IRISH PHARMACY UNION
The voice of community pharmacy

Medicines Authentication – Frequently Asked Questions

Section 1: Medicines Authentication System

1.1 What is medicines authentication all about?

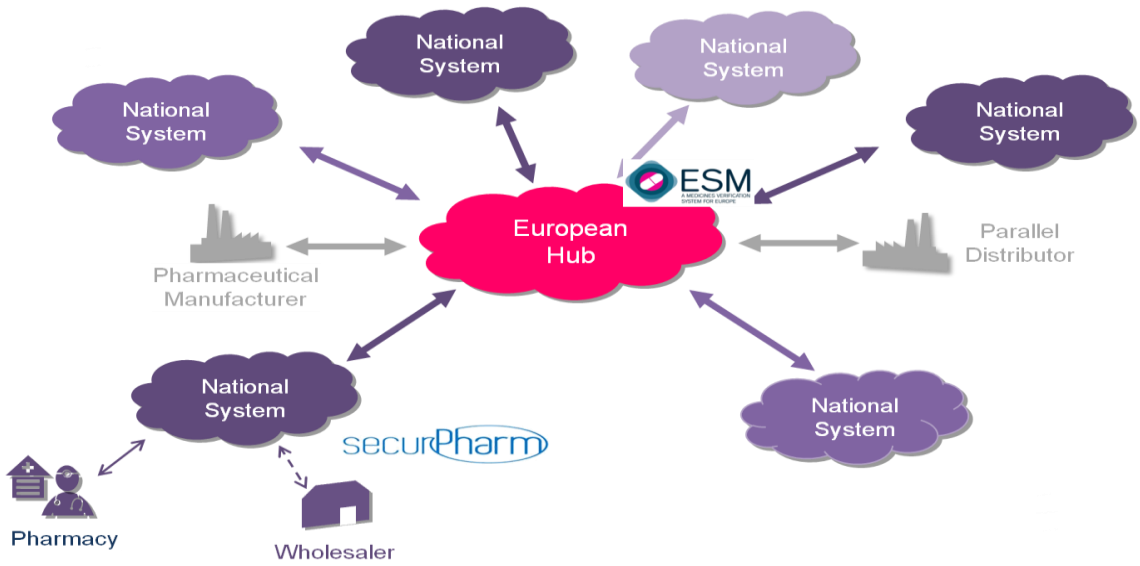
In 2011, the European Commission published legislation called the Falsified Medicines Directive which aims to prevent falsified medicines getting into the supply chain. Guidelines were published by the Commission in February 2016, setting out exactly what manufacturers, wholesalers and pharmacists need to do to ensure that the medicines supplied to patients are authentic.

In summary, all EU pharma companies (originator companies, generic companies and parallel distributors) must put a two-dimensional (2D) barcode on each pack of medicine. The 2D barcode contains a number which is unique to each and every individual product pack. They must also put an anti-tampering device (tamper-evident seal) on each pack – see Figure 1.

