IRISH MEDICINES VERIFICATION ORGANISATION

Impact of Windsor Framework

UPDATE FOR WHOLESALERS

05 NOVEMBER 2024

Outline

- General update on FMD in Ireland
- Brexit/Windsor Framework
- Support available from IMVO

General update on FMD in Ireland

Statistics

	No.
End-users connected to IMVS	**2085**
Pharmacies	1898
Hospitals	101
Wholesalers	84
Other dispensing outlets	2
MAHs registered with IMVO	**364**

Scanning activity – Jan-Nov 2024

Alert rates

- **Trends from the past 4 weeks:**

  Week 41 alert to scan ratio: 0.29% (0.10% end-user alert rate, 0.02% adjusted*)
  Week 42 alert to scan ratio: 0.15% (0.10% end-user alert rate, 0.02% adjusted)
  Week 43 alert to scan ratio: 0.10% (0.10% end-user alert rate, 0.02% adjusted)
  Week 44 alert to scan ratio: 0.10% (0.09% end-user alert rate, 0.01% adjusted)

- **Analysis from latest EMVO monitoring report – August 2024**

  Overall alert to scan ratio across Europe: 0.08%
  Minimum alert to scan ratio: 0.00% (Slovakia)
  Maximum alert to scan ratio: 1.97% (Liechtenstein)

** Adjusted rate excludes alerts caused by exempt medicinal products (EMPs) and alerts from non-IE end-users scanning IE packs via IMTs*

Summary of alerts

- Baseline end-user alert rate is consistently in region of 0.02% as avoidable alerts relating to FMD software and scanners are now uncommon
- Issues which drive alert rate in Ireland include:
  - Exempt medicinal products arriving in a decommissioned state into Ireland
  - Borrowings between pharmacies and hospitals
  - Hospital aggregation errors
  - Spikes due to MAH procedural errors
  - Transactions on Irish packs scanned in other markets
- IMVO is taking all steps possible to investigate all alerts
  - But … key gap is failure of some end-users (mostly) & MAHs to provide feedback on their investigations as we cannot definitively ascertain root cause and close alert without this

NMVS Alerts

- IMVO uses the ***NMVS Alerts*** alert management system (AMS)
- Usage of NMVS Alerts by MAHs and end-users to give feedback on their alert investigations is increasing

European Medicines Verification System (EMVS)

- EMVS (including IMVS) continues to perform well – no significant incidents or unplanned downtimes
- Two releases of IMVS in 2024 – R14 in May, R15 on 3 November

Brexit / Windsor Framework (WF)

FMD impacts of Brexit and 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

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 presented anywhere on the outer packaging of the medicine
  - The text must be conspicuous and clearly legible, at least 7-point font per current MHRA guidance

    UK Only
  - ‘UK Only’ may be printed anywhere on pack – some companies plan to add it to ‘human readable’ barcode data panel

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 to packs released to market in UK after 1 Jan 2025
  - From FMD perspective, this has implications for packs brought into Ireland as EMPs 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 wholesalers 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)
  - HPRA Q&A on Windsor Framework states that "*the movement of UK or NI packs from NI to IE, intended to be supplied under Article 5(1) of EU Directive 2001/83/EC as EMPs will still be permitted [post Windsor Framework] where an authorised equivalent product is not available in Ireland, in line with the requirements outlined in the HPRA Guide to the Notification System for Exempt Medicinal Products*"
- FMD issues will arise where these UK packs carry 2D barcodes
  - Option of verifying /decommissioning these EMPs 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 when UK single market packs are scanned in EEA after 1Jan 2025

Pack type	Outcome when 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 end-users*

- 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*

Useful information about WF

Ireland:

- IMVO information on WF (including FAQs)
- HPRA Q&A on Windsor Framework **– last updated 25 Oct 2024**
  - Further questions can be sent to brexit@hpra.ie and HPRA will update the Q&A as necessary
- Delegated Regulation (EU) 2016/161 - consolidated version

UK:

- MHRA Guidance on labelling and packaging of medicinal products for human use following agreement of the Windsor Framework (last updated 13 Sept 2024) and accompanying MHRA WF Q&A
- MHRA Wholesalers & manufacturers guidance following agreement of the Windsor Framework
- MHRA Windsor Framework Webinars

Support available from IMVO

What support is available? (1/2)

- **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*

** Monitored during business hours only – for urgent out of hours issues, please phone or email service desk*

What support is available? (2/2)

- **Visit our website** www.imvo.ie
  - **FAQs:** https://www.imvo.ie/support/faqs/
  - **Registering as MAH:** https://www.imvo.ie/system-users/getting-connected-to-the-imvs/
- 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/

General information

- **Follow us on social media**
  - LinkedIn: IMVO | Irish Medicines Verification Organisation
  - X/Twitter: @imvo_Ireland
- **HPRA**
  - FMD: http://www.hpra.ie/homepage/medicines/special-topics/falsified-medicines-legislation
  - Queries: compliance@hpra.ie
- **European Commission Q&A on Safety Features** – available on IMVO website

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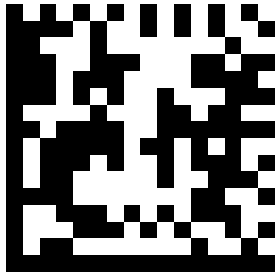

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