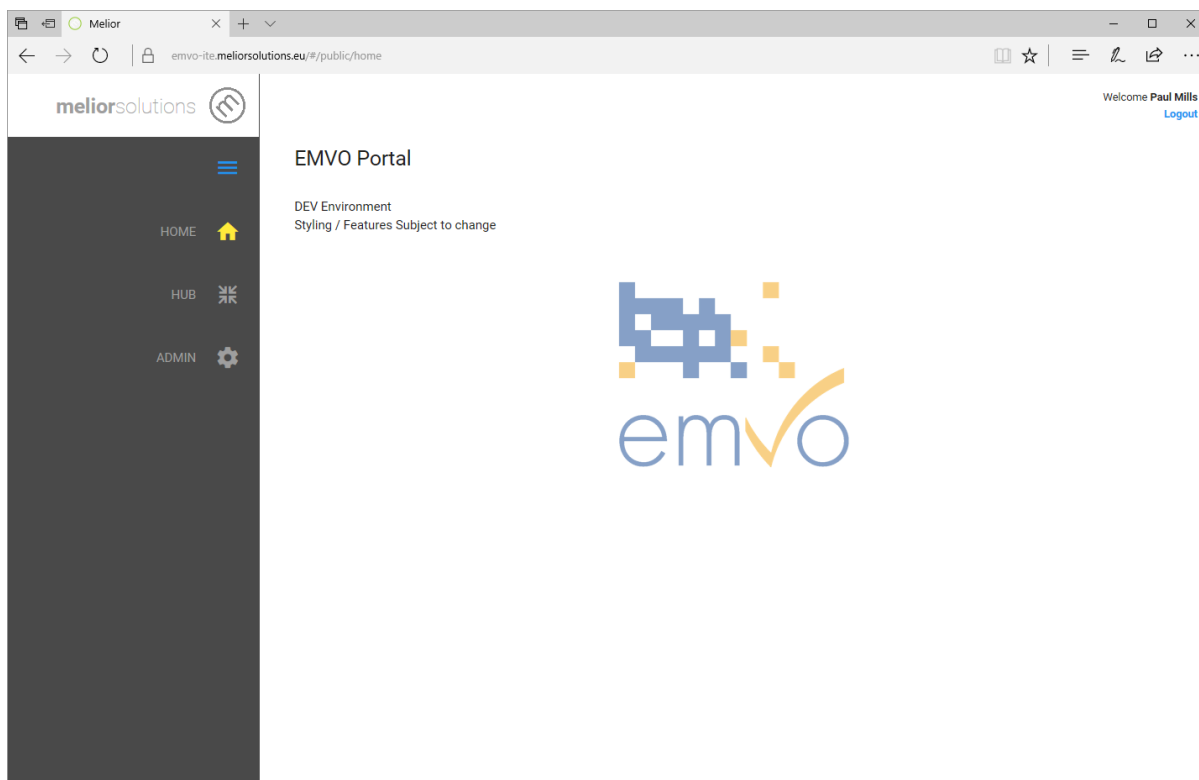


Figure 38 – EMVO Gateway Landing Page

Clicking on the 'Login' icon will redirect you to the identity service which will validate your credentials and allow access if correct credentials have been used.

Initially, the organisation administrator will have set up the gateway profile to work for your organisation and this means adding 'Users', 'Groups' and 'Sources' and then assigning the users to the groups and the groups to the activity 'Roles'.

This is undertaken by accessing the identity portal which can be found on the following links.


- ITE: <https://home-ite.meliorsolutions.eu>
- IQE: <https://home-iqe.meliorsolutions.eu>
- Production: <https://home.meliorsolutions.eu>

Note, this is a common identity service provision used for more than the EMVO Gateway and thus some functionality may not be available as it is used for other applications.



