HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Extension of FMD Use and Learn Period, Ireland, May 2019

Decision to extend 'use and learn' phase

New FMD safety feature requirements came into effect on 9th February. During this time, the system in Ireland has been in 'use and learn' phase to ensure the continuity of safe supply of medicines to patients while all parties gained a better understanding of the new system.

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) has been closely monitoring progress since go live on 9th February. Taking all factors into account, the group has decided that **the use and learn period will be further extended until 9th September 2019** to allow additional time for the system to stabilise. The situation will be reviewed again at that stage.

Progress since go live

Significant progress has been made on several fronts since 9th February:

- The **vast majority of pharmacies, hospitals and wholesalers** have registered with IMVO and are connected to the national system.
- Between **50,000 and 60,000 thousand scans** are taking place daily in Irish pharmacies, hospitals and wholesalers and this number is growing week on week.
- Barcode data for over **100 million packs** has been uploaded to the national system by manufacturers. The number of packs bearing 2D barcodes in pharmacies will increase over the coming weeks and months as these packs work their way through the supply chain.
- Extensive analysis of alerts is taking place across Europe, resulting in greater understanding of their root causes and the rollout of initiatives to reduce the number of alerts being generated.

Alerts

It was anticipated that significant numbers of alerts would be generated by the verification system across Europe after go-live due to technical glitches and other teething problems as the system bedded in. Over 600,000 alerts have been generated in Ireland since 9th February. There are many root causes for these alerts including system bugs, data not uploaded or uploaded incorrectly by manufacturers, as well as actions related to the scanning of packs by pharmacies, hospitals and wholesalers,

including scanner configuration issues, errors in how FMD systems handle barcode data, and the wrong type of barcode or non-FMD packs being scanned.

Across Europe, national medicines verification organisations (NMVOs) – including IMVO, the European Medicines Verification Organisation (EMVO), manufacturers/marketing authorisation holders (MAHs) and bodies representing end-users (pharmacies, hospitals and wholesalers) have been sharing knowledge and experience relating to alerts and how to eliminate them. Actions taken to address the known causes include bug fixes, the issuing of guidance on configuration of scanners and end-user systems, as well as contacts with end-users and manufacturers generating the largest numbers of alerts.

What will happen during the next phase of use and learn?

During the next phase of use & learn, efforts to eliminate avoidable errors will intensify across Europe. Here in Ireland, this will require co-operation between IMVO, pharmacies, hospitals, wholesalers and manufacturers/MAHs. It is expected that all parties will take whatever action they can to support this objective, including co-operating with alert investigations by IMVO and complying with guidance issued by IMVO and regulatory authorities such as the HPRA and PSI. IMVO will not be investigating individual alerts during this period but will continue to focus on trends and unusual events.

The instructions issued at the start of the use and learn period in February will continue to apply during this next phase, i.e.:

1. All medicinal products released by MAHs for the Irish market since 9th February should bear the safety features as required i.e. a tamper proof seal (anti-tamper device) and 2D barcode.
2. Wholesalers, pharmacies and hospitals must scan all medicines bearing the safety features and if an alert or any other unexpected message is flagged, should continue to supply packs to patients in accordance with their existing procedures, unless they have overriding concerns that a falsified medicine is involved.
3. All alerts generated in pharmacies, wholesalers and hospitals, upon scanning a pack during the 'use and learn' phase are forwarded by the system to the IMVO, the HPRA and the manufacturers/MAHs so that they can be investigated and monitored.
4. Notwithstanding the above, if a pharmacist or wholesaler has reason to believe that packaging has been interfered with, based on their examination of the anti-tampering device on the pack, they must report their concern to the HPRA (as a suspected quality defect via the usual reporting mechanisms) and not supply the pack.

National legislation including the provisions of Article 23 of the Delegated Regulation was introduced in February, however, **offences for breaches of the legislation will not be commenced until after the use and learn phase.**

What am I expected to do now?

Wholesalers

Continue with the instructions as outlined at 2-4. above. Additional information obtained since the system went live that may be helpful is detailed below.

- Check that your scanner is correctly configured. If unsure, contact the supplier of the scanner or IMVO for further guidance (email: info@imvo.ie or 01-5715320).
- Start scanning if you haven't already done so but only scan FMD packs. Do NOT scan the following as doing so is likely to generate alerts:
  - Packs **without an anti-tamper device**, even if there is a 2D barcode. The absence of the anti-tamper device is an indicator that the pack is not an FMD pack.
  - **Linear barcode or QR codes**
  - OTC packs that carry 2D barcodes. These are not FMD packs.
  - **Medical devices** that carry 2D barcodes. These are not FMD packs.

  (See Figures 1 and 2 for more information on what an FMD pack looks like and what barcodes to scan/not scan)
- Make sure your FMD system is set in the correct mode when scanning, e.g. 'supply', not verification, if you want to decommission the pack.
- Co-operate with requests for information from IMVO when they are investigating alerts.
- Consider scanning (with the scanner set to 'verification' mode) one pack from each incoming batch to verify that all is in order. Remember to set the scanner back to 'supply' mode when going to decommission packs. If the verification scan flags an issue relating to the data, it would be helpful if feedback can be provided to the relevant manufacturer/MAH, so they can take action to correct the problem.

Final reminder to register with IMVO / connect to national system if you haven't already done so

- See IMVO website for details of how to register.
- If you have registered with IMVO but not yet connected your FMD system to the national system, you must do so as soon as possible using the technical details that were emailed by IMVO after your registration application was processed.

Manufacturers / MAHs

Continue with the instructions as outlined at 1. above. Additional information obtained since the system went live that may be helpful is detailed below.

- Ensure that data is correctly uploaded to the EU Hub for serialised packs:
  - Upload corrected data if you become aware of errors with a batch.

  - Upload data for serialised packs that were placed on the market in Ireland prior to 9th February. Otherwise, these packs will generate alerts when scanned by an end-user.
  - Ensure that expiry dates being uploaded to the EU Hub are identical to those encoded in the 2D barcodes on packs – see recent EMVO letter of announcement re expiry date mismatches for further details.
  - Contact the EMVO Helpdesk if you any queries about data upload:
    - Email: helpdesk@emvo-medicines.eu
    - Tel: +372 611 90 44
- Co-operate with requests for information from IMVO when they are investigating alerts.
- See HPRA website for MAH-specific information about alerts and quality defect reporting obligations.
- If you have any queries about alerts generated in the Irish system, please contact IMVO (email: alert.support@imvo.ie).

Figure 1

Figure 2