



Appendix 4 - Field Safety Warnings and End-of-Life notification

Developers must have processes in place to ensure that they comply with Vigilance requirements. This is not always easy when apps are distributed via App stores or downloaded without any registration process. This distribution route often results in no/poor traceability so manufacturers should have alternative methods to inform users of any relevant Safety or other warnings.

Field Safety Notices (FSN)

FSNs are issued to notify users of a Field safety corrective action and are intended to reduce a risk of death or serious deterioration in the state of health and must be notified to MHRA as per [guidance on vigilance](#).

For online apps, a summary of the Field Safety Notice should be displayed at the app's start-up and a link to the full FSN should be made available in-app.

This should also apply to Cybersecurity notices.

Also see:
[MEDDEV 2.12/1 rev.8](#)
and
[Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8](#)

End-of-Life notification.

Users should be made aware of Decommissioning/End-of-Life notifications by use of in-app alerts wherever possible.

Information about this should include reasonable timelines for end of support and time to remove the device from the market. When planning end of support, future management of cybersecurity aspects and systems' compatibility should also be addressed, as should continuation of Post Market Surveillance if devices are still functioning on the market.

Manufacturers should be aware of App store requirements that may require that an app retain some useful function to remain listed on an app store.

[IMDRF/SaMD WG/N23 – 8.7](#)

