IRISH MEDICINES VERIFICATION ORGANISATION

Webinar for pharmacies and hospitals

V3.0 NOVEMBER 2024

Agenda

- Windsor Framework
- Current issues
- Support available from IMVO

Windsor Framework

FMD impact of Brexit

- UK left EU on 31 Jan 2020 and EU law continued to apply in UK during transition period until 31 Dec 2020
- Because of Northern Ireland Protocol (which was part of the Brexit agreement and aimed to avoid a hard border on the island of Ireland), NI remained in EU's regulatory system for medicines after 31 Dec 2020
- From an FMD perspective, the impact of Brexit was that:
  - FMD was discontinued in GB (England, Scotland, Wales) on 31 Dec 2020 and all GB end-users were disconnected from UK national medicines verification system (NMVS)
  - FMD remained mandatory in NI and UK NMVS became known as UKNI NMVS
  - Data upload by manufacturers to UKNI NMVS was optional for packs intended for sale in GB, but mandatory for packs intended for sale in NI – in practice, most continued to upload data for packs sold throughout the UK
  - UK packs finding their way into EU markets could still be decommissioned via intermarket transactions ('IMTs') against UKNI NMVS

What is the Windsor Framework (WF)?

- Windsor Framework ('WF') is a post-Brexit legal agreement between EU and UK, adopted in March 2023, which adjusts operation of Northern Ireland Protocol in several areas, including medicines:
  - It aims to ensure people in NI have access to all medicines at same time and under same conditions as rest of the UK
- WF is due to take effect on 1 Jan 2025, subject to UK providing EU with written guarantees of compliance with WF requirements by that date – expectation is this will happen
- WF is relevant to Ireland due to our traditional links to the UK in terms of joint IE/UK packs and UK-only packs sourced as exempt medicinal products (EMPs)/ unlicensed medicines/ULMs to address shortages

Impact of Windsor Framework in UK

Northern Ireland

- FMD no longer applies in Northern Ireland from 1 Jan 2025
- UKNI NMVS will be disconnected from EMVS
- NI end-users will be disconnected from UKNI system
- All data in the UKNI NMVS (including backups) will be permanently and irretrievably erased

Impact of Windsor Framework in UK (ctd)

Packs placed on UK market post WF

- Must be labelled 'UK Only'
- **Current** MHRA Guidance on labelling and packaging of medicinal products for human use following agreement of the Windsor Framework states following re safety features:
  - UK-licensed packs must not carry EU FMD safety features. This means that any 2D barcode that is present, if scanned, should not be recognised in the EU repositories system, and any such code present would need to be fully removed or covered
  - Companies are encouraged to continue using anti-tamper packaging
  - Any stock in existing packaging already placed on the market in UK pre-WF may be supplied until its expiry date

‘UK Only’

MHRA Guidance

- When using the ‘UK Only’ label on packaging, the following will apply:
  - ‘UK Only’ may be printed anywhere on pack – some companies plan to add it to ‘human readable’ barcode data panel
  - The text must be conspicuous and clearly legible, at least 7-point font per current MHRA guidance

UK Only

Will a new UK falsified medicines system be introduced?

- UK Medicines and Medical Devices Act 2021 provides legal basis for setting up a UK falsified medicines system post Brexit
- MHRA WF Q&A states that *"The UK is considering all options for a national falsified medicines system, including a do nothing option. Any proposal would be subject to industry consultations."*
- Notwithstanding lack of clarity on a future UK falsified medicines scheme, it appears that many manufacturers plan to avail of option to continue to apply 2D barcodes and anti-tampering devices to packs released to market in UK after 1 Jan 2025
  - From FMD perspective, this has implications for UK packs brought into Ireland – i.e. as exempt medicinal products (EMPs)/ unlicensed medicines/ULMs – after 1 Jan 2025

What happens in Ireland after 1 January 2025?

FMD in Ireland

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

Impact of Windsor Framework (WF) on joint IE/UK packs

- Joint IE/UK packs may no longer be released to Irish or UK markets after WF takes effect on 1 Jan 2025
  - Similar prohibition on continuation of joint packs between UK and any other EU market(s)
- For joint IE/UK packs released to Irish and UK markets **prior** to1 Jan 2025
  - These may remain in circulation until their expiry date
  - Don't anticipate any new problems when these packs are scanned in Ireland after 1 Jan 2025

Impact of Windsor Framework on UK single market packs in circulation in Ireland

- i.e. UK packs brought into Ireland as exempt medicinal products (EMPs)/unlicensed medicines (ULMs)
- FMD issues will arise where these UK packs carry 2D barcodes
- Option of verifying /decommissioning these packs via IMTs against UKNI NMVS is gone
- **From 1 January 2025, every UK pack with 2D barcode that is scanned in Ireland will generate an exception/alert** (same will apply across the EU)

