



IRISH
MEDICINES
VERIFICATION
ORGANISATION

IMVO Registration Webinar for Pharmacies & Hospitals

V11.0 4TH FEBRUARY 2019

Outline

- ▶ Housekeeping
- ▶ CPD certificate of attendance
- ▶ Introduction to EMVS / IMVO
- ▶ What exactly is involved for pharmacies & hospitals?
- ▶ How to register with IMVO, including walk-through of online registration form
- ▶ Who to contact for support
- ▶ IMVO pilot
- ▶ Q&A



CPD Certificate of Attendance

- ▶ If you would like a certificate of attendance for CPD purposes, please email your name to registration@imvo.ie after the webinar



IIOP

INSTITIÚID CÓGAIŚÍOCHTA NA hÉIREANN
IRISH INSTITUTE OF PHARMACY

IMVO Registration Webinar

Introduction to EMVS / IMVO



Falsified Medicines Directive (FMD)

- ▶ Falsified medicines are fake medicines that pass themselves off as real, authorised medicines
- ▶ EU Falsified Medicines Directive 2011/161/EU sets out series of measures to tackle growing threat of falsified medicines including:
 - ▶ Registration of online retailers of medicines & EU 'common logo'
 - ▶ Tighter controls on active pharmaceutical ingredients
 - ▶ Tighter controls on wholesalers
 - ▶ Mandatory new 'safety features' on medicines packs - **unique identifiers** and **anti-tamper device**



 Click to verify
if this website
is operating
legally

Safety features

- ▶ Safety features are mandatory for most Rx medicines; OTC medicines largely excluded
- ▶ Unique identifiers:
 - ▶ Embedded in 2D dot matrix barcode on pack
 - ▶ 'Unique identifier' = product code + pack serial no. + batch no. + expiry date
- ▶ Commission 'Delegated Regulation'* (DR) setting out more details about safety features, including obligations of manufacturers, wholesalers, pharmacies, hospitals, was published in Feb 2016
- ▶ New requirements come into effect on **9th February 2019**



