



NEWSLETTER

DECEMBER 2024
ISSUE 4

NIXIT

The context of *NIXIT (Northern Ireland Exit)* is directly connected to BREXIT, and we would like to outline below the *impact of these changes on the Falsified Medicines Directive (FMD)*.

The Northern Ireland Protocol (which was part of the Brexit agreement) stipulated that NI remain in the EU's regulatory system for medicines after 31st of December 2020.

Therefore, FMD remained mandatory in NI, data upload by manufacturers to UKNI NMVS was mandatory for packs intended for sale in NI.

The *Windsor Framework* 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.



NIXIT

The most important changes brought by the Windsor Framework (WF) in the FMD context:

- ❖ *FMD no longer applies in Northern Ireland from 1 January 2025.*
- ❖ *UKNI system will be disconnected from the EU Hub at 23.00 GMT (00.00 CET) on 31 Dec 2024.*
- ❖ *NI End-Users will be disconnected from the UKNI system and all data in the UKNI MVS will be permanently and irretrievably erased.*
- ❖ *UKNI system will be closed down.*
- ❖ *All prescription medicine products released into the UK market must be labelled 'UK Only'.*
- ❖ *From 1 January 2025, any EU packs destined for the UK will need to be Decommissioned for Export in EMVS.*
- ❖ *Joint EEA/UK packs may not be placed on market in the EEA or UK after WF takes effect on 1 January 2025.*



MASTER DATA GUIDE

EMVO has recently shared the newly revised Master Data Guide, designed to provide clear guidance and an improved flow of information.

The document can be found on EMVO's website under *Knowledge Database -> Documents Overview -> On-boarding Partner (OBP)*.

Key updates include:

- ❖ **Clarification of Mandatory Fields:** Specifies which fields are required, including the newly made mandatory fields introduced with the EU Hub Release 1.16.
- ❖ **Enhanced Definitions:** Offers clearer explanations for easier understanding.
- ❖ **Content and Format Refresh:** Ensures information is organized and visually accessible.
- ❖ **New Glossary Addition:** A quick reference to key terms.



HAPPY HOLIDAYS!

The OSMR Team sends you the warmest holiday wishes during this beautiful season!



office@osmr.ro

www.osmr.ro



+40 371 400 348