Figure 1: Safety Features

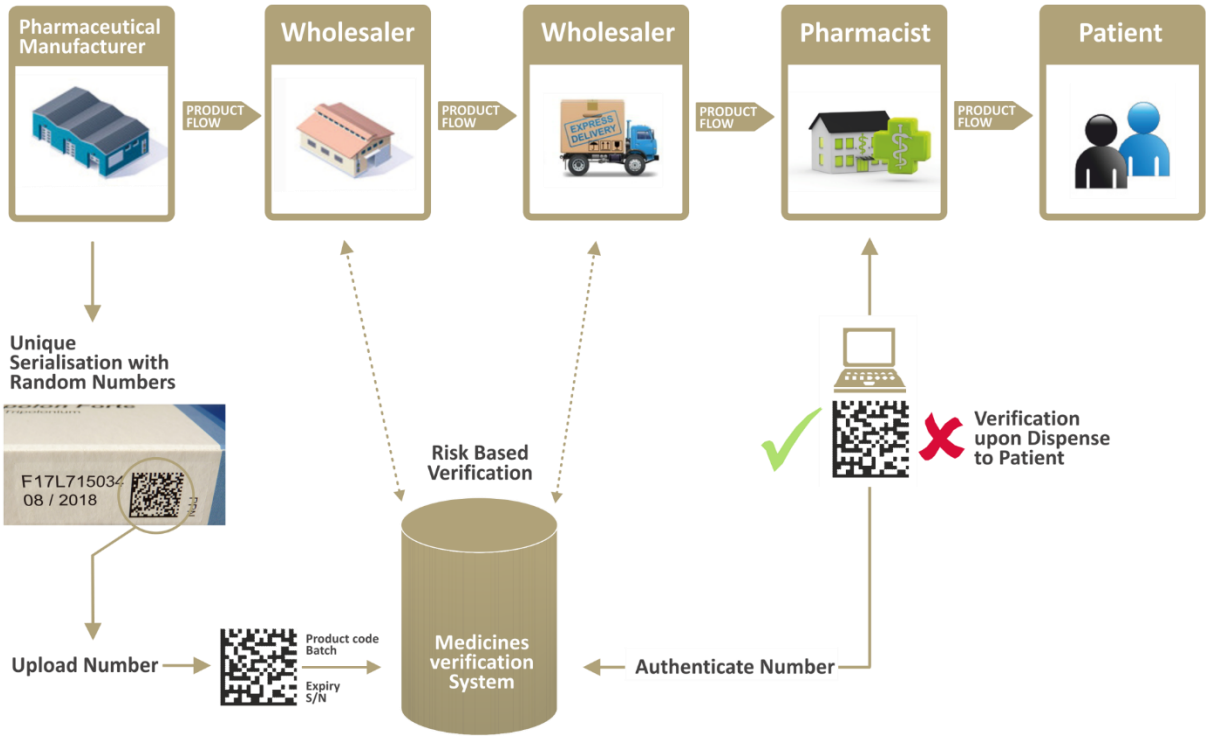
The manufacturers must upload these unique identifiers for all their European packs into a central database – the European Medicines Verification System (EMVS), also called the EU Hub. Data relating to medicines destined for a particular market, e.g. Ireland, will be transferred to the relevant National System. For Ireland, this is the Irish Medicines Verification System (IMVS) – see Figure 2.

Figure 2: Architecture of EU Hub and National Systems



As medicines pass through the supply chain, they must be verified and/or authenticated. Wholesalers will only verify medicines on an ad hoc basis, determined by a risk assessment. Community pharmacies must authenticate every medicine at the point of dispensing by scanning the 2D barcode, although they can also verify when stock arrives in the pharmacy, if they so wish – see Figure 3. They must also check that the tamper-evident seal has not been broken.

Figure 3: Verification and Authentication Process



1.2 What is the difference between verification and authentication?

- **Verification:** A medicine can be scanned to verify it is in the IMVS and that it is not marked as dispensed, expired or recalled. This can be done at any point the medicine is in stock and does not change the status of the medicine in the central system. Wholesalers will do this on an ad hoc basis following risk assessment, e.g. if a medicine comes from a different supplier than usual or if a medicine is returned by a pharmacy.
- **Authentication:** When supplying a medicine to a member of the public, the medicine must be scanned to verify it is in the IMVS and that is not marked as dispensed, expired or recalled. Authentication causes the status of the medicine to be marked as 'supplied', meaning if the same number is scanned again, it will be flagged to the person scanning it. Community pharmacies must do this for all relevant medicines dispensed or supplied.

1.3 What information is on the 2D barcode?

Under the legislation, the unique identifier must be encoded in a 2D barcode and be readable by a commonly used scanner, i.e. a 2D scanner. The unique identifier must also be visible on the medicinal product in a human-readable format in case the barcode is unreadable by the scanner. The barcode will consist of the medicinal product's:

- Product code;
- Serial number;
- National reimbursement number or other national number (not required in Ireland);
- Batch number; and
- Expiry date.

1.4 What does the tamper-evident seal look like?

This is a seal which allows visual verification of whether the packaging of a medicine has been tampered with. It can be either a foil or plastic seal, similar to that on many medicines currently – see Figure 1. It could also be that the cardboard outer packaging is glued shut and it can be a section of the box which is serrated and must be punched out.