* Commission Delegated Regulation (EU) 2016/161

Pack with safety features

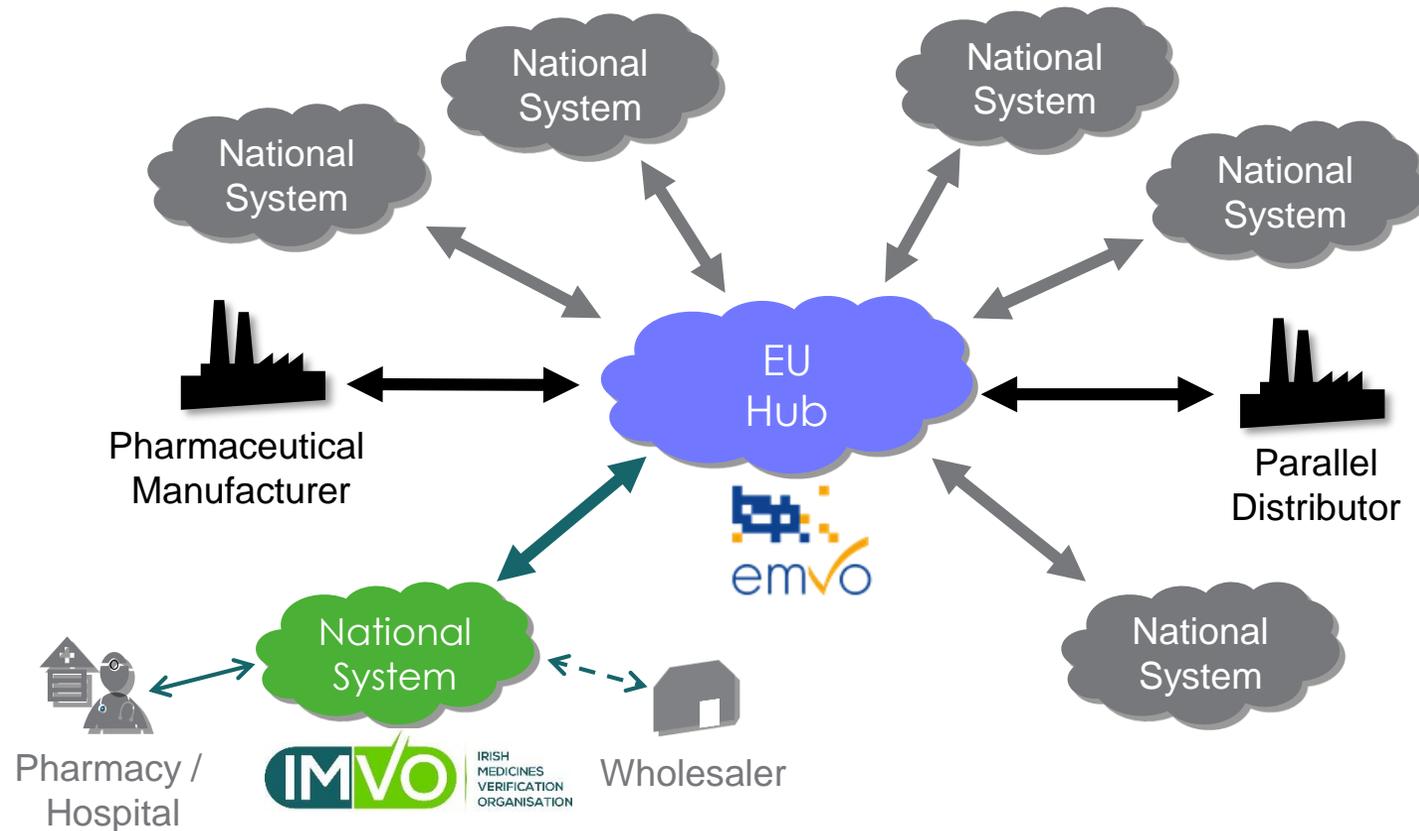


Anti-tampering device

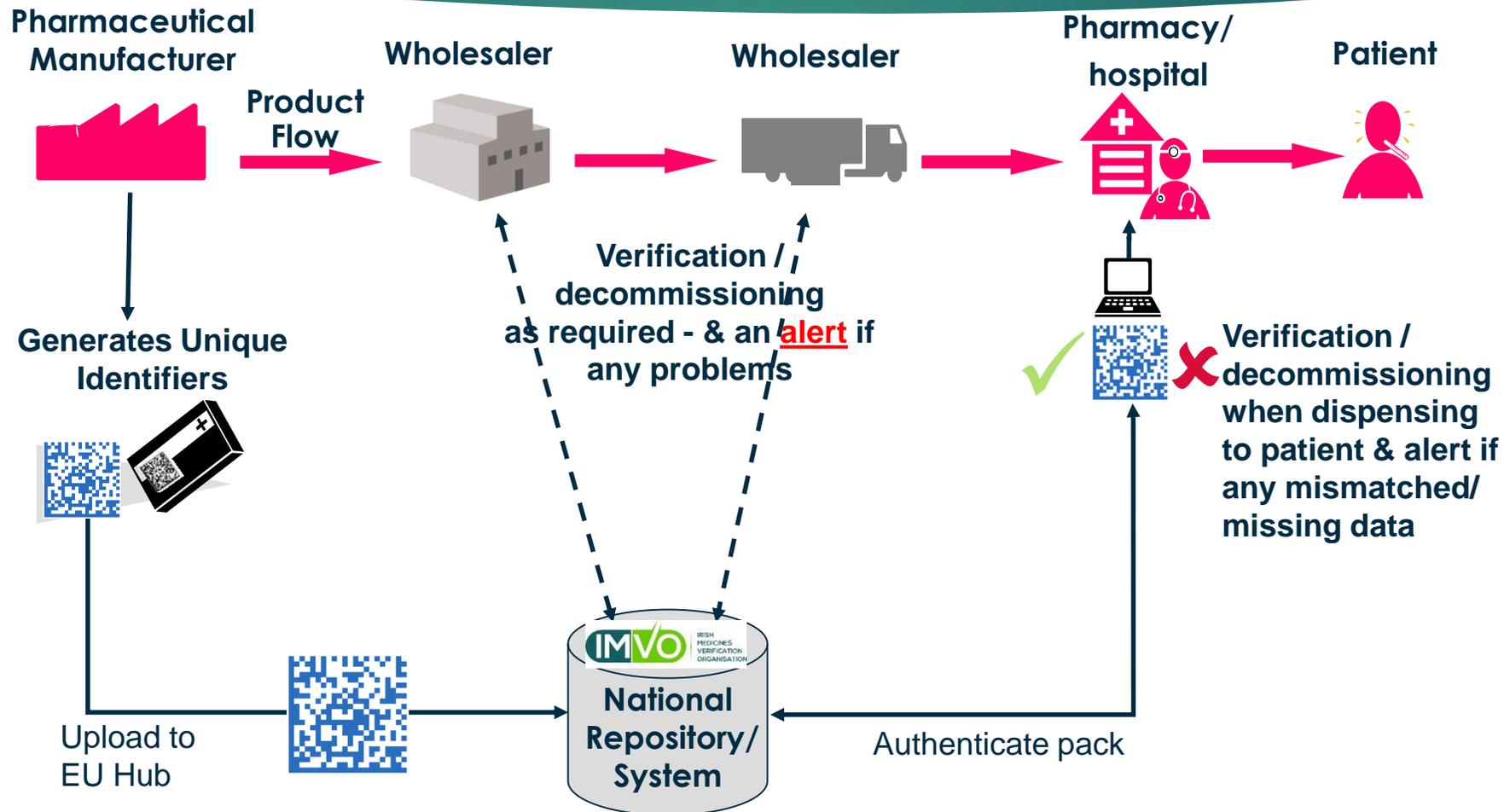
Safety features

Unique Identifier

Overview of European Medicines Verification System (EMVS)



Medicines authentication – how will process work?



Medicines authentication – how will process work in health services?

- ▶ Requirement to verify authenticity of medicines & decommission unique identifiers applies to all in-scope products supplied to patients in ‘healthcare institutions’
- ▶ **Definitions:**
 - ▶ **‘Healthcare institution’:** *“hospital, in- or out-patient clinic or health centre” (Delegated Regulation)*
 - ▶ **“in or out-patient clinic:** *“in or out-patient/day patient clinic under the management or control of a hospital” (DoH definition)*
 - ▶ **Health centre:** *“health centre under the management or control of a hospital” (DoH definition)*
- ▶ HSE has project team in place to oversee implementation



About IMVO

- ▶ **Role is to set up & manage national repository for Ireland**
- ▶ Set up in April 2017 by five organisations involved in medicines supply chain in Ireland
- ▶ Key tasks:
 - ▶ Select IT provider to develop & maintain repository (Solidsoft Reply)
 - ▶ Ensure full interconnectivity of repository with EU Hub
 - ▶ Register & verify credentials of system end-users in Ireland
 - ▶ Levy fees on pharma companies to pay for national system
 - ▶ Monitor national system & manage alerts



PDF

Who pays for all this?

- ▶ IMVO is funded by:
 - ▶ membership subscriptions paid by IMVO member organisations
 - ▶ fees charged to marketing authorisation holders whose product data will be hosted in repository
- ▶ Pharmacists, hospitals and wholesalers will not pay for repository system costs ... but have to pay their own implementation costs (as per DR)



Data access & ownership

- ▶ No patient data transmitted to IMVO repository
- ▶ Everyone owns their own data
- ▶ No-one has access to data of other parties except for verification purposes, or to investigate an alert, or with their agreement
- ▶ Competent authorities may access data for specific purposes:
 - ▶ Supervising functioning of repository and investigating incidents of falsification
 - ▶ Reimbursement
 - ▶ Pharmacovigilance or pharmacoepidemiology



Why is 9th Feb 2019 deadline important?

- ▶ Manufacturers cannot release in scope medicines to market after this date without safety features
- ▶ Packs on the market without safety features on 9th Feb 2019 may continue to be supplied until their expiry date
- ▶ **Medicines with safety features cannot be supplied to patients after 9th Feb 2019 if you have not authenticated it by:**
 - ▶ Checking anti-tamper device and
 - ▶ Scanning barcode to verify & decommission unique identifiers



IMVO Registration Webinar

**What exactly is involved for
pharmacies & hospitals?**



When must pharmacy or hospital verify & decommission a pack?

- ▶ When pack is being dispensed/supplied:
 - ▶ **Community pharmacies** – at ‘time of supplying it to the public’
 - ▶ **Hospitals** – at any time after pack arrives in hospital (anti-tamper device check must be done at time of supply)
- ▶ In case of bulk pack, decommission once only when pack is opened for 1st time
- ▶ Pack intended for destruction
- ▶ Pack is being supplied as sample to competent authority, e.g. PSI, HPRA
- ▶ Authorised medicine being supplied for use in a clinical trial



Type of barcodes to scan and not to scan!

Data matrix (2D barcode)

PC: 20000608627252

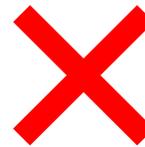
SN: 0085530921

Lot: AB123C4

EXP: 19/03/2021



Linear (1D) Barcode



QR Code



Other points of note

- ▶ Can reverse decommissioning subject to following conditions:
 - ▶ Must be done within 10 days of decommissioning and in the same location
 - ▶ Recommissioning not allowed if pack:
 - ▶ was supplied to patient or
 - ▶ is marked in national system as expired, recalled, withdrawn, stolen, destroyed
- ▶ Cannot return packs to wholesalers if already decommissioned



'Article 23'

- ▶ Article 23 of Delegated Regulation states that Member States may require wholesalers to verify safety and decommission packs supplied to:
 - ▶ Persons authorised or entitled to supply medicines to the public who do not operate in healthcare institutions (e.g. GPs)
 - ▶ Vets & retailers of veterinary medicines / dentists / opticians
 - ▶ Paramedics & emergency medical practitioners
 - ▶ Army, police & other government institutions maintaining stocks for civil protection & disaster control
 - ▶ Universities/higher education institutions for purpose of research & education
 - ▶ Prisons
 - ▶ Schools
 - ▶ Hospices / nursing homes

'Article 23' (ctd)

- ▶ DoH has confirmed that Article 23 will be applied in full in Ireland
- ▶ Article 23 not applicable to medicines supplied to 'healthcare institutions'
- ▶ Pharmacies & hospitals who supply persons covered by Article 23 will also be required to do decommissioning for them

What happens if system is down?

- ▶ **National system** - continue scanning packs and data will upload automatically when national system is back
 - ▶ Once scanned, pack may be supplied
 - ▶ In the event that alert message is returned when national system is back, will need to take action
- ▶ **Pharmacy/hospital FMD system** - use emergency online link to verify & decommission pack by typing in unique identifier data (printed on pack) – this feature will be available shortly.

What happens if there is an alert?

- ▶ Detailed guidance on alert handling following barcode scan will be issued by PSI and HPRA
- ▶ If pack looks like it has been tampered with, do not supply it (even if barcode scan was fine)
 - ▶ Report concerns re anti-tamper device to HPRA via their website - <https://www.hpra.ie/homepage/about-us/report-an-issue>



IMVO Registration Webinar

How to register with IMVO



Key Terms (ctd)

End-User

- ▶ Pharmacy, hospital, wholesaler or any other person 'authorised or entitled to supply medicines to the public' that wishes to connect to national system for purpose of verifying and decommissioning packs
- ▶ Reference to End-User 'organisation' in online registration form:
 - ▶ This may be an individual pharmacy/hospital or pharmacy/hospital group
 - ▶ Each organisation registered has its own IMVO account linked with one email address within End-User organisation (i.e. email address of 'Super User')
 - ▶ All connections from End-User organisation's FMD system to national system are managed through that email address
- ▶ Can register different companies under single 'End-User' account provided they are related, e.g. one company controls the other(s) or they are under common control



Key Terms (ctd)

Super User

- ▶ Super User is emailed technical details needed to connect your organisation's FMD system(s) to national system
- ▶ Super User is person who set up connection from specific computers or devices ('clients') in each premises ('location') to national system
 - ▶ Your IT software provider may provide support for this step
- ▶ Super User must be a person within your organisation – role cannot be assigned to your IT software provider
- ▶ Super User email address can only be used once for IMVO registration



