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 CÓGAISÍOCHTA NA hÉIREANN
IRISH INSTITUTE OF PHARMACY

IMVO Registration Webinar

Introduction to EMVS / IMVO

IRISH
MEDICINES
VERIFICATION
ORGANISATION

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

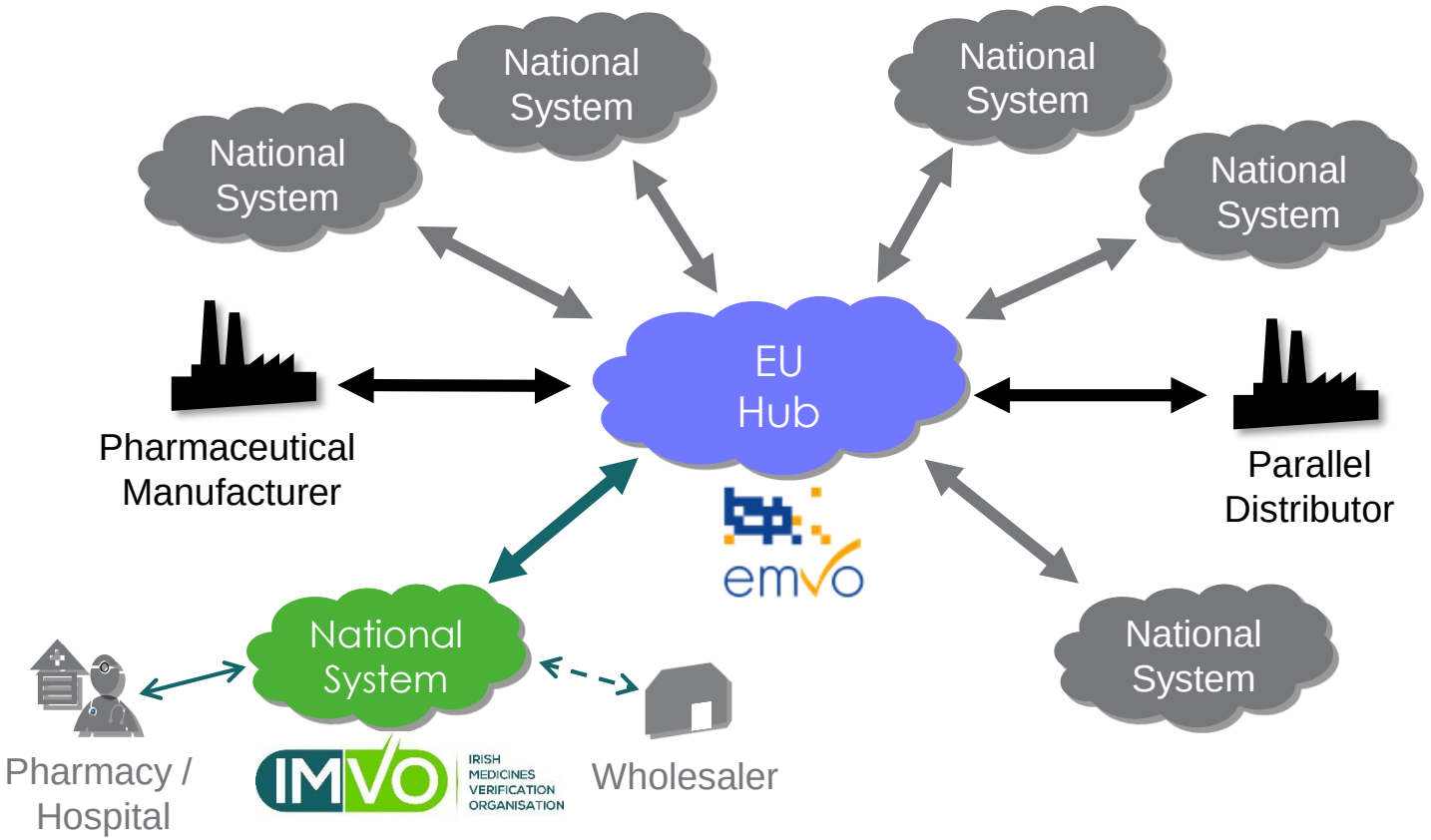
NDC: 59148 011 13
SN: 100000000001
EXP: AUG 22 2015
Lot: AB100613

Anti-tampering device

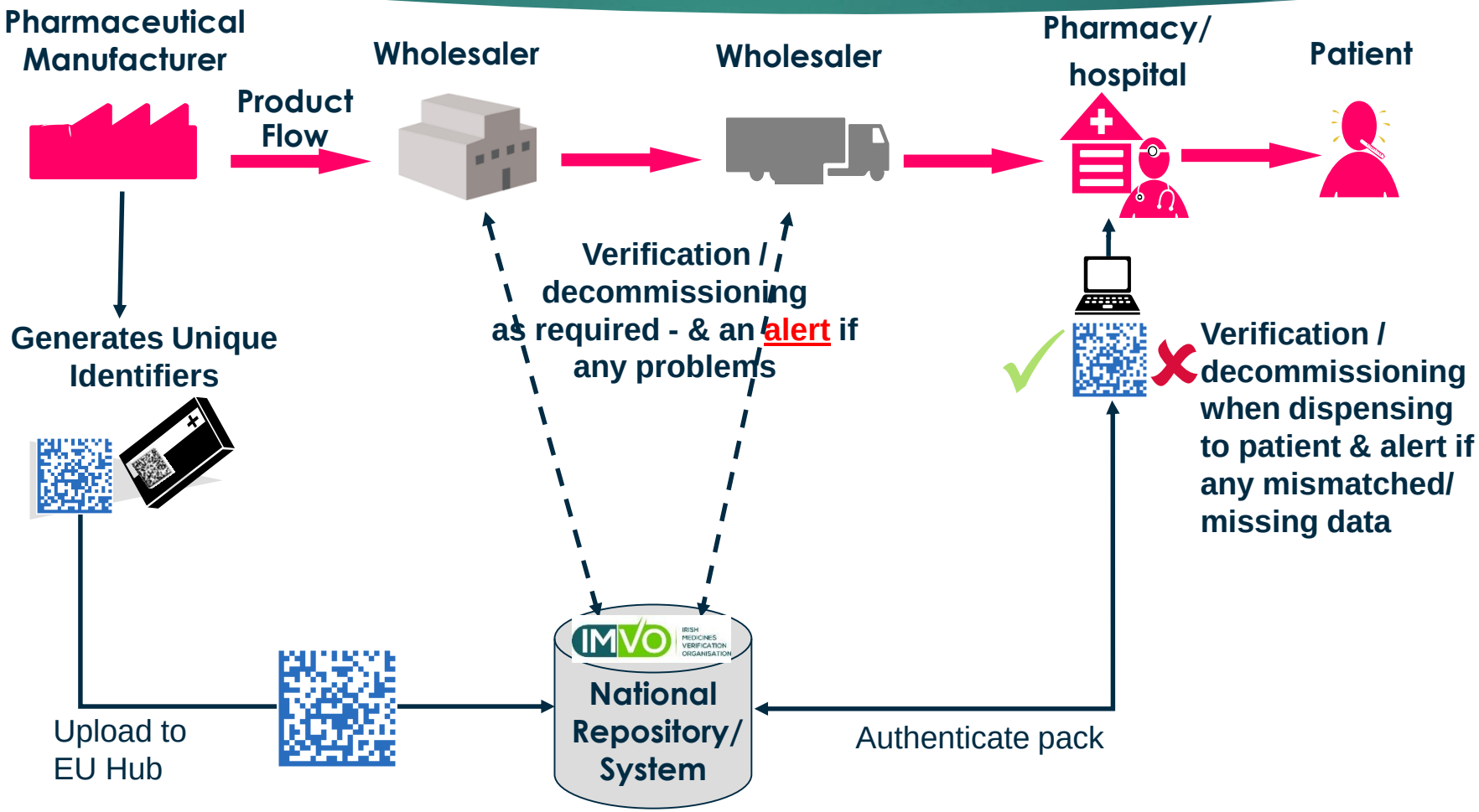
Safety features

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

AIPPD

ipha IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

IMVO IRISH MEDICINES VERIFICATION ORGANISATION

IRISH PHARMACY UNION The voice of community pharmacy

medicines for ireland

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

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How to register with IMVO

Key Terms

IT software provider

- Provider of IT system that you will use for scanning barcodes - 'FMD system'
- Contract must be in place with this IT software provider
- See IMVO website for list of FMD systems that have certified to connect to national system - http://www.imvo.ie/stakeholders1/it-software-providers

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

Key Terms (ctd)

Authorised Representative

- Person who completes the online registration form
- Final step in online registration is to accept 'IMVO T&Cs for End-Users' which are legally binding – so person completing form must have authority to accept T&Cs on behalf of organisation
- Authorised representative also assigns the 'Super User' role for the organisation
  - May nominate themselves or assign role to someone else in the organisation

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

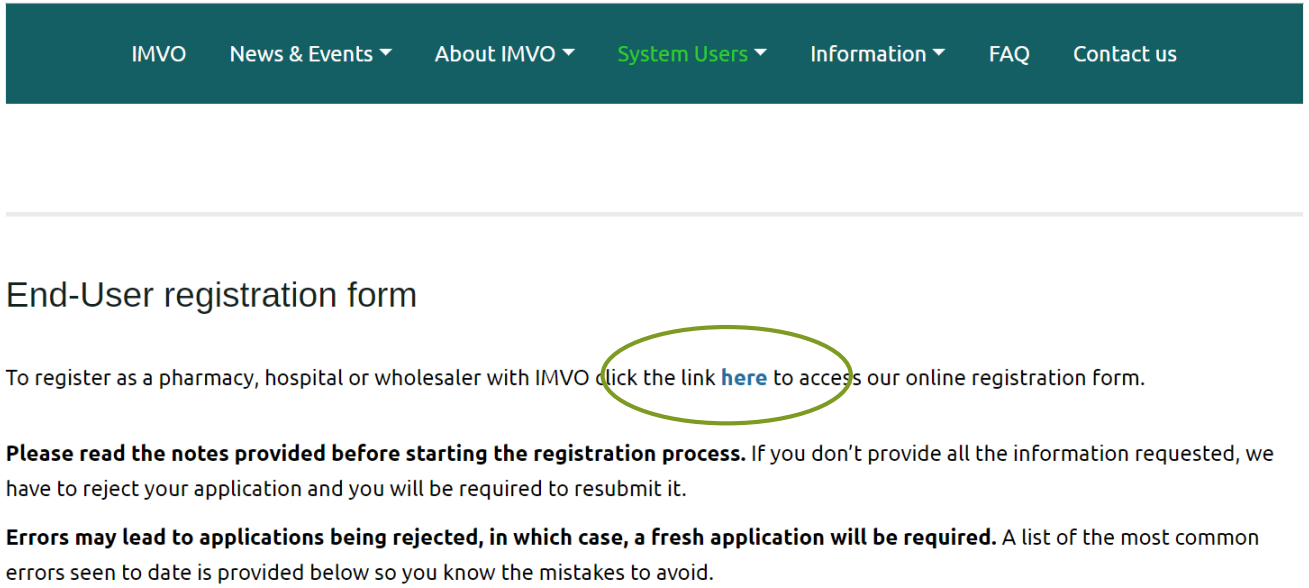
Walk-through of online registration form