1.5 Who is responsible for implementing medicines authentication in Ireland?

The Irish Medicines Verification Organisation (IMVO) has been established as a not-for-profit company limited by guarantee to implement a system for medicines authentication under the legislation. Its founder members include: Association of Irish Pharmaceutical Parallel Distributors (AIPPD); Irish Pharmaceutical Healthcare Association (IPHA); Irish Pharmacy Union (IPU); Medicines for Ireland (generics industry); and Pharmaceutical Distributors Federation Ireland (PDF). The Hospital Pharmacists' Association of Ireland (HPAI) and BioPharmaChem Ireland (BPCI) have also been actively involved in the IMVO Steering Group since its inception in 2015 and the IMVO will continue to collaborate closely with both organisations.

The IMVO has worked with the Health Products Regulatory Authority (HPRA) to ensure that the Irish repository system meets the highest regulatory standards. Other important stakeholder organisations for IMVO include the Department of Health (DoH), Health Service Executive (HSE) and the European Medicines Verification Organisation (EMVO).

1.6 Who pays for all of this?

The cost of developing the IMVS, i.e. the Irish national system, is borne by the manufacturers (originator companies, generic companies and parallel distributors); this includes everything up to the interface with the wholesalers and pharmacies. Community pharmacies are responsible for connecting with the interface and having scanners in place to read the codes. All stakeholders involved in the IMVO (AIPPD, IPHA, IPU, MfI and PDF) jointly contribute to the governance of the IMVO.

1.7 When did medicines authentication start?

The regulation took effect three years after the Commission's Regulation was published on 9 February 2016, so full implementation was mandatory from 9 February 2019.

1.8 Who owns the data held in the system?

Manufacturers, wholesalers and pharmacists only have ownership of, and access to, the data they generate when they interact with the IMVS. This means that pharmacists own the data that they create and no one else can access or use it, except the HPRA for auditing purposes.

1.9 Who has access to the data?

The HPRA can request access to specific data from the IMVS for supervisory purposes or when investigating potential incidents of falsification. Neither the IMVO nor any of the participating organisations will have access to the pharmacy data.

1.10 Where will the data be stored?

The IMVS data will be stored in two data centres, Dublin and Amsterdam.

Section 2: Process of Medicines Authentication in Community Pharmacies

IMPORTANT - Use and Learn Phase

The implementation of medicines authentication across the EU is largely an IT project. In the early phase of implementation there will be a transition period or 'use and learn' phase so as not to unduly disrupt the supply of medicine to patients. As you scan to authenticate medicines, data on alerts raised by the IMVS will be collected and analysed. During the transition period, irrespective of the response and message (green, amber or red), all products are good to supply.

2.1 What medicines do I need to authenticate?

All prescription-only medicines, including generics, have to be authenticated, unless the HPRA decides otherwise. Non-prescription medicines do not need to be authenticated unless specified. At present, the only non-prescription medicines identified for medicines authentication are omeprazole 20mg and 40mg hard gastro-resistant capsules. This does not apply to omeprazole tablets or 10mg capsules. There are currently no OTC omeprazole 20mg and 40mg hard gastro-resistant capsules on the Irish market. The HPRA can decide if they wish to include other non-prescription medicines in future; however, currently they have no plans to do so.

2.2 Do I have to authenticate veterinary medicines?
No. The rules apply only to medicinal products for human use. However, if you supply human medicines to an animal owner on foot of a prescription or you supply human medicines to a vet on foot of a requisition, you must authenticate at the time of supply.

2.3 Do I have to authenticate fridge lines?
Yes, if they are prescription-only.

2.4 Do I have to authenticate vaccines?
Yes. All vaccines, including those supplied through the HSE cold chain, e.g. flu vaccines, must be authenticated.

2.5 Do I need to verify medicines received from the wholesaler/manufacturer?
There is no requirement to do this but you can if you wish.

2.6 Can I just authenticate all medicines when they arrive in the pharmacy?
No, authentication must be done during the dispensing process.

