IRISH MEDICINES VERIFICATION ORGANISATION

Corporate Strategy

2025-2027

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Our Origins and Role

We are a non-profit organisation mandated by EU law

Since the Irish Medicines Verification Organisation (IMVO) was established in 2017, our raison d'être has been patient safety and service to others.

Uniquely, we are a private organisation that operates on a non-profit basis under a mandate defined in EU law, notably the EU Falsified Medicines Directive (2011/62/EU) ['FMD'] and Commission Delegated Regulation (EU) 2016/161 ['Delegated Regulation'].

We operate the Irish Medicines Verification System (IMVS), thereby assuring patients of the authenticity of prescription medicines they receive in the Irish healthcare system. Pharmacies, hospitals and wholesalers of prescription medicines in Ireland are connected to the IMVS. Marketing authorisation holders (MAHs) upload data for prescription medicines placed on the Irish market to the IMVS. IMVO provides a range of supports to these IMVS users to help them meet their FMD obligations. IMVO doesn't have any regulatory or enforcement functions.

Our Origins and Role

In addition to protecting patients in Ireland from the threat of falsified medicines being supplied through legitimate channels, we support the Health Products Regulatory Authority (HPRA) in their important work of detecting and preventing falsified medicines in this country.

IMVO's founding members represent the end-to-end prescription medicines supply chain in Ireland:

- Affordable Medicines Ireland, representing parallel distributors
- Irish Pharmaceutical Healthcare Association, representing manufacturers of innovative medicines
- Irish Pharmacy Union, representing community pharmacists
- Medicines for Ireland, representing manufacturers of generic and biosimilar medicines
- Pharmaceutical Distributors Federation, representing full-line wholesalers

IMVO works closely with the Department of Health, HPRA, PSI (The Pharmacy Regulator), Health Service Executive (HSE) and Private Hospitals Association Ireland via the 'Safety Features Oversight Group' to oversee implementation of FMD in Ireland

“We operate the Irish Medicines Verification System (IMVS), thereby assuring patients of the authenticity of prescription medicines they receive in the Irish healthcare system.”

The EMVS

We are part of the European Medicines Verification System (EMVS)

IMVO is part of a robust pan-European verification system established on foot of the EU Falsified Medicines Directive (FMD).

Every country in the European Economic Area (EEA) is required to have in place a national medicines verification system (NMVS), which is managed by a national medicines verification organisation (NMVO).

All the national systems across Europe are connected via an 'EU Hub', which is managed by the European Medicines Verification Organisation (EMVO).

The EU Hub and national systems, including the IMVS, collectively constitute the 'European Medicines Verification System' (EMVS).

Further information about the EMVS is available in Annex I.

Our Environment

The world in which IMVO and its members and IMVS users operate has changed significantly since 2021 when our first Corporate Strategy was finalised, and continues to evolve bringing new challenges and opportunities. We operate in a volatile, uncertain, complex and ambiguous environment. Agility is key to delivering our remit in an environment where patient needs and expectations continue to become more individualised.

Digitalisation

The Covid pandemic has accelerated digital transformation nationally and internationally, not just in private organisations but also in public bodies and throughout the healthcare system. The Department of Health's 'Digital for Care: A Digital Health Framework for Ireland 2024-2030' sets out a clear ambition to digitally transform health services in Ireland and improve access for patients.

Cyber Security

Events like the HSE cyber attack in 2021 illustrate very starkly, the downsides of our reliance on the digital world and the ever-increasing likelihood and impact of cyber attacks.

Sustainability

Climate change, dwindling natural resources, and growing demands on energy supply are disrupting business operations and supply chains in unexpected ways and present new challenges and opportunities.

Our Environment

Illegal Supply of Medicines

Most cases of falsification have been detected in the illegal supply chain (often via unauthorised sales on the Internet). This is a significant concern given the large number of medicines in circulation outside the legal supply chain in Ireland, which do not offer the authenticity assurances of those subject to FMD controls.

Medicine Shortages

The problem of medicines shortages does not show any signs of abating despite ongoing efforts of all stakeholders to find solutions. Our collective efforts will be required to find innovative solutions.

Brexit

The legacy of Brexit continues. The implementation of the Windsor Framework from 1 January 2025 could impact on medicines supply in Ireland and affect user confidence in the IMVS.

New Roles and Laws

Other changes will come from the current review of the EU pharmaceutical legislation and the planned expansion of pharmacist roles in Ireland as part of moves to enhance primary care and patient access to services.