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As with all of the EMVO Gateway operational screens, the left hand side of the screen is a pull-out menu bar accessed by clicking/pressing on the  symbol. (screen below as shown for an administrator)

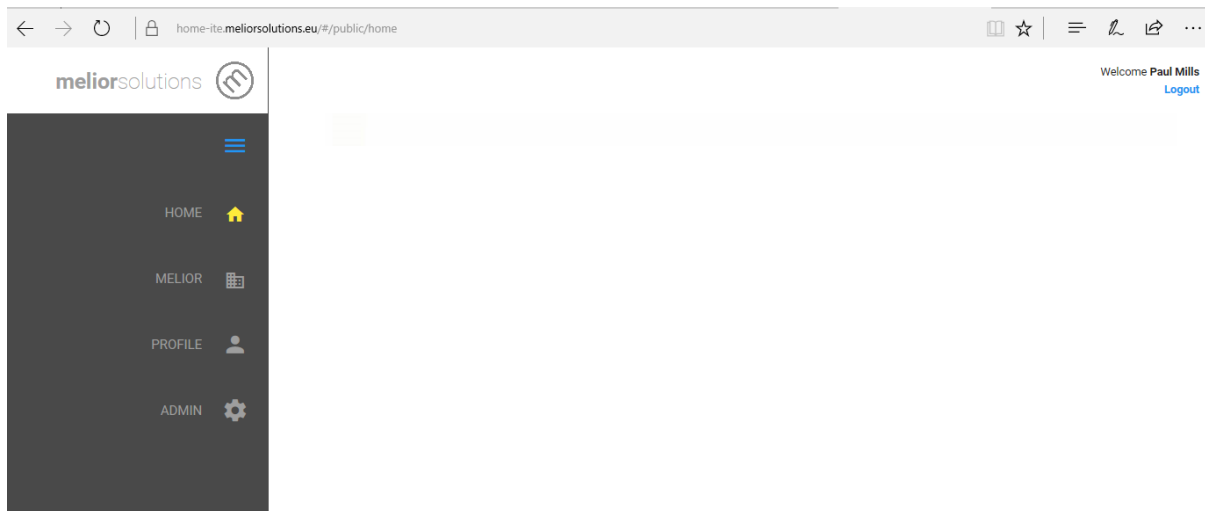


Figure 39 - Identity Service Landing Page

Once logged in the options available in the menu bar are:

- Home – returns the user to the screen shown above.
- Melior – Provides access to a contact details page (not to be confused in the EMVO context with the EMVO website at www.emvo-medicines.eu)
- Profile – allows the logged in user to amend their password.
- Admin – allows the logged in user (administrator) to set up 'User' accounts and 'Groups'

Let's explore the 'Admin' section in more detail.



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4.7 Admin

The 'Admin' section of the identity service is used to set up and administer 'Users' and 'Groups'.

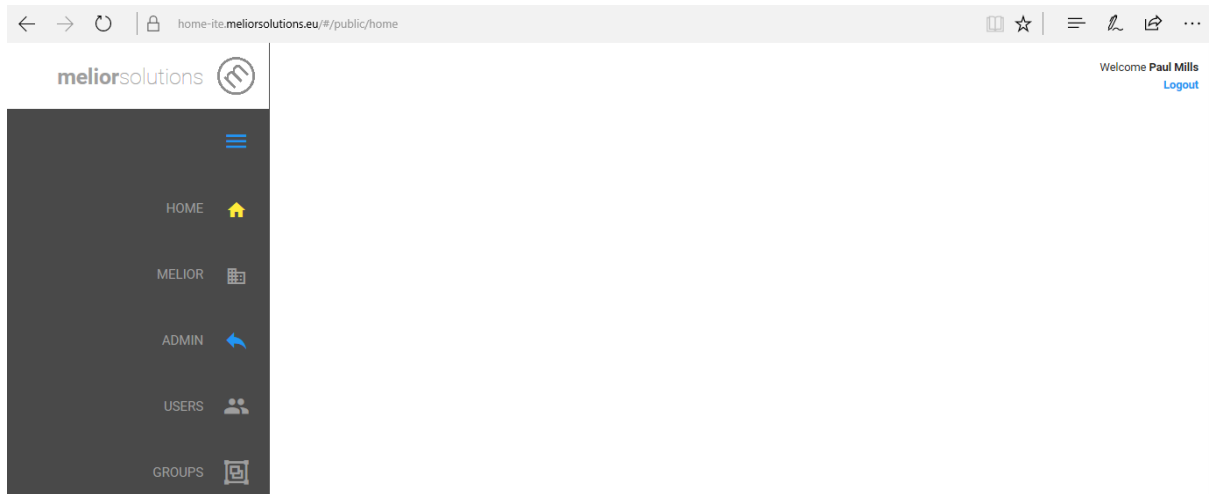


Figure 40 - Identity Service Admin



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4.7.1 Users

The 'Users' section is where users are added and managed. Here we can see three accounts have been created, two are 'Admin' accounts, one is a 'User' account.