2.7 What is the dispensing process?
The dispensing process starts when a prescription is received in the pharmacy and continues until the medicine is supplied to the patient – refer to your *SOP for Dispensing Process*.

2.8 When exactly do I scan the medicine?
This will vary from pharmacy to pharmacy, depending on what best suits the workflow of the pharmacy; it can be when preparing a prescription or at handover to the patient. The most logical time to scan the medicine is when it is removed from the shelf before dispensing.

2.9 What happens when I scan a medicine?
When the barcode is scanned, the number is checked in the IMVS to see if it is a valid serial number, or if it is marked as previously dispensed; the vast majority will be good to supply.

2.10 How long will it take to authenticate a medicine?
The maximum response time of an individual repository is 300 milliseconds. If the system has to check repositories in other Member States, e.g. for ULMs, each stage will take a maximum of 300 milliseconds.

2.11 What do I do about broken bulk?
When you part-dispense a medicine from a pack, you will authenticate the pack when it is first opened and you should mark the pack as authenticated. The next time you dispense from this part-pack, you do not need to authenticate. Remember, this process is to identify falsified medicines; if the medicine was not falsified when you first dispensed it, it will not be falsified on subsequent dispensings.

2.12 What about original pack dispensing?
Whilst it would be easier to carry out medicines authentication if pharmacies only dispensed original packs, this could prove problematic from a patient safety perspective for medicines

such as antibiotics or benzodiazepines. However, pharmacies may decide it is preferable to dispense 28-day supplies of medicines for chronic conditions.

2.13 What do I do about phased dispensing?

Dispensing medicines on a phased basis should not be any different to normal dispensing, i.e. authenticate the pack on dispensing.

2.14 What do I do about MDS dispensing?

When you are removing medicines from their original pack to put into a monitored dosage system (MDS), you must authenticate the pack at that time. If you only use part of the pack, treat in the same way as for broken bulk, i.e. authenticate the pack when it is first opened and mark the pack as authenticated. The next time you dispense from this part-pack, you do not need to authenticate.

2.15 What do I do with unlicensed medicines (ULMs)?

If a medicine does not have a licence in Ireland, but does have a licence in another EU country, it will have a 2D barcode. When you scan a ULM, the system will first check for the unique serial number of the medicine in the IMVS. If it is not there, the system will then check the EMVS which in turn will check the relevant Member State system then report back to your PC that the medicine's unique identifier is indeed in the system.

2.16 Can I authenticate a number of medicines at the same time?

Whilst the regulation allows for this, the system does not, as yet, facilitate batch authentication through an aggregated code, i.e. barcode information for a number of medicines associated with one single code.

2.17 Can the system verify what goes into the bag, then authenticate the bag label when handing the prescription to the patient?

No. The IMVS is designed to authenticate medicines individually. However, the software interface, or computer programme, for medicines authentication may be capable of being programmed to meet pharmacy requirements; any additional functionality such as this would require local development. Some interface providers may offer such a solution.

2.18 What do I do about medicines supplied on foot of a requisition?

If you supply medicines on foot of a requisition, e.g. to a dispensing doctor, dentist, optician, vet, ship or other organisation, you must authenticate each medicine before it leaves your pharmacy.

2.19 What do I do about medicines supplied to nursing homes?

You should treat medicines supplied to patients in nursing homes the same way as you treat medicines supplied to other patients, i.e. you authenticate each medicine before it leaves your pharmacy. If the nursing home requisitions medicines on a stock order, you authenticate each medicine before supply.

2.20 How will the system deal with recalls?

The recall process will continue to operate as usual, i.e. the pharmacy will receive a 'Dear Healthcare Professional' letter with instructions on what to do about the recall i.e. pharmacies will receive recall information from the manufacturer/HPRA in the normal way.

However, if a medicine is recalled, the manufacturer or parallel distributor will update the system (both at EMVS and IMVS level), marking the relevant batch numbers as being recalled. If a pharmacy omits to return the recalled medicine, as part of their usual SOP, and tries to dispense it at a later date, when the barcode is scanned, the system will indicate that the product has previously been recalled. If you received recall information from the manufacturer/HPRA, you must not dispense such medicines to patients.