IMVO Registration

- ▶ No fees for registration
- ▶ 4 step process:
 1. Complete online registration form so we have all your details
 2. Accept IMVO's End-User T&Cs when completing form
 3. IMVO carries out legitimacy check
 4. Technical registration / connection – most complex part
- ▶ We are aiming to process applications within 7 working days
- ▶ NB – if you are a community pharmacy & also have a wholesaler's authorisation, two separate registrations with IMVO are required



1. Online registration form

- ▶ Access to online registration is via IMVO website, under 'System Users' tab
 - ▶ If you have difficulty accessing online form, email us at registration@imvo.ie to request a Word version
- ▶ Form must be completed in one session – allow at least 15 mins (longer if registering several locations)
- ▶ Form must be completed by 'Authorised Representative'



1. Online registration form (ctd)

- ▶ Information to have to hand before you start filling in form:
 - ▶ Name of 'organisation' to be registered
 - ▶ Details for each 'location' (premises) you want to register – name, address, PSI retail pharmacy business reg. no.
 - ▶ Details of 'authorised representative' - name, position, email address
 - ▶ Name of your IT software provider (s)
 - ▶ 'Super User' name, position, email address



IMVO Registration Webinar

Walk-through of online registration form



Accessing IMVO online registration

- ▶ Access to online registration is via IMVO website under 'System Users' tab:

<http://www.imvo.ie/stakeholders1/register-imvo>

- ▶ Click on the word '**here**' that is bold highlighted in blue



End-User registration form

To register as a pharmacy, hospital or wholesaler with IMVO click the link **here** to access our online registration form.

Please read the notes provided before starting the registration process. If you don't provide all the information requested, we have to reject your application and you will be required to resubmit it.

Errors may lead to applications being rejected, in which case, a fresh application will be required. A list of the most common errors seen to date is provided below so you know the mistakes to avoid.

Step 1. End-user information

- ▶ Enter name of the organisation that you wish to register as an End-User with IMVO
- ▶ Select your organisation type from the drop-down box
- ▶ If you have selected 'Other' please enter any relevant additional information in box provided. e.g. "clinic", "hospital not registered as retail pharmacy", etc. and enter website address if you have one

Note: Hovering over any of the box descriptions will provide additional description guidance

The screenshot shows the IMVO (Irish Medicines Verification Organisation) website interface for the 'End-User Registration' process. The page is titled 'Step 1. End-user information' and features a navigation bar with a 'Home' link. Below the navigation bar, there is a progress indicator showing six steps, with 'Step 1' highlighted. The main form area is titled 'End-User Information' and contains two input fields: 'End-User Name *' and 'Type of Organisation *'. The 'Type of Organisation *' field is a dropdown menu. Below these fields, there is a text box for additional information, with the instruction: 'If 'Other' was selected for 'Type of Organisation', provide details'. At the bottom of the form, there is a 'Next' button. The footer of the page displays the IMVO logo and the text 'Irish Medicines Verification Organisation End-User Registration'.

IMVO IRISH MEDICINES VERIFICATION ORGANISATION

Home

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

End-User Information

End-User Name *

Type of Organisation *

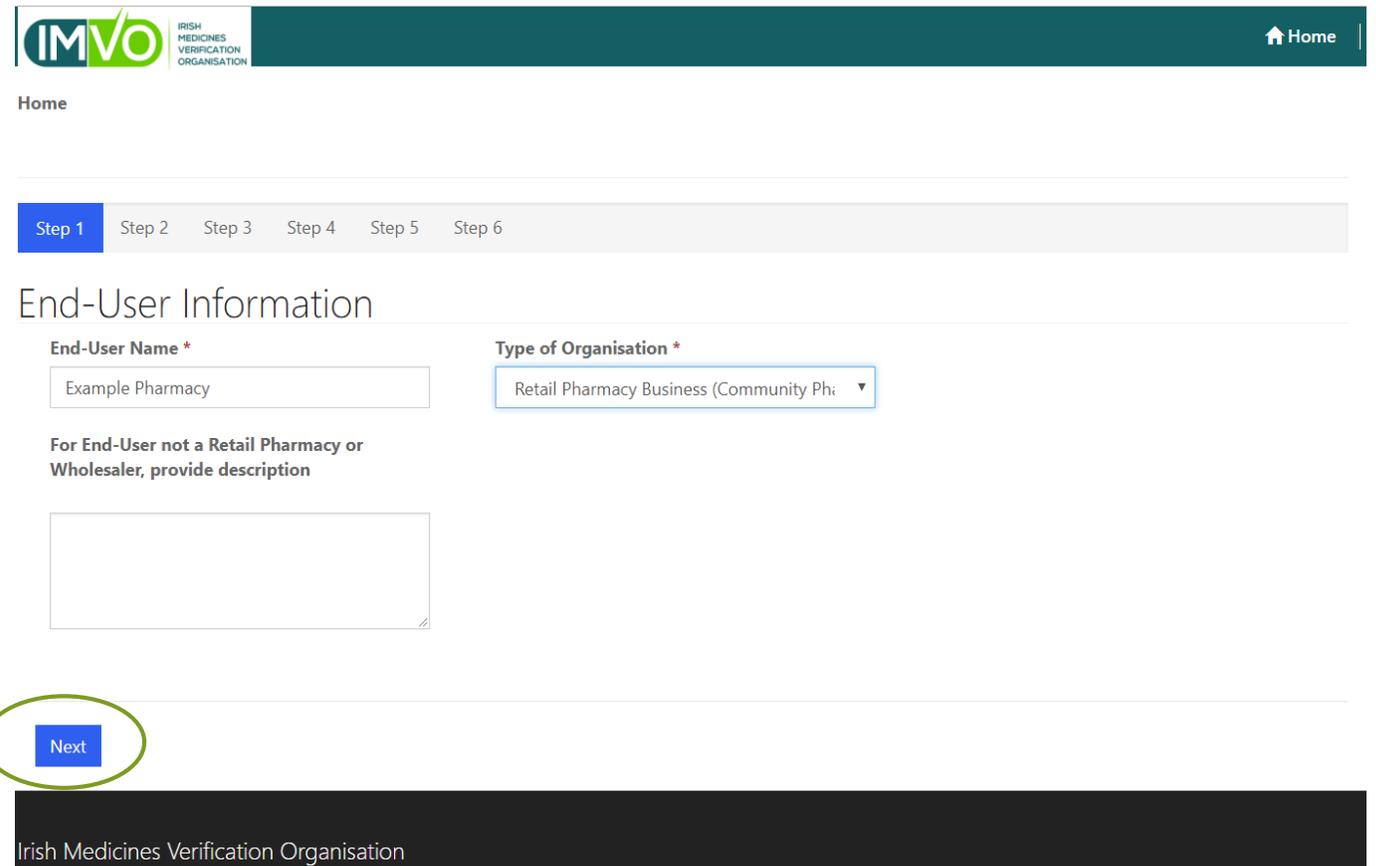
If 'Other' was selected for 'Type of Organisation', provide details

Next

Irish Medicines Verification Organisation
End-User Registration

Step 1. End-user information completed

- ▶ Once you are satisfied that all information is correct click 'Next' to move on to Step 2



The screenshot shows the IMVO (Irish Medicines Verification Organisation) website interface. At the top left is the IMVO logo and name. At the top right is a 'Home' link. Below the header is a progress bar with six steps: Step 1 (highlighted in blue), Step 2, Step 3, Step 4, Step 5, and Step 6. The main heading is 'End-User Information'. There are two input fields: 'End-User Name *' with the text 'Example Pharmacy' and 'Type of Organisation *' with a dropdown menu showing 'Retail Pharmacy Business (Community Ph)'. Below these is a text area with the instruction 'For End-User not a Retail Pharmacy or Wholesaler, provide description'. At the bottom of the form is a blue 'Next' button, which is circled in green. The footer contains the text 'Irish Medicines Verification Organisation'.