IRISH MEDICINES VERIFICATION ORGANISATION

Corporate Strategy

2025-2027

Our Progress to Date

Our first Corporate Strategy adopted in 2021 focused internally on achieving operational excellence within the IMVS and within IMVO as an organisation. It also clearly articulated that IMVO's purpose is to protect patients in Ireland from falsified medicines by operating the IMVS.

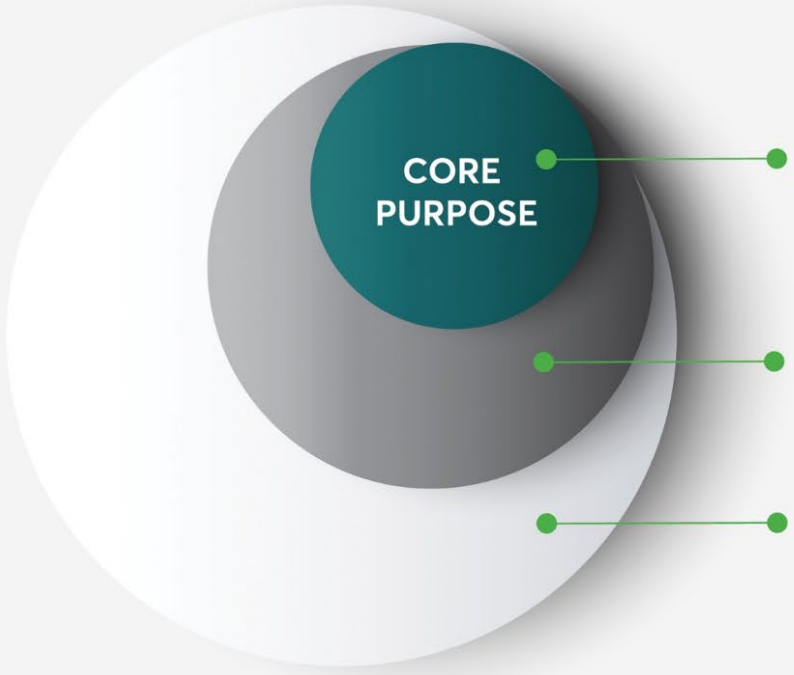
An important priority was how IMVO could support IMVS users beyond our core role of running the IMVS, particularly when the initial 'use and learn' phase of the FMD rollout in Ireland ended in May 2022.

Our first strategy has been largely delivered as intended:

- IMVO as an organisation has matured with well-developed systems and processes managed by a highly skilled team. We are recognised as a valued, independent voice and contributor in Ireland and across the EMVS network
- The EMVS (incorporating the IMVS) has now reached steady state and proven itself to be highly stable and reliable
- Alert rates in Ireland have fallen consistently in the last two years due to significant efforts by all parties to minimise avoidable procedural and technical alerts
- Scanning rates remain lower than desired however steady progress is being made

Our Purpose

Protecting Ireland's patients from falsified medicines by operating the IMVS



TO OPERATE THE IMVS

- To operate and manage the IMVS
- To ensure that all alerts are investigated
- To work with the EMVO and other NMVOs to ensure the seamless operation of the EMVS

ENABLE AND SUPPORT OUR STAKEHOLDERS USING THE IMVS

- To provide end-users and MAHs with the support and resources they require to use the IMVS and manage alerts seamlessly

ADD VALUE TO OUR STAKEHOLDERS

- To identify ways in which IMVO and the IMVS can add value for IMVO members, IMVS users, patients and other stakeholders

What We Can Offer

1. **Collaborative Networks**
   Critical to the successful rollout of the EMVS across Europe has been the deep collaboration across diverse stakeholders at national and EU level. We value pooling resources, building supportive, trusting relationships with stakeholders and minimising the potential to reinvent the wheel. Healthcare in Ireland is moving towards a whole-of-system approach underpinned by enhanced integration. We can help support this process by sharing insights and experiences in building a truly collaborative ecosystem.

2. **Systemic Insights**
   Our daily engagement with pharmacies, hospitals, wholesalers and pharmaceutical companies gives us a unique insight into how the medicines supply chain is operating in Ireland, the practical challenges of medicines shortages, the fragmented nature of IT systems and the challenges of high administrative burdens across the supply chain.

3. **Expertise in Complex IT Project Rollout**
   We have a wealth of knowledge acquired from our experience of rolling out a large and complex IT project within tight deliverables. We are happy to share our experience to help others involved in digital transformation projects operating within the medicines supply chain and healthcare ecosystem.