Accessing IMVO online registration

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

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

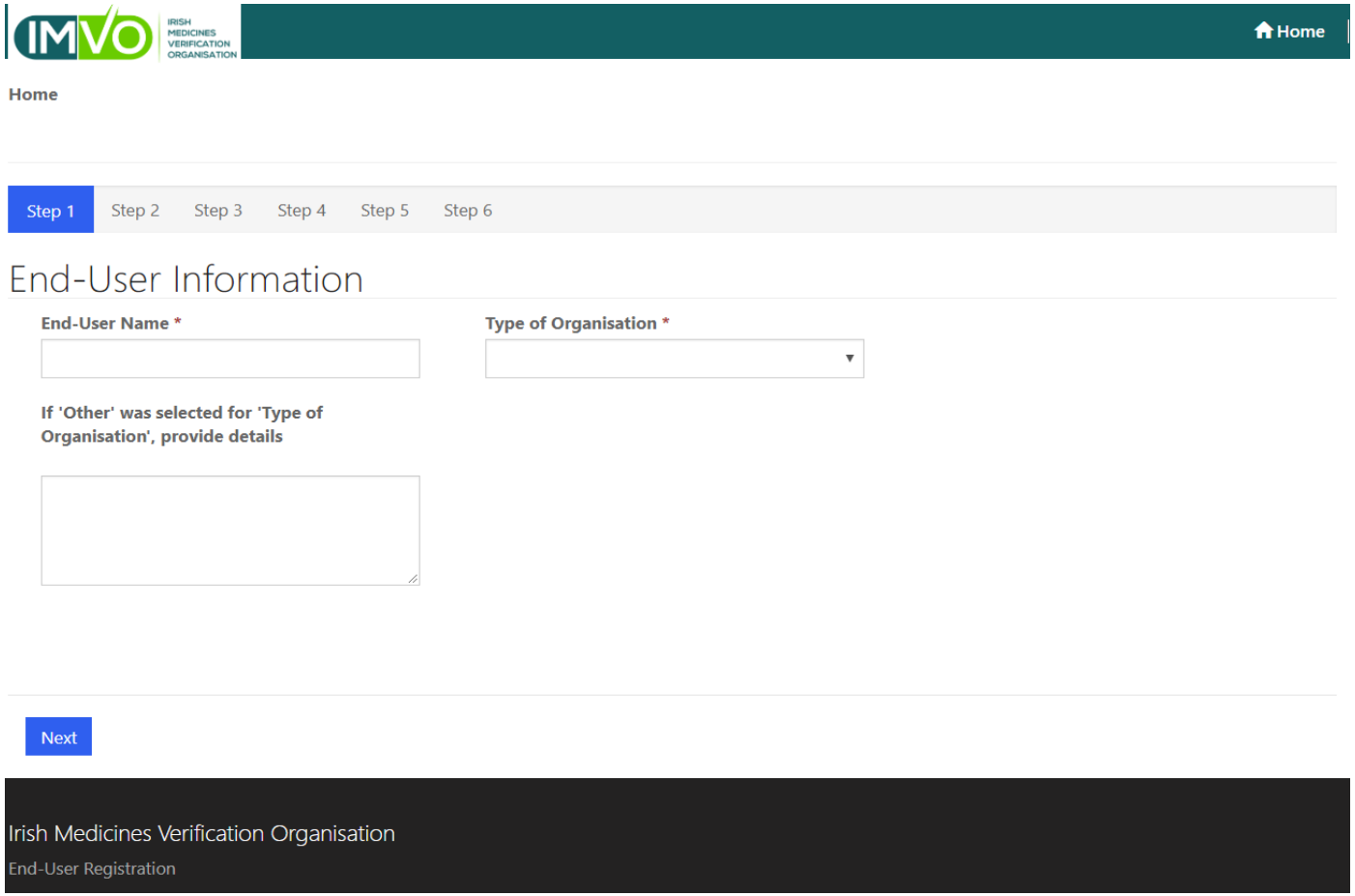
- Click on the word '**here**' that is bold highlighted in blue



Step 1. End-user information

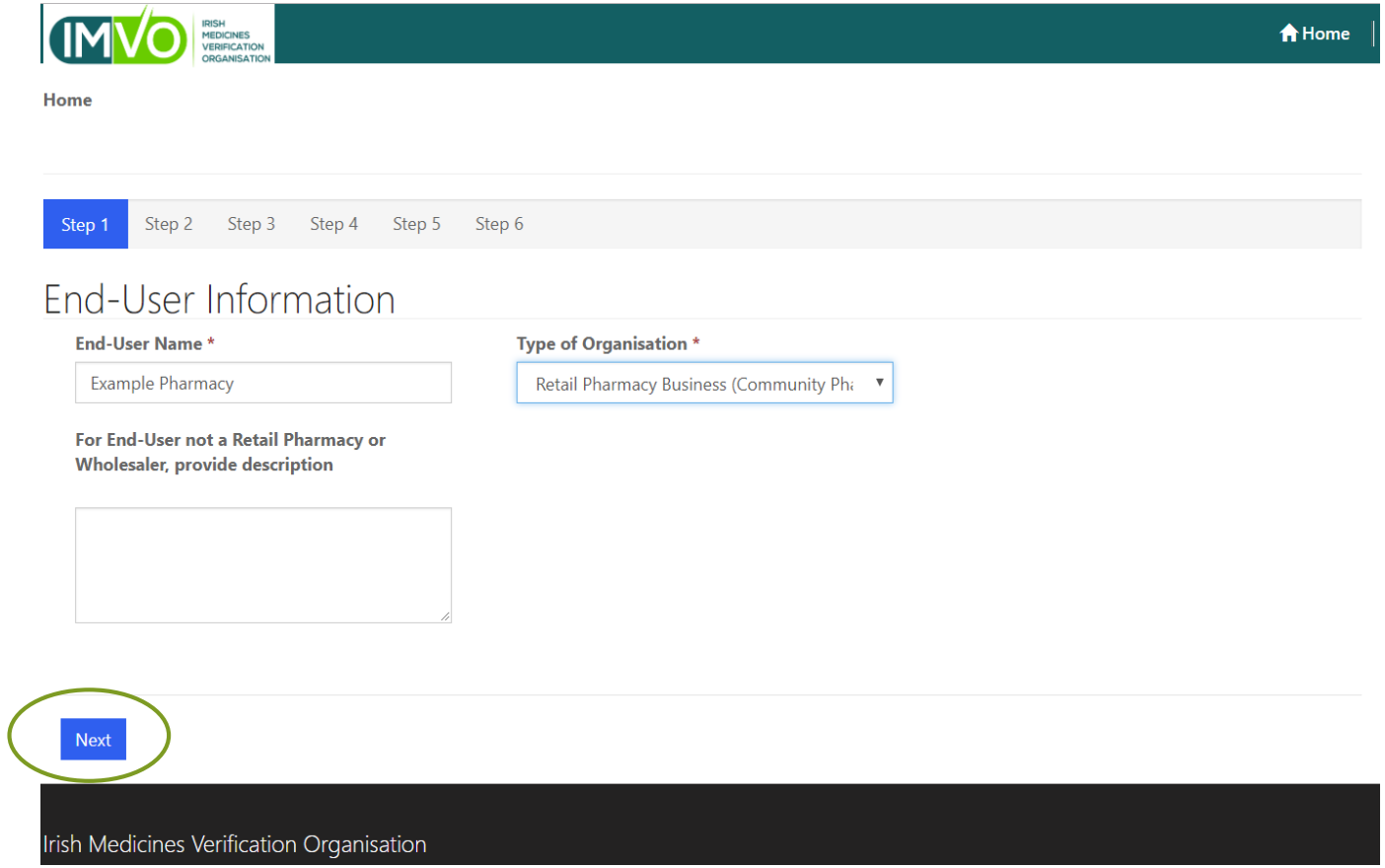
- Enter name of the organisation that you wish to register as an End-User with IMVO
- Select your organisation type from the drop-down box
- If you have selected ‘Other’ please enter any relevant additional information in box provided. e.g. “clinic”, “hospital not registered as retail pharmacy”, etc.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