Step 2. Add location

- ▶ Each premises belonging to the end-user organisation is a 'location'
- ▶ You can register more than one location
- ▶ Click on 'Add location'

The screenshot shows the IMVO (Irish Medicines Verification Organisation) End-User Registration interface. At the top, the IMVO logo and 'IRISH MEDICINES VERIFICATION ORGANISATION' are visible on the left, and a 'Home' link is on the right. Below the header, a progress bar indicates the current step: 'Step 1' is completed (checked), 'Step 2' is the active step (highlighted in blue), and 'Step 3' through 'Step 6' are pending. The main heading is 'Location'. A blue 'Add Location' button is circled in green. Below this, a text instruction reads: 'Please enter details of each location (premises) within your organisation that will be connected to the IMVO repository. You may list more than one location by repeating the "Add Location" step.' A table with the following columns is shown: 'Location ↑', 'Address Line 1', 'Address Line 2', 'Town', 'County', 'Eircode', and 'Telephone Number'. Below the table, a message states 'There are no records to display.' At the bottom of the page, there are 'Previous' and 'Next' navigation buttons. The footer contains the text 'Irish Medicines Verification Organisation' and 'End-User Registration'.

Home

Step 1 ✓ Step 2 Step 3 Step 4 Step 5 Step 6

Location

Add Location

Please enter details of each location (premises) within your organisation that will be connected to the IMVO repository. You may list more than one location by repeating the "Add Location" step.

Location ↑	Address Line 1	Address Line 2	Town	County	Eircode	Telephone Number
There are no records to display.						

Previous Next

Irish Medicines Verification Organisation
End-User Registration

Step 2a. Add location details

In the pop-up box:

- ▶ Enter name of location
- ▶ Enter address
- ▶ Enter telephone number
- ▶ Enter Eircode
- ▶ If registered as retail pharmacy business with PSI, enter PSI registration number*
- ▶ Click 'Submit'

* Must be pharmacy registration number, not your PSI pharmacist reg. no. or pharmacy GMS no.

The screenshot shows a web application interface with a 'Create' pop-up window titled 'Add Location'. The form is divided into two main sections: 'Name' and 'ADDRESS'. The 'Name' section has a text input field containing 'Example Pharmacy - Somewhere'. Below it is a note: 'Please enter the pharmacy name, hospital name or wholesaler name, e.g. "Brown's Pharmacy", "White's Hospital", "Green's Wholesale Ltd", NOT the town or city where it is located.' There are two optional input fields: 'If a Retail Pharmacy Business, enter PSI RPB registration no.' with the value '1234', and 'If a wholesaler, enter WDA number:'. The 'ADDRESS' section includes 'Address Line 1' (Main Street), 'Address Line 2' (empty), 'Town' (Somewhere), 'County' (Dublin 6W), 'Telephone Number' (01-1234567), and 'Eircode' (empty). A blue 'Submit' button is circled in green at the bottom of the form. The background shows a navigation menu with 'Home', 'Step 1', and 'Location' options.

Step 2b. Add location information completed

The screenshot displays the IMVO (Irish Medicines Verification Organisation) End-User Registration interface. At the top, the IMVO logo and name are visible on the left, and a 'Home' link with a house icon is on the right. Below the header, the word 'Home' is centered. A progress bar shows six steps: Step 1 (checked), Step 2 (highlighted in blue), Step 3, Step 4, Step 5, and Step 6. The main heading is 'Location', with an 'Add Location' button on the right. A text instruction reads: 'Please enter details of each location (premises) within your organisation that will be connected to the IMVO repository. You may list more than one location by repeating the "Add Location" step.' Below this is a table with the following columns: Location ↑, Address Line 1, Address Line 2, Town, County, Eircode, and Telephone Number. A single row of data is shown: 'Example Pharmacy - Somewhere', 'Main Street', 'Somewhere', 'Dublin 6W', and '01-1234567'. A dropdown arrow is visible at the end of the row. At the bottom, there are 'Previous' and 'Next' buttons. The footer contains the text 'Irish Medicines Verification Organisation' and 'End-User Registration'.

Home

Home

Step 1 ✓ Step 2 Step 3 Step 4 Step 5 Step 6

Location [Add Location](#)

Please enter details of each location (premises) within your organisation that will be connected to the IMVO repository. You may list more than one location by repeating the "Add Location" step.

Location ↑	Address Line 1	Address Line 2	Town	County	Eircode	Telephone Number
Example Pharmacy - Somewhere	Main Street		Somewhere	Dublin 6W		01-1234567

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Irish Medicines Verification Organisation
End-User Registration

Step 2c. Add additional location(s)

If you have additional locations to register:

- ▶ Click on 'Add location' again and enter the details of the additional location.
- ▶ Click 'Submit'
- ▶ Repeat for all additional locations

The screenshot shows the 'Add Location' form in the IMVo system. The form is titled 'Add Location' and is part of a 'Create' process. It contains the following fields and sections:

- Name ***: A text input field containing 'Example Pharmacy - Somewhere Else'.
- ADDRESS**: A section containing:
 - Address Line 1**: A text input field containing 'Side Street'.
 - Address Line 2**: An empty text input field.
 - Town**: A text input field containing 'Somewhere Else'.
 - County**: A dropdown menu with 'Cork' selected.
 - Telephone Number**: A text input field containing '021-1234567'.
 - Eircode**: An empty text input field.
- If a Retail Pharmacy Business, enter PSI RPB registration no.**: A text input field containing '5678'.
- If a wholesaler, enter WDA number:**: An empty text input field.

The 'Submit' button at the bottom of the form is circled in green. The background shows a navigation menu with 'Home', 'Step 1', and 'Location' options.

Step 2d. Add additional location(s) completed

- ▶ Once you have added all the locations, you wish to register, click on 'Next' to move to Step 3

IMVO IRISH MEDICINES VERIFICATION ORGANISATION [Home](#)

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Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Location [Add Location](#)

Please enter details of each location (premises) within your organisation that will be connected to the IMVO repository. You may list more than one location by repeating the "Add Location" step.

Location ↑	Address Line 1	Address Line 2	Town	County	Eircode	Telephone Number
Example Pharmacy - Somewhere	Main Street		Somewhere	Dublin 6W		01-1234567 <input type="button" value="v"/>
Example Pharmacy - Somewhere Else	Side Street		Somewhere Else	Cork		021-1234567 <input type="button" value="v"/>

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Irish Medicines Verification Organisation
End-User Registration

Step 3. Super User information

- ▶ Enter details of your organisation's 'Super User':
 - ▶ First and Last name
 - ▶ Position in organisation
 - ▶ Email address*
 - ▶ Telephone number
- ▶ Click on 'Next' to move to Step 4

***NB** 'Healthmail' email addresses cannot be used for IMVO registration

The screenshot shows the IMVO registration interface. At the top, the IMVO logo and 'IRISH MEDICINES VERIFICATION ORGANISATION' are visible. A progress bar indicates that Step 3 is the current step, with Steps 1 and 2 completed. The main heading is 'Super User'. Below this, a paragraph explains that the user should provide details of the person who will act as the 'Super User' for their organisation, and that emails with technical onboarding information will be sent to the nominated Super User. The form contains several input fields: 'First Name' (with 'Good' entered), 'Last Name' (with 'Example' entered), 'Position in End-User Organisation' (with 'Owner' entered), 'Email Address' (with 'good.example@gmail.com' entered), and 'Telephone Number' (with '01-1234567' entered). At the bottom of the form, there are 'Previous' and 'Next' buttons. The 'Next' button is circled in green, indicating it should be clicked to proceed to Step 4. The footer of the page displays 'Irish Medicines Verification Organisation' and 'End-User Registration'.

