Department of Health & Social Care

Medicines & Healthcare products Regulatory Agency

Windsor Framework: Information for pharmacists and medicines procurers

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 Northern Ireland Protocol had to be authorised for Northern Ireland by the European Commission.

This information is designed to help pharmacists, pharmacy technicians and those with responsibility for procuring medicines understand the main changes that have be 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 are approved and licensed on a UK-wide basis by the MHRA and medicines will be supplied in the same packs across the whole UK. It also provides for the disapplication of FMD safety features for medicines marketed and supplied in Northern Ireland.

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 this date, without the '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

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 legacy packaging to be physically present in the UK by 1 January 2025 – as long as stock in legacy packaging has been released by a Qualified Person before 1 January 2025 for supply to the territory for which it was released, it can move through the supply chain as usual, until it expires. This is the same for Northern Ireland and Great Britain. In Northern Ireland, PLNI licences remain valid but are rare and will become rarer as manufacturers transition to UK-wide licences.

For more information on labelling, packaging and stickering, please visit Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework - GOV.UK

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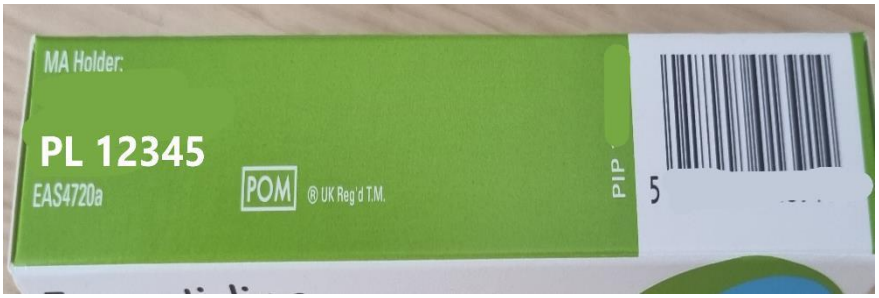
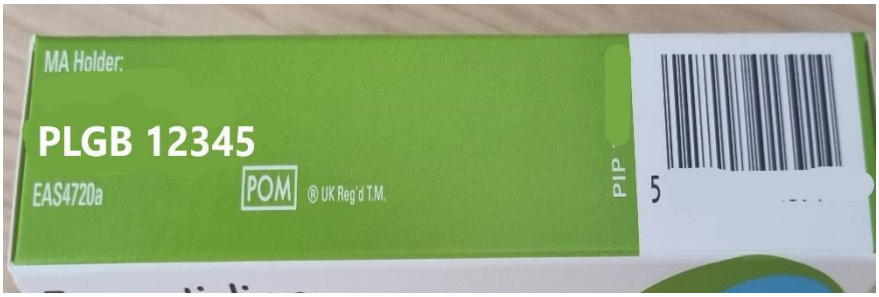
Pre-1 January 2025 packaging

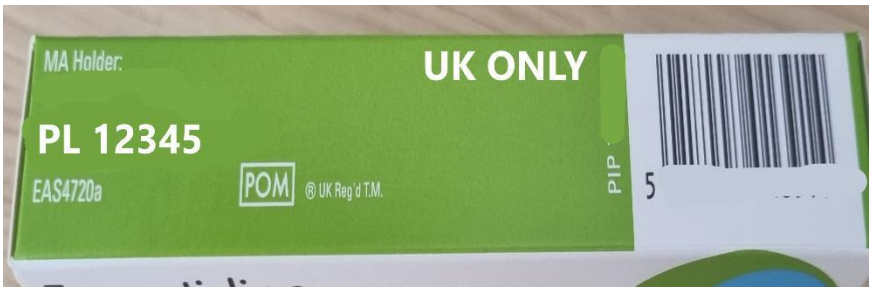


UK-wide pack with no ‘UK Only’ marking



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

Post-1 January 2025 packaging



UK-wide pack with ‘UK Only’ marking

UK-wide pack with ‘UK Only’ marking

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2D barcodes and serial numbers

Presently, prescription 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 2025, 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 to SecurMed from Patient Medication Records or Enterprise Resource Planning systems are disabled.

SmPC & PIL

From 1 January 2025, the product information including Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) approved in Great Britain will apply across the UK. Healthcare professionals in Northern Ireland may therefore notice differences in the SmPC for products previously approved in Northern Ireland via a centralised EU authorisation. In the rare circumstance where the difference leads to a significant change of clinical practice, affecting patient safety in Northern Ireland, Healthcare professionals will be notified via a Direct to Healthcare Professional Communication (DHPC).

Frequently asked question

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

   Yes. Products on the market prior to 1 January 2025 can remain on the market until the date of expiry, in the territory for which they were released.