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



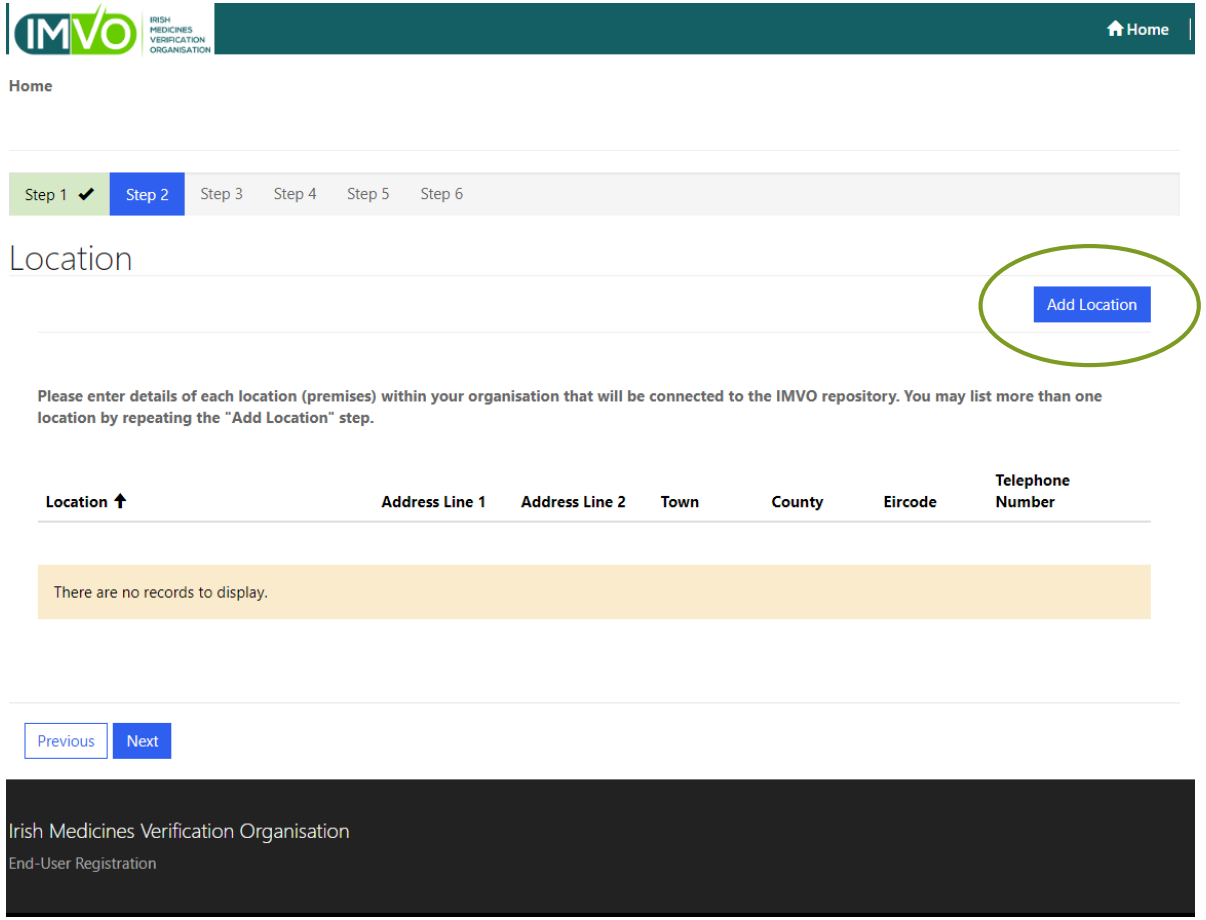
Step 1. End-user information completed

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



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’

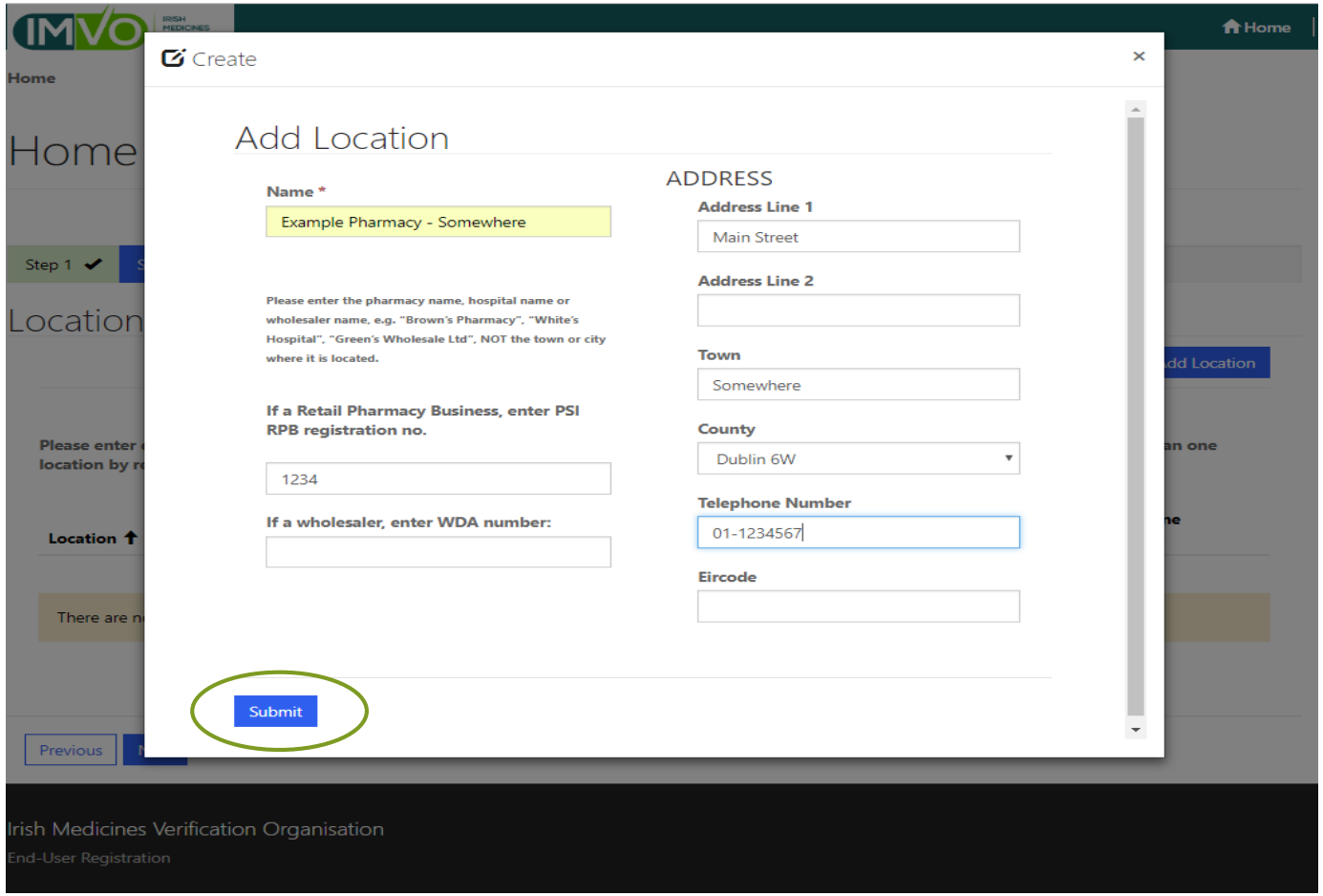


Step 2a. Add location details

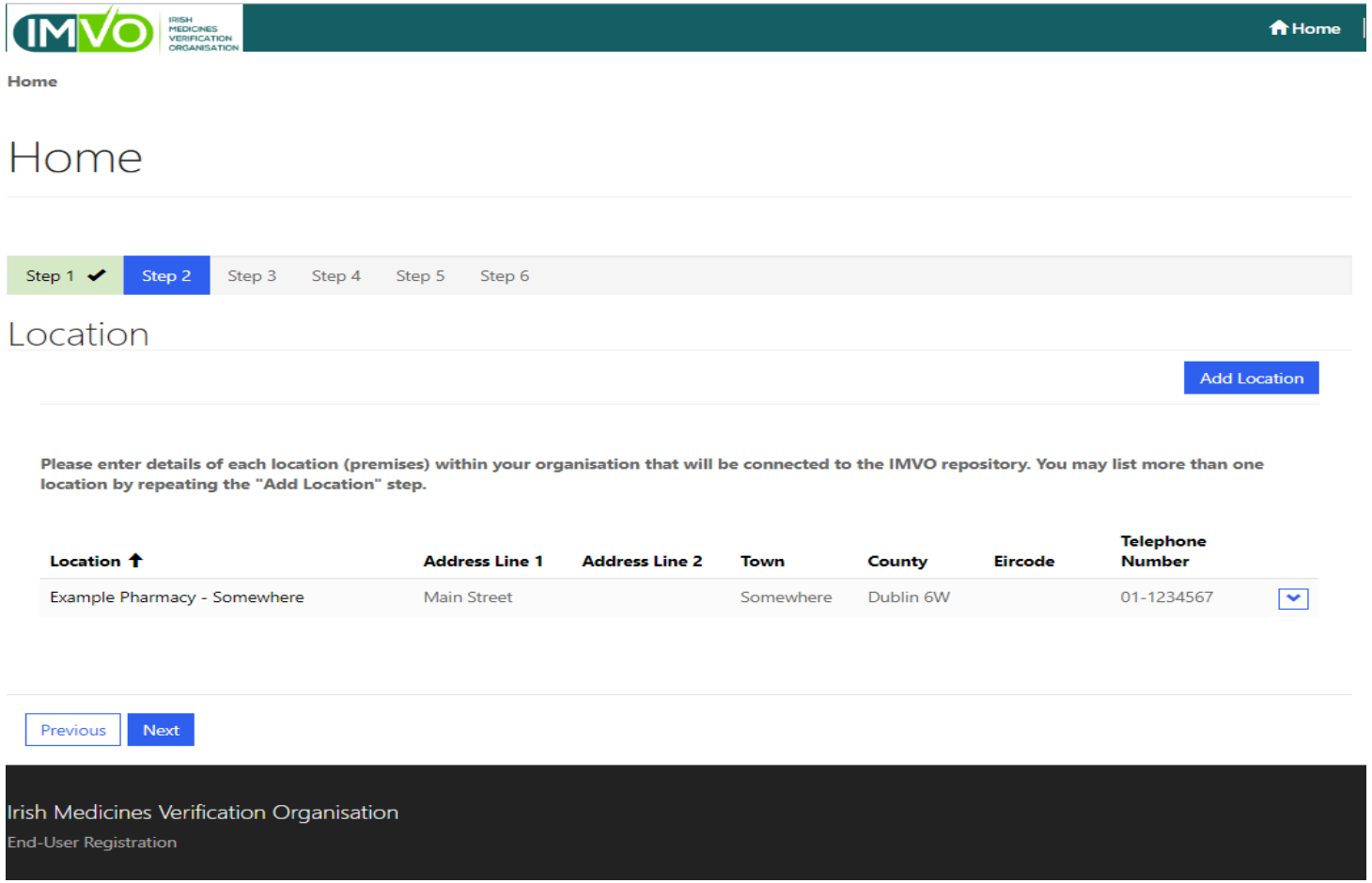
In the pop-up box:

- 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.