Step 4. End-User IT Software Provider

- ▶ Enter details of your IT software provider* by clicking on 'Add IT Provider'
- ▶ You will have the option to repeat this step to add additional IT software providers

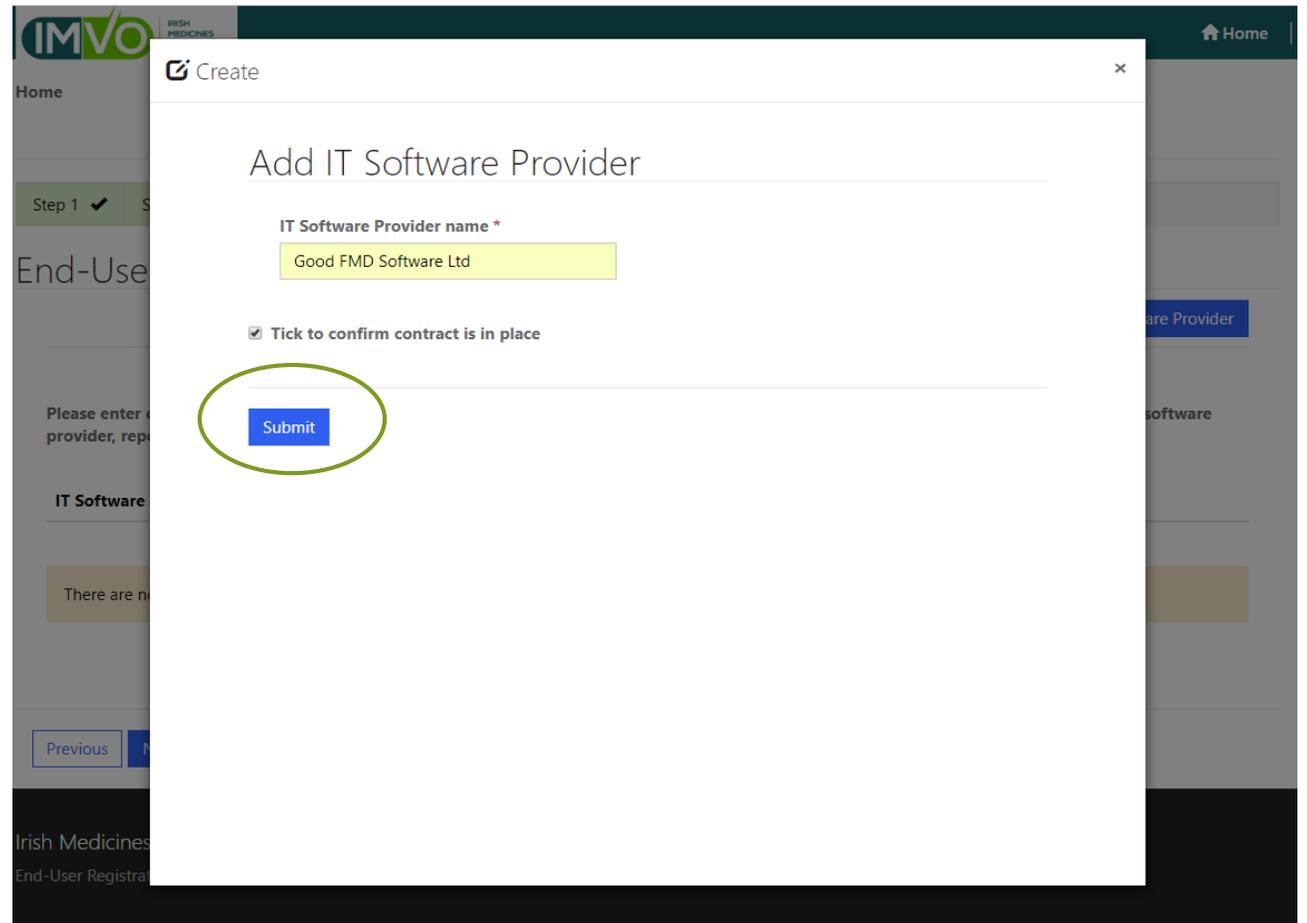
* **NB** - provider of your FMD system

The screenshot shows the IMVO (Irish Medicines Verification Organisation) website interface for Step 4 of the End-User Registration process. The header includes the IMVO logo and a 'Home' link. A progress bar at the top indicates that Step 4 is the current step, with Steps 1, 2, and 3 marked as completed. The main heading is 'End-User's IT Software Provider(s)'. A blue button labeled 'Add IT Software Provider' is circled in green. Below this, a text prompt asks the user to enter details of the provider of the system used to connect to the IMVO repository, noting that multiple providers can be added by repeating the step. A label 'IT Software Provider name' with an upward arrow is positioned above a large, empty text input field. A yellow message box below the input field states 'There are no records to display.' At the bottom, there are 'Previous' and 'Next' navigation buttons. The footer contains the text 'Irish Medicines Verification Organisation' and 'End-User Registration'.

Step 4a. End-User IT software provider information

In the pop-up box:

- ▶ Enter name of your IT software provider
- ▶ Tick the check box to confirm you have a contract with the IT software provider
- ▶ Click 'Submit'



The screenshot shows a web application interface with a 'Create' pop-up box. The background is a dark grey sidebar with the IMVO logo and navigation links. The pop-up box is white and titled 'Add IT Software Provider'. It contains a text input field for 'IT Software Provider name *' with the value 'Good FMD Software Ltd'. Below this is a checked checkbox labeled 'Tick to confirm contract is in place'. At the bottom of the form is a blue 'Submit' button, which is circled in green. The background also shows a progress indicator for 'Step 1' and a 'Home' link in the top right corner.

Step 4b. End-User IT software provider information completed

 IRISH MEDICINES VERIFICATION ORGANISATION Home

Home

Step 1 ✓ Step 2 ✓ Step 3 ✓ Step 4 Step 5 Step 6

End-User's IT Software Provider(s)

Add IT Software Provider

Please enter details of the provider of the system that your organisation will use to connect to the IMVO repository. To list more than one IT software provider, repeat "Add IT software Provider" step.

IT Software Provider name ↑

Good FMD Software Ltd ▼

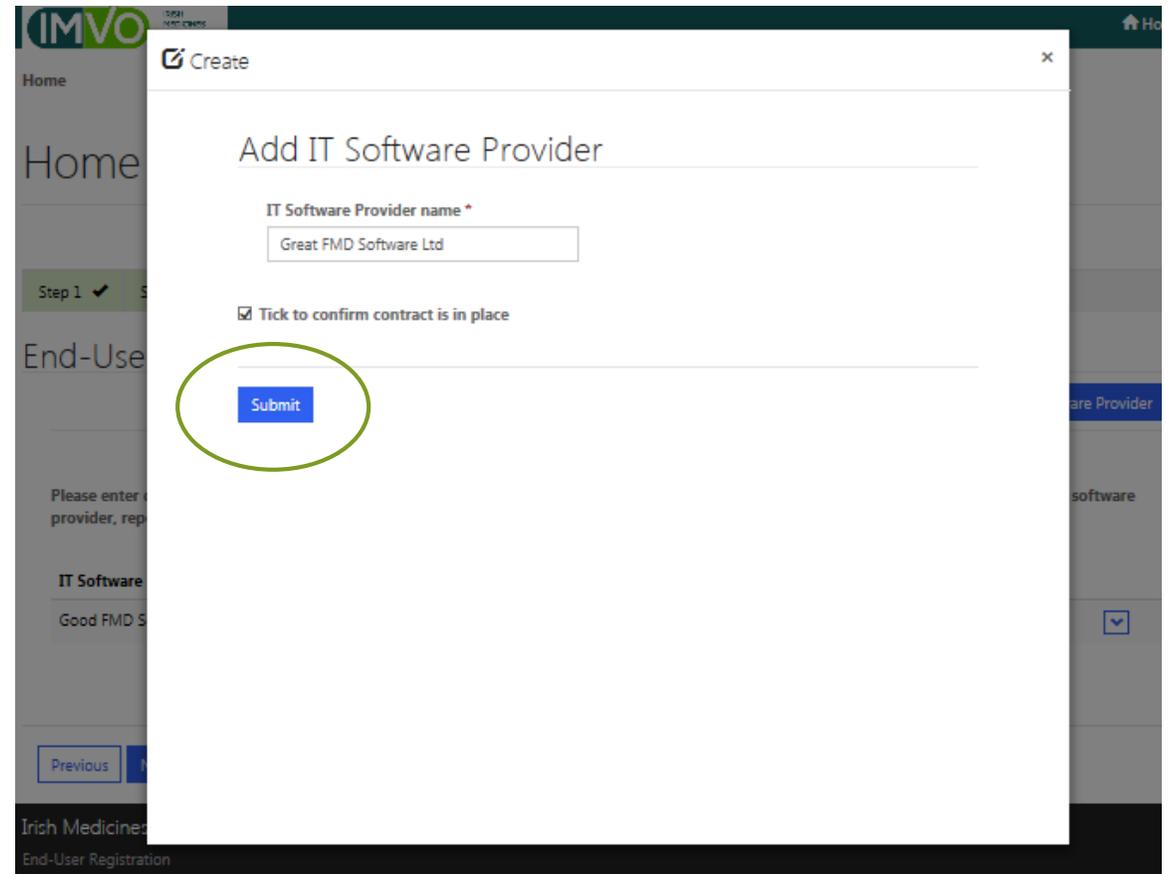
Previous Next

Irish Medicines Verification Organisation
End-User Registration

Step 4c. Add additional End-User IT software provider

If you are using more than one IT software provider:

- ▶ Click on 'Add IT provider' again and enter the details of your 2nd IT software provider.
- ▶ Click 'Submit'
- ▶ Repeat these steps for all additional IT software providers



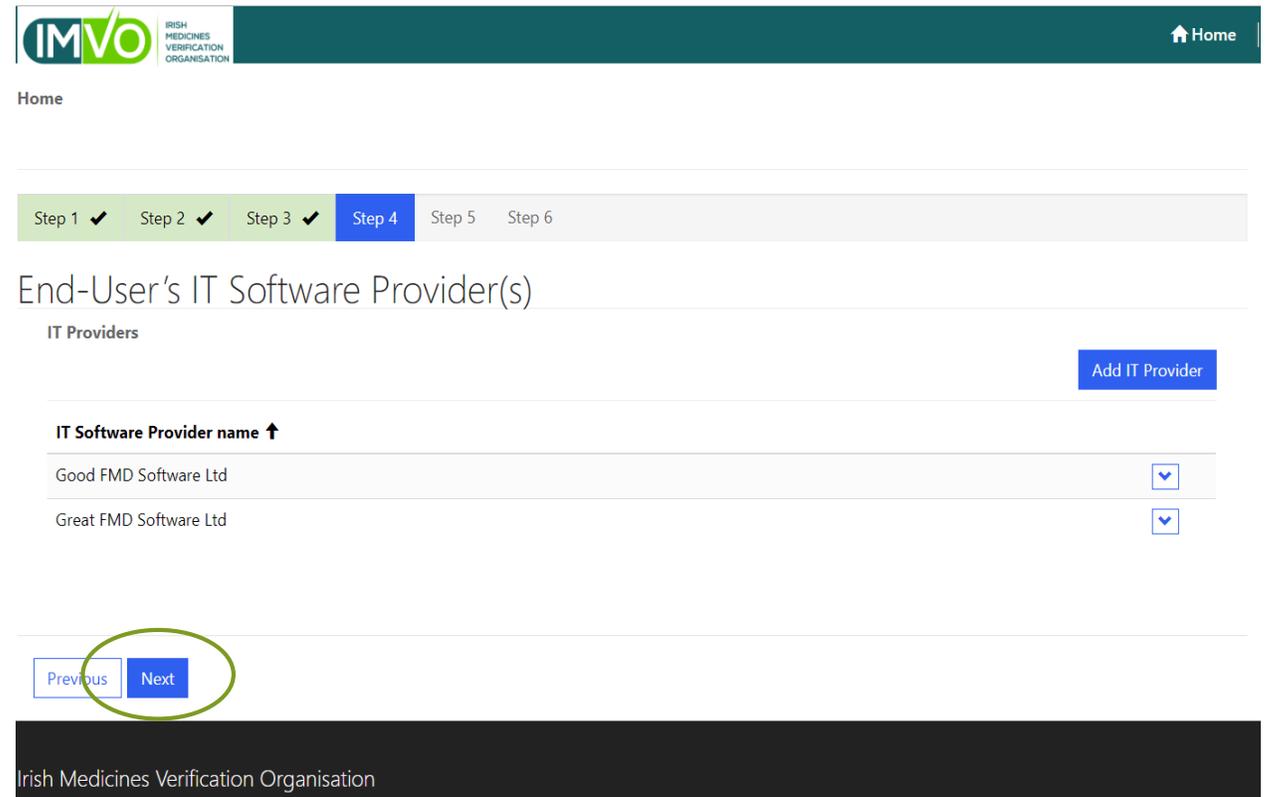
The screenshot shows a web application interface for adding an IT software provider. The main window is titled "Create" and contains the following elements:

- A header "Add IT Software Provider" with a close button (X).
- A text input field labeled "IT Software Provider name *" containing the text "Great FMD Software Ltd".
- A checkbox labeled "Tick to confirm contract is in place" which is checked.
- A blue "Submit" button, which is circled in green.

The background shows a sidebar with navigation options: "Home", "Step 1 ✓", "End-Use", "Please enter provider, rep", "IT Software", "Good FMD S", "Previous", and "Irish Medicines End-User Registration".

Step 4d. Add additional End-User IT software provider completed

- ▶ Once you have added your IT software provider(s), click on 'Next' to move to Step 5



The screenshot shows the IMVo (Irish Medicines Verification Organisation) website interface. At the top, there is a navigation bar with the IMVo logo and a 'Home' link. Below the navigation bar, a progress indicator shows six steps: Step 1 (checked), Step 2 (checked), Step 3 (checked), Step 4 (active), Step 5, and Step 6. The main heading is 'End-User's IT Software Provider(s)'. Underneath, there is a section titled 'IT Providers' with an 'Add IT Provider' button. A dropdown menu is open, showing 'IT Software Provider name ↑' with two options: 'Good FMD Software Ltd' and 'Great FMD Software Ltd'. At the bottom of the form, there are two buttons: 'Previous' and 'Next'. The 'Next' button is circled in green, indicating the action to be taken. The footer of the page reads 'Irish Medicines Verification Organisation'.

Step 5. Authorised Representative information

- ▶ Enter details of Authorised Representative:
 - ▶ Name
 - ▶ Position in organisation
 - ▶ Email address
 - ▶ Telephone number
- ▶ Click on 'Next' to move to Step 6

The screenshot shows the IMVo (Irish Medicines Verification Organisation) website interface. At the top, there is a navigation bar with the IMVo logo and a 'Home' link. Below the navigation bar, a progress indicator shows six steps: Step 1, Step 2, Step 3, Step 4, Step 5 (highlighted in blue), and Step 6. The main content area is titled 'Authorised Representative of End-User' and contains four input fields: 'Name' (with 'Good Example' entered), 'Position in End-User Organisation' (with 'Owner' entered and highlighted in yellow), 'Email Address' (with 'good.example@gmail.com' entered), and 'Telephone Number' (with '01-1234567' entered). At the bottom of the form, there are two buttons: 'Previous' and 'Next'. The 'Next' button is circled in green, indicating it is the action to be taken. The footer of the page contains the text 'Irish Medicines Verification Organisation' and 'End-User Registration'.

Home

Step 1 ✓ Step 2 ✓ Step 3 ✓ Step 4 ✓ Step 5 Step 6

Authorised Representative of End-User

Name
Good Example

Position in End-User Organisation
Owner

Email Address
good.example@gmail.com

Telephone Number
01-1234567

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Irish Medicines Verification Organisation
End-User Registration

Step 6. Acceptance of Terms & Conditions

To accept IMVO End-User Terms & Conditions (T&Cs):

- ▶ Click 'Download Terms & conditions Here' to access copy
- ▶ Read T&Cs
- ▶ Click the 'I Accept' box
- ▶ Click 'Submit' to complete your registration

The screenshot shows the IMVO (Irish Medicines Verification Organisation) registration process at Step 6. The header includes the IMVO logo and a 'Home' link. A progress bar at the top indicates that Steps 1 through 5 are completed, and Step 6 is the current step. The main content area is titled 'Terms & Conditions' and contains the following text: 'As the Authorised Representative of your organisation by clicking "I Accept", you acknowledge that you have read, understood and consent to be bound by IMVOs End-User Terms and Conditions.' Below this text is a checked checkbox labeled 'I Accept' and a link 'Download Terms & Conditions Here'. At the bottom of the form, there are two buttons: 'Previous' and 'Submit'. The 'Submit' button is circled in green, indicating it is the next action to be taken. The footer of the page reads 'Irish Medicines Verification Organisation' and 'End-User Registration'.

Step 7. Online registration completed



[Home](#)

[Home](#)

Home

Thank you for submitting your registration application. We will review the information you have provided and respond within 7 working days.

