Department of Health & Social Care

Medicines & Healthcare products Regulatory Agency

# Windsor Framework: Information for pharmaceutical wholesalers

The Windsor Framework introduces a UK-wide licensing regime, meaning that the same medicinal products, in the same packs with the same packaging will be available across the whole UK. The Medicines and Healthcare products Regulatory Agency (MHRA) will license all medicines across the UK, including novel medicines, which under the original Protocol had to be authorised for Northern Ireland by the European Commission.

This information is designed to help wholesalers understand the main changes that have been introduced by the Windsor Framework's medicines arrangements which came into effect on 1 January 2025.

From this date, the Windsor Framework introduces new rules in the UK for product licensing, labelling, and the EU Falsified Medicines Directive (FMD). It will ensure that medicines can be approved and licensed on a UK-wide basis by the MHRA and medicines can be supplied in the same packs across the UK. It also provides for the disapplication of FMD safety features for medicines marketed and supplied in Northern Ireland. All other arrangements for Great Britain to Northern Ireland supply continue uninterrupted.

## Labelling and packaging

- From 1 January 2025, all new medicines released to the UK market must bear a clearly legible 'UK Only' marking on the outer packaging. For six months, this can be done using a sticker (until 30 June 2025). This requirement applies across the UK, it is not specific to Northern Ireland.

- Products released for the UK market by a Qualified Person (QP) before 1 January 2025, without 'UK only' marking, can continue to be distributed until the expiry date of the product.

- From 1 January, all products with a 'PLGB' authorisation number will automatically become valid for UK wide supply, as long as they are marked 'UK Only'. Any products with a 'PLNI' authorisation number continue to be restricted to Northern Ireland only.

- The MHRA has permitted the early implementation of 'UK Only' labelling requirements for products with a current 'PL' (UK-wide) authorisation number or a 'PLGB' authorisation number prior to 1 January 2025.

## Supply movement from 1 January 2025 for products already released prior to this date

- Products released for the **UK market** (PL number) by a Qualified Person before 1 January, without 'UK only' marking, can continue to be distributed **to the whole UK** until the expiry date of the product.

- Products released for the **GB market** (PLGB number) **without "UK only"** marking can only be **supplied to GB**, including after 1 January 2025, unless they are also on the NIMAR list.

- Products released for the **GB** market (PLGB number) **with "UK only"** marking can be supplied **UK wide** from 1 January 2025

- Any products with a 'PLNI' authorisation number continue to be restricted to supply in Northern Ireland only.

## Supply movement for products released post 1 January 2025

Any products with a 'PLNI' authorisation number continue to be restricted to supply in Northern Ireland only.

This means that for a period of time a mixture of packaging types will be present on the UK market, as packs released prior to 1 January 2025 move through the supply chain.

There is no requirement for products in old packaging to be physically present in the UK by 1 January 2025 – as long as stock in old packaging has been released by a Qualified Person before 1 January 2025 for supply to the UK market, it can move through the supply chain as usual, until it expires. This is the same for Northern Ireland and Great Britain.

## Packaging pre-1 January 2025


UK-wide pack with no ‘UK Only’ marking


Great Britain-only pack with no ‘UK Only’ marking

## Packaging post-1 January 2025


UK-wide pack with ‘UK Only’ marking


UK-wide pack with ‘UK Only’ marking

# 2D barcodes and serial numbers

Presently, all medicines packs valid for supply to the Northern Ireland market, which includes UK-wide medicines with a 'PL' authorisation number and Northern Ireland-only medicines with a 'PLNI' authorisation number, must bear a serial number and 2D barcode, encoding data uploaded to the EU's repositories system under the EU's Falsified Medicines Directive. These EU features will no longer apply from 1 January, but packs may, optionally, still bear 2D barcodes and serial numbers that are not recognised by the EU's repositories system. N.B. Products bearing the EU FMD safety features released before 1 January 2025 can continue to move through the supply chain until their expiry date and will not need to be verified or decommissioned at any point in the supply chain.

From 1 January 2025, SecurMed, the UK medicines verification organisation, will cease to operate, all data stored in its databases will be deleted. It is recommended that connections or interfaces from ERP systems to SecurMed are disabled.

## What does this mean for me?

- **QP certified goods** in Northern Ireland (NI) may be released to the UK without Responsible Person for import (RPi) oversight.
- **UK licensed medicines may no longer be stored in the EEA** after supply and being placed 'on the UK market' (meaning it has received QP certification).
- **MHRA Compliance teams will inspect against Windsor Framework requirements** from 1 January 2025.

# Import and export requirements

- 'UK Only' livery does not prevent export of medicines where local legislation allows. See further guidance.
- These products cannot be supplied to the EU, including Ireland, unless in compliance with regulatory pathways and guidance from respective national competent authorities
- Both UK and EU livery medicine imported to GB requires RPi oversight.
- UK and EU livery medicine imported to NI does not require RPi oversight.
- All UK medicines released on or after 1 January 2025 may freely circulate in UK market once QP certified and released.
- The Northern Ireland MHRA Approved Route (NIMAR) will remain in force.
- PL NI products can only be circulated in NI.

# Frequently asked questions

1. **Can I continue to supply previously purchased medicines (that do not bear 'UK Only' labelling and obtained prior to 1 January 2025)?**

   Yes. Products on the market (QP batch released for the UK or GB) prior to 1 January 2025 can remain on the market until the date of expiry. If the product is a PLGB only product, then it can't go to NI unless accompanied by NIMAR.

2. **Can I continue to supply medicines after the 1 January 2025 which do not bear the 'UK Only' labelling on its packaging?**

   Yes. Existing packaging which was released before 1 January 2025, without 'UK Only' can remain on the market until the date of expiry. Note, that products released before 1 January which hold PLGB licenses and do not bear 'UK only' labelling on the packaging can only continue to be supplied to GB.

   Any product that has been QP released before 1 January 2025 in livery not bearing 'UK only' can continue to move through the supply chain regardless of its physical location, to be distributed to the territory for which it was released. So, wholesalers can continue to buy and distribute such products until their date of expiry.

3. **Can I supply any medicines obtained with 'UK Only' labelling prior to 1 January 2025? For example, is it possible that 'UK Only' packaging will be in circulation in 2024?**

   Yes, packaging bearing 'UK Only' can be supplied prior to 1 January 2025. To assist with the implementation of Windsor Framework arrangements, the MHRA has permitted the early implementation of 'UK Only' on PL and PLGB packaging. This means Marketing Authorisation Holders can release stock to the market bearing 'UK Only' labelling on their packaging prior to 1 January 2025, and these stocks can subsequently be supplied.

4. **What should I do if I receive invalid stock? Who should I contact and report this to?**

   Wholesale distributors must immediately inform the Licensing Authority by reporting to the Good Distribution Practice (GDP) Inspectorate at GDP.Inspectorate@mhra.gov.uk, the Yellow Card Scheme, and the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified. Any falsified medicinal products found in the supply chain should immediately be physically segregated and stored in a dedicated area away from all other medicinal products as soon as possible.

# Further information

For further information, please email windsor.framework@dhsc.gov.uk