Admin > Users

USERS

+ CREATE NEW USER

Search Users

Find User: search id, name or email

Status: All

Id	Name	Email	Status	Enabled	
jcrane	Jack Crane	jcrane@meliorsolutions.com	Admin	✓	VIEW
plea	Pete Lea	plea@meliorsolutions.com	Admin	✓	VIEW
pmills	Paul Mills	pmills@meliorsolutions.com	User	✓	VIEW


1 / 1

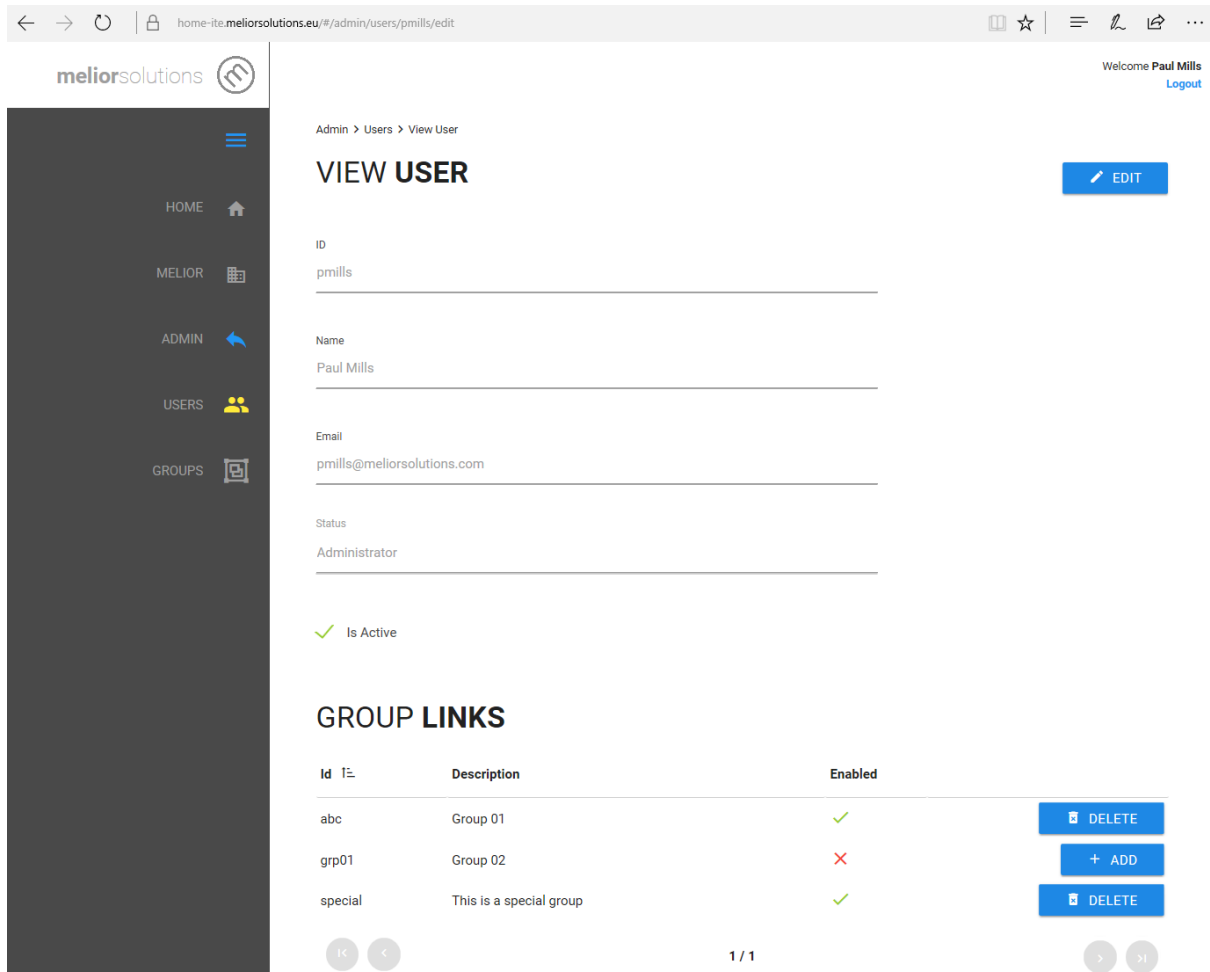
Figure 41 - Identity Service Users List

Admin accounts are indicated by the symbol, user accounts by the symbol.