Irish Medicines Verification Organisation

End-User Registration

2. End-User Terms & Conditions

- ▶ Must accept IMVO T&Cs for End-Users during online registration
- ▶ These set out obligations of End-User and IMVO
- ▶ T&Cs available to download in online registration portal and on <https://www.imvo.ie/stakeholders1/register-imvo>
- ▶ No amendments possible to T&Cs
- ▶ 30 days' notice will be given of any changes to T&Cs - if you do not accept changes, must notify us in writing



3. IMVO Legitimacy Check

- ▶ IMVO obliged under Delegated Regulation to *“put in place security procedures ensuring that only users whose identity, role and legitimacy has been verified can access the repository ...”*
- ▶ Information required to carry out legitimacy check will be provided by you via online registration form
- ▶ We may contact you if any info. is unclear or cannot be verified, e.g. PSI number on form doesn't match number on PSI website



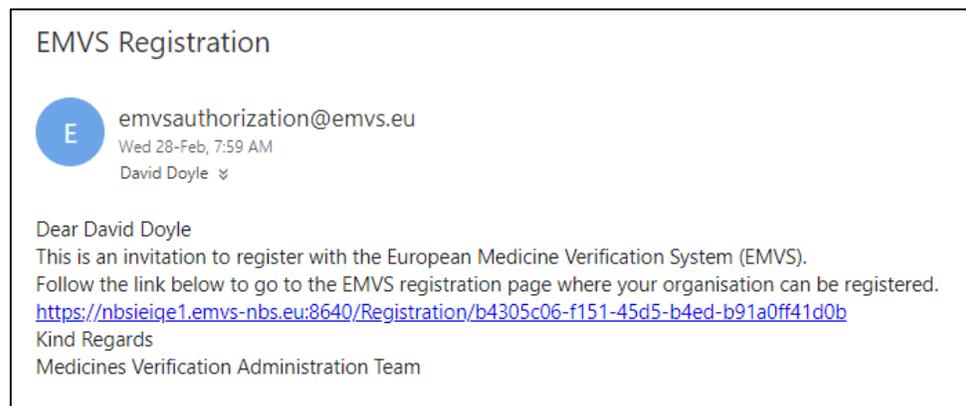
4. Technical registration / connection

- ▶ After you registered with IMVO, you have to complete technical connection of your system to national system
- ▶ After IMVO's legitimacy check is complete, your nominated 'Super User' will receive technical information by email to complete the connection
- ▶ Info. sent in 2 two separate emails because '2-factor authentication' is required for security purposes
- ▶ If not experienced with IT, recommend you contact your software provider for support with remaining steps after you have changed your password



4. Technical registration / connection (ctd)

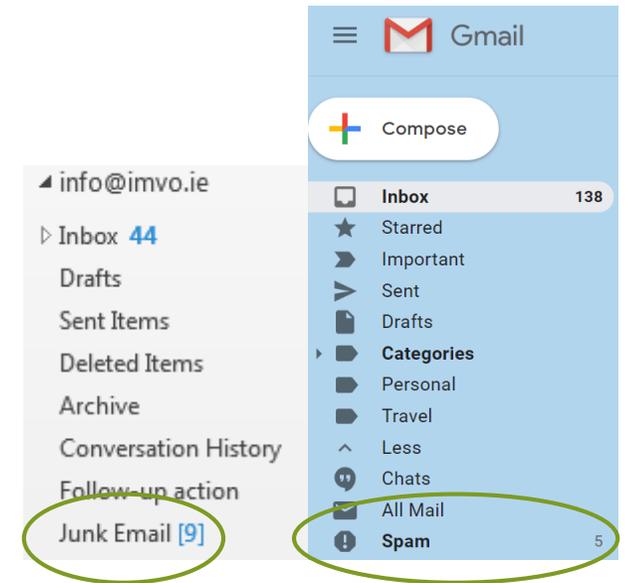
- Step 1:** Super User will receive a welcome email with registration code from IMVO (**registration@imvo.ie**)
- Step 2:** Super User will also receive a registration email from Solidsoft Reply (**emvsauthorization@emvs.eu**) inviting you to register with 'European Medicines Verification System (EMVS)'



4. Technical registration / connection (ctd)

Important pointers about welcome / registration emails:

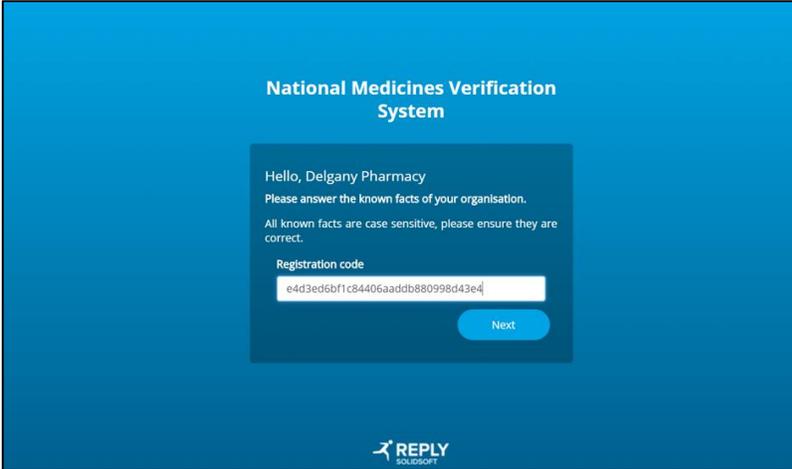
- ▶ If you can't find these emails in your Inbox:
 - ▶ Are you looking in the right Inbox? – we will send emails to your Super User's email address
 - ▶ Check your 'Junk' or 'Spam' email folders
 - ▶ Occasionally, email(s) may be blocked in firewall / by antiviral software
- ▶ Registration email is valid for **45 days**



4. Technical registration / connection (ctd)

Step 3: Click the link contained in email from **emvsauthorization@emvs.eu**.

Step 4: Input **Registration code** contained in Welcome email from IMVO into the link you have opened and click 'Next'. Please copy and paste the code directly into the white box and ensure you don't copy **blank spaces**.



The screenshot shows a web interface for the National Medicines Verification System. The page has a blue background. At the top, it says "National Medicines Verification System". Below that, there is a dark blue box containing the following text: "Hello, Delgany Pharmacy", "Please answer the known facts of your organisation.", and "All known facts are case sensitive, please ensure they are correct." There is a white input field labeled "Registration code" containing the alphanumeric string "e4d3ed6bf1c84406aadb880998d43e4". To the right of the input field is a blue button labeled "Next". At the bottom of the page, there is a logo for "REPLY" with "SOLUTIONS" written below it.

4. Technical registration / connection (ctd)

Step 5: A further email will be sent from emvsauthorisation@emvs.eu that will contain details of your username (this will be your email address), temporary password and another link to complete the registration process

EMVS Administration User Account

 emvsauthorization@emvs.eu
Wed 28-Feb, 8:03 AM
David Doyle

Dear user,

Your Medicines Verification Administration Portal account has been created with:
username: david.doyle@imvo.ie
password: wg%q\$0TC

To complete your registration, follow the link below:
<https://nbsieige1.emvs-nbs.eu:8640/users/ConfirmAccount?id=38e50150-bbc0-4429-8ad4-c4607b5f7ccb&token=Q2ZESjhQd20rcWVYcC9CSWtsRi9HUHp5K0JTQ1pjQXVidU1IS3c1VXcxNkZldUFYWXRkaW43aXJOSVhiMUU1dGVzTTZrTVA0V0lwajNLMUkraWJHWHXk1bmdMeHkzV0tLUktwYW40aUJXY2hLYiV1VGtlbWpHc3d2c0h3cVh0YmF3QjJkckl5TGxxbitmL2R0Wlh3a3VPU3YwK3RieVZKdkFtWINURGJ4c2ZjSXV6MWU0My93Uy9KMFIkQeTJYRUNKNW1zTUJFRUdjamlwnNm9gTVlrZES0JtyyZ3ZmZ1UxOk9jZlZ5OUZYNTJwZUlvdHNWOWFzRExWSmZZRTZPdG02Z2dFdz09>

You will be asked to change your password in order to activate your account. Please note that your password must be at least 8 characters long with at least one of each of the following types of character:

- Uppercase characters
- Lowercase characters
- Digits
- Non alphanumeric characters (!\$%&=+@#)