2. **Can I continue to supply medicines ordered from suppliers/manufacturers after the 1 January 2025, but which do not bear the 'UK Only' labelling on its packaging, or do I need to return these back to my suppliers?**

   Yes, you can continue to supply medicines received from bona fide sources, such as wholesalers, that do not bear the ‘UK Only’ label after 1 January 2025. Medicines released to the market by Marketing Authorisation Holders (MAHs) prior to 1 January 2025 are not required to bear ‘UK Only’ labelling on their packaging, therefore these medicines may remain on the market until their expiry date.

For more information on labelling, packaging and stickering, please visit Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework - GOV.UK

However, you need to ensure that if you receive product with a PLGB license that does not display “UK only”, it is not supplied to Northern Ireland unless it is on the Northern Ireland MHRA Authorised Route (NIMAR) list, even after 1 January 2025.

If received from a bona fide source such as a wholesaler, you can be assured that the MHRA and the Medicines Regulatory Group (MRG) within the Department of Health will be inspecting manufacturers and wholesalers in line with Windsor Framework requirements from 1 January 2025.

3. Can my pharmacy, clinic, etc., 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’ labelling 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’ labelling on PL and PLGB packaging. This means MAHs can release stock to the market bearing ‘UK Only’ on their packaging prior to 1 January 2025 and these stocks can subsequently be supplied.

4. What products are exempted from the ‘UK only’ labelling requirements?

All medicines authorised for the UK or Northern Ireland (NI) market must bear the ‘UK Only’ labelling requirements, which includes all General Sale List (GSL), Pharmacy Only (P), and Prescription Only Medicine (POM) medicines.

However, medicines that do not have a UK or NI authorisation are not required to bear ‘UK Only’. This means unlicensed medicines, imported medicines, extemporaneously-prepared products, compliance aids and other actions under Section 10 of the Medicines Act 1968, etc. will not be required to bear ‘UK Only’ on their outer packaging after 1 January 2025.

5. I have pharmacy businesses across the UK. Can I move compliant stock between my pharmacies in NI and GB?

The Windsor Framework does not alter the movement of medicines within the UK. Pharmacies within the same legal entity can continue to move compliant stock between their premises within the same business entity. All other movements of medicines, i.e. those outside the same legal entity, can only be carried out under an appropriate authorisation, such as a Wholesaler Dealer’s Licence (WDA) issued by the MHRA.

6. I have pharmacy businesses in NI and EEA, e.g. Ireland, can I move stock between my pharmacies?

The appropriate authorisation, such as a WDA issued by the MHRA, will continue to be required for the movement of medicines between NI and EU and EEA, including premises in Ireland.

After the 1 January 2025, medicines authorised for the UK or NI market will only be able to be sold in the UK and export markets where it is lawful for them to be placed on the

market or supplied as unlicensed medicines in those markets in which the national competent authority accepts them. These products cannot be distributed to Ireland or elsewhere in the EU, other than via regulatory pathways for unauthorised medicines subject to EU rules and conditions, for example as exempt medicinal products (unlicensed medicines) in line with EU rules and conditions.

7. **How will pharmacy teams be able to check whether stock was QP-certified in 2024 (without 'UK Only') if it was ordered after the 1 January 2025 from suppliers?**

   Medicines released to the market by MAHs prior to 1 January 2025 are not required to bear 'UK Only' labelling on their packaging, therefore these medicines may remain on the market until their expiry date. Whilst pharmacy teams are not expected to check whether stock without 'UK Only' labelling has been QP certified prior to 1 January 2025, pharmacy teams should continue to exercise due diligence when placing orders for medicines. Pharmacy teams can continue to supply medicines received from bona fide sources, such as wholesalers, that do not bear 'UK Only' after 1 January 2025.
   You should note that pharmacies in Northern Ireland are not able to take product which was meant for GB (PLGB) without "UK only" on the pack, unless it is on the NIMAR list.

   If received from a bona fide source such as a wholesaler, you can be assured that the MHRA will be inspecting manufacturers and wholesalers in line with Windsor Framework requirements, from 1 January 2025.

8. **What should a pharmacy do if they receive invalid stock? Who should they 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.

9. **How should any potential patient complaints be handled? Who should they contact and report any issues to?**

   Wholesale distributors must immediately inform the Licensing Authority by reporting to the 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.

Glossary of terms

- **UK-wide Marketing Authorisation (MA):** a product licensed by the MHRA, across the whole of the UK, (this may include marketing authorisations (MAs) with a PL or PLGB prefix).

- **NI MA (PLNI):** a product licensed by the MHRA that covers Northern Ireland (NI) only as the territorial application with PLNI as the MA number prefix.

- **GB MA (PLGB):** a product licensed by the MHRA that covers Great Britain (GB) only as the territorial application with PLGB as the MA number prefix.

Further information

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