FMD Use and Learn Due for Closure

What does this mean for Hospital Pharmacists?

The Safety Features Oversight Group[1] continues to oversee progress with FMD implementation in Ireland. FMD has been in a 'use and learn' phase for pharmacies, hospitals and wholesalers in this country since February 2019 due, in part, to the impact of Covid-19 and Brexit.

When will use and learn end in Ireland?

The Safety Features Oversight Group, following consultation with all relevant stakeholders, has now agreed a plan for ending use and learn on a phased basis concluding at the end of Q1 2022 (see table 1 for details).

What prerequisites must be met to end use and learn?

The following prerequisites have been defined by the Safety Features Oversight Group to ensure that end-users and marketing authorisation holders (MAHs) are ready for the end of use and learn, minimising disruption for them and for patients:

- Alert rate at 0.05% or lower, i.e., alerts generated by pharmacies, hospitals and wholesalers ('end-users'), as a % of the total number of end-user scans[2];
- All end-users scanning packs in accordance with their obligations under the Commission Delegated Regulation on Safety Features (EU) 2016/161 as amended;
- Avoidable alerts minimised by addressing issues with scanners, software, MAH data and procedural errors;
- Clear instructions available for all parties on what to do if there is an alert, including clear responsibilities for deciding if packs may be supplied or not, i.e., alert handling guidance in place;
- Fast efficient process for communication between parties;
- Clarity on impact of Brexit on supply chain/alerts;
- Capacity of end-users to deal with alerts in face of challenges of Covid-19;
- European Medicines Verification System has the capacity to cope with Covid-19 vaccines and treatments.

Efforts are continuing on several fronts to achieve each of these prerequisites and IMVO is working closely with all relevant stakeholders to support them. The Safety Features Oversight Group will monitor progress against each prerequisite on a regular basis to ensure that everything is in place to move to the next phase of the plan, including targeted communications with each group on details of what is involved for them.

What is the advice for pharmacies, hospitals, wholesalers and MAHs while we are still in use and learn?

1. Pharmacies, hospitals and wholesalers are expected to comply with their obligations under the Commission Delegated Regulation (EU) 2016/161 to scan packs and verify safety features during use and learn.

o If an alert or any other unexpected message is flagged when a pack is scanned, the pack should still be supplied to the patient in line with your existing procedures, unless you have overriding concerns that a falsified medicine is involved.

o If you have grounds for believing that a pack has been interfered with or could be falsified, please report this to the HPRA, by email to qualitydefects@hpra.ie or using the HPRA's online reporting system https://www.hpra.ie/homepage/about-us/report-an-issue (select the online form 'Medicine Quality Issue / Defect').

2. If you have any queries about your FMD obligations, please contact the PSI (Retail Pharmacy Businesses), HSE FMD project team (public hospitals), HPRA (wholesalers, MAHs, manufacturers, parallel importers, parallel distributors) or IMVO.

3. Parallel importers and parallel distributors should continue to comply with the guidance issued to them by the HPRA on 7th February 2020.

4. MAHs should continue to investigate the alerts they receive and ensure that any necessary preventative actions related to alerts that result from data upload or other issues pertaining to the MAH's activities are put in place in a timely manner. As previously advised, MAHs are not required to carry out a documented investigation of A7/ A24 alerts (pack already decommissioned) and A68 alerts (batch ID mismatch) except in the following circumstances:

   o Where they know they have caused the alert(s) themselves due to, for example, repeating decommissioning transactions when the packs are under their control; or

   o Where an end-user (pharmacy, hospital or wholesaler) contacts them about such an alert; or

   o Where the HPRA or IMVO contacts them about such an alert.

5. Please contact IMVO if you have any other queries or need support on any matter. Queries specifically related to FMD software should be sent to your FMD software provider.

[1] Comprising Irish Medicines Verification Organisation (IMVO), Department of Health, Health Products Regulatory Authority (HPRA), Pharmaceutical Society of Ireland (PSI), Health Service Executive (HSE) and Private Hospitals Association (PHA).

[2] The following are excluded when calculating the % alert rate as they have no impact on Irish end-users – alerts generated by MAH transactions and alerts from intermarket transactions (IMTs), i.e. alerts on Irish packs generated by end-users in other markets.