IRISH MEDICINES VERIFICATION ORGANISATION

Impact of Windsor Framework

UPDATE FOR MAHS

22 OCTOBER 2024

Outline

- General update on FMD in Ireland
- Brexit/Windsor Framework
- MAH fees 2025

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-Oct 2024

Alert rates

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

  Week 38 alert to scan ratio: 0.11% (0.10% end-user alert rate, 0.02% adjusted*)
  Week 39 alert to scan ratio: 0.12% (0.11% end-user alert rate, 0.02% adjusted)
  Week 40 alert to scan ratio: 0.11% (0.11% end-user alert rate, 0.02% adjusted)
  Week 41 alert to scan ratio: 0.29% (0.10% end-user alert rate, 0.02% 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
- We are aiming to connect to EU AMS Hub in 2025

European Medicines Verification System (EMVS)

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

Brexit / Windsor Framework (WF)

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 FMD perspective, the impact of Brexit was that:
  - FMD was discontinued in GB on 1 Jan 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
  - UK NMVO, SecurMed, became the UKNI NMVO
  - Data upload by manufacturers (OBPs – onboarding partners) 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
  - UK single market packs finding their way into EEA markets could still be decommissioned via intermarket transactions (IMTs) against UKNI NMVS

What is the Windsor framework?

- 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:
  - WF aims to ensure people in NI have access to all medicines at same time and under same conditions as rest of the UK
  - Includes safeguards, most labelling, to ensure that UK packs do not enter EU Single Market
- Regulation (EU) 2023/1182 amended Directive 2001/83/EC as amended to give legal effect to WF provisions re medicines
  - Provides for effective date of 1 Jan 2025, subject to UK providing written guarantees of compliance with WF requirements by that date – expectation is this will be done on time

Impact of Windsor framework in UK (1/2)

Northern Ireland

- FMD no longer applies in Northern Ireland from 1 Jan 2025
- UKNI system will be disconnected from EU Hub at 23.00 GMT (00.00 CET) on 31 Dec 2024
- NI end-users will be disconnected from UKNI system
- All data in the UKNI MVS (including backups) will be permanently and irretrievably erased
- All MAH agreements and end user license agreements will be terminated by SecurMed
- UKNI NMVS system will be closed down
- SecurMed UK will be liquidated

Impact of Windsor framework in UK (2/2)

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 (i.e. QP released prior to 1 Jan 2025) may be supplied until its expiry date

Impact of Windsor framework on joint EEA/UK packs

- Joint EEA/UK packs may not be placed on market in EEA or UK after WF takes effect on 1 Jan 2025
  - Shared inner packaging components may continue to be used, e.g. multi-lingual blister foils and joint leaflets, provided the UK and EU marketing authorisations remain aligned
- Joint EEA/UK packs released to EEA/UK market prior to 1 Jan 2025
  - These may remain in circulation until their expiry date according to guidance issued by HPRA (IE) and MHRA (UK)
  - Don't anticipate any new problems when these packs are scanned after 1 Jan 2025 as EMVS will recognise them and the technical changes being made will prevent synchronisation issues
  - OBPs have to remove 'GB' from product master data for these packs to prevent upload failures from 1 Jan 2025; in the interim, OBPs have been advised to amend upload software to prevent retries when initial upload attempt has failed

Impact of Windsor framework on UK single market packs in circulation in EEA

- i.e. UK single market packs brought into EEA markets (e.g. under Article 5(1) and Article 126a of Directive 2001/83/EC) – often sourced to address shortages and other local supply issues
- FMD issues will arise where UK packs carry 2D barcodes
- Option of verifying /decommissioning these packs via IMTs against UKNI NMVS is gone
- From 1 Jan 2025, every UK single market pack with 2D barcode that is scanned in EEA will generate an exception/alert
- See next slide for more details

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]**
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

European activity to prepare for WF

- Technical changes to EMVS to prepare for disconnection of the UKNI NMVS which will be completed by early November
- 'NIXIT Working Group' made up of EMVO and NMVO personnel is overseeing detailed preparations, including managing communications to OBPs (onboarding partners) who upload data to EMVS via EU Hub
- EMVO has issued Q&A on Windsor Framework
- Windsor Framework be one of the topics covered in series of 'Upcoming Changes' workshops for OBPs and their connection providers in October and November

What's happening in Ireland?

- Medicines shortages remains a significant problem in Ireland and many medicines are sourced from the UK as exempt medicinal products under Article 5(1) of Directive 2001/83/EC to meet patient need
- IMVO has worked closely with the Department of Health, HPRA, PSI (the Pharmacy Regulator) 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 EMVS, however, it is not technically possible to prevent UK packs from generating alerts when scanned from 1 January 2025 onwards
- IMVO will be communicating extensively with end-users over the coming weeks to explain:
  - That all scans of UK packs with 2D barcodes will generate an alert or exception post WF
  - What to do next when they get exception/alert, including explaining the new 'Market not available' exception – this advice has been aligned with HPRA, PSI and DoH
  - Why this is happening – to avoid the impression that the national system has stopped working correctly leading to loss of confidence in FMD
- Planning for extra support calls and emails to IMVO service desk at beginning of January
- HPRA has published Q&A on Windsor Framework to assist manufacturers, MAHs and wholesalers

Advice provided to Irish end-users

- From 1 January 2025, the only way to avoid an alert/exception with UK packs is **not to scan them**
- If you inadvertently scan a UK pack, you will get an **amber** or **red** alert 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 to report this

Above advice has been agreed with HPRA, DoH and PSI

Useful information about WF

- Delegated Regulation (EU) 2016/161 - consolidated version
- EMVO Nixit Q&A – includes links to guidance from EMA, EU Commission, etc.
- UK:
  - MHRA Guidance on labelling and packaging of medicinal products for human use following agreement of the Windsor Framework (last updated 12 Sept 2024) and accompanying MHRA WF Q&A
  - MHRA Wholesalers & manufacturers guidance following agreement of the Windsor Framework
  - MHRA Windsor Framework Webinars
- **Ireland:**
  - HPRA Q&A on Windsor Framework
  - Further questions can be sent to brexit@hpra.ie and HPRA will update the Q&A as necessary
- **Malta:**
  - NCA website: Brexit - Regulatory considerations

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*
- **MAH account/registration/invoice queries** – email mah@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/

MAH fees 2025

MAH fees

- 2025 Annual User Fee for MAHs has been set at €6,000
  - Rebates of 60% are available for MAHs with turnover < €100,000 (prior year data) – new application to be made each year
- Invoices will be issued by IMVO in Jan 2025, due for payment by 9 February 2025
- We will email all MAHs in November to check contact details and request PO numbers, and will include details of how to apply for fee rebate
- If you need to change MAH or register a new MAH during the year, contact mah@imvo.ie for guidance on process and fees payable

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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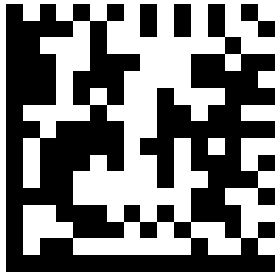

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