FMD Use and Learn Period in Ireland to End on Phased Basis from 31st January 2020

Introduction

The National Safety Features Oversight Group comprising the Irish Medicines Verification Organisation (IMVO), the Department of Health, the Health Products Regulatory Authority (HPRA), the Pharmaceutical Society of Ireland (PSI), the Health Service Executive (HSE) and the Private Hospitals Association (PHA) continues to meet regularly to monitor implementation of FMD in Ireland. Excellent progress has been made in all sectors over the last few months:

1. The alert rate (number of alerts vs number of scans) has fallen from a high of 20% to 1.6%.
2. The understanding of the root causes of alerts and how to eliminate avoidable errors has increased significantly. The information gathered from all the scans and alerts generated to date has been crucial for this to happen.

All alerts generated in pharmacies, wholesalers and hospitals, upon scanning a pack during the use and learn period, are forwarded by the system to the IMVO, the HPRA and the manufacturers/MAHs so that they can be investigated, monitored and resolved.

Ending of use and learn period

The use and learn period will end on a phased basis **starting from 31st January 2020**.

Planning for the end of 'use and learn' will continue over the coming weeks. The Safety Features Oversight Group, taking into account all relevant factors, will determine the different phases and communicate details to affected parties.

What am I expected to do now?

Advice issued in previous communications about 'use and learn' still applies:

1. ***Manufacturers:***
   - Ensure all packs that are in scope of the FMD requirements released to the market since 9th February **bear safety features**, i.e. 2D barcode and anti-tamper device.
   - **Data** for all serialised packs, including those placed on the market before 9th February, must be **uploaded** to the national system via the EU Hub.
   - Co-operate with all requests for **further information relating to alerts**.
2. ***Wholesalers, pharmacies and hospitals:***
   - Ensure your FMD system(s) is **connected to the IMVS** and working correctly.

- **Scan medicines bearing safety features** in accordance with the obligations to verify and decommission packs placed on wholesalers, pharmacies and hospitals by the Commission Delegated Regulation on Safety Features and Irish national legislation (see also IMVO website for guidance)**.** The data generated from these scans is critical for identifying root causes of alerts and other issues that need to be resolved in order to ensure an orderly ending of the use and learn period, with minimal disruption to end-user workflow and patient supply.
- If an alert or any other unexpected message is flagged, **continue to supply packs** in accordance with your existing procedures, unless there are overriding concerns that a falsified medicine is involved.
- Notwithstanding the above, if you have reason to believe that packaging has been interfered with, based on your examination of the anti-tamper device or anything else unusual with the pack or its contents, you must **report this concern to the HPRA as a suspected quality defect** (via the usual reporting mechanisms) and not supply the pack.
- **Pharmacies with wholesaler's authorisations** are reminded that they require a **separate registration with IMVO and connection to the national system** for their wholesaling activities. The pharmacy connection to the national system must not be used for wholesaling activities (and vice versa).
- Co-operate with all requests for **further information relating to alerts**.

After the use and learn period ends, every single alert will have to be investigated and the risk of the pack being falsified must be ruled out before it can be supplied. It is therefore critical to ensure that all avoidable alerts are eliminated early before the use and learn period ends to minimise disruption for everyone, especially patients. To achieve this objective, all parties are requested to intensify efforts now to address issues that are causing alerts and errors, such as:

- Pack data for FMD packs not correctly uploaded by MAHs to the national system via EU Hub;
- Pharmacy, wholesaler and hospital FMD software issues leading to incorrect barcode data being sent to the national system;
- Scanners incorrectly configured;
- Simple mistakes during scanning such as:
  - Trying to decommission when in verify mode;
  - Decommissioning packs that are already decommissioned;
- Decommissioned packs being returned to wholesalers.

IMVO will work with all groups over the coming weeks to further raise awareness of how to identify and fix these problems. Furthermore, a national procedure will be finalised for managing alerts after use and learn, including detailed guidance on what each party needs to do to investigate and close out an alert. These guidelines will set out the roles and responsibilities of pharmacies, hospitals, wholesalers, MAHs, IMVO and the HPRA, so there is clarity for everyone after the use and learn period ends.

For further information

IMVO
Website: www.imvo.ie
Queries re alerts: alert.support@imvo.ie
Queries re end-user registration/connection to national system: registration@imvo.ie
Tel: +353 1 5715320

HPRA
Website:

- General FMD information: https://www.hpra.ie/homepage/medicines/special-topics/falsified-medicines-legislation
- Reporting product defects: https://www.hpra.ie/homepage/about-us/report-an-issue

Queries: compliance@hpra.ie
Tel: +353 1 6764971

PSI
Website: https://www.thepsi.ie/gns/Pharmacy_Practice/FalsifiedMedicinesDirective.aspx
Queries: info@psi.ie
Tel: +353 1 2184000

EMVO (for manufacturer queries relating to EU Hub & uploading of data)
Website: www.emvo-medicines.eu
Support queries: helpdesk@emvo-medicines.eu
Tel: +372 611 90 44

HSE
Queries re FMD: FMD.support@hse.ie