Responses if UK single market packs are scanned in Ireland after 1 Jan 2025

Pack type	Outcome if scanned after 1 Jan 2025
If product code/batch ID are known to EMVS (i.e. pack data was uploaded to EMVS before 1 Jan 2025)	'Market not available' **exception [new]:** '*The product code or batch is unknown locally. Inter-market communication error. Do not retry*'
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' **A2 alert**
If product is not known to EMVS	'Product code unknown' **exception**
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 NMVS
Recalled / withdrawn / expired UK packs	No pack state info. available – scan may not indicate if pack is recalled / withdrawn / expired

Preparations for Windsor Framework

- IMVO has worked closely with the Department of Health, HPRA, PSI and colleagues in other NMVOs and EMVO over the last 18 months to assess and mitigate the FMD impacts of the WF
  - Some of the issues identified have been resolved via changes to the EMVS, however, it is not technically possible to prevent UK packs from generating alerts when scanned from 1 Jan 2025 onwards
- Communications underway to explain the FMD impacts of the WF to pharmacies, hospitals, wholesalers, manufacturers and marketing authorisation holders (MAHs) in Ireland and what to do to minimise problems
- HPRA has published Q&A on Windsor Framework to assist manufacturers, MAHs and wholesalers
- Planning for extra support calls and emails to IMVO service desk at beginning of January

Advice to pharmacies and hospitals on how to avoid FMD issues with UK packs from 1 Jan 2025

- After 1 Jan 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 (as per previous slide). 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 to report this

**Advice has been agreed with HPRA, PSI and Department of Health*

Windsor Framework: Useful resources and support

- IMVO service desk is open every day except Christmas Day – contact details are provided at end of the presentation
- Dedicated page on IMVO website (including FAQs): Windsor Framework – IMVO
- Webinars for pharmacies and hospitals held throughout Oct and Nov
  - Slides and the recording are available here on our website.
  - Please encourage your staff to watch the recording or view the slides
  - Leonie Clarke will present at IIOP 'In conversation with …' series on Weds 27 Nov
  - Mop-up webinar will be held in December if there is demand
- Articles in November editions of pharmacy publications – IPU Review article
- Article in the November issue of the Irish Pharmacist
- Printed A5 cards will be posted to every pharmacy and hospital by early December
- HPRA Q&A on Windsor Framework