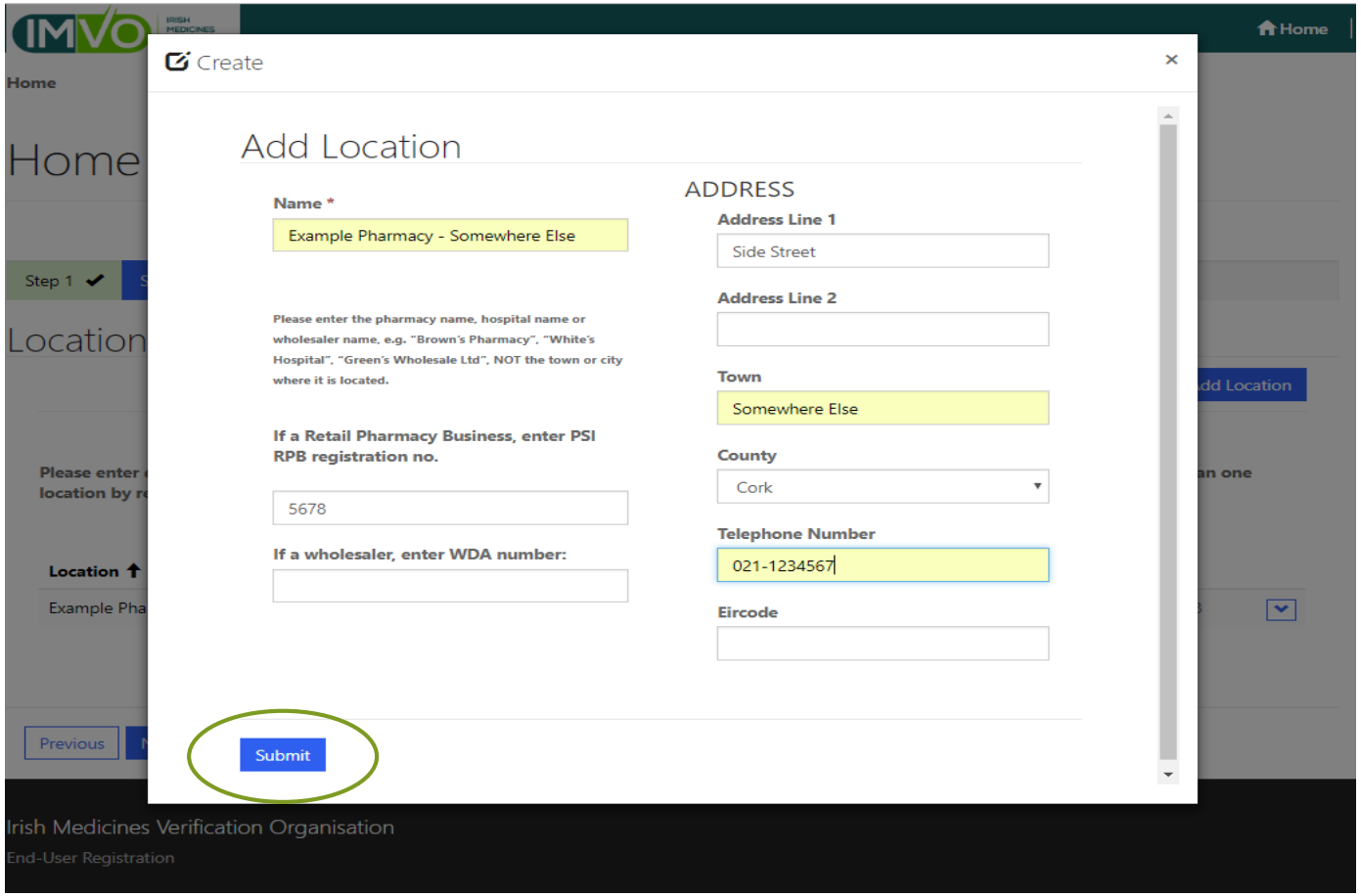
Step 2b. Add location information completed



Step 2c. Add additional location(s)

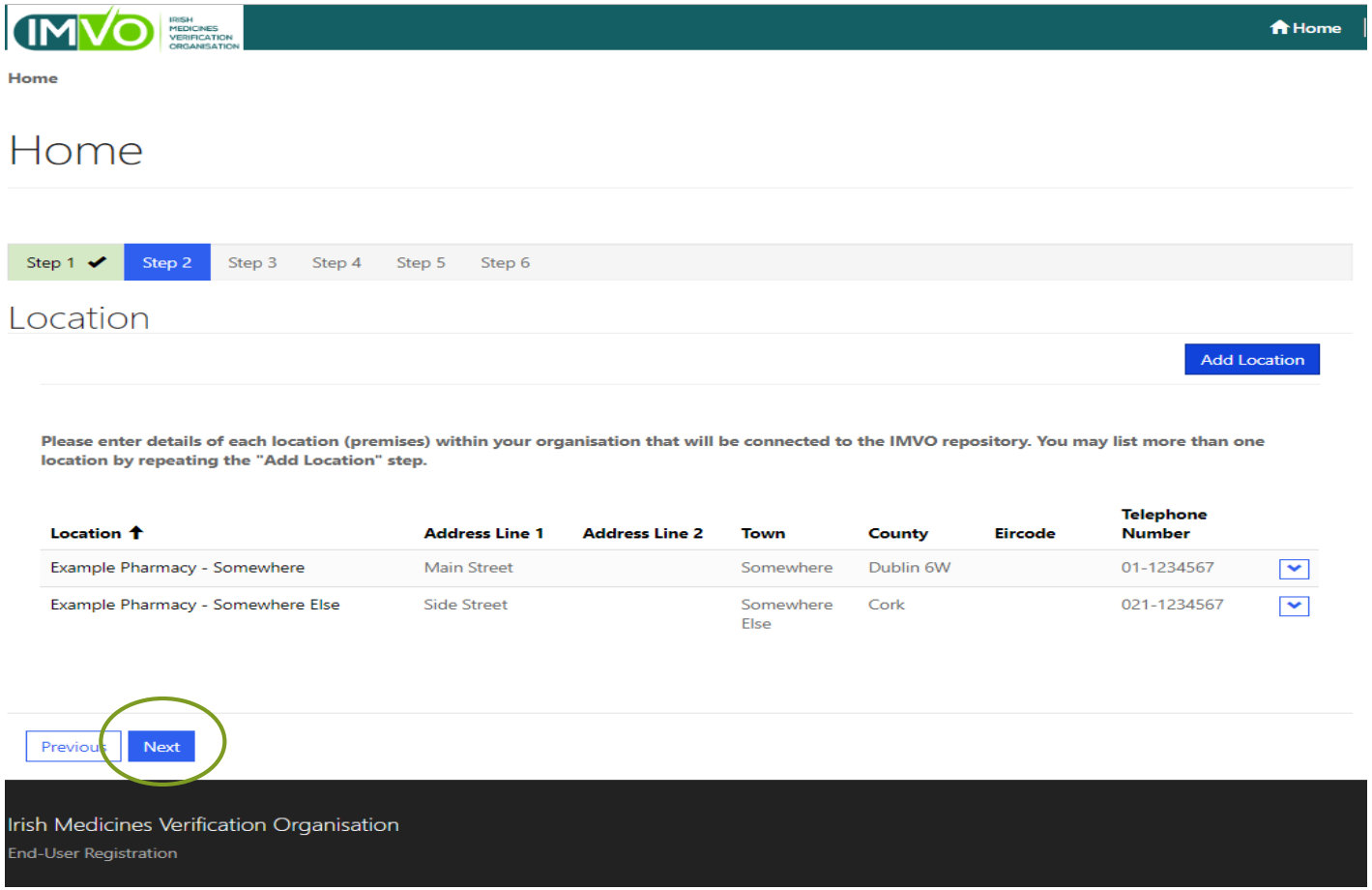
If you have additional locations to register:

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



Step 2d. Add additional location(s) completed

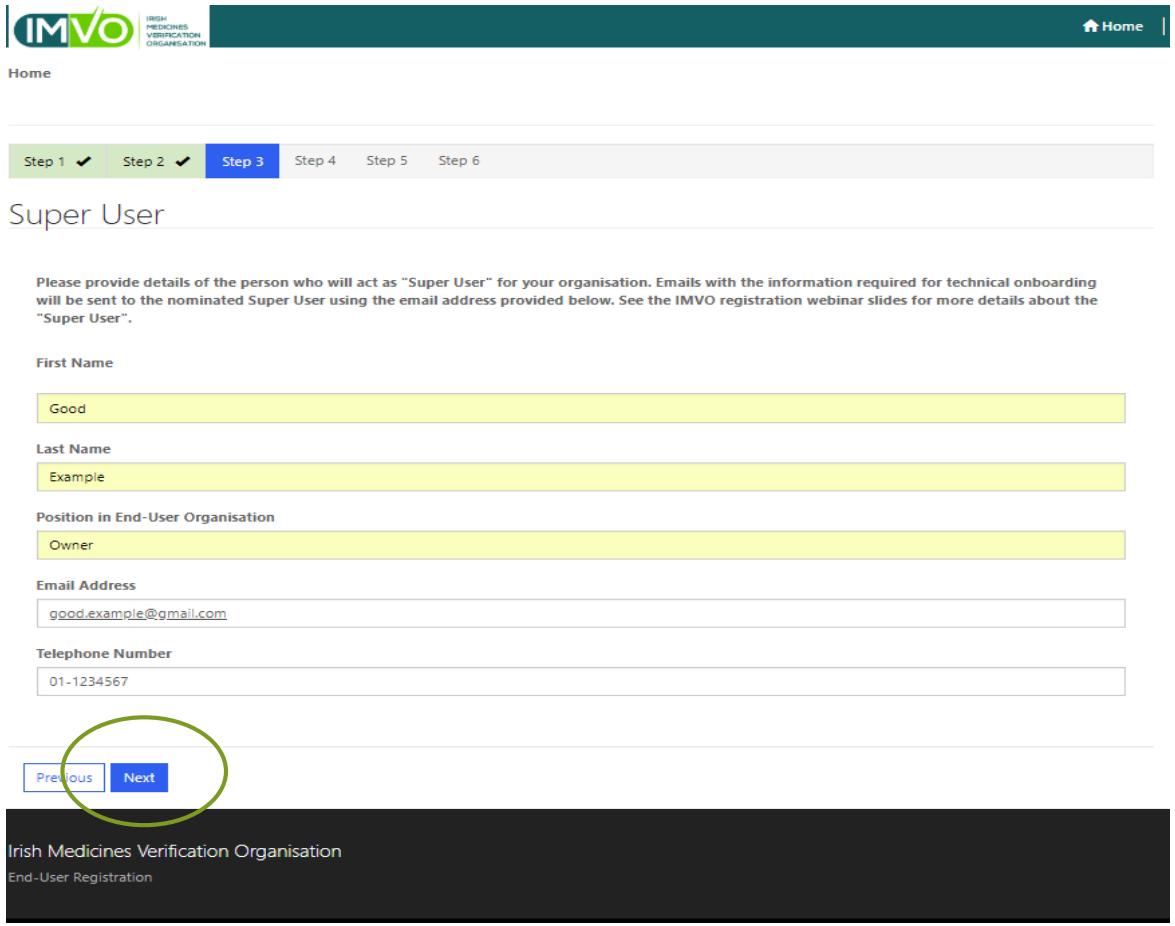
- Once you have added all the locations, you wish to register, click on ‘Next’ to move to Step 3