2.21 Will the system manage patient-level recalls?

No, as the system does not contain any patient information. If you receive a patient-level recall after having dispensed a medicine to a patient, you should follow the usual process in your *SOP for Dealing with the Recall or Withdrawal of Medicinal Products*.

2.22 How will the system deal with expired/out-of-date medicines?

The 2D barcode contains the expiry date of the product. If you attempt to dispense the product after the expiry date has passed, the system will alert you to the fact that the medicine has expired. You must not dispense such medicines to patients.

However, during the transition period these messages may be ignored.

2.23 Will the system identify if the wrong medicine has been selected from the dispensary shelf compared to the prescription?

No.

2.24 I ordered a medicine in error and now wish to return it to the wholesaler. Do I need to authenticate the medicine before returning it to the wholesaler?

No, you do not authenticate as the medicine still needs to remain 'live' in the system. The wholesaler will verify the medicine on receipt and it will then be available to be supplied to another pharmacy.

2.25 I ordered a medicine for a particular patient, dispensed and authenticated it and left it aside for the patient to collect. When they came back to the pharmacy, they said they no longer required that medicine. I now wish to return it to the wholesaler. What do I need to do before returning the medicines to the wholesaler?

As you have authenticated the medicine, you need to 'recommission' the medicine before returning, as this can only be done by the party that authenticated it in the first place.

2.26 What happens if/when I lend stock to another pharmacy?

- **Lending a complete pack:** The lending pharmacy should verify the medicine before it leaves the pharmacy and the borrowing pharmacy will authenticate the medicine during the dispensing process.

- **Lending part of a pack:** The lending pharmacy will ensure the original pack was authenticated before it leaves the pharmacy and let the borrowing pharmacy know it has been authenticated.

2.27 What do I do when disposing of out-of-date or damaged stock?

If the stock is damaged, authenticate the stock first before disposal.

2.28 What do I do if medicines are stolen from my pharmacy?

In relation to medicines authentication, there is nothing that you can do as you will not know what the 2D barcodes are for such medicines.

2.29 Can the system be used to control stock of High Tech medicines?

No. The IMVS is not a stock management system, although you do have to authenticate High Tech medicines.

2.30 What can I do if I dispense a medicine for a patient and authenticate it but the patient does not call back to collect it?

Once you have authenticated a medicine, you can put it back into the IMVS (i.e. recommission) within ten days. Recommissioning is not possible after 10 days. If you have medicines awaiting collection, you should have a process to take them off the shelf and recommission them to the IMVS within 10 days, i.e. a weekly process to check uncollected medicines and, where necessary, recommission them to the IMVS and put them back in stock.

2.31 If I need to supply a medicine to a patient in an emergency, do I need to authenticate it first?

If you need to administer a medicine in an emergency, e.g. adrenaline, you may not have time to authenticate it before administration so you should administer the medicine first and authenticate later. However, it would be good practice to ensure such emergency medicines are verified when received from the wholesaler. If you are simply making an emergency supply of a medicine, the medicine should be authenticated before being given to the patient in the normal way.

2.32 Will patients start bringing medicines they have purchased elsewhere (e.g. Spain, online) into my pharmacy to be authenticated?

This should not happen as this is an EU-wide regulation that applies to both bricks-and-mortar and online pharmacies so the medicine should already have been authenticated by the supplying pharmacy.

2.33 What do I do if the HPRA and/or PSI require stock as a sample during inspection?

There will be a provision to mark a pack as a sample for the HPRA and/or PSI. However, this will rarely happen.

2.34 Do I need to have a Standard Operating Procedure (SOP) for medicines authentication?

You should adapt your *SOP for the Dispensing Process* to accommodate medicines authentication. A template SOP is available on the IPU website.

Section 3: Problems with Medicines Authentication

3.1 What happens if the system/broadband fails?

If the IMVS is unavailable, the software interface, or computer programme, for medicines authentication will record the scanned codes and they will be authenticated when the IMVS is back up and running. In the meantime, medicines can be suppled as normal.