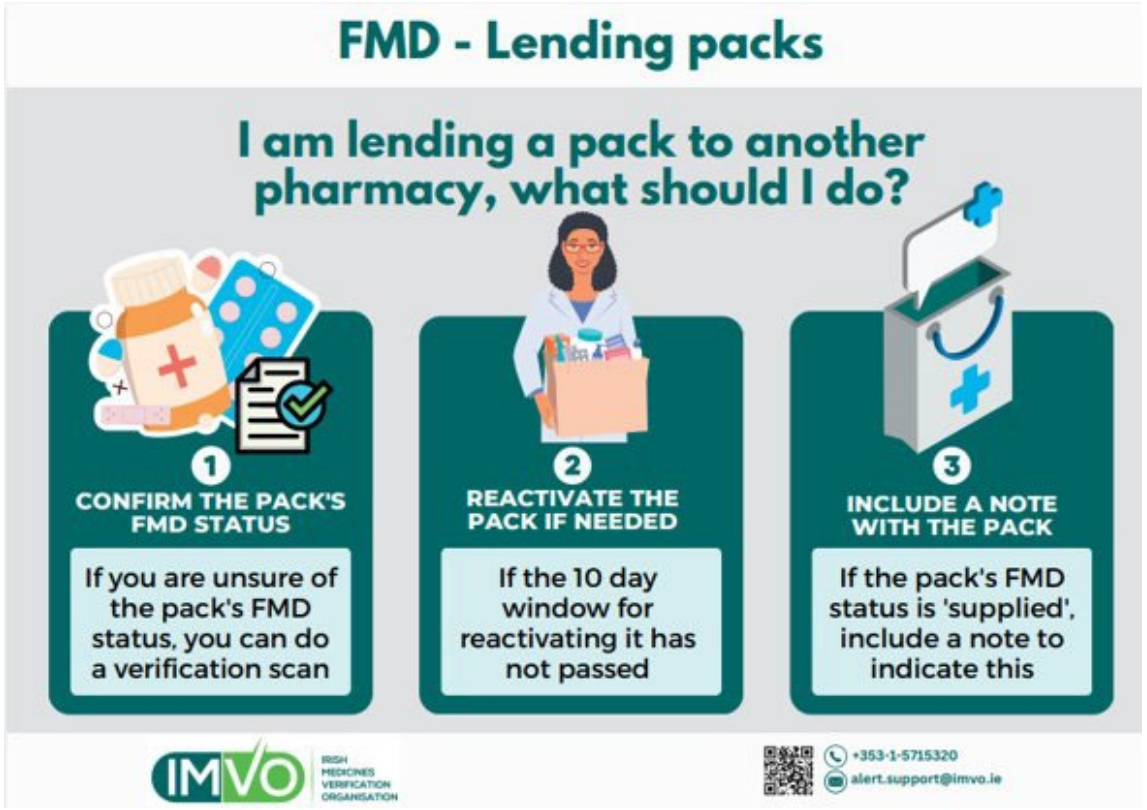
Current Issues

Scanning mode

Incorrect scanning mode in FMD software

- **Verification:** A medicine may be scanned to verify it is in the IMVS and its status, i.e. is it 'active' or marked as expired or decommissioned as dispensed, recalled, locked, exported, stolen etc.
- **Decommissioning:** 'Decommission' under FMD means changing the status of a pack from active in the supply chain to e.g. supplied, destroyed, sample etc.

Borrowings


FMD - Lending packs
I am lending a pack to another pharmacy, what should I do?
1
CONFIRM THE PACK'S FMD STATUS
If you are unsure of the pack's FMD status, you can do a verification scan
2
REACTIVATE THE PACK IF NEEDED
If the 10 day window for reactivating it has not passed
3
INCLUDE A NOTE WITH THE PACK
If the pack's FMD status is 'supplied', include a note to indicate this
IMVO
IRISH MEDICINES VERIFICATION ORGANISATION
+353-1-5715320
alert.support@imvo.ie


FMD - Borrowing packs
I am borrowing a pack from another pharmacy, what do I need to do?
1
CONFIRM THE PACK'S FMD STATUS
When you receive a pack, its FMD status should be 'Active'
2
IF UNSURE OF THE PACK'S FMD STATUS, VERIFY THE PACK
Carry out a verification scan. This will indicate the current FMD status of the pack. If the pack is 'Active', decommission it and supply it to the patient
3
IF THE PACK'S STATUS IS NOT 'ACTIVE', CONFIRM WITH THE LENDING PHARMACY THAT THEY HAVE ALREADY DECOMMISSIONED IT
If they can't confirm that they decommissioned the pack then withhold the pack and contact IMVO for advice
4
IF THE LENDING PHARMACY CONFIRMS THEY HAVE DECOMMISSIONED THE PACK
The pack can be supplied to the patient. Do not scan it again as this will generate an alert
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Estramon® & Utrogestan®

- Estramon - German ULM
- Four batches decommissioned as 'Sample' in error by the manufacturer
  - NK1274
  - NL7876
  - NL3207
  - NL1901
- Utrogestan - French ULM
- One batch decommissioned prior to import to Ireland
  - E1240022

Scanning to supply/dispense will cause an alert

How often did pharmacies get alerts during July 2024?

Percentiles	No. of alerts	What does this mean?
90th percentile	**2**	90% of pharmacies had this amount or fewer alerts during this time period
80th percentile	**1**	80% of pharmacies had this amount or fewer alerts during this time period
70th percentile	**1**	70% of pharmacies had this amount or fewer alerts during this time period
60th percentile	**0**	60% of pharmacies had this amount or fewer alerts during this time period

How often did pharmacies get alerts during October 2024?

Percentiles	No. of alerts	What does this mean?
90th percentile	**8**	90% of pharmacies had this amount or fewer alerts during this time period
80th percentile	**6**	80% of pharmacies had this amount or fewer alerts during this time period
70th percentile	**4**	70% of pharmacies had this amount or fewer alerts during this time period
60th percentile	**3**	60% of pharmacies had this amount or fewer alerts during this time period
50th percentile	**2**	50% of pharmacies had this amount or fewer alerts during this time period
40th percentile	**1**	40% of pharmacies had this amount or fewer alerts during this time period

Ozempic® example

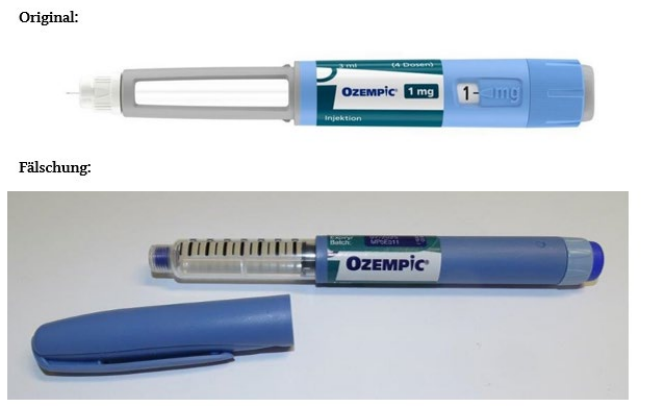
European Medicines Agency (EMA) 18 October 2024