What We Can Offer

4. **Support for Sustainability in The Medicines Supply Chain**
   We operate in a world of finite resources. Committing to being sustainable requires careful stewardship to optimise outcomes, increase productivity and reduce waste. Being proactive in terms of sustainability represents an opportunity to add to the common good. We can help to provide solutions for our stakeholders, including enhancing supply chain efficiency; minimising waste due to expired medicines; supporting automation of administrative tasks and leveraging the 2D barcoding infrastructure.

5. **A Neutral and Collaborative Space**
   We offer our members a neutral and collaborative space, independent of commercial considerations, to work together and with other key stakeholders to solve common problems and enhance the security and sustainability of the medicines supply chain as well as patient safety and outcomes.

Our Strategic Direction

Moving from implementation to operational excellence and beyond

“Our new Corporate Strategy 2025-2027 aims to expand IMVO’s offering while staying true to our purpose of protecting patients in Ireland from falsified medicines by operating the IMVS”

Introducing Our New Strategy

Our new Corporate Strategy 2025-2027 is the result of significant reflection within the IMVO Board and consultations with our members and key external stakeholders, including the Department of Health, HPRA and PSI who expressed strong support for the proposed approach. The strategy also takes account of broader discussions within the EMVS community on a future strategy for the EMVS.

Our new strategy aims to expand IMVO's offering while staying true to our purpose of protecting patients in Ireland from falsified medicines by operating the IMVS. The ambition embodied in this new strategy is reflected in our updated vision and mission:

Vision:

A secure and sustainable supply chain where patients are confident about the authenticity of prescription medicines they receive in the Irish healthcare system

Mission:

We manage the IMVS to assure patients about the authenticity of their prescription medicines and we harness IMVO's potential to enhance the security and sustainability of the legitimate supply chain

Introducing Our New Strategy

Over the lifetime of this strategy, operating the IMVS and supporting IMVS users will remain key priorities for IMVO, as will our commitment to operational excellence, recognising that the bar for this is constantly rising.

The key change in this new strategy is that we will build on the firm foundations now in place to further support patient safety and supply chain efficiency. We want to explore how to harness our current strengths and the opportunities offered by our changing environment for the benefit of our members, IMVS users and wider stakeholders, including patients. We want to leverage our knowledge, expertise and influence to become a trusted voice for change.

We will plan our activities around four strategic pillars to deliver on our mission and achieve our vision:

1. **Patient Safety**
2. **Partnership**
3. **Leadership**
4. **Excellence**

Our Corporate Strategy Summary

PURPOSE: Protecting patients in Ireland from falsified medicines by operating the IMVS

VISION: A secure and sustainable supply chain where patients are confident about the authenticity of prescription medicines they receive in the Irish healthcare system

MISSION: We manage the IMVS to assure patients in Ireland about the authenticity of their prescription medicines and we harness IMVO's potential to enhance the security and sustainability of the medicines supply chain

STRATEGIC PILLARS: Patient Safety | Partnership | Leadership | Excellence

VALUES: Trust | Collaboration | Ambition | Agility | Innovation

“The key change in this new strategy is that we will build on the firm foundations now in place to further support patient safety and supply chain efficiency”

Our Strategic Pillars

1. Patient Safety

- Work with other NMVOs, EMVO and our NMVS supplier to enhance the robustness, reliability and security of the EMVS
- Ensure that IMVS users are equipped and supported to meet their FMD obligations seamlessly
- Identify opportunities in collaboration with other stakeholders to support increased scanning rates in Ireland
- Support the HPRA and PSI in their role of supervising compliance with FMD. We will also support the HPRA in its investigations into illegal and falsified medicines
- Seek to mitigate the FMD impacts of Brexit and other external developments on the supply of prescription medicines in Ireland
- Optimise use of the IMVS's capabilities to manage recalls and withdrawals and to identify stolen medicines in Ireland
- Increase awareness amongst policy makers of IMVO's role in assuring the authenticity of prescription medicines supplied to patients in the Irish healthcare system

Our Strategic Pillars

2. Partnership

- Continue to work closely with other NMVOs and EMVO to support harmonisation of common processes and sharing of knowledge and expertise to optimise use of resources
- Explore how IMVO can contribute to addressing the problem of medicines shortages
- Identify ways in which IMVO can support the Department of Health, HPRA, PSI and HSE in achieving their strategic goals
- Share our expertise in change management and digital transformation projects to support the rollout of the Digital Health Framework for Ireland and ICT initiatives in the healthcare system
- Support the HPRA, patient organisations and other relevant bodies in raising public awareness of how to source medicines safely