(Registration invitation will expire in 7 days)

Kind Regards
Medicines Verification Administration Team

4. Technical registration / connection (ctd)

Step 6: Click on the link, enter your username (email address), temporary password provided and also, a new password which must:

- ▶ Be at least 8 characters long
- ▶ Contain at least one of the each of following types of characters:
 - ▶ Uppercase (capital letter)
 - ▶ Lowercase
 - ▶ Digit (number)
 - ▶ One of the following alpha-numeric characters: ! \$ % & = + @ # . - _

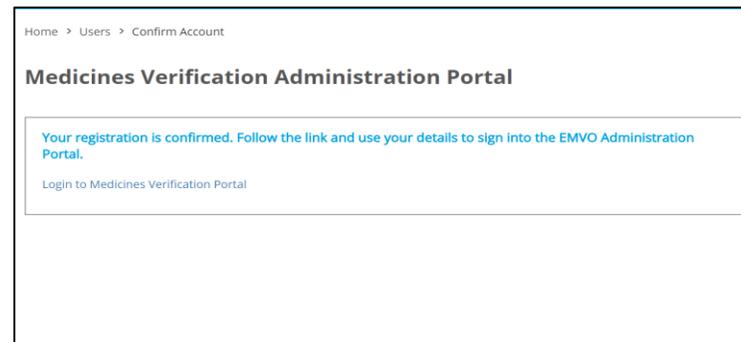


Note down your user name and new password

4. Technical registration / connection (ctd)

Step 7: Your (End-User) organisation's account is now registered and you should click the link provided to login using your username (email) and the new password you just created

The NMVS link is <https://nbsieprod.emvs-nbs.eu:8640/>



Common errors seen so far (1/2)

- ▶ No location details provided
- ▶ No IT software provider details entered
- ▶ IT software provider listed is pharmacy system provider, not FMD system provider (which may be different)
- ▶ No contact details entered for Authorised Representative
- ▶ Location name not stated correctly, e.g. 'Cork' is not a location name!
- ▶ Same Super User email address used for more than one End-User – consider if locations concerned could be registered under same End-User



NB - Errors may lead to applications being rejected & you will have to start again in that case

Common errors seen so far (2/2)

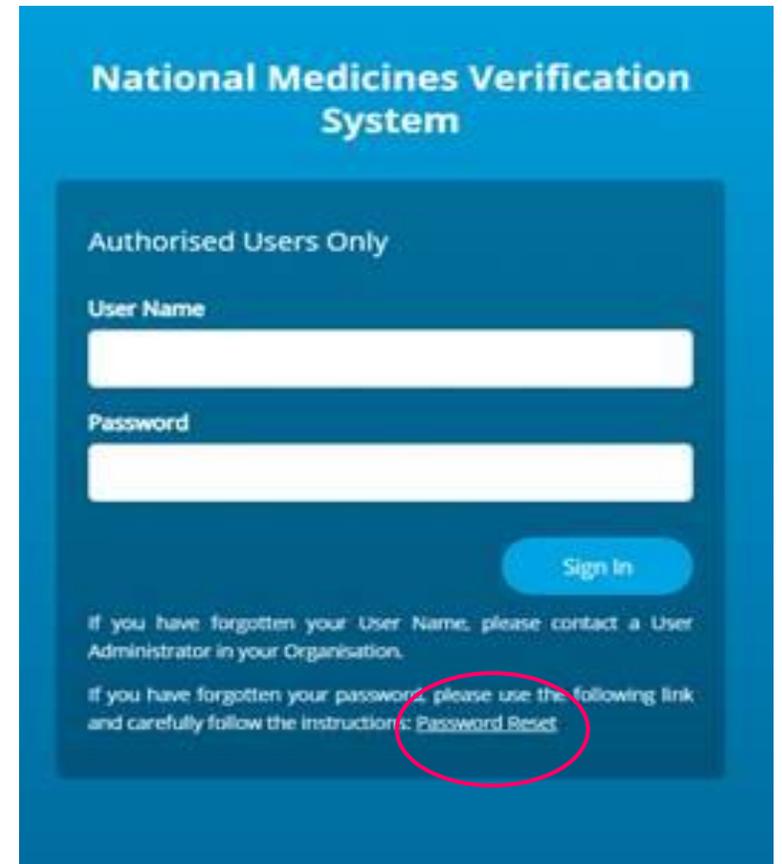
► Common errors when completing organisation registration

Error message	Action
'password mismatch'	Log into the National Medicines Verification System Portal - https://nbsieprod.emvs-nbs.eu:8640/ - and repeat the change password step again and make sure that your password conforms to all the specified requirements
'link has expired' The registration link sent to you is valid for 45 days. If you try to use it after that, it will not work.	You need to contact us by phone or email to have a new registration link issued to you
'email address already registered by another user'	You need to contact us by phone or email to have your account reset to fix the password problem.
'user account not confirmed'	Contact us to have your account re-set.
'unable to find user'	Contact us to have your account re-set.

NMVS account login/password reset link

- ▶ If you need to login or change your password go to the following link:

<https://nbsieprod.emvs-nbs.eu:8640/>



The screenshot shows the login interface for the National Medicines Verification System. It features a blue header with the system name, a dark blue login box with 'User Name' and 'Password' fields, a 'Sign In' button, and instructions for forgotten credentials. A red circle highlights the 'Password Reset' link in the instructions.

National Medicines Verification System

Authorised Users Only

User Name

Password

[Sign In](#)

If you have forgotten your User Name, please contact a User Administrator in your Organisation.

If you have forgotten your password, please use the following link and carefully follow the instructions: [Password Reset](#)

Scheduling your IT software provider appointment

- ▶ If you need support from your IT software provider to complete technical connection, schedule appointment with them:
 - ▶ As soon as you are ready - don't delay!
 - ▶ For a time when you / they will be able to have full, uninterrupted access to computer / device which is to connected to national system
- ▶ Have following to hand when IT software provider is getting you connected:
 - ▶ Your username and new password
 - ▶ List of locations registered with IMVO – locations that are connected to national system **must** match this list

IMVO Registration Webinar



Who to contact for support?

- ▶ Check '**Support Guide**' on [Pharmacies & Hospitals](#) page of IMVO website first
- ▶ Key contacts:
 - ▶ *IMVO registration* – registration@imvo.ie or 01-5715320
 - ▶ *FMD system queries* – your IT software provider
 - ▶ *Problems with scanner/computer* – equipment provider
 - ▶ *Process queries in community pharmacies* – IPU
 - ▶ *Implementation in HSE* – FMD.support@hse.ie



IMVO Registration Webinar

IMVO Pilot



Overview of pilot

- ▶ Pilot ran from May 2018 until now
- ▶ Aim of pilot - to ensure that national system functions correctly with pharmacy, hospital & wholesalers' FMD systems and associated IMVO procedures work efficiently
- ▶ 30 pharmacies, 2 hospitals, 4 wholesalers, 6 manufacturers and 6 IT software providers involved
- ▶ System used in pilot is fully functioning system with live data – 'pilot' was actually a controlled ramp-up
- ▶ Pilot participants also tested their own procedures
- ▶ IPU supported pilot in community pharmacy



Pilot feedback

- ▶ Scanning is quick
- ▶ Simple & clean interface on pharmacy screens
- ▶ Technical onboarding / connection is complicated
- ▶ Some technical issues with wireless bluetooth scanners
- ▶ Bugs in system were identified & resolved
- ▶ **Lack of serialised packs in supply chain**



For more information ...

- ▶ **Pharmacies & hospitals section of IMVO website**
- ▶ **Email/letter sent to you by IMVO** about registration
- ▶ **PSI Practice Update on FMD**
- ▶ **IPU Medicines Authentication FAQ & Checklist** – available on Pharmacies & hospitals section of IMVO website
- ▶ **European Commission Q&A on Safety Features** – available on FAQ section of IMVO website
- ▶ **Other useful websites:**
 - ▶ **UK FMD Working Group for Community Pharmacy:** <http://www.fmdsource.co.uk/>
 - ▶ **European Medicines Verification Organisation (EMVO):** <https://www.emvo-medicines.eu/>
 - ▶ **HPRA:** <http://www.hpra.ie/homepage/medicines/special-topics/falsified-medicines-legislation>



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