FAQ for end users (pharmacies, wholesalers) in the Czech Republic

What is the meaning of the term Windsor framework?

The Windsor Framework, officially known as Windsor Framework – Regulation (EU) 2023/1182, is a legal agreement between the European Union (EU) and the United Kingdom (UK) following Brexit. This agreement addresses the special status of Northern Ireland (NI) after the UK's departure from the EU. Due to the absence of a hard border between Northern Ireland and the Republic of Ireland, different rules applied in Northern Ireland regarding the movement of goods compared to the rest of the UK. This included the regulation of medicinal products, which were subject to the Falsified Medicines Directive (FMD 2011/62/EU), as they were in the EU. However, the tensions caused by the differing regulatory landscape in Northern Ireland compared to the rest of the UK led to adjustments in the Windsor Framework, which will come into effect on January 1, 2025. Under these changes, Northern Ireland will leave the EU's single market (referred to as NIXIT). Some of the changes introduced by the Windsor Framework will also affect EU member states in relation to the FMD. However, it is not expected that these changes will cause issues for end-users, such as pharmacies and distributors, using the National Medicines Verification System (NMVS) in the Czech Republic.

When did the Windsor framework come into effect?

The Windsor Framework came into effect on November 1, 2023.

What does NIXIT mean from the FMD perspective?

In connection with Northern Ireland's departure from the single market, it will be disconnected from the European Medicines Verification System (EMVS) on January 1, 2025

What changes will apply in the UK as of January 1, 2025 in relation to FMD?

FMD application will come to an end in the UK as of January 1, 2025. The medicines verification system in the UK will be disconnected and data deleted from EMVS.

What will be the impact on the end users in the Czech Republic?

The FMD will still apply across the entire European Union as of January 1, 2025. The obligations for end users in the Czech Republic (pharmacies and wholesalers) will remain unchanged. The key impact will be on packaging in the UK that is being transferred to EU markets.

Will UK packs still have 2D codes and anti tampering devices (ATD)?

Some 2D barcodes may remain on UK packs, as well as anti tampering devices (ATD), even after they are no longer subject to FMD. However, the presence of UK 2D barcodes intended for FMD, which would be uploaded to the EMVS after January 1, 2025, is prohibited under FMD requirements. If these barcodes are printed on the pack, they must be completely covered or removed.

How will packs intended for the UK market be labeled from January 1, 2025?

All packs placed on the UK market from January 1, 2025, will be labeled as "UK only." However, it is expected to take some time before packs with this additional text appears on the market. The "UK only" label can be applied to the outer packaging of medicinal products using a sticker until June 30, 2025. After this date, it must be printed directly on the outer packaging.

Should packs labeled UK only“ be verified as per FMD (EU 2016/161)?

Packs labeled "UK only" placed on the UK market from January 1, 2025, should not contain a 2D barcode from an FMD perspective. Verifying such pack will trigger an alert in the CZMVO system, but this will not prevent the dispensing or any other handling of the pack.

How to handle a pack of a medicinal product intended for the UK market that contains an FMD code?

The obligations for end-users in the Czech Republic (pharmacies and wholesalers) regarding the FMD will remain unchanged. The end-user must verify all packs with a 2D barcode. After the disconnection of UK systems, all UK packs with 2D barcodes scanned in the Czech Republic will generate an alert, as the pack data will no longer be available in the Czech Medicines Verification System **(CZMVS)** for verification. However, if no other conditions preventing the dispensing of the packare violated, it can still be dispensed to the public.

What are the so-called „joint packs“?

These are common packs intended for both the UK and EU markets. Such packs will no longer be possible to distribute on both markets, except for those that are already in circulation and whose data was uploaded to the EMVS and included in distribution before January 1, 2025..

What are „legacy packs“?

These are "older packaging" of medicinal products whose batches were placed on the UK market in compliance with legal regulations before the entry into force of Regulation (EU) 2023/1182, and which have not been repackaged or relabeled after this date.
2025.

Can an alert be triggered when verifying/decommissioning a pack of a medicinal product with a UK identifier after January 1, 2025?

After the disconnection of the UK system, all UK packs with 2D barcodes scanned in the Czech Republic will generate an alert, as the pack data will no longer be available in the CZMVS for verification. If such pack is scanned, the system will generate an alert based on the root cause:

- **Alert A70** – System not available, target market (UK) is disconnected from EMVS (operational code B1020001).
- **Alert A22** – Market not found (operational code B1020001).
- **Alert A1** – Product code (PC) unknown, no master data for the medicinal product in EMVS.

However, these types of alerts do not prevent the dispensing or any other handling of the pack.

Is it possible to dispense medicinal product pack with a UK identifier, even if it triggered an alert?

It depends on the type of alert; it is necessary to check the anti tampering device (ATD). If the packaging is in good condition, it can be dispensed until its expiration date.

What is the procedure for selling medicinal products to the UK after January 1, 2025?

After this date, the selling entity must remove packs from the EU repository that is being exported to the UK, marking it as "Exported“. The serial number will be decommissioned, but it can be reactivated at the same location within 10 days.

Should EU/EEA packs intended for EU/EEA markets that are supplied through wholesalers in Northern Ireland be decommissioned?

EEA authorised packs intended for the EEA market that are supplied via wholesalers in Northern Ireland, should not be decommissioned prior to being sent to Northern Ireland.

Where can I find more information?

For the latest information on NIXIT and the Windsor Framework, we recommend monitoring the following links:

- NOOL website: www.czmvo.cz
- SÚKL website: www.sukl.gov.cz
- Information and frequently asked questions for MAH/OBP regarding NIXIT are also available on the EMVO website: www.emvo-medicines.org