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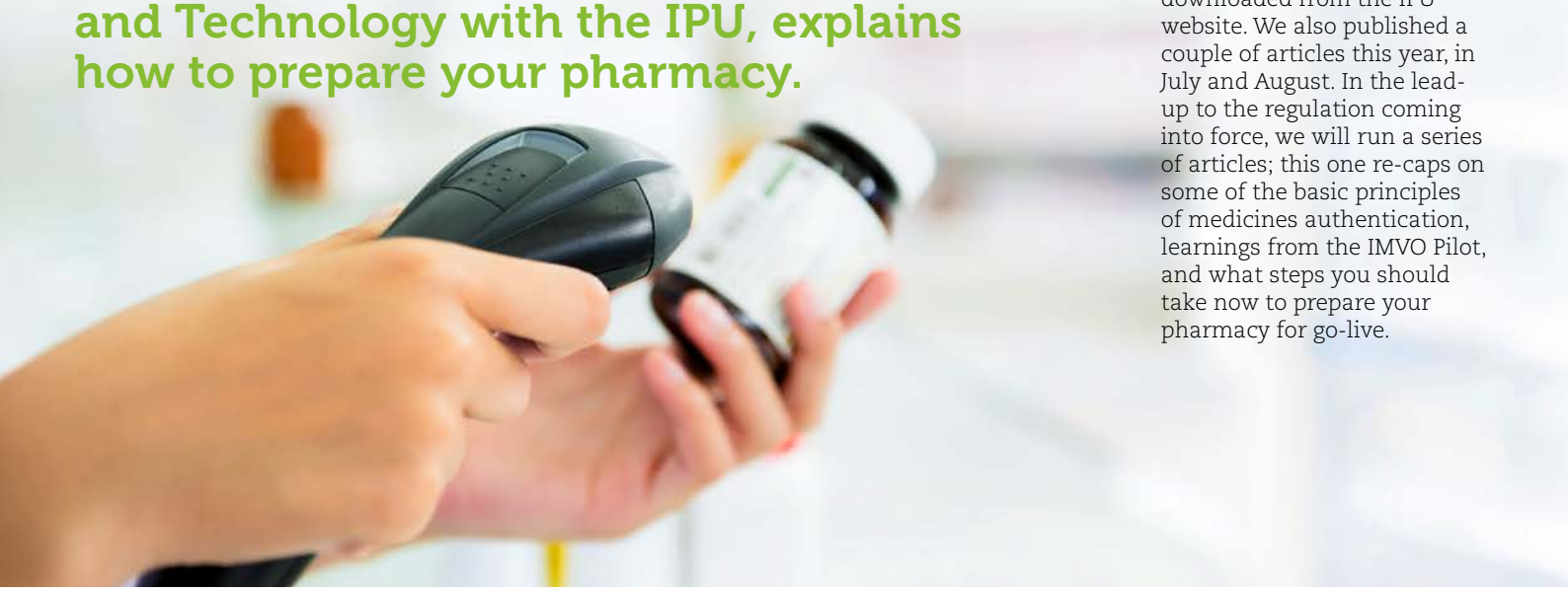
Medicines authentication: Get your pharmacy ready

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, explains how to prepare your pharmacy.



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. To answer your queries, we sent all members a document of Frequently Asked Questions (FAQ) in January 2018, which can be downloaded from the IPU website. We also published a couple of articles this year, in July and August. In the lead-up to the regulation coming into force, we will run a series of articles; this one re-caps on some of the basic principles of medicines authentication, learnings from the IMVO Pilot, and what steps you should take now to prepare your pharmacy for go-live.

Figure 1: **Safety features**

What is medicines authentication all about?

In 2011, the European (EU) Commission published legislation, entitled the Falsified Medicines Directive, which aims to prevent falsified medicines entering the supply chain. Guidelines were published by the EU 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 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 will also put an anti-tampering device (tamper-evident seal) on each pack – *see Figure 1*.

You will start to see medicine packs come into your pharmacy with the above 2D barcode and tamper-proof seal. From 9 February 2019, you will be legally required to authenticate the medicine and mark it is 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 need to check that the seal has not been broken and then you will need to 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 work-flow 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); Irish

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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 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 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 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.

IMVO Pilot and IPU Report

Over the last number of months, IMVO has been running a pilot to fully test the IMVS. From the IPU's perspective, the aim of the pilot was to evaluate the effect of medicines authentication on community pharmacy. We had over 40 pharmacies participating in the pilot to test and evaluate:

- Interface providers;
- Connecting to the IMVS;
- Scanners;
- The effect on pharmacy workflow; and
- The support received by the interface providers, IMVO and the IPU.

We surveyed the pharmacy participants in the pilot and all interface providers. We will use this information to further guide you on what to do next. A report has been produced and you can find it by logging on to www.ipu.ie > Professional > SOPs & Guidelines > Medicines Authentication.

Initial steps

We will now look at the initial steps you should take this month, namely:

1. Choosing an interface;
2. Connecting to the IMVS; and
3. Obtaining a scanner.

Choosing an interface

By interface, we mean the software that connects you to the IMVS. There are a number of options and they are all listed in the report on the members' section of the IPU website – go to www.ipu.ie > Professional > SOPs & Guidelines > Medicines Authentication > Interface Providers. Our advice is to contact some interface providers now and choose one.

Connecting to the IMVS

To connect to the IMVS, you will have to complete an onboarding process with IMVO and register with them. There are two parts to the process; IMVO will collect information from you in order to check your credentials and will then issue the technical details required to connect your system to the IMVS. IMVO will open onboarding in mid-October and they will send all registered pharmacies an email with instructions of how to get started. Once you are registered with IMVO, your interface provider will assist you with getting your system connected to the IMVS.

Obtaining a scanner

The IPU will send each pharmacy one scanner over the coming months. However, you may need more than one, and your interface provider will be able to assist you with further options.

Next steps

Our article next month will focus on the effect of medicines authentication on your pharmacy workflow, and who to go to for support.