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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 is a requirement on pharmacists to authenticate medicines during the dispensing process from 9 February 2019. The new EU law affects the entire pharmaceutical supply chain; this article examines how.

Effective 9 February, the EU Medicines Authentication Regulation is upon us. While pharmacy is at the cold face of the Regulation, it affects the whole supply chain in the EU, from manufacturing and import, right through to hand-over to the patient. This article sets out the work of stakeholders in Ireland to meet the new requirements.

First off, 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 a 2D barcode and tamper-proof seal, and from 9 February 2019 you will be legally required to authenticate the medicine and mark it as supplied before you dispense to a patient.

EMVO

The European Medicines Verification Organisation (EMVO) was created as a joint initiative of EU stakeholders, representing manufacturers (Medicines for Europe, EFPIA, EAEPC), wholesalers (GIRP) and community pharmacists (PGEU) to deliver the European Medicines Verification System (EMVS) – the EU system at the centre of medicines authentication. The establishment of EMVO is mandated by EU law, specifically the FMD.

IMVO

Like EMVO, the establishment of the Irish Medicines Verification Organisation (IMVO) is mandated by EU law. Pharmaceutical manufacturers and marketing authorisation holders are obliged to set up, and fund, a not-for-profit legal entity to manage each national repository across the EU. In Ireland, IMVO is the relevant organisation. Its founder members include; the Association of Irish Pharmaceutical Parallel Distributors (AIPPD); the Irish Pharmaceutical Healthcare Association (IPHA); the Irish Pharmacy Union (IPU); Medicines for Ireland (generics industry); and the Pharmaceutical Distributors

Figure 1: **Safety features**

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 is working with the Health Products Regulatory Authority (HPRA) to ensure that the Irish national system meets the highest regulatory standards. Other important stakeholder organisations for the 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 is now the IMVO General Manager. Now that the IMVO is up and running, Leonie and her team are responsible for delivering the Irish Medicines Verification System (IMVS).

Manufacturers

While wholesalers and pharmacists connect to their national system, i.e. the IMVS, manufacturers and marketing authorisation holders (MAHs) connect to the European system, i.e. the EMVS.

Pinewood Healthcare

Pinewood Healthcare is a manufacturer of liquids, creams, ointments, and powders for the pharmaceutical and medical industries in Ireland and international markets. Discussing their preparation for 9 February, Jeffrey Walsh, Head of Sales with Pinewood, said, "Our preparations are highly advanced from both a manufacturing and wholesale point of view. Considerable expense has been outlaid to facilitate updating production lines, as well as utilising third party sources to implement the FMD. In relation to wholesaling, we will be decommissioning and verifying for some customers, so effectively these projects have required additional resources while at the same time minimising the effect on everyday business. We have installed new IT platforms and additional working capital has been deployed to secure extra stock to avoid and minimise the impact of stock outages as 9 February approaches. In parallel, we are working extremely hard with our contract manufacturers to make sure that all future stock, which has and will be confirmed for manufacture and scheduled to be delivered to Pinewood, will of course have tamper proof seals and 2D barcodes in order to be compliant with the FMD legislation."

PCO Manufacturing

PCO Manufacturing is a parallel importer of pharmaceutical products into Ireland. Derek Colman, Consultant Project Manager for PCO Manufacturing, explains, "The Falsified Medicines Directive is arguably the largest and most complex project ever undertaken by the European Pharma Supply Chain and, for Parallel Distributors (PD), the complexity is even greater. As a repackaging facility, bound by the principles of Good Manufacturing Practice (GMP), we perform all of the FMD operations of a manufacturer (i.e. pack serialisation, tamper evidence and the upload of batch data to the European Hub). In addition, we must also capture and verify the safety features on each pack of medicine imported in order to facilitate our production process.

"In early 2016, PCO developed a comprehensive project plan in order to properly prepare for, and achieve, FMD compliance by the 9 February 2019 implementation date. The identification of production serialisation machinery, and the design and integration of appropriate software, was at the forefront of this plan. However, the development of the project has impacted on almost every department within the company through process changes.

