Medicines authentication – a complete guide

Following the publication of the Delegated Regulation (EU) 2016/161 (the Regulation) under the Falsified Medicines Directive 2011/62/EU (FMD), there will be a requirement on pharmacists to authenticate medicines during the dispensing process from 9 February 2019. Alan Reilly, Head of Information and Technology with the IPU, provides a complete guide to help get your pharmacy ready.

The Irish Pharmacy Union (IPU is working closely with the Irish Medicines Verification Organisation (IMVO) and other stakeholders for a smooth implementation of medicines authentication in this country.

In the October and November editions of the *IPU Review*, we ran articles setting out the basic principles of medicines authentication, and it is worth repeating those points again with a subset of our Frequently Asked Questions (FAQ). This article will then look at the more practical issues: how to set up your pharmacy; who to go to for support; and a final checklist that you can tear out and keep as a reference.

Frequently Asked Questions

What is medicines authentication all about?

In 2011, the European Commission published legislation called the Falsified Medicines Directive, which aims to prevent counterfeit or 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) will put safety features, i.e. an anti-tampering device (tamper-evident seal) and a two-dimensional (2D) barcode, on each pack of medicine placed on the market. The 2D barcode contains a number which is unique to each and every individual product pack – *see Figure 1*.

You will start to see medicine packs come into your pharmacy with the 2D barcode and tamper-proof seal. From 9 February 2019, you will be legally required to authenticate the medicine and mark it as supplied.

How do I do that?

To set your pharmacy up for medicines authentication, you will need:

- Hardware – a barcode reader; and
- Software – an interface into the Irish Medicines Verification System (IMVS).

For all packs with a 2D barcode and a tamper-proof seal, you will check that the seal has not been broken and you will scan the 2D barcode. The software will then connect to the IMVS to authenticate the medicine and mark it as supplied. You will do this scanning at some stage during the dispensing process, at a point that suits the workflow in your pharmacy. The system has been designed to do this scan in under 300 milliseconds, to help minimise the extra workload.

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: the Association of Irish Pharmaceutical Parallel Distributors (AIPPD); the Irish

Figure 1: **Safety features**

Pharmaceutical Healthcare Association (IPHA); the 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 IMVO will continue to collaborate closely with both organisations.

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

For the last number of years, Leonie Clarke MPSI, has been the lead project manager for IMVO and has recently been appointed as the IMVO General Manager. Now that IMVO is up and running, Leonie and her team are responsible for delivering the Irish Medicines Verification System (IMVS).

Why should I authenticate medicines?

The short answer is – because it is a legal requirement. Medicines authentication is provided for in the Delegated Regulation (EU) 2016/161 under the Falsified Medicines Directive. Because it is a regulation, and because Ireland is a member of the EU, it will become Irish law on 9 February 2019 – much like the EU General Data Protection Regulation (GDPR), which came into force in May of this year.

Setting up your pharmacy

In this section of 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.

To set up your pharmacy for medicines authentication, you need to take the following steps:

1. ***Read the IPU Medicines Authentication FAQ***
   In October 2018, all IPU members received 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. If you don't have a hard copy to hand, you can download a copy from the IPU website.

2. ***Read the IPU Interface Providers Report***
   IMVO held a pilot over the summer months. The aim of the IMVO pilot was to fully test the IMVS (the national system), the systems that interface with it and their supporting workflows, e.g. initial interface connection, pharmacy on-boarding and user testing. The IPU supported the pilot and approximately 40 member pharmacies participated. We used the pilot to evaluate:
   - Hardware (barcode readers / scanners);
   - Software (interface to the IMVS); and
   - Support (from interface providers, IMVO and the IPU).

   The IPU Interface Providers Report focuses on the software element, the interface necessary to connect your pharmacy to the IMVS. It includes details based on responses to two IPU surveys and feedback from pharmacies that participated in the pilot. 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). You can view the full report on the IPU website. As an overview, the nine that responded are:
   - Clanwilliam Health – www.clanwilliamhealth.com;
   - HE Clissmann – www.clissmann.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; and
- 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. If you need further advice, please 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. To help you, there is a template contract on the IPU website entitled Pharmacy IMVS Interface Contract.

5. ***Register with IMVO***
In October and November, IMVO sent all registered pharmacies in Ireland an email requesting you to register with the IMVS. If you cannot find the email, please check your SPAM or Junk mail folder. To register with IMVO, go www.imvo.ie > News > link to registration page.