- Falsified packs of Ozempic® (semaglutide, 1 mg, solution for injection) have been identified at wholesalers in the EU and the UK
- In the EU, each medicine pack has a unique 2D barcode and serial number so that it can be tracked in an EU-wide electronic system. When the packs of the falsified Ozempic® were scanned, the serial numbers were shown to be inactive, thereby alerting operators to a potential falsification

ema.europa.eu

Federal Institute for Drugs and Medical Devices (BfArM)

- Initial investigations by the manufacturer Novo Nordisk A/S have shown that there is no semaglutide in the counterfeit pack Ozempic®
- According to the results of the German official testing laboratory Chemical and Veterinary Investigation Office (CVUA) Karlsruhe, the affected pens contain insulin



Images of original and counterfeit drug Ozempic® (Copyright Original Novo Nordisk; Copyright Forgery CVUA Karlsruhe)

Bfarm.de

‘Decommissioned at another location’ alerts

“Pack already decommissioned/supplied/dispensed at another location”

- You will not have sufficient information to be able to draw any conclusions about the authenticity of the pack and must contact IMVO for assistance
- Packs that generate these responses must be quarantined until a genuine reason for the prior decommissioning has been established and falsification has been ruled out

What support is available?

- **Contact our service desk**
  - **Tel:** **+353-1-5715320**
  - **Email:** info@imvo.ie
  - **Opening hours:**

    Weekdays: 08.00-20.00
    Saturday: 09.00-18.00
    Sun/public holidays: 11.00-18.00

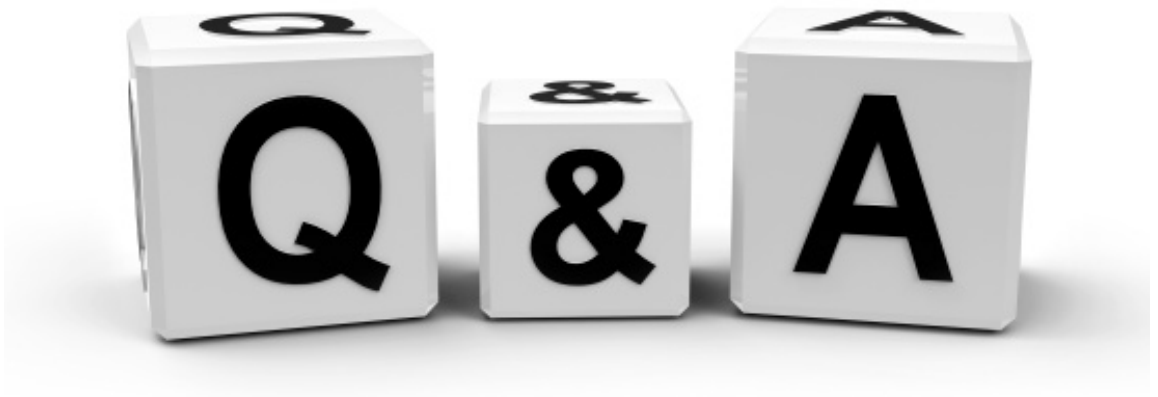
- To **contact us about an alert**, use *NMVS Alerts* or email alert.support@imvo.ie

What support is available? (ctd)

- **Visit our website** www.imvo.ie
  - **FAQs:** https://www.imvo.ie/support/faqs/
- Guidance videos on a range of topics, including *NMVS Alerts* are available on IMVO's **YouTube channel:** https://www.youtube.com/@irishmedicinesverification5361
- **Live IMVS status** is available at: https://status.nmvo.eu/
- **Bespoke support sessions for pharmacies by** phone, Zoom or Teams

For more information …

- **Follow us on social media**
  - LinkedIn: IMVO | Irish Medicines Verification Organisation
  - Twitter: @imvo_Ireland
- **PSI**
  - FMD: https://www.thepsi.ie/gns/Pharmacy_Practice/FalsifiedMedicinesDirective.aspx
  - Queries: info@psi.ie
- **HPRA**
  - FMD: http://www.hpra.ie/homepage/medicines/special-topics/falsified-medicines-legislation
  - Brexit: http://www.hpra.ie/homepage/about-us/stakeholders/brexit/brexit---latest-information



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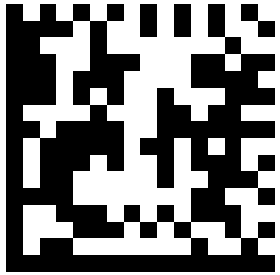

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