Our Strategic Pillars

3. Leadership

- Work to bring about meaningful strengthening of EMVS governance and agreement on robust and ambitious long-term strategic plans for the EMVS
- Build our expertise and networks to become a highly trusted source of knowledge about medicines verification
- Establish a multi-stakeholder supply chain forum to identify and advocate for enhancements in supply chain security, efficiency and sustainability
- Work with policy makers, EMVS colleagues and other stakeholders to explore the use of barcodes for the benefit of supply chain partners and patients
- Explore how IMVO can work within the scope of the Delegated Regulation with policy makers and other relevant bodies to address public health challenges in Ireland
- Consider partnerships with academic institutions to build an evidence base for new projects and activities

Our Strategic Pillars

4. Excellence

- Keep under review the optimal organisational design and funding model for IMVO to support delivery of our strategy
- Optimise our ability to attract and retain high calibre staff by supporting employee development, diversity, well-being and by offering purposeful work
- Enhance our operations through digital transformation, to streamline processes and improve overall effectiveness
- Enhance IMVO's security posture to mitigate the risk of cyber-attack and threats to data integrity
- Develop and implement an 'Environmental, Social and Governance' (ESG) plan

Our Values

We build trust through our commitment to integrity, transparency, and respect for everyone involved. Our dependable and effective medicines verification system is designed to be trusted and appreciated by all users, including patients

We work collaboratively with all our stakeholders and the systems we are part of and that we depend upon to deliver our ambition

We harness our expertise and networks, push boundaries and strive for excellence to improve the medicines verification eco-system for all our stakeholders

We are future focused and continuously adapt to our changing dynamic environment to meet the needs of our stakeholders

We strive to deliver value for stakeholders and staff by having an innovative and creative learning culture

Implementing Our Strategy and Measuring Success

- The implementation of this strategy will be monitored and reviewed by the IMVO Board and Chief Executive
- The four strategic pillars in the strategy and associated activities will underpin our annual business plans which are approved by the Board. These plans will include KPIs and timelines for implementation and be aligned with the Board's risk appetite
- The delivery of these business plans will be central to the achievement of this strategy
- We will continually gather information on the needs of IMVS users and other IMVO stakeholders to ensure operational excellence and responsiveness to emerging challenges
- The strategy will be adapted as needed if we are required to undertake an unplanned stream of work or to adapt to any unexpected changes in our environment

Annex I – Further Information on the EMVS

How the EMVS operates

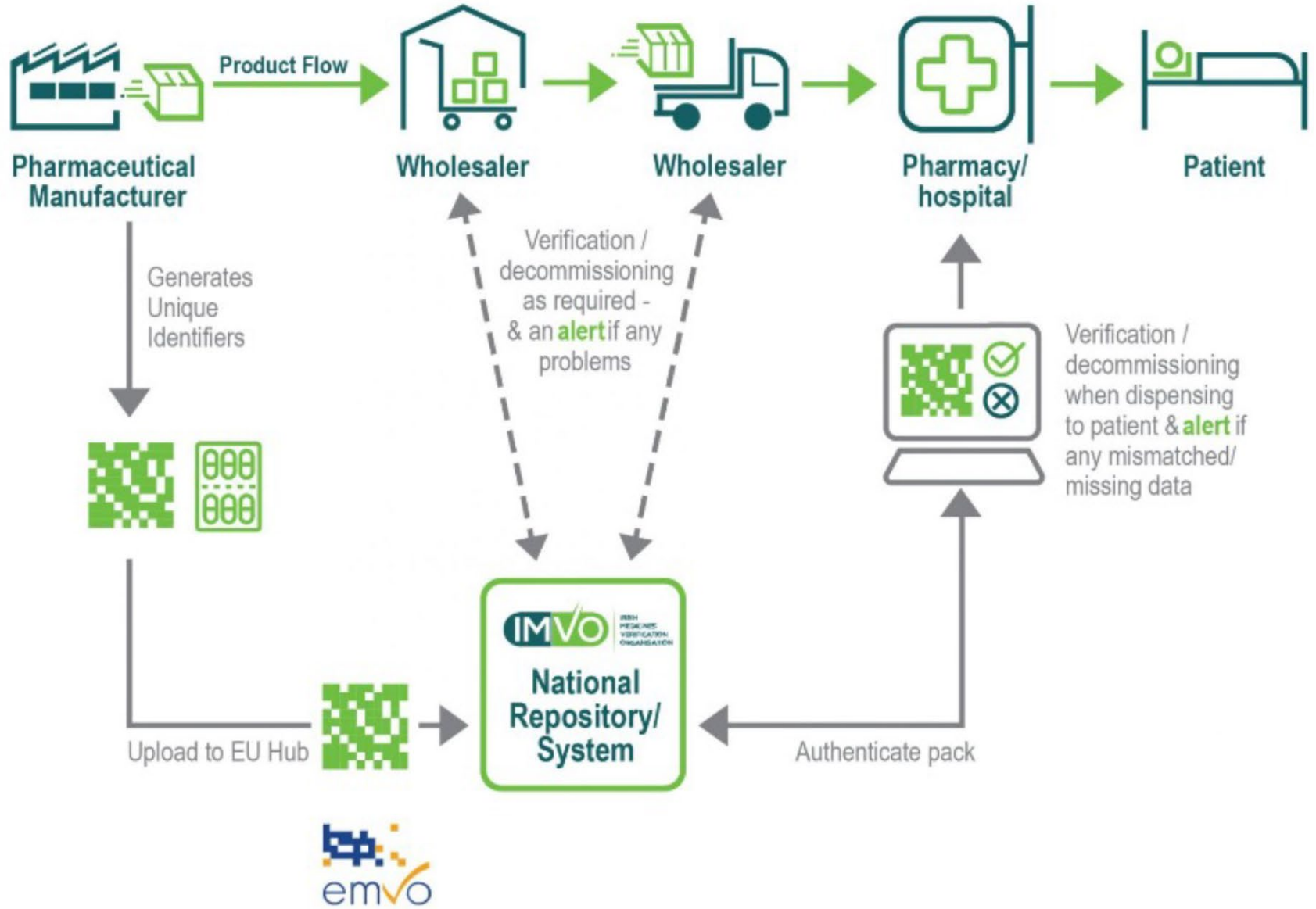
The Falsified Medicines Directive was a groundbreaking piece of EU legislation.

