

Table 1: Plan for ending use and learn in Ireland

Date	Phase	Details	Impacted stakeholders			Comment
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
Q3 2021	Phase 1 Primary wholesalers scan packs at goods inwards	Primary wholesalers to scan sample of packs at goods inwards and quarantine them if there are alerts due to data issues, until these issues have been resolved by MAHs.	✓			Repeat of voluntary programme originally planned for March 2020 – HPRA will contact relevant wholesalers to establish their interest in taking part.
1 st September 2021	Phase 2 RAG changes for wholesalers	Wholesaler 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.		✓		Wholesalers have full visibility over alerts generated when they scan packs, leading to heightened awareness of scanner/ software/ procedural issues.
10 th January 2022	Phase 3 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.

Date	Phase	Details	Impacted stakeholders			Comment
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
10 th January 2022	Phase 4 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.
1 st February 2022	Phase 5 Pilot of alert handling procedures with pharmacies, hospitals and wholesalers	Pilot of alert handling process. All alerts generated as a result of scanning activity to be 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.
28 th February 2022	Phase 6 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.		✓		
28 th March 2022	Phase 7 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.			✓	