3.2 What happens if the barcode is damaged or the scanner can't read the barcode?

The unique identifier must be visible on the medicinal product in a human-readable format in case the barcode is unreadable by the scanner. You can manually enter the code to authenticate the medicine. However, if the scanner can't read the 2D barcode and you can't read the human-readable code because of damage, it is recommended that the medicine is not supplied to the public.

3.3 What happens if a product does not have a 2D barcode?

There are still many medicines in the supply chain, in both wholesalers and pharmacies, that do not have the new tamper-evident seal and 2D barcode. These medicines can continue to be dispensed until such supplies are exhausted. You are only required to scan a product if it has the 2D barcode. If the product does not have a code, it does not need to be scanned but can still be dispensed. Medicines without the 2D barcode will eventually work their way out of the supply chain.

3.4 What happens if a falsified medicine is detected?

During the transition period or 'use and learn' phase, irrespective of the response and message (green, amber or red), all products are good to supply. IMVO and the HPRA will use this period to analyse the data on alerts raised and produce guidance for scenarios if and when a falsified medicine is detected.

3.5 My internet/broadband is slow. Will that affect the system?

No. The system is designed to work on very little internet speed.

Section 4: Additional Questions & Answers

4.1 Who ensures that pharmacies are complying with medicines authentication?

The PSI will measure compliance based on registrations with IMVO and scanning activity in your pharmacy.

4.2 What happens if I do not authenticate?

It is a legal requirement for pharmacists to authenticate medicines upon dispensing. Pharmacists registered with the PSI make a statutory declaration upon registration and subsequent continued registration undertaking to comply with all pharmacy and medicines legislation.

4.3 Why isn't the system used for reimbursement?

The DoH and HSE were consulted and decided not to use the IMVS for reimbursement purposes as there is already a functioning electronic reimbursement system in place.

4.4 Do I need to authenticate medical devices?

Another EU regulation called the Medical Devices Regulation will require some kind of verification of medical devices but details have not yet been confirmed.

4.5 Do hospital pharmacies have to comply with medicines authentication?

Yes, although they may do it slightly differently than community pharmacies owing to their particular workflow.

4.6 What happens if wholesalers directly supply medicines to doctors, dentists, vets etc.?

In such cases, the wholesaler must authenticate the medicines before supply.

4.7 Are there any implications for data protection?

No, because the system does not contain any personal data.

4.8 I have a wholesale account to facilitate medicines being transferred between the pharmacies in my chain. What else do I need to do?

Pharmacies with a wholesale licence will need to have two separate registrations with the IMVO, one for the pharmacy business and one for the wholesale business. There will be a separate interface to manage the wholesale activities.

4.8 I have just opened a pharmacy, how I set myself up for medicines authentication?

Follow the IPU Guide and Checklist in Appendix I.

Appendix I

Ten-point checklist – Set up your pharmacy medicines authentication

To prepare you pharmacy for medicines authentication, you will need to follow ten steps. This article explains each step and there is a checklist at the end to assist you in your preparations. Throughout the article, reference will be made to information and reports on the IPU website, you can access this information on **www.ipu.ie > Professional > SOPs and Guidelines > Medicines Authentication.**

1. Read the IPU Medicines Authentication FAQ

We produced a book of Frequently Asked Questions (FAQ) to inform you of everything you need to know about medicines authentication and how it will be implemented in Ireland – you can download a copy from the IPU website here.

2. Read the IPU Interface Providers Report

The *IPU Interface Providers Report* focuses on the software element, the interface, necessary to connect your pharmacy to the Irish Medicines Verification System (IMVS). It includes details based on responses to two IPU surveys and feedback from pharmacies that participated in a pilot held by the Irish Medicines Verification Organisation (IMVO). We surveyed 11 interface providers and nine responded. Out of those nine, only six were part of the IMVO pilot (at the time of the survey). For full information, get the report from the IPU website here. As an overview, the nine that responded are:

- Clanwilliam Health - www.clanwilliamhealth.com
- HE Clissmann - http://ezfmd.com/
- McLernons - www.mclernons.ie
- MedAspis - www.medaspis.com
- Optel Group - www.optelgroup.com
- Quick Pharm Solutions - www.quickpharmsolutions.com
- SolidSoft Reply - www.verilite.eu
- Touchstore - www.touchstore.ie
- TraceLink - www.tracelink.com