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

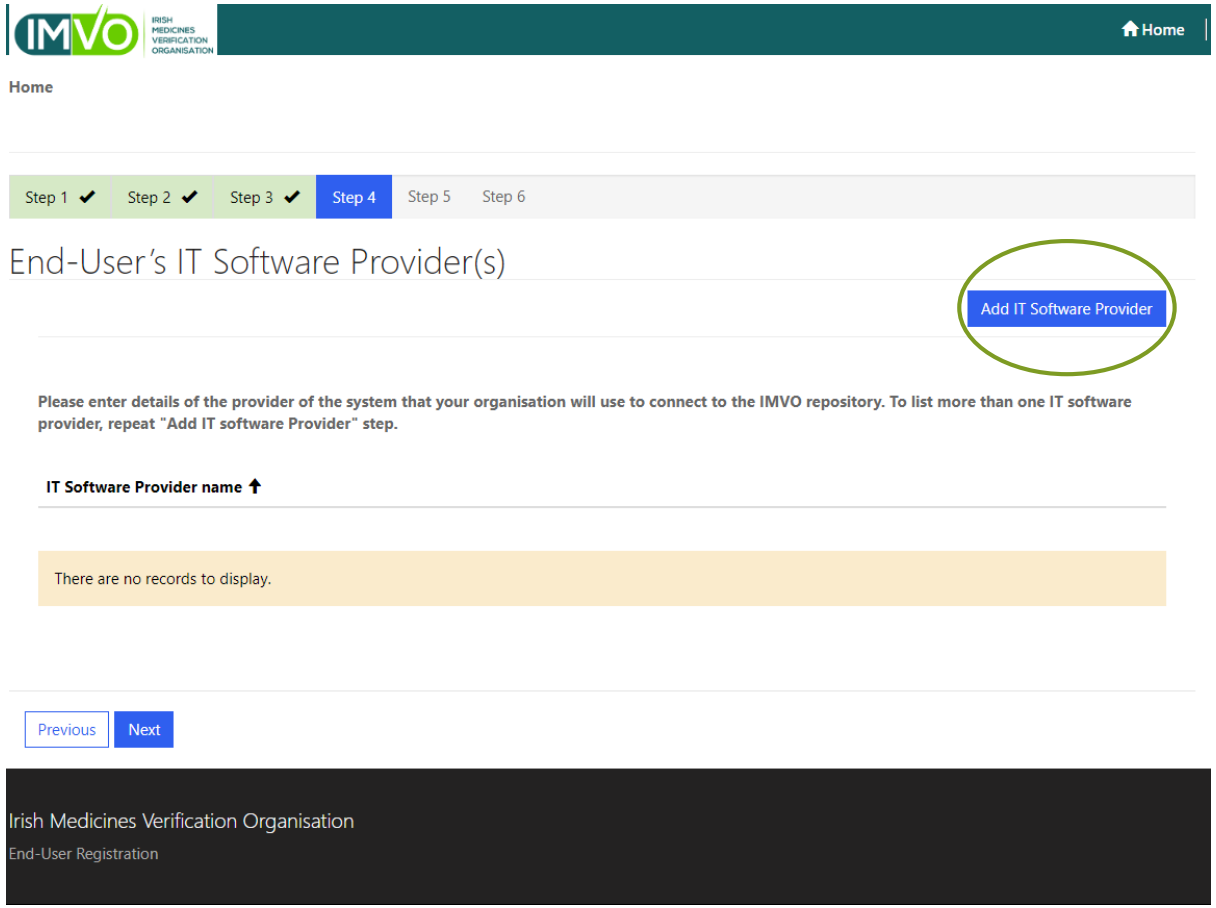
*__NB__ 'Healthmail' email addresses cannot be used for IMVO registration