It introduced several fundamental measures to prevent falsified prescription medicines infiltrating the legal supply chain and from reaching European patients. These included a requirement for safety features on medicines packs - an anti-tampering device and a 2D barcode containing information about the medicine known as 'unique identifiers' (product code, batch identifier, expiry date and unique serial number).

The 2D barcodes on packs are scanned at different points in the supply chain and the data is checked against the data held in the EMVS, enabling the authenticity of the pack to be verified prior to supply to a patient.

If the details are not found or the status of the pack doesn't match the information in the EMVS, an alert is generated. The matter is investigated to establish if the alert could be due to a technical or procedural error. If no root cause can be found, the pack is considered to be a 'suspected falsification' and the matter is escalated to the relevant national competent authority for follow-up, i.e. the HPRA in Ireland.

Ownership of and access to data stored in the EMVS, including the purposes for which it may be used by national competent authorities is defined in the Delegated Regulation.


Product Flow
Pharmaceutical Manufacturer
Wholesaler
Wholesaler
Pharmacy/ hospital
Patient
Generates Unique Identifiers
Verification / decommissioning as required - & an alert if any problems
Verification / decommissioning when dispensing to patient & alert if any mismatched/ missing data
National Repository/ System
Upload to EU Hub
Authenticate pack
emvo

End-user transactions per annum*

14 billion in EMVS

100 million in IMVS

Number of connected users – EMVS and IMVS*

COMMUNITY PHARMACIES

115,000 1,900

WHOLESALERS

4,000 85

MARKETING AUTHORISATION HOLDERS

3,000 380

HOSPITALS

6,700 100

*Numbers provided are rounded and vary from time to time

Annex II – Glossary

EMVO
European Medicines Verification Organisation

EMVS
European Medicines Verification System (comprising EU Hub and all connected national systems including the IMVS)

End-users
Pharmacies, hospitals, wholesalers and other persons authorised or entitled to supply medicines to the public who are connected to the IMVS to verify and decommission medicines bearing 2D barcodes

Delegated Regulation
Commission Delegated Regulation (EU) 2016/161

FMD
Falsified Medicines Directive (Directive 2011/62/EU)

HPRA
Health Products Regulatory Authority

HSE
Health Service Executive

ICT
Information and Communications Technology

IMVS
Irish Medicines Verification System (which is part of the EMVS)

Annex II – Glossary

IMVS users
All parties who use the IMVS – end-users, MAHs and designated national competent authorities, e.g. HPRA

MAH
Marketing authorisation holder

NMVO
National medicines verification organisation

NMVS
National medicines verification system

PSI
Pharmaceutical Society of Ireland (The Pharmacy Regulator)

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