New users are created by clicking/pressing the [+ CREATE NEW USER](#) button.

Each user profile contains the same elements, each of which has to be populated by the administrator.

			
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home-ite.meliorsolutions.eu/#/admin/users/pmills/edit

Welcome Paul Mills
[Logout](#)

Admin > Users > View User

VIEW USER

[EDIT](#)

ID
pmills

Name
Paul Mills

Email
pmills@meliorsolutions.com

Status
Administrator

✓ Is Active

GROUP LINKS

Id	Description	Enabled	
abc	Group 01	✓	DELETE
grp01	Group 02	✗	+ ADD
special	This is a special group	✓	DELETE

1 / 1

Figure 42 - Identity Service User Profile

Here we have:

- ID – used by the system to track user activity. The ID is system unique and cannot be amended once the account is created.
- Name – used to contain the name of the user and is able to be amended post account creation.
- Email Address – has to be correctly completed as the initial account information and any subsequent password refresh/reset will be sent to this address.
- Status – either the account is an Admin or a User.
- 'Is Active' – allows the account to be disabled and enabled.
- Group Links – allows the various the user to become a member of one or more 'Groups'.



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4.7.2 Groups



The 'Groups' section allows the administrator to declare a series of 'placeholders' against which users can later be added. Groups can be considered as 'buckets' to which users can be assigned such that instead of assigning individual users to specific Roles, users can be attached to Groups and the Groups can be assigned to roles – this scheme, commonly adopted with Active Directory and similar schemes e.g. LDAP, allows easier management of access to activity profiles. For example, if user01 is a standard operator who along with twenty of his colleagues is permitted access to five different Roles, without groups the Admin would have to assign user01 and his twenty colleagues to all five Roles. Adding twenty users and user 01 to five Roles is 105 operations. Adding the same number of users to a group and then adding the group to five Roles is 21 + 5 operations, 79 less than the cumbersome way. Also, if a new user02 was added and needs the same Role access it would be one operation to add the user to the group (not five).

The user in the screen shot from the previous section is part of three groups, abc, grp01 and special. In the screen shot below we can see that the Role 'Create Packs' has the group 'special' assigned to it, thus any user with the group assignment 'special' is able to create packs/batches.

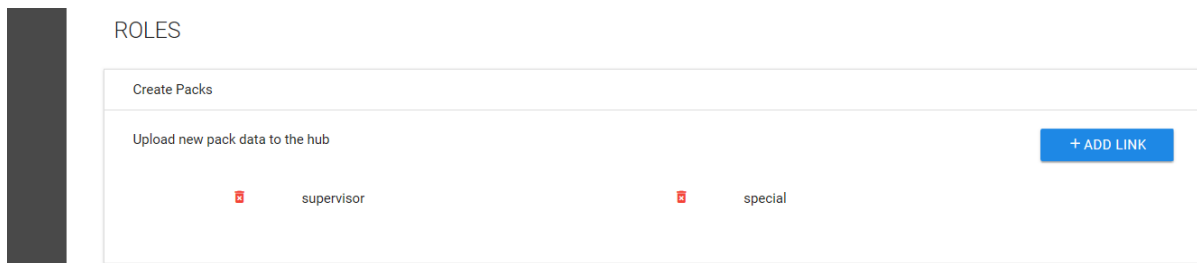


Figure 43 - Group Assignment to Role/Activity

You can now see that numerous other links have been displayed on the left hand side of the page. Some of these may not result in access to a given area (for example, original pack manufacturers will probably not also have a Distributor/Repacker capability)



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5 References

	EMVO_0077_On-boarding Guideline/Manual
	EMVO_0086_On-boarding Presentation
	EMVO_0014_EMVS Req Spec Part I General Introduction and Overview
	EMVO_0015_EMVS Req Spec Part II Use Case Diagrams and Descriptions
	EMVO_0016_EMVS Req Spec Part III Use Case Process Step Descriptions
	EMVO_0017_EMVS Req Spec Part IV Exceptions - Exception Handling - Alerts
	EMVO_0018_EMVS Req Spec Part V Non-Functional, Operational and Test Harness Requirements
	EMVO_0019_EMVS Req Spec Part VI Glossary
	EMVO_0059_EMVS Req Spec Part VII Additional Requirements for Delegated Regulation Compliance