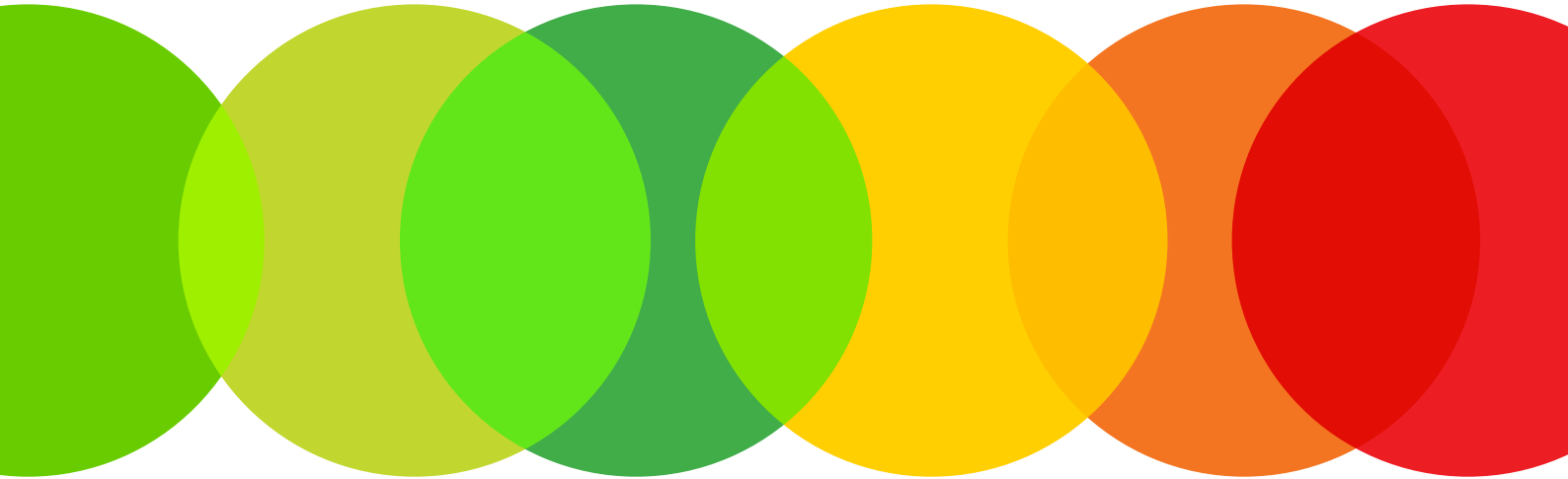




IRISH  
MEDICINES  
VERIFICATION  
ORGANISATION



# Windsor Framework and FMD in Ireland

## Advice for pharmacies and hospitals

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# Windsor Framework and FMD in Ireland

The Windsor Framework is a post-Brexit legal agreement between the EU and the UK and will have an impact on several areas including medicines. It is due to come into effect on 1 January 2025.

## How will the Windsor Framework have an impact in Ireland?

FMD still applies across the EU post Windsor Framework, and FMD obligations for pharmacies and hospitals in Ireland are unchanged.

The key impact of the Windsor Framework relates to UK packs that move into EU markets. Some of the changes introduced by the Windsor Framework will have an impact from an FMD perspective in Ireland where the UK is a source of exempt medicinal products (EMPs) (also known as unlicensed medicines, or ULMs).

**Until 31 December 2024, most EMPs/ULMs sourced from the UK will not generate alerts when scanned in Ireland, as the data for these packs in the UK system can be retrieved via the Irish Medicines Verification System (IMVS). After the disconnection of the UK system, all UK packs bearing 2D barcodes that are scanned in Ireland will generate an alert, as the pack data will no longer be available to the IMVS to verify the pack.**

## Advice to pharmacies and hospitals

- After 1 January 2025 the only way to avoid an alert/exception with UK packs is **not to scan them**.
- If you inadvertently do scan a UK pack, you will get an **amber** or **red** alert/exception message on your FMD software. Notwithstanding this, you may supply the pack unless:
  - You have overriding concerns that a falsified medicine is involved or believe the pack has been interfered with; or
  - The pack has expired. Your FMD software may not be able to flag that the pack is expired because of the UK system having been disconnected
- Always check the anti-tampering device on the pack (if there is one)
- If you have any reason to believe the pack has been interfered with, please report this to the HPRA as a product quality defect and do not supply the pack. Email [qualitydefects@hpra.ie](mailto:qualitydefects@hpra.ie) to report this.

## Responses when UK single market packs are scanned in Ireland after 1 January 2025

Pack type	Outcome when scanned after 1 January 2025
If product code/batch ID are known to EMVS (i.e. pack data was uploaded to EMVS before 1 January 2025)	'Market not available' <b>exception (new)</b> : <i>The product code or batch is unknown locally. Inter-market communication error. Do not retry</i>
If product code is known but batch ID is unknown (i.e. product was set up in EMVS but batch data was not uploaded)	'Batch not found' <b>A2 alert</b>
If product is not known to EMVS	'Product code unknown' <b>exception</b>
2D barcode does not contain 4 data elements, e.g. no serial number	Response will depend on FMD software and whether the scan is transmitted to the IMVS
Recalled / withdrawn / expired UK packs	No pack state info. available – scan may not indicate if pack is recalled / withdrawn / expired

## What support is available?

Contact our service desk

**Tel:** 01-5715320  
**Email:** [info@imvo.ie](mailto:info@imvo.ie)  
**Opening hours:**  
Weekdays: 08.00-20.00  
Saturday: 09.00-18.00  
Sun/public holidays: 11.00-18.00

To **contact us about an alert**, use **NMVS Alerts** or email [alert.support@imvo.ie](mailto:alert.support@imvo.ie)

For more information on the Windsor Framework, including FAQs, visit [www.imvo.ie](http://www.imvo.ie)