Medicines & Healthcare products
Regulatory Agency

Guidance

Wholesalers & manufacturers guidance following agreement of the Windsor Framework

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Contents

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1. Overview

This guidance is designed to support manufacturers and wholesale dealers authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) and the associated Qualified Persons (QPs), Responsible Persons (RPs) and Responsible Persons for Import (RPis) in order to implement the arrangements of the Windsor Framework for human medicines.

Marketing Authorisation Holders (MAH) will need to ensure changes are communicated to the manufacturer in a timeframe which will enable the manufacturer to ensure that all batches it produces have the correct labelling and product information.

This guidance is intended to be read in conjunction with the labelling and packaging guidance and associated Q&As (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework).

The Windsor Framework sets out the long-term arrangements for the supply of medicines into Northern Ireland. It will ensure that human medicines can be approved and licensed on a UK-wide basis by the MHRA and provides for the disapplication of European Union (EU) Falsified Medicines Directive (FMD) safety features for medicines marketed and supplied in Northern Ireland.

To preclude onward movement of these medicines into any part of the EU, or European Economic Area (EEA) while ensuring medicines use the same packaging and labelling across the UK, all medicines on the UK market must be labelled as ‘UK Only’.

These measures will commence on 1 January 2025[footnote 1]. This means that from this date:

- All new medicines and medicines in Northern Ireland that currently fall under the scope of the EU Centralised Authorisation Procedure will be authorised by the MHRA for the UK market. See further guidance on the transition of licences (https://www.gov.uk/government/publications/uk-wide-licensing-for-human-medicines/uk-wide-licensing-for-human-medicines).
- These products 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. These products will not be available on the market in Ireland or elsewhere in the EU, other than via regulatory pathways for unauthorised medicines subject to EU rules and conditions, for example as unlicensed medicines subject to EU rules and conditions. -Packaging for all products for the UK market must

carry a clearly legible ‘UK Only’ label. Stickering can be used until 30 June 2025.

- Joint packs between the UK and EU will no longer be possible. -PLGB licences will become UK wide MAs from 1 January 2025.

2. Glossary of terms

For the purposes of clarity and consistency, this guidance uses the following definitions of key terms:

- **QP:** Qualified Person
- **RP:** Responsible Person
- **RPi:** Responsible Person for Import
- **EMVS:** European Medicines System Verification

3. Guidance for QPs

3.1 Labelling and packaging requirements

From 1 January 2025, to enable medicines to use the same packaging and labelling across the UK, packaging for all UK human medicinal products (Prescription Only Medicine and Pharmacy and General Sales List) must carry a clearly legible ‘UK Only’ label to be placed on the UK market. This is inclusive of parallel imported products. Any stock in existing packaging already QP certified and placed on the market (in Great Britain and Northern Ireland) can continue to be supplied to patients in the relevant territory until the date of expiry. See further guidance (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework) on labelling and packaging requirements. This means that any stock QP certified from 1 January 2025 must include “UK Only” on the packaging.

3.1.1 Application of ‘UK Only’ label

When using the ‘UK Only’ label on packaging, the following will apply, as set out in section 4 of the labelling and packaging

guidance (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#uk-only-label-requirements) and Article 5 of Regulation (EU) 2023/1182: [footnote 2]

'UK Only' may be presented anywhere on the outer packaging of the medicine so long as it is in a conspicuous place in such a way that it is easily visible. It shall not in any way be hidden, obscured, detracted from, or interrupted by any other written or pictorial matter or any other intervening material.

- 'UK Only' must be clearly legible and indelible. The font size shall be at least 7 and the label must be in line with current MHRA expectations and best practice guidance. Packaging for larger-sized products should take into account the need for the 'UK Only' to be easily visible and clearly legible.
- There are no other font or style requirements other than stated above.
- Packaging for all UK Homeopathic (NR) medicinal products should state 'UK Only' in line with the requirements stated in section 11 of the labelling and packaging guidance (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#traditional-herbal-thr-and-homeopathic-nr-and-hr-medicinal-products).

3.1.2 Stickering with "UK Only" label

The 'UK Only' statement can be applied to the outer pack, via an indelible sticker for a limited period of 6 months, to 30 June 2025. After this date, 'UK Only' must be printed directly onto the packaging. Stickering will not be accepted after this date.

For Parallel Import products (PLPIs), see further guidance (https://www.gov.uk/government/publications/uk-parallel-import-licences-following-agreement-of-the-windsor-framework/uk-parallel-import-licences-following-agreement-of-the-windsor-framework).

Where products are imported without the 'UK Only' label, stickering may be performed locally within the UK prior to QP certification and release to the market. Stickering must be undertaken at a site holding a Manufacturers/Importers Authorisation (MIA) authorising Secondary Packaging and named on the Marketing Authorisation (MA) and must not obscure packaging information.

To ensure the continued supply of medicines to Northern Ireland and for the sole purpose of adding ‘UK Only’ stickers to packs released prior to midnight 31 December 2024, MA holders should use the notification process (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#notification-process) to name the MIA holders (authorised for secondary packaging) that they intend to use. QP responsibilities are as defined in EU GMP Annex 16, specifically Chapter 1.4.1.