"Another aspect is that PCO is both a manufacturer and a wholesaler which means that not only did we require software systems to enable connection to the European Hub (EMVO) but we also required a software system to connect to the Irish national database (IMVS). Easy FMD software has allowed us to do this seamlessly.

"PCO was one of the first MA holders to achieve a live connection to the EU Hub. On 30 May 2018, following two years of hard work and dedication by our superb multi-functional team, PCO very proudly became the first Irish MA holder to serialise and upload a batch onto the EU hub.

"While the uploading of our first batch to the EU Hub was certainly a significant milestone to celebrate, we very quickly realised that this was but a small step on the road to FMD compliance of our full portfolio of over 600 products. The process has been challenging and time-consuming, particularly in the following areas:

- We have had to amend the packaging of each one of those products through variations to the HPRA/EMA and packaging redesign. This follows through to the amendment of our repackaging processes for each of those products;
- We estimate that FMD will increase our average repackaging cost by 50%; and
- The challenge of the implementation of our new FMD machinery into our repackaging processes which are already quite automated.

"Now, as we return to work for the new year, we have an incredibly busy five weeks ahead of us as we approach D-Day of 9 February. We are confident, however, that our efforts will not be in vain. Our portfolio will be FMD compliant and we will be in a position to continue to provide our excellent service to our extensive and loyal customer base."

AstraZeneca

AstraZeneca

Fintan McKearney, IS / IT Manager, explains the AstraZeneca approach and raises some concerns, "The AstraZeneca programme to comply with the EU FMD was kicked off in October 2015. Our capital investments within the broader Global Traceability Programme are in the range of over $200 million by 2020, which includes line upgrades and IT systems. The EU FMD programme alone includes review and changes of 2,300 SKU's, 32 markets and 90 packaging lines

"Furthermore, 70+ professionals across all EU markets have been trained in preparation of GoLive, and further training and internal and external communication is planned for early 2019, including the creation of an external web page.

"Our primary concern short-term, is that the number of alerts from pharmacies we may expect are extremely hard to predict, and could be very high in some countries. This may lead to an initial surge in alert investigations, which we predict could grow during the initial six months post-GoLive, as more serialised packs start to reach pharmacies. We are confident all our efforts will ensure the successful launch and implementation of the EU FMD."

Wholesalers

In accordance with Article 23 of the Regulation, a wholesaler may verify and decommission medicinal products before it supplies that product to an institution other than a dispensing hospital or pharmacy, e.g. dispensing doctors.

UnitedDrug

United Drug Ireland (UDI

Cormac O'Callaghan, Head of Information Technology at United Drug Ireland (UDI), explains some of the technical and process implications of the Regulation, "UDI, as part of the McKesson Group, has been actively developing an integrated platform between our ERP (an IT system to manage core business processes) and warehouse systems to facilitate the identification of products, suppliers and customers within our warehouse environments to allow for:

- Verification of products where appropriate;
- Supply for our Article 23 customers; and
- Decommission of products where necessary.

"The changes implemented to our full line wholesale and pre-wholesale have been significant and have brought about new challenges with the extra handling required for the millions of medicinal packs that are managed and distributed to our customers. These challenges have been overcome with changes to our systems, infrastructure and our operational processes.

"We recognise the significance of what will be delivered on 9 February, but we also recognise that this is the start of a transition into our new supply chain, where serialisation becomes the standard and we are cognisant of the new challenges that may arise as the FMD processes are embedded and matured into our industry,

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which can only happen with the continued collaboration between all parties involved in such a critical supply chain."

Community pharmacies

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).

The IPU provided all pharmacy members with a 2D barcode reader, supplied in November 2018 by a company called AIS Limited. 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.

Scanning

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.

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, Dispensing Process 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.

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. 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.

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.

Support

As set out in this article, 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.*

IPU FAQ and Checklist

For more information, read the IPU Medicines Authentication FAQ and Checklist on our website: www.ipu.ie > Professional > SOPs and Guidelines > Medicines Authentication.