

## IMPORTANT UPDATE ABOUT FMD AND THE END OF USE AND LEARN – January 2022

The Safety Features Oversight Group has agreed an updated timetable for the phased ending of the 'use and learn' period for FMD in Ireland. The new timings take account of the impact of the Omicron wave of COVID-19 and the decision before Christmas to defer phases 3 and 4 originally scheduled for 10 January.

The final date for ending use and learn has been pushed back to **Monday, 30 May** and dates of interim phases have also been adjusted. The table below sets out the new dates for each phase.

Dates	Phase	Details	Impacted stakeholders		Comment
			Wholesalers	Pharmacies / hospitals	
Monday 28 <sup>th</sup> February	<b>Phase 3</b> Use & learn ends for <u>returns</u> to wholesalers	All alerts generated when scanning returned packs must be investigated, and suspected falsification ruled out.	✓	✓	Eliminates risk of decommissioned packs returned to wholesalers causing alerts when re-sold. Pharmacies and hospitals must not return decommissioned packs to wholesalers.
Monday 28 <sup>th</sup> February	<b>Phase 4</b> RAG changes for pharmacies & hospitals	Pharmacy and hospital FMD software to display red/ amber/ green (RAG) colour coded responses, depending on outcome when pack is scanned – currently most systems are showing green responses for all scans, regardless of whether there is an alert.		✓	Pharmacies and hospitals have full visibility over alerts generated when they scan packs, leading to heightened awareness of scanner/ software/ procedural issues.
Monday 14 <sup>th</sup> March	<b>Phase 5</b> Pilot of alert handling procedures with pharmacies, hospitals and wholesalers	In pilot, alerts generated as a result of scanning activity are investigated but it is not necessary to withhold packs from supply until the alert is resolved.	✓	✓	This phase provides an opportunity to pilot and refine agreed alert handling process without impacting on supply to patients. The pilot will be managed by IMVO and start with a small number of participants and build from there.

Dates	Phase	Details	Impacted stakeholders		Comment
			Wholesalers	Pharmacies / hospitals	
Monday 9 <sup>th</sup> May	<b>Phase 6</b> Use & learn ends for wholesalers for all remaining activities	All alerts generated by wholesalers must be investigated, and suspected falsification ruled out, before the relevant packs may be returned to saleable stock or supplied.	✓		
Monday 30 <sup>th</sup> May	<b>Phase 7</b> End of use & learn for pharmacies and hospitals	All alerts generated by pharmacies and hospitals must be investigated, and suspected falsification ruled out, before the relevant packs may be supplied.		✓	

Detailed information about phases 3 and 4 and how to prepare for these will be sent to pharmacies, hospitals and wholesalers shortly.

IMVO will continue to work with pharmacies, wholesalers, hospitals/HSE and marketing authorisation holders to reduce avoidable alerts between now and the end of use and learn. A further priority will be to finalise alert management guidance and to rollout training, guides and other supports to ensure that all parties understand what to do when alerts are generated, including what communication channels to use. The HPRA and PSI will also provide guidance as required to the relevant parties.

In the meantime, if you require support with any aspect of FMD, please visit the IMVO website [www.imvo.ie](http://www.imvo.ie) or contact IMVO at [info@imvo.ie](mailto:info@imvo.ie).