IRISH MEDICINES VERIFICATION ORGANISATION

EU Falsified Medicines Directive Use and Learn Phase

Key date for pharmacies and hospitals

Monday 30 May – End of FMD use and learn

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The **'use and learn' phase** is scheduled to end in Ireland on 30 May 2022. The key change after this date is that you will not be able to supply a pack that generates an alert unless the alert has been fully investigated and a root cause has been found and falsification ruled out. This flyer will provide you with information on how to prepare for this.

Topic	Details	What to do next
Intensify efforts to prevent alerts due to software, scanners and procedural errors.	Make sure your scanner is configured correctly; otherwise, it could misread data from the 2D barcode leading to an alert.	'Check your scanner' and 'Fix your scanner' guidance for the most commonly used scanners is available on the IMVO website. If you're unable to resolve the matter yourself, contact your FMD software provider or scanner provider.
	If you're seeing lots of **red** and amber responses when you scan packs and your scanner is working correctly, there could be an issue with your FMD software.	Installing all FMD software upgrades will reduce the risk of software-related alerts. If you see extra alerts after an upgrade/installation of other software (including antivirus software) on the same device as your FMD software, contact your FMD software provider.
Ensure your staff are trained on how to scan correctly and how to deal with any alerts that do arise.	Update your dispensing SOPs to describe the relevant processes and train all staff involved in scanning packs and handling alerts, including locums.	Attend IMVO's webinars for pharmacies and hospitals – all your team members are welcome to attend. The slides and recordings from these webinars are available on the IMVO website.
	Most pharmacy and hospital alerts arise due to procedural errors, such as: • Repeatedly decommissioning the same pack. • Decommissioning borrowed packs that were decommissioned in the lending pharmacy or hospital. • Scanning a 2D barcode that is very close to a linear barcode.	• If you're partially dispensing from a pack, it must only be decommissioned once, on the first dispensing. • For borrowed packs, if the lending pharmacy or hospital has not indicated whether the pack is already decommissioned, you can check this by carrying out a 'verification' scan with your FMD software. • Cover linear barcodes close to 2D barcodes to avoid scanning them by mistake
How to know if you have an alert and what to do next?	When you verify or decommission a pack, an amber or **red** response from your FMD software indicates there is some mismatch between the information from the scan and what is in the IMVS. The exception/alert message will give you a high-level summary of what has happened and includes a link to an 'Alert help' page on the IMVO website. IMVO continually monitors the IMVS for large numbers of alerts in individual pharmacies and hospitals that could suggest a scanner or software issue. We will contact you if this happens in your location to help sort out the issue.	The 'Alert help' page on the IMVO website will walk you through how to identify a root cause for the alert and fix it (if it is something under your control such as a scanner, software, or procedural issue). If successful, you may go ahead and supply the pack. If you can't identify a root cause, set the pack aside until you are informed of the outcome of the marketing authorisation holder's (MAH) investigation of the alert. Keep the pack in the pharmacy/hospital until the MAH or HPRA advises you what to do next with it.
Tell us the outcome of your investigation of the alert.	MAHs are required to investigate most alerts raised in pharmacies and hospitals. • If you find a root cause on your side, the MAH needs to be informed so they can stop their investigation. • If you can't find a root cause, you will need to know the outcome of the MAH's investigation before supplying the pack. • If neither you nor the MAH can find a root cause, the MAH may need a photo of the pack and will give you feedback on their findings. In a very small number of cases, they may ask you to return the pack for examination.	*NMVS Alerts* is an alert management system being rolled out by IMVO to speed up communications between end-users, MAHs and IMVO about alerts. No software is required to use it and there are no fees. When an alert representing a potential falsification is generated in your pharmacy or hospital, you will be emailed a link to access the relevant alert information in *NMVS Alerts*. You can use this link to provide feedback and check for any updates about the alert from the MAH or IMVO. A 5-minute video explaining *NMVS Alerts* in more detail is available on the IMVO website. If you don't want to use *NMVS Alerts*, you may email your alert feedback to alert.support@imvo.ie or phone us. We will also use email to send you information from the MAH. However, this is likely to be a slower method of communication.
Contact IMVO if you need help.	IMVO is here to help you prepare for the end of use and learn and support you with alert investigations.	Contact us by phone or email – see details overleaf.