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; and
- '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;

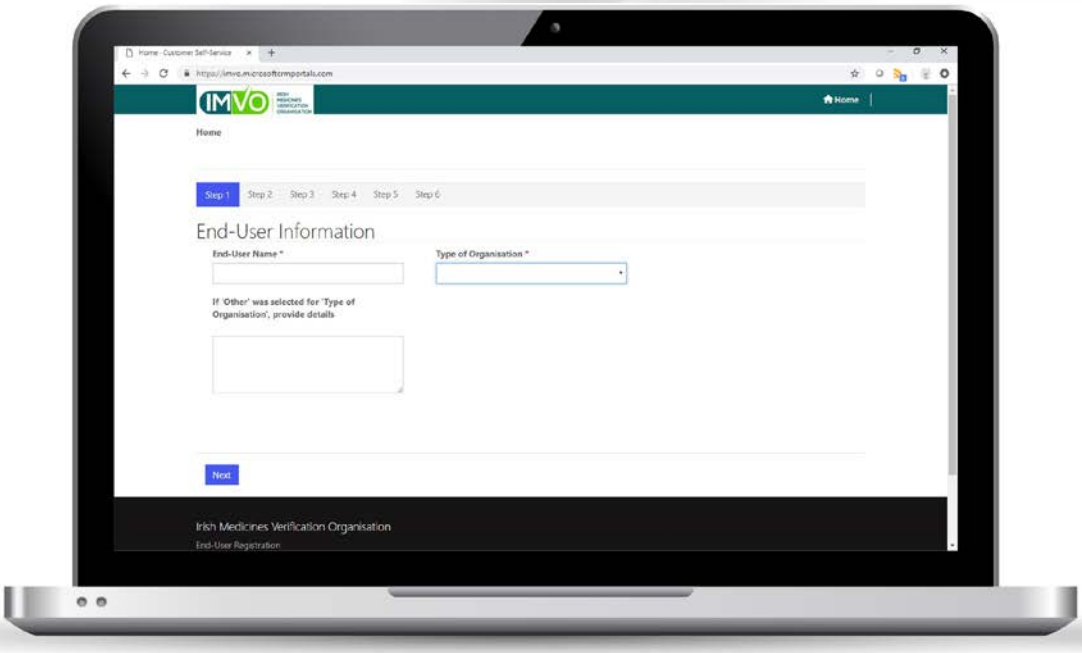
ii. Accept IMVO's End-User T&Cs when completing the form;

iii. IMVO carries out legitimacy check; and

iv. Technical registration / connection.

The last step is the most complex. After the legitimacy check is complete, your nominated 'Super User' will receive two 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 the interface is connected to the IMVS.

7. ***Set up your scanner(s)***
By now, you will have also received a Datalogic Quickscan QD2430 scanner from the IPU, supplied by a company called AIS Limited. This is to get your pharmacy up and running. All the necessary information regarding installation and support will be contained in the box. 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 with this if required).

While we are providing members with a scanner, your pharmacy may need more than one barcode reader, or you may wish to use a different scanner. There are many options for barcode readers and you can find further information on our website – see the List of Scanner Providers report. You

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can also 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 01 620 5742. There is also an IPU section on their website, www.aisltd.ie > services > IPU.

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 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.

We surveyed the pharmacy participants in the pilot and all interface providers; feedback on the effect on pharmacy workflow was consistent. Most pharmacies authenticated the product as it was selected from the shelf and before it was labelled. One pharmacy explained two scenarios. The first is a prescription handed in and prepared while the person was in the pharmacy. Each item was checked as it came off the shelf by the individual dispensing the prescription. The second scenario relates to prescriptions prepared and labelled in advance. The full prescription was collected and then scanned by the relevant dispenser when preparing the script.

While there will be an impact on workflow, it is important to find a point in your pharmacy's workflow that will minimise any disruption. For this reason, most pilot participants set up authentication in the dispensary at, or near, each workbench. Some put it in a central position near the bagging process. 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 > Dispensing Process.

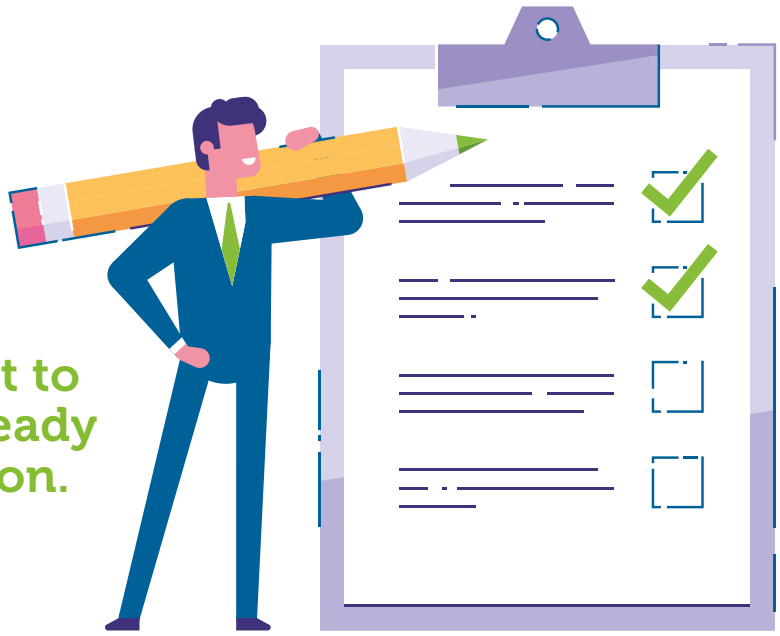
10. ***Start scanning***
While the regulation does not come into force until 9 February 2019, it is really important to start scanning products as soon as you are set up. This will help you identify what is the best point for medicines authentication in your pharmacy and, if issues arise, to report them to IMVO or the appropriate stakeholder.

Support

There are a number of stake-holders 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*	

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