Final – 22nd Dec 2021

IMPORTANT UPDATE ABOUT FMD AND THE END OF USE AND LEARN – December 2021

The next two phases of the end of use and learn plan for FMD that were scheduled to take effect on 10 January have been **deferred until further notice**, i.e., phase 3 (wholesalers to investigate alerts on returned packs) and phase 4 (red/amber/green colours switched on in FMD software for pharmacies and hospitals). See table below for details of what this means in practice.

This decision has been made by the Safety Features Oversight Group due to the unprecedented situation that has arisen with Covid and the pressures this poses for pharmacies, hospitals and wholesalers, given the rapidly expanding Covid booster programme and staffing levels being impacted due to Covid.

Phase	Original plan	Updated advice for impacted parties
Phase 3 **Use & learn ends for returns to wholesalers**	All alerts generated when wholesalers scan returned packs must be investigated by them to rule out suspected falsification.	This phase is now deferred until further notice Wholesalers are not required to investigate alerts generated on returns. These packs may be returned to saleable stock (subject to your usual returns procedures) even if they generate alerts, unless you have overriding concerns that a falsified medicine is involved.
Phase 4 **Red/amber/green changes for pharmacies and hospitals**	Pharmacy and hospital FMD software to display colour coded responses, depending on the outcome when the pack is scanned	This phase is now deferred until further notice. This means that for most FMD software, you will continue to see green responses for all scans, regardless of whether there is an alert. Pharmacies and hospitals do not need to take any action. IMVO will inform the FMD software providers directly. The advice to pharmacies and hospitals on what to do if you see alerts remains unchanged: You may continue to supply packs that generate alerts to patients in accordance with your existing procedures, unless you have overriding concerns that a falsified medicine is involved. However, if you have reason to believe that packaging has been interfered with, based on your examination of the anti-tampering device on the pack, you must report your concern to the HPRA (as a suspected quality defect via the usual reporting mechanisms) and not supply the pack.

The Safety Features Oversight Group will meet in January to review next steps in terms of the end of use and learn plan, including the later phases scheduled for February and March. Further updates, including the new dates for phases 3 and 4, will be issued in due course.

In the meantime, if you require support with any aspect of FMD, please visit the IMVO website www.imvo.ie or contact IMVO at info@imvo.ie.