3. Pick an interface provider

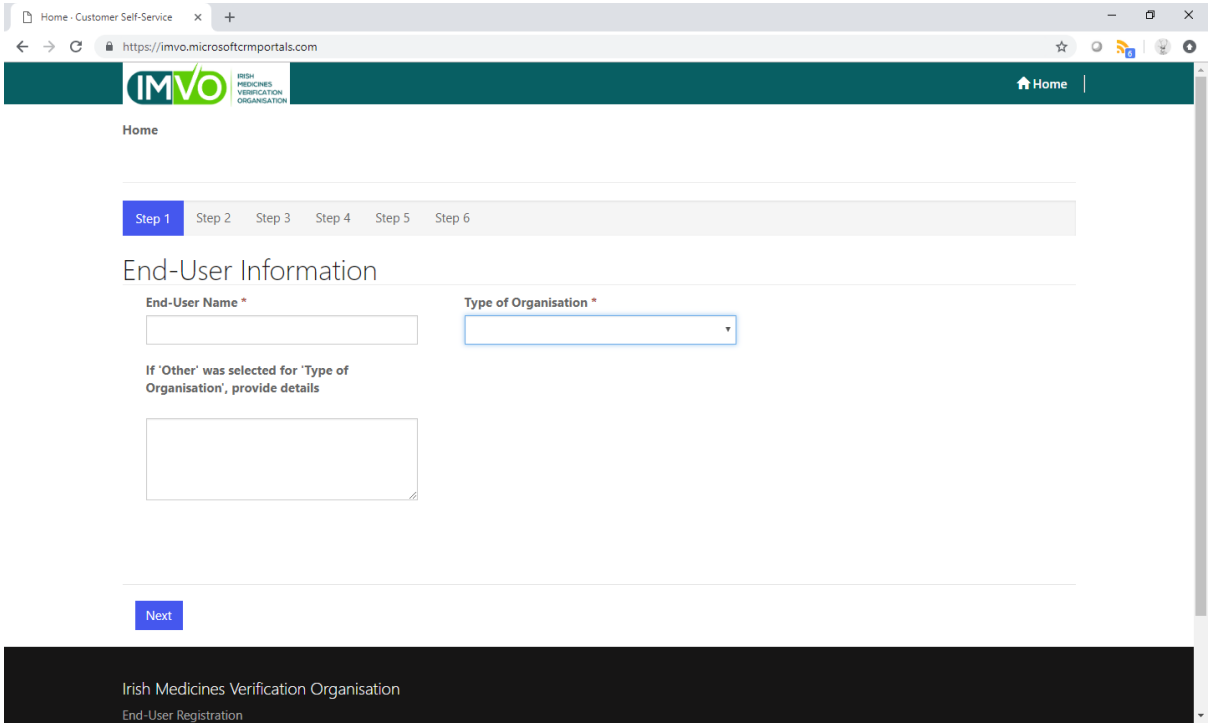
Before you go any further, you need to pick an interface provider. You cannot register with IMVO until you do so. To help you make a decision, use the *IPU Interface Providers* report on the IPU website here. If you need further advice, call the IPU.

4. Put a contract in place

When you pick your interface provider, you will need a contract. This is also necessary to register with IMVO. Your chosen interface provider will provide you with a contract and we produced a template contract for your information, it is on the IPU website here.

5. Register with IMVO

To register with IMVO, go https://www.imvo.ie/stakeholders1/register-imvo.



You will be asked for the following information during registration:

- Name of 'organisation' to be registered, i.e. your registered pharmacy name
- Details for each 'location' (premises) you want to register: name, address, your pharmacy's PSI number
- Details of 'authorised representative': name, position, email address – i.e. your supervising pharmacist or business owner
- Name of your IT software provider(s) – you cannot register without this
- 'Super User' name, position, email address – i.e. the administrator for your pharmacy

There are four steps to the process:

i. Complete the online registration form so IMVO will have all your details
ii. Accept IMVO's End-User T&Cs when completing the form
iii. IMVO carries out legitimacy check
iv. Technical registration / connection

The last step is the most complex. After the legitimacy check is complete, your nominated 'Super User' will receive 2 emails with information to connect your FMD system to the IMVO system – one from registration@imvo.ie with an important registration code and another from emvsauthorization@emvs.eu with a link to complete the registration (where you will use the registration code).

