IRISH MEDICINES VERIFICATION ORGANISATION

Corporate Strategy 2021-2023

Taking Stock and Affirming Direction

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Contents

Introduction

Protecting Irish patients from falsified medicines is what IMVO is all about. We have achieved much since our formation in 2017, including setting up the IMVS and connecting over 2000 pharmacies, hospitals and wholesalers, as well as onboarding over 300 MAHs whose pack data is hosted in the IMVS. Prioritising governance in a time of set up has provided a framework that has facilitated compliance with our legal obligations, strong working relationships between the IMVO team and the Board, and strong relationships with the Department of Health, HPRA, PSI, HSE, other national medicines verification organisations and EMVO.

The Board's commitment to collaboration in delivering IMVO's legal mandate fuels our ambition as evidenced by this, our first Corporate Strategy.

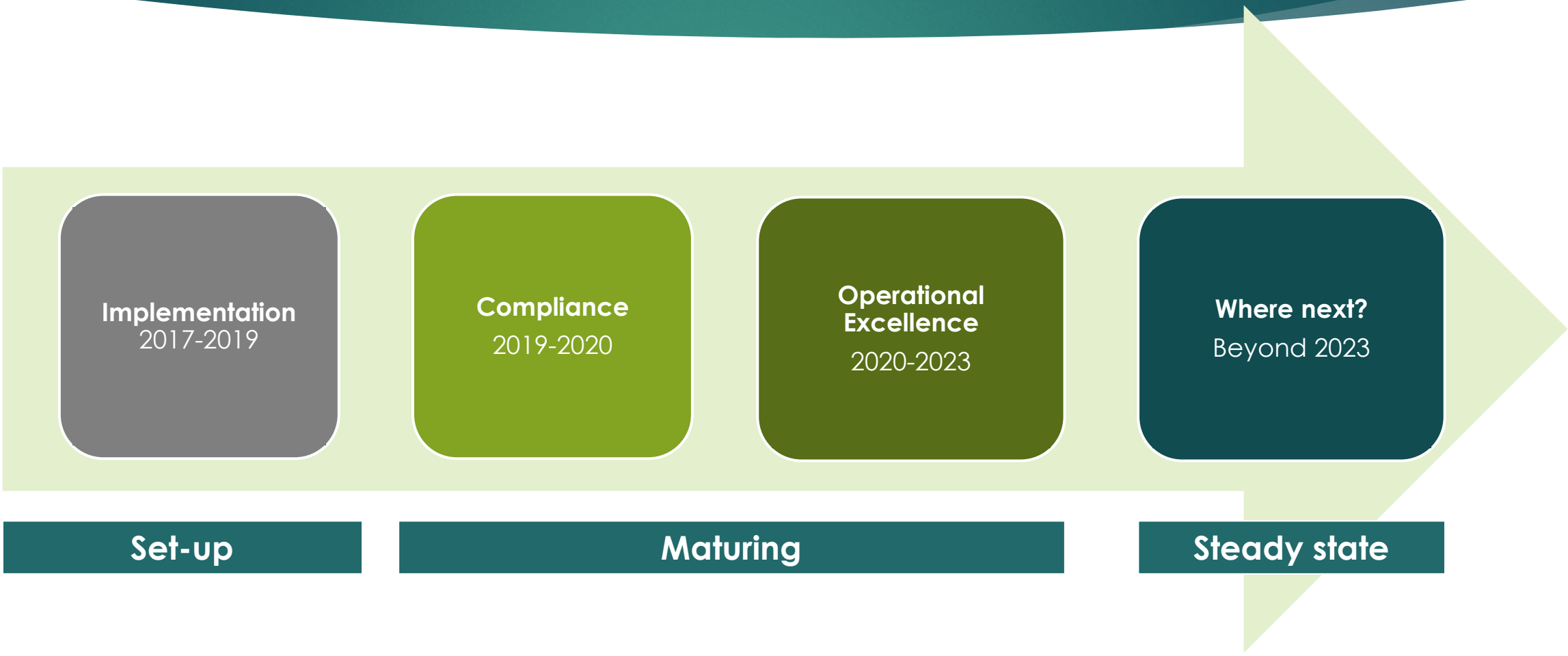
The focus for the next 3 years is to move from compliance to operational excellence. Our vision for operational excellence is all encompassing, going beyond systems and processes, to ultimately developing a culture that consistently delivers value to our members, employees, and IMVS users through excellence in everything we do. This will be important as we support IMVS users in moving out of 'use and learn' and meeting their FMD obligations in full. We believe we must focus on 4 key areas to deliver operational excellence:

- Strong governance
- System stability & usability
- Patient safety & alert management
- Partnerships & collaboration

We envision the IMVO of the future as a collaborative, trusted partner supporting the Irish healthcare system in protecting Irish patients from falsified prescription medicines and working seamlessly with EMVO and other NMVOs to deliver an integrated pan-European verification system.

IMVO Strategic Direction

Moving from implementation to operational excellence & beyond



Corporate Strategy Overview

Vision

To support an environment where patients are confident about the authenticity of prescription medicines they receive in the Irish health care system

Purpose

To protect Irish patients from falsified medicines

Values

Trusted	Accessible	Collaborative	Excellence	Agile	Creative

Mission

To operate and manage the IMVS on behalf of our members so that end-users and MAHs can fulfil their legal obligations under the Falsified Medicines Directive and protect Irish patients from falsified medicines

Corporate Goals

To manage and operate an efficient, reliable, easy to use trusted verification system for Irish end-users within the EMVS	To support end-users and MAHs to use the IMVS and manage alerts generated from the system

Proposition

Operational excellence

To develop a culture that consistently delivers value to our members, employees, and IMVS users through excellence in everything we do

Strategic Pillars

Strong governance	System stability & usability	Patient safety & alert management	Partnership & Collaboration

IMVO Purpose

To protect Irish patients from falsified medicines

Add value	• To identify ways in which IMVO and the IMVS can add value for IMVO members, IMVS users and patients
Enable & Support	• To provide end-users and MAHs with the support and resources they require to use the IMVS and manage alerts seamlessly
Core Purpose: Operate IMVS	• To operate and manage the IMVS • To ensure that all alerts are investigated • To work with EMVO and other NMVOs to ensure seamless operation of the EMVS

IMVO Mission

To operate and manage the IMVS on behalf of our members so that end-users and MAHs can fulfil their legal obligations under the Falsified Medicines Directive and protect Irish patients from falsified medicines

WHAT IMVO DOES (services it provides)	HOW IMVO DOES IT (approach)
• We operate and manage the IMVS that enables the authentication of medicinal products.	• We monitor operation of the system and track key metrics, including alerts. • We take action to ensure that FMD considerations are adequately addressed for matters such as Brexit and Covid-19 vaccines rollout.
• We work with other NMVOs and EMVO to support the operation of the EMVS as single integrated system.	• We work with SSR and the SSR CG to maintain a single build of the SSR national system which is fit for purpose and constantly improved. • We are a significant contributor to EMVO groups and activities.
• We work collaboratively with end-users and MAHs to help them understand and meet their legal obligations.	• We provide information and support on connecting to the IMVS (end-users) & registering with and paying fees to IMVO (MAHs). • We define requirements for, and certify, end-users' FMD software. • We provide technical support to end-users.
• We ensure that all alerts are investigated.	• We work with stakeholders to develop alert management guidance that clearly defines roles and responsibilities for all parties. • We support alert investigation activity. • We implement 'NMVS Alerts' to facilitate easy communications between parties involved in an alert.
• We work with the DoH, HPRA, PSI, HSE, Private Hospitals Association individually and collectively in the Safety Features Oversight Group to ensure a cohesive approach to FMD implementation in Ireland.	• We put forward proposals and recommendations on matters such as use & learn. • We provide information to support decision making and co-ordinate implementation of the Group's decisions. • We provide whatever support the PSI and HPRA request for enforcement activities.