3.1.3 Early release to market

The ‘UK Only’ label can be applied to packaging and released to the Great Britain market before 1 January 2025.

PLGB medicines featuring “UK Only” labelling which have been QP certified prior to midnight 31 December 2024 will be valid for immediate supply to the Northern Ireland market after 1 January 2025. QPs should have mechanisms in place to ensure PLGB packs are compliant with the requirements of MHRA guidance prior to release. PLGB packs that have been QP certified prior to midnight 31 December 2024 which do not feature ‘UK Only’ on packaging cannot be supplied into Northern Ireland unless featured on the NIMAR list as defined within the Human Medicines Regulations 2012 SI167A and 167B.

Further information can be found in section 8 of the labelling and packaging guidance (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#early-release-to-market).

3.1.4 Joint packs and export packs

From 1 January 2025, joint EU/UK packs can no longer be QP certified and released to the UK supply chain. A joint pack is one that is shared with another EU country or countries that present administrative details for both the UK and the other markets sharing the pack. Information relevant to other markets will need to be removed from the outer cartons for these packs when the ‘UK Only’ statement is added, and these changes should be made within the same submission. Packs QP certified up to (and including) 31 December 2024 may continue to be supplied until their expiry date. Shared inner packaging components, such as multi-lingual blister foils and joint leaflets may continue to be used, provided that the UK and EU licences remain aligned.

3.1.5 Traditional Herbal (THR) and Homeopathic (HR) medicinal products

UK Herbal (THR) and Homeopathic (HR) medicinal products do not require a 'UK Only' label to be applied to packs but have the option to apply the 'UK Only' label for consistency in accordance with the guidelines for label application. See section 11 of the labelling and packaging guidance (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#traditional-herbal-thr-and-homeopathic-nr-and-hr-medicinal-products) for further information.

3.1.6 Medical devices

Medical devices are outside of the scope of this guidance, however combination products which are medicinal products will be required to comply with MHRA guidance.

3.2 Falsified Medicines Directive

The Falsified Medicines Directive will be disapplied UK-wide from midnight 31 December 2024 and the UK repository will no longer be accessible.

As set out in section 6 of the labelling and packaging guidance (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#disapplication-of-fmd-safety-features-and-encoding-of-pack-information-under-uk-law), UK-licenced 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.

MA holders may choose to apply the following features on UK packaging, although this is not compulsory:

- a 2D barcode (Data Matrix), which may encode data including information about the specific medicinal product, the expiry date, batch number, Global Trade Item Number, and serial number if applicable;
- a serial number of any format;
- a tamper evident seal.

3.2.1 EU based QPs

Where QP batch certification is performed in EU and packs display a 2D barcode in line with this guidance, the RPi should confirm that:

- That a pack is not recognised by the EU repositories system.
- If an FMD-compliant barcode, meaning one recognised by the EU repositories system, were to be present, this has been fully removed or covered. As noted above, other 2D barcodes may be present.

3.2.2 UK based QPs

Where the QP batch certification is performed in the UK and a pack has been imported from the EU, companies should seek written assurances or evidence from suppliers that:

-Where a pack displays a 2D barcode, this is not an FMD-compliant barcode, meaning one recognised by the EU repositories system.

- If an FMD-compliant barcode, meaning one recognised by the EU repositories system, were to be present, this has been fully removed or covered. As noted above, other 2D barcodes may be present.

Any company parallel importing medicines from the EU must seek written assurances or evidence from suppliers that goods have been decommissioned prior to receipt into the UK as UK companies will be unable to independently verify this activity has occurred.

As the UK repository will no longer exist, this will prevent the risk of uploading to the repository in error. Should a company become aware of circumstances or situations where goods have been, or could be uploaded to EMVS in error, please report this to gdpinspectorate@mhra.gov.uk, fmd.gmpenquiries@mhra.gov.uk and the relevant EU National Competent Authority.

Any instances of suspected falsification (including physical signs of tampering) are to be reported in the usual way via the Yellow Card reporting system (https://yellowcard.mhra.gov.uk/falsified).

3.3 Northern Ireland MHRA Approved Route

The Northern Ireland MHRA Approved Route (https://www.gov.uk/government/publications/the-northern-ireland-mhra-

authorised-route-nimar/the-northern-ireland-mhra-authorised-route-nimar) (NIMAR) has been designed to ensure that patients in Northern Ireland can continue to access prescription-only medicines (POMs) should clinical need be unable to be met through authorised products or any other existing regulatory routes, prior to the implementation on 1 January 2025. To date this has been used primarily to protect patient health in NI, by allowing PLGB products to be supplied to NI where there is no alternative authorised product applicable in NI available.

With the implementation of these measures, most PLGB licensed products currently on the NIMAR list (https://www.gov.uk/government/publications/medicines-eligible-for-northern-ireland-mhra-authorised-route) will no longer require inclusion on the list and may be removed.

However, PLGB licensed products which are QP certified prior to midnight 31 December 2024 and non-compliant with the labelling requirements, e.g., which do not feature 'UK Only' on the packaging, will not automatically be permitted to freely circulate to Northern Ireland. Any company wishing to supply such products should consult the NIMAR list to ensure the product is included on it, prior to undertaking any supply.