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

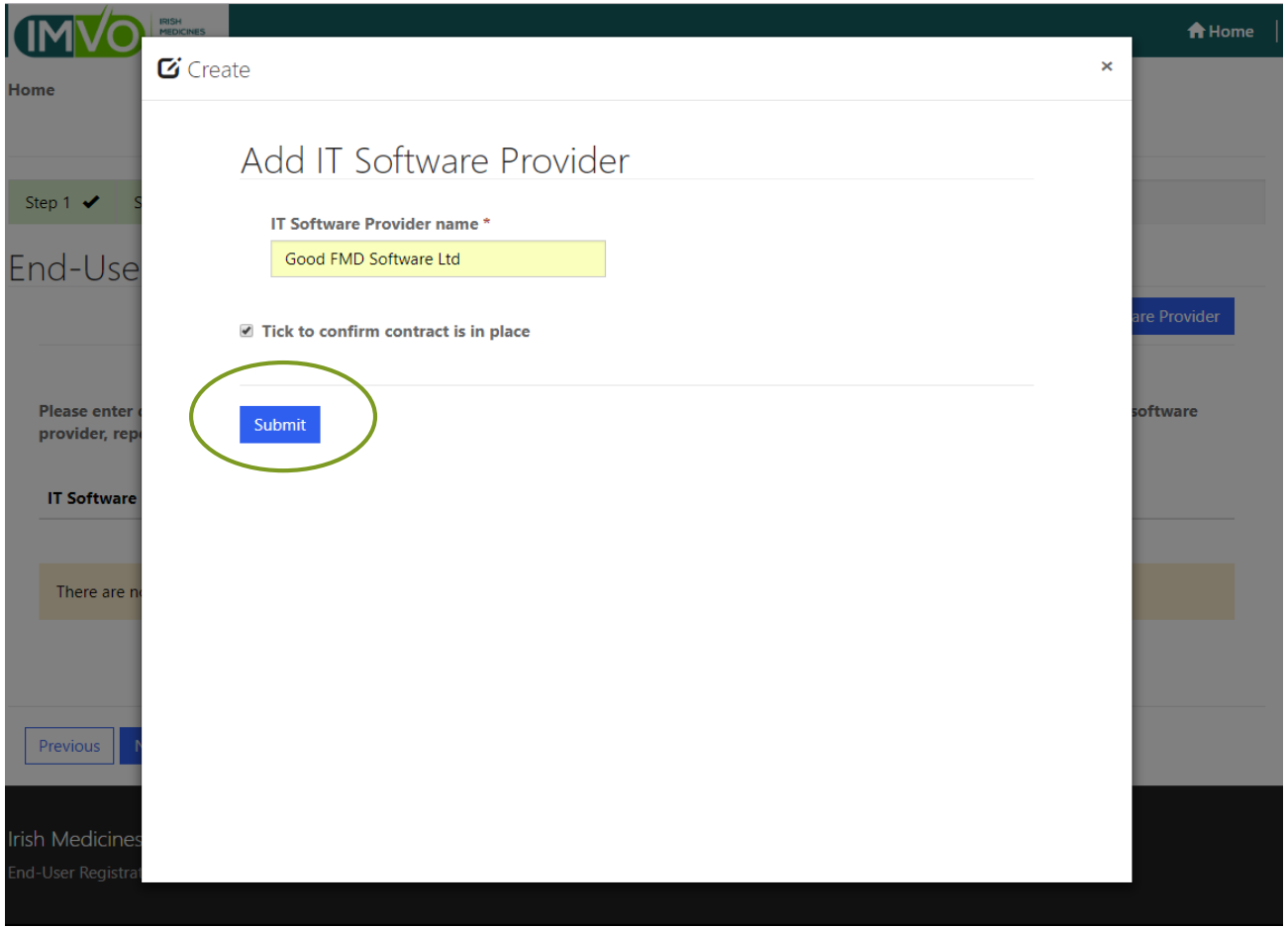
* **NB** - provider of your FMD system



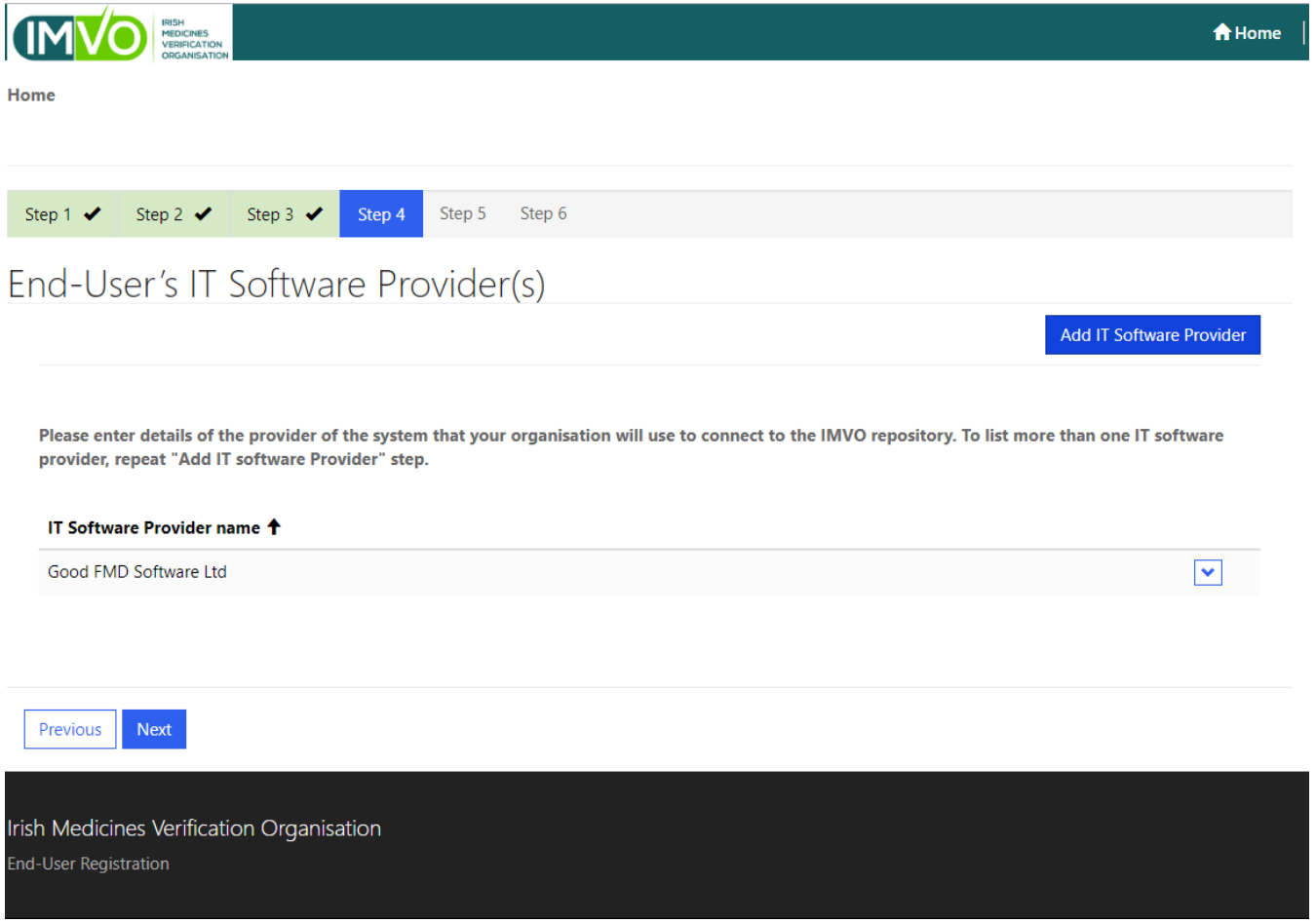
Step 4a. End-User IT software provider information

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’



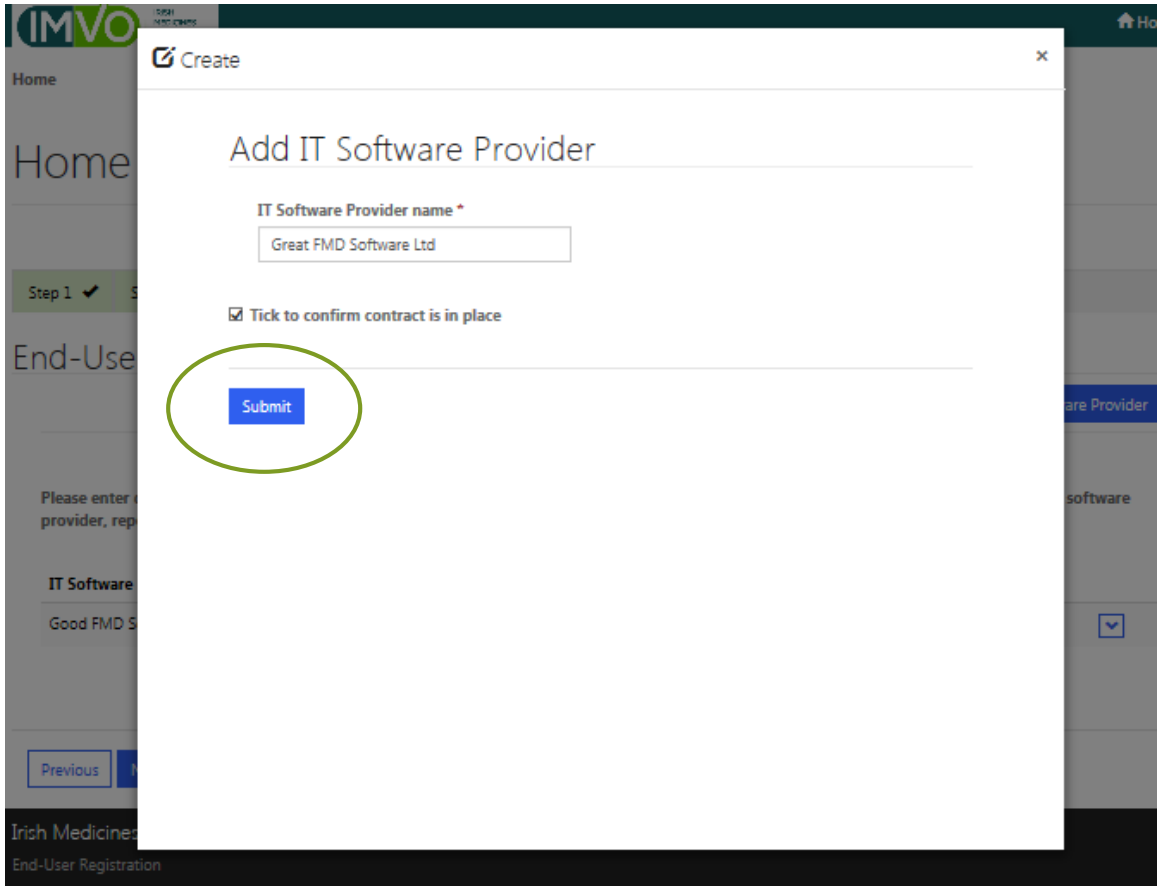
Step 4b. End-User IT software provider information completed



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

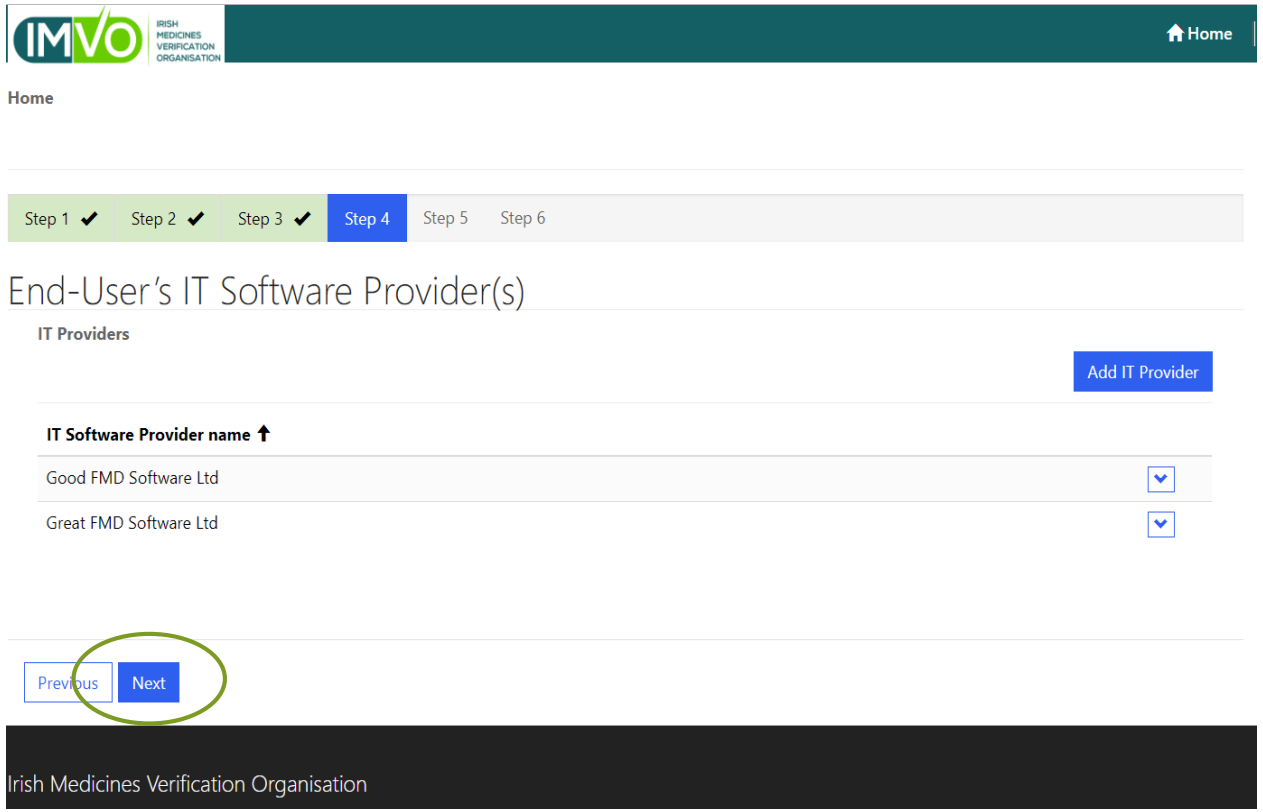
If you are using more than one IT software provider:

- 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



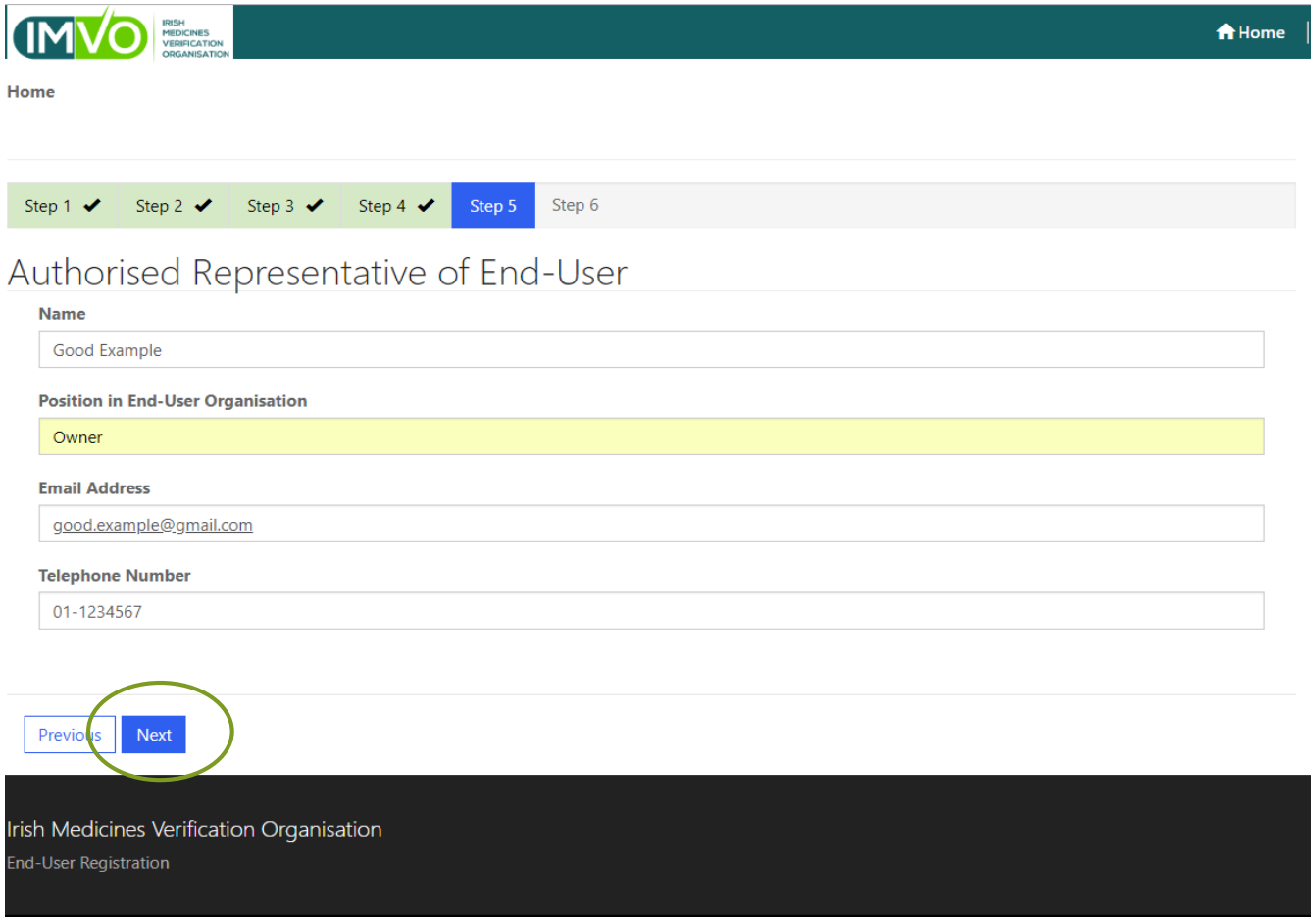
Step 4d. Add additional End-User IT software provider completed

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



Step 5. Authorised Representative information

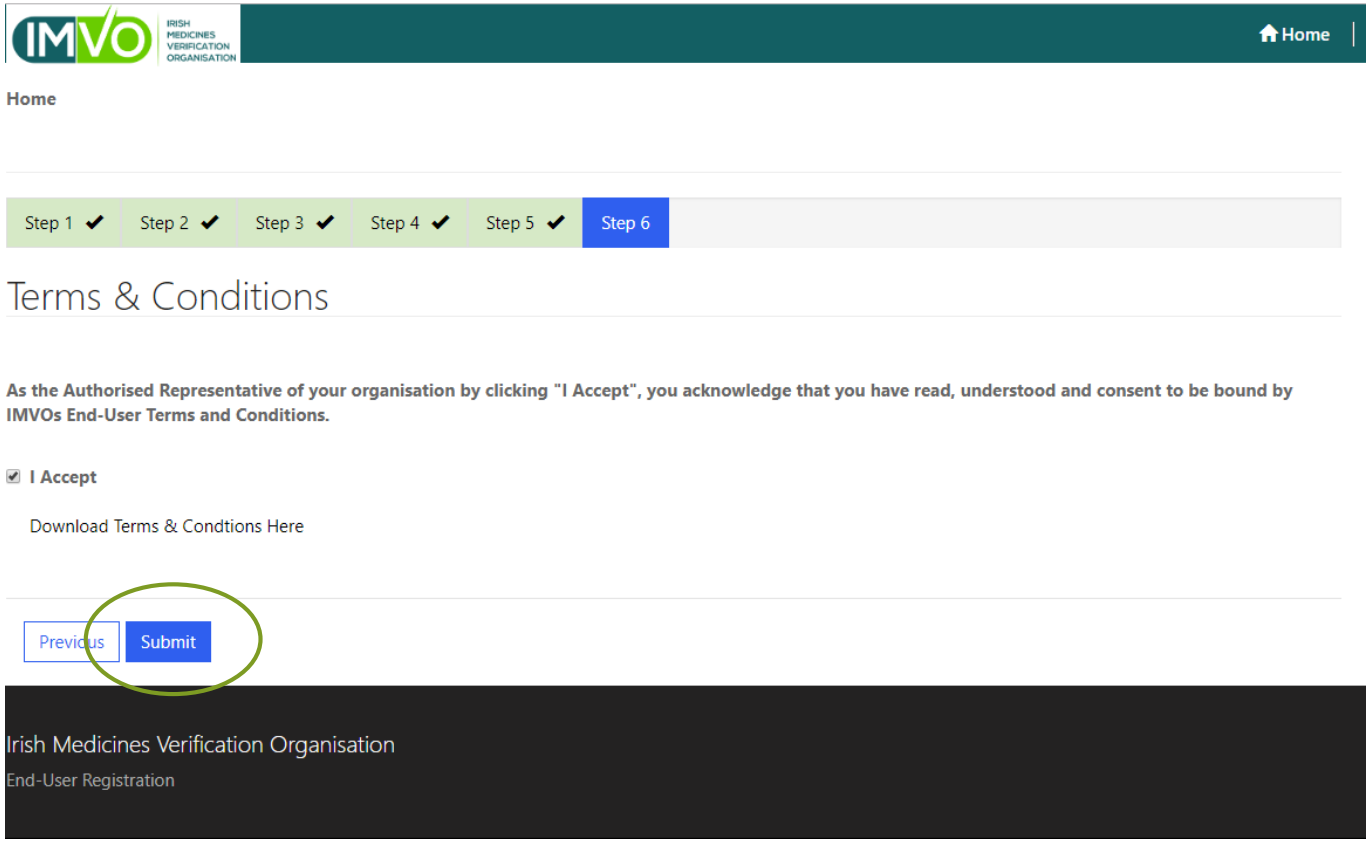
- Enter details of Authorised Representative:
  - Name
  - Position in organisation
  - Email address
  - Telephone number
- Click on ‘Next’ to move to Step 6



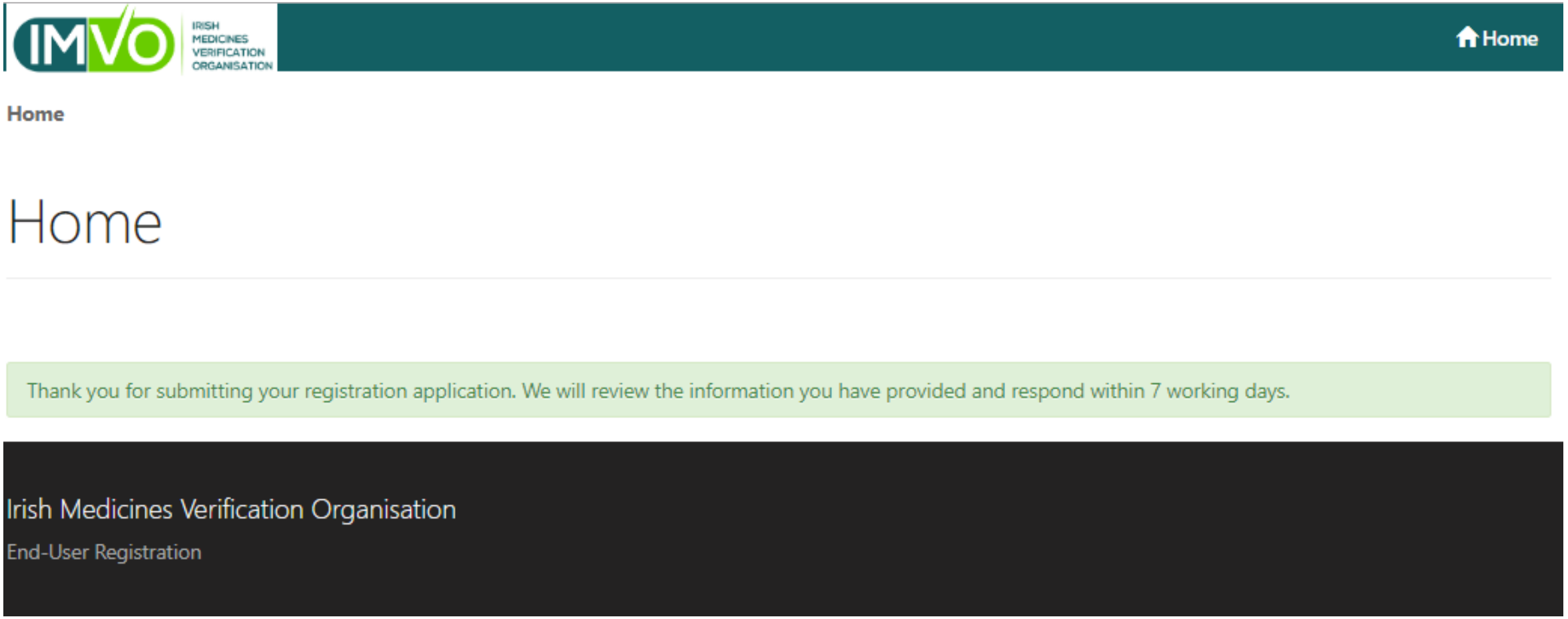
Step 6. Acceptance of Terms & Conditions

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



Step 7. Online registration completed



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 receives 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)'

EMVS Registration

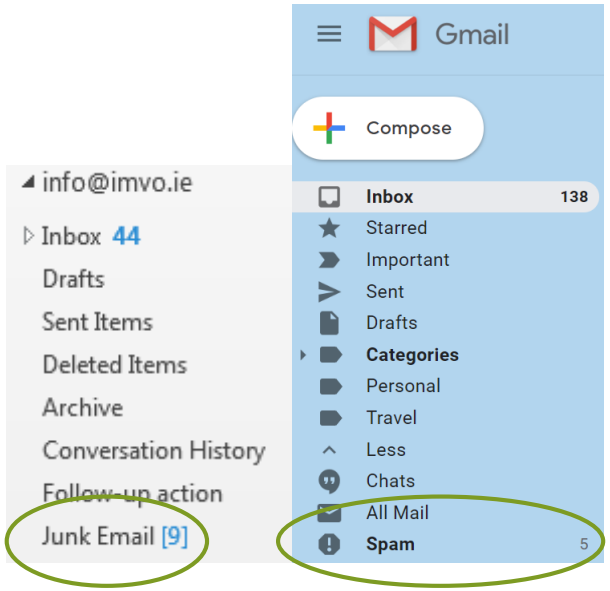
E emvsauthorization@emvs.eu
Wed 28-Feb, 7:59 AM
David Doyle