In most cases, your interface provider will support you with the step (this is another good reason to have one in place). If not, IMVO will provide support. For all issues relating to registration, you can call IMVO on 01 571 5320 or email registration@imvo.ie.

6. Set up your software

Each interface is installed differently. Some providers will install the interface remotely, some will provide a download, others will visit your pharmacy. You can install the interface on your dispensary computer(s) or on a separate PC. Some interface providers will offer a completely separate device, e.g. a tablet or iPad, purely for medicines authentication. Whatever the set-up in your pharmacy, after your registration is complete, you should check with your provider that interface is connected to the IMVS. You only need an interface on one computer in your pharmacy; however, you may install it on more than one if that suits your workflow.

7. Set up your scanner(s)

In 2018, the IPU provided members Datalogic Quickscan QD2430 scanner supplied by a company called AIS Limited – this scanner is widely used across all pharmacies. You can speak with AIS about further options or consult with your interface provider who may also have scanners on offer. If you have any questions about the scanner provided by the IPU, you can call AIS on 01 6205742. There is also an IPU section on their website: www.aisltd.ie > services > IPU.

Once you are registered with IMVO and your interface has been installed, you should ensure the scanner works with your interface (your interface provider will assist you if required).

8. Update your workflow

Article 25 of the Regulation states that "Persons authorised or entitled to supply medicinal products to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public at the time of supplying it to the public." So, when exactly do you scan the medicine? This will vary from pharmacy to pharmacy, depending on what best suits the workflow of the pharmacy; it can be when preparing a prescription or at handover to the patient. The most logical time to scan the medicine is when it is removed from the shelf before dispensing. We have inserted medicines authentication into the IPU Dispensing Process template SOP but you can move it to where it best reflects your workflow.

When the barcode is scanned, the number is checked in the IMVS to see if it is a valid serial number, or if it is marked as previously dispensed, recalled or expired; the vast majority will be good to supply. The maximum response time of an individual repository is 300 milliseconds. If the system has to check repositories in other Member States, e.g. for ULMs,

each stage will take a maximum of 300 milliseconds. This means, the system is designed to be fast to have minimal effect on pharmacy workflow. Remember, the interface does not need to be part of your dispensary system, or even on the same computer; it can be a fully standalone system giving you flexibility and options.

9. Update your SOP

The Regulation requires that you scan the medicine during the dispensing process, which starts when a prescription is received in the pharmacy and continues until the medicine is supplied to the patient – you will need to amend your SOP for Dispensing Process accordingly, and there is an updated SOP on the IPU website; go to www.ipu.ie > Professional > SOPs and Guidelines > Medicines Authentication.

10. Start scanning

For products with both an anti-tamper device (a security seal) AND a 2D barcode:

- Ensure the tamper-evident seal is intact
- Scan the 2D barcode to authenticate the medicine against the Irish Medicines Verification System (IMVS) – this scanning action will electronically mark the pack as supplied (i.e. dispensed).

Support

There are a number of stakeholders involved in medicines authentication, so who do you go to for support? To simplify things, let's break it down to the four core elements:

Hardware:	If you have trouble with the scanner, then contact the supplier e.g. AIS
Software:	If you have trouble with the interface, then contact the interface provider
Registration:	If you have any issues registering with the national system, then contact IMVO
Professional:	If you have any questions about what to scan and when, contact the IPU

Checklist

Use this ten-point checklist to ensure your pharmacy is ready for medicines authentication. Our advice is to act now.

1.	Read the IPU FAQ	
2.	Read the IPU Interface Providers Report	
3.	Pick an interface for your pharmacy	
4.	Sign a contract with the interface provider	
5.	Register with IMVO	
6.	Set up your software	
7.	Set up your scanner(s)	
8.	Adapt your workflow	
9.	Update your SOP	
10.	Start scanning	