IMVO Values

Trusted	Accessible	Collaborative	Excellence	Agile	Creative
To operate a reliable and efficient medicines verification system that is valued and trusted by all who use it and by other stakeholders, including patients To act with integrity in everything that we do	To ensure end-users and MAHs have ready access to our services in order to allow them to be compliant with FMD obligations To ensure the IMVS is continually available to support medicines authentication	To achieve our objectives by working collaboratively and in partnership with our members, end-users and MAHs, other national stakeholders, other NMVOs and EMVO	To aim for excellence in everything we do	To continuously adapt to changing end-user/ MAH dynamics, regulatory requirements, changing technology and work practices	To adopt a creative mindset when solving problems and engaging with our members and other stakeholders

Operational Excellence Proposition

Operational excellence

A culture that consistently delivers value to our members, employees and IMVS users through excellence in everything we do

EMVS	IMVO	End-Users & MAHs	Alert Management
• The EMVS (including the IMVS) has matured and is operating smoothly • New functionality successfully rolled out, e.g. aggregation, alert management Hub • Brexit no longer causing any issues	• IMVO is ranked in the top tier of NMVOs in Europe • IMVO is trusted by its stakeholders • Highly skilled, high performing team • Processes and record keeping are automated to the fullest extent possible • Support queries to IMVO are managed promptly and consistently • Highly effective QMS • Future-planning focused • Paid for services offered	• Scanning medicines is a seamless part of pharmacy, hospital and wholesaler operations, and many of them are using the scans for other purposes • End-users and MAHs know exactly where to get help quickly if problems arise • Simple processes for end-users and MAHs to register and maintain their IMVO accounts (including online self-service portal)	• End-users and MAHs are comfortable managing alerts that arise, with minimal disruption for patients and the supply chain • Alert communications between all the relevant parties are managed via easy to use alert management system • Technical/system/data errors and alerts are rare • Falsified medicines that find their way into the supply chain are identified ('real' alerts)

Strategic Pillars to Deliver Operational Excellence Proposition

Operational excellence

A culture that consistently delivers value to our members, employees and IMVS users through excellence in everything we do

Strong governance	System stability & usability	Patient safety & alert management	Partnership & collaboration
• Maintain strong governance in IMVO • Ensure organisational resilience as people change • Review HR Strategy to ensure IMVO is an attractive employer • Optimise processes & QMS • Value for money	• Improved end-user experience. • Prioritise and enhance EMVS integration & interoperability. • Identify areas for enhancing system stability and maturity. • Ensure system has capacity to cope with changes in capacity demands and new functionality. • Ensure data integrity	• Ensure end-users and MAHs are ready for end of use & learn to minimise disruption for them and patients • Support speedy resolution of alerts by all parties in supply chain, including rollout of NMVS Alerts & integration with EMVS alert management Hub • Continue efforts to eliminate avoidable alerts • Raise awareness amongst general public of role of safety features in assuring that their medicines are genuine	• Communicate effectively with our members & IMVS users • Maintain strong relationships with DoH, HPRA, PSI and other such stakeholders • Collaborate with EMVO & NMVOs to build the EMVS community & strong EMVS governance • Identify opportunities to work with other NMVOs & EMVO to reduce duplication of effort • Identify opportunities to add value for members, end-users & MAHs

Terminology

Term	Details
EMVO	European Medicines Verification Organisation
EMVS	European Medicines Verification System (comprising EU Hub & all national systems)
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 & decommission medicines bearing 2D barcodes
FMD	Falsified Medicines Directive
IMVS	Irish Medicines Verification System (which is part of EMVS)
IMVS users	All parties who use the IMVS – end-users and MAHs
MAH(s)	Marketing Authorisation Holder(s) whose pack data is hosted in IMVS
NMVO(s)	National medicines verification organisation(s)
NMVS	National medicines verification system
SSR	Solidsoft Reply - supplier of the IMVS
SSR CG	Solidsoft Reply Customer Group – grouping of NMVOs who use the SSR NMVS

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