Dear David Doyle
This is an invitation to register with the European Medicine Verification System (EMVS).
Follow the link below to go to the EMVS registration page where your organisation can be registered.
https://nbsieiqe1.emvs-nbs.eu:8640/Registration/b4305c06-f151-45d5-b4ed-b91a0ff41d0b
Kind Regards
Medicines Verification Administration Team

4. Technical registration / connection (ctd)

Important pointers about welcome / registration emails:

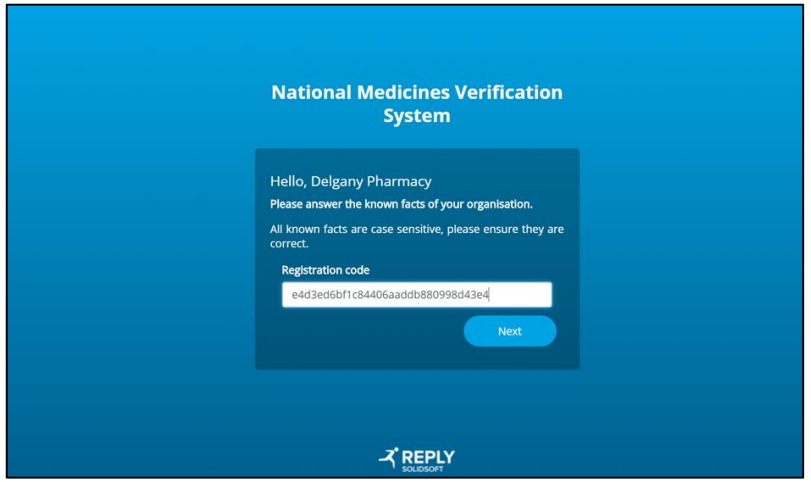
- If you can't find these emails in your Inbox:
  - Are you looking in the right Inbox? – we will send emails to your Super User's email address
  - Check your 'Junk' or 'Spam' email folders
  - Occasionally, email(s) may be blocked in firewall / by antiviral software
- Registration email is valid for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



4. Technical registration / connection (ctd)

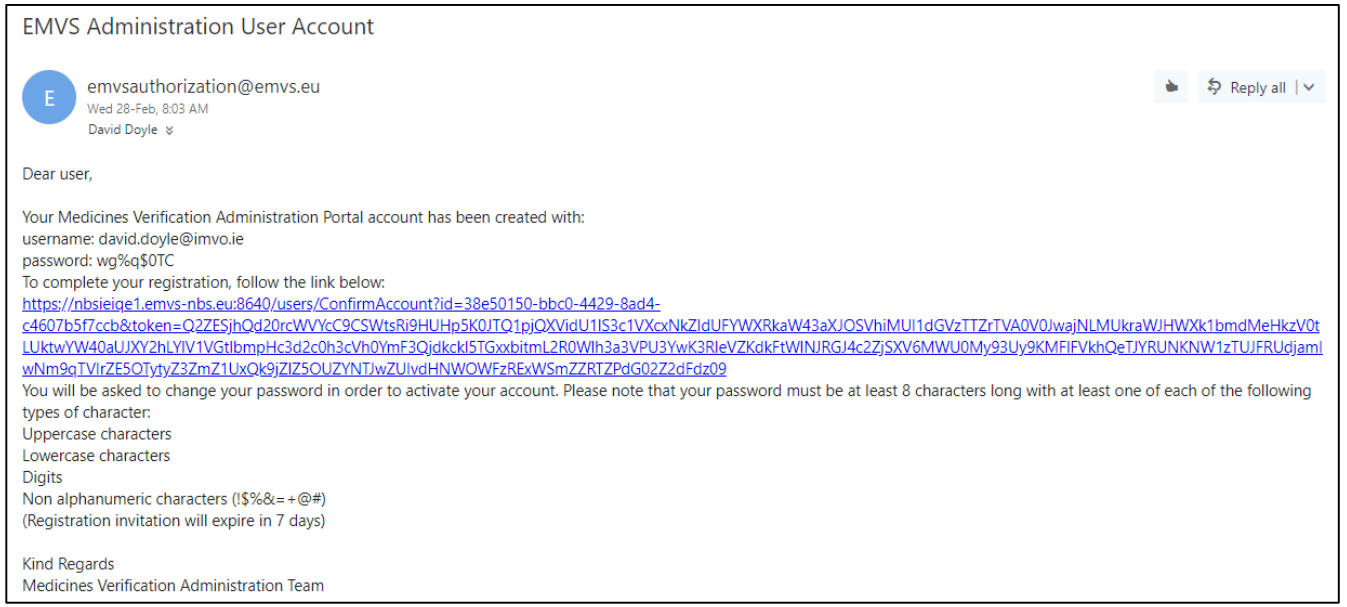
Step 3: Click the link contained in email from **emvsauthorization@emvs.eu**.

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**.



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

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

Reply all

Dear user,

Your Medicines Verification Administration Portal account has been created with:
username: david.doyle@imvo.ie
password: wg%q$0TC
To complete your registration, follow the link below:
https://nbsieiqe1.emvs-nbs.eu:8640/users/ConfirmAccount?id=38e50150-bbc0-4429-8ad4-c4607b5f7ccb&token=Q2ZESjhQd20rcWVYcC9CSWtsRi9HUHp5K0JTQ1pjQXVidU1IS3c1VXcxNkZldUFYWXRkaW43aXJOSVhiMUI1dGVzTTZrTVA0V0JwajNLMUkraWJHWXk1bmdMeHkzV0tLUktwYW40aUJXY2hLYlV1VGtlbmpHc3d2c0h3cVh0YmF3QjdkckI5TGxxbitmL2R0Wlh3a3VPU3YwK3RleVZKdkFtWlNJRGJ4c2ZjSXV6MWU0My93Uy9KMFlFVkhQeTJYRUNKNW1zTUJFRUdjamlwNm9qTVlrZE5OTytyZ3ZmZ1UxQk9jZlZ5OUZYNTJwZUlvdHNWOWFzRExWSmZZRTZPdG02Z2dFdz09
You will be asked to change your password in order to activate your account. Please note that your password must be at least 8 characters long with at least one of each of the following types of character:
Uppercase characters
Lowercase characters
Digits
Non alphanumeric characters (!$%&=+@#)
(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:

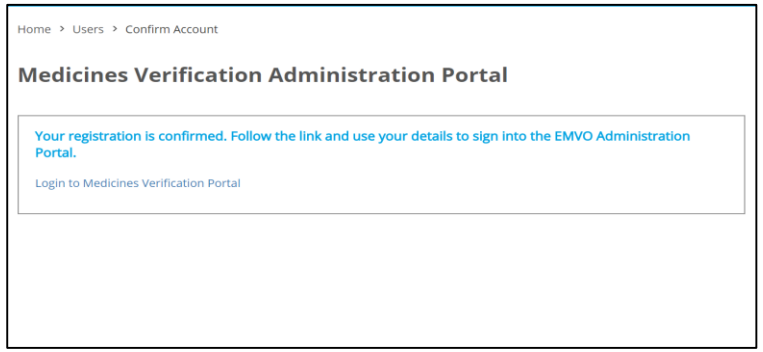
- Be at least 8 characters long
- Contain at least one of the each of following types of characters:
  - Uppercase (capital letter)
  - Lowercase
  - Digit (number)
  - One of the following alpha-numeric characters: ! $ % & = + @ # . - _

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)

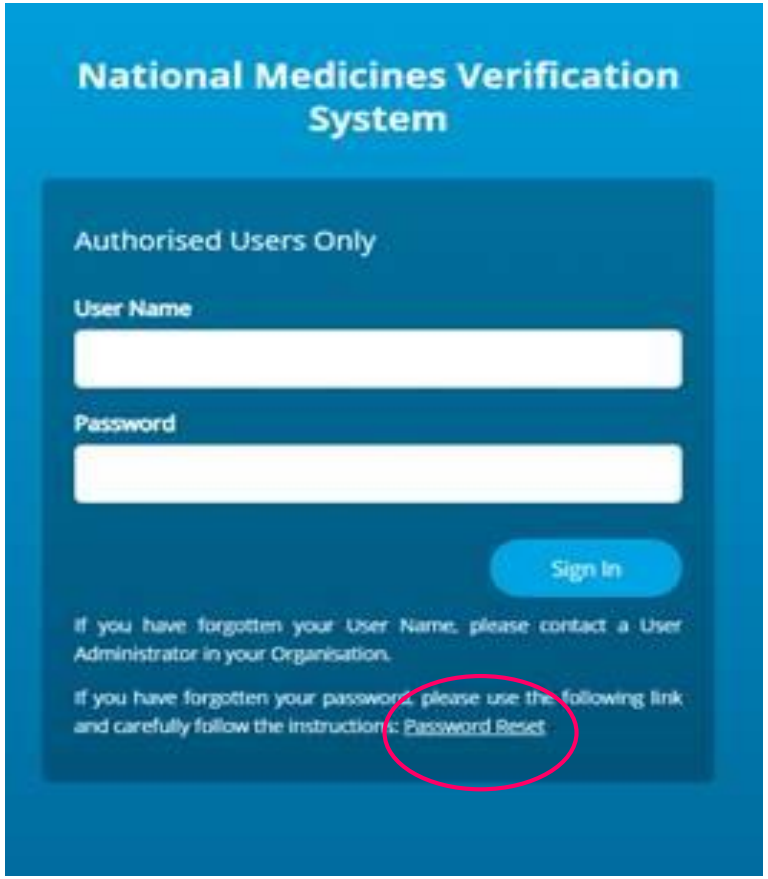
- Common errors when completing organisation registration

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/



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, interrupted 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

IMVO Registration Webinar

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