The NIMAR list will remain in force to continue to facilitate the supply of packs into Northern Ireland were there to be circumstances where no alternative authorised medicines are available.

For further information regarding inclusion on the NIMAR list, please contact the Department of Health and Social Care (DHSC) (https://www.gov.uk/government/publications/the-northern-ireland-mhra-authorised-route-nimar/the-northern-ireland-mhra-authorised-route-nimar#nimar-and-the-windsor-framework).

3.4 Export activity

All new packs must be labelled as 'UK Only' from 1 January 2025 to preclude onward movement of medicines with UK livery into any part of the EU and EEA, while ensuring medicines use the same packaging and labelling across the UK. The inclusion of 'UK Only' on packaging does not mean that goods cannot be exported to other countries or territories outside the EU.

Medicines featuring 'UK Only' on their packaging may continue to be exported after 1 January 2025 to any country or territory where the export of those medicines is compliant with local legal

requirements or provisions, and where those medicines do not feature on the DHSC export ban list. The MHRA expects any organisation exporting medicines to be able to confirm that this activity has been undertaken in line with both UK legislation and applicable requirements in the receiving country.

3.5 Activities performed in Northern Ireland

The MHRA remains the National Competent Authority in Northern Ireland. Northern Ireland based QPs who are named on a Northern Ireland GMP authorisation may continue to perform batch certification for both UK and EU markets where the site of batch release is located within Northern Ireland.

Northern Ireland companies utilising MHRA approved sites in Great Britain may only release those goods to the UK.

Companies located within Great Britain may utilise any MHRA approved Northern Ireland sites to facilitate the supply of medicines UK wide, where they are not subject to any other restrictions.

Sites located in Northern Ireland may continue to be used to store medicines for the UK and EU territories, respectively, however must ensure that medicines must only be supplied to their intended markets.

Table 1 below identifies where goods may be QP certified and recognised depending on where MHRA authorised sites are located.

Table 1: Recognised Territory

	GB	NI	EU
Site of batch release			
Great Britain (GB)	YES	YES	NO
Northern Ireland (NI)	YES	YES	YES

3.6 EEA Storage facilities

From 1 January 2025, it will no longer be possible to utilise EEA located storage facilities to store ‘UK Only’ labelled medicines that have been physically placed on the market in the UK. For example, it will no longer be possible to send goods into the EEA from the UK for storage purposes.

UK label inventories that have been QP certified in the EU and held at a manufacturing site or pre-wholesaler may continue to be stored there until supplied into the UK.

3.7 Location of QP

QPs named on a MHRA Manufacturing and Import Authorisation (MIA) must be resident in the UK. The MHRA policy on remote certification remains unaltered.

4. Guidance for Responsible Person for Import (RPi)

A wholesale dealer in Great Britain may only import QP certified medicines from countries on the Approved Country for Import list (https://www.gov.uk/government/publications/list-of-approved-countries-for-authorised-human-medicines/list-of-approved-countries) if certain checks are made by the RPi. See further guidance on acting as a RPi (https://www.gov.uk/guidance/acting-as-a-responsible-person-import).

Wholesalers should ensure that QP certified goods received after midnight on 31 December 2024 intended for UK-wide supply are compliant with the guidance and regulatory requirements[footnote 3]. PLGB goods QP certified prior to midnight on 31 December 2024 which do not feature ‘UK Only’ labelling may not be supplied into Northern Ireland, unless it is on the NIMAR list.

Medicinal products sourced from Northern Ireland, including an EU livery inventory, do not require RPi oversight.

4.1 Wholesale dealing activities & RP functions

Licence holders are reminded of their obligations to ensure medicines procured are compliant with the conditions of their

licences. Wholesalers should ensure that, when importing goods under the RPi process, the goods that are QP certified after midnight on 31 December 2024 are compliant with the conditions of MHRA guidance and feature ‘UK Only’. Should goods suspected to not comply be identified, please contact gdpinspectorate@mhra.gov.uk for further advice.

It is recognised that medicines released up to (and including) 31 December 2024 may not be compliant with MHRA guidance and will be free to circulate in line with the conditions of their Marketing Authorisation until dispensing or expiry. Please see the packaging and labelling guidance (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#supply-of-existing-stock-in-existing-packs) for further information.

Where QP certified non-compliant PLGB medicines are to be supplied into Northern Ireland, wholesalers should refer to the NIMAR list (https://www.gov.uk/government/publications/medicines-eligible-for-northern-ireland-mhra-authorised-route) to determine if a product can be supplied. If a non-compliant product is removed from the NIMAR list, remaining stock that is already on the Northern Ireland market can be distributed. However, once a product is removed from the NIMAR list, it is not possible to supply new stock from Great Britain to Northern Ireland under NIMAR.

Medicines with UK-wide MAs released prior to 31 December 2024 may continue to be supplied UK wide until the expiry or dispensing of those medicines, whichever comes first, and do not require ‘UK Only’ labelling.

PLNI medicines released prior to 31 December 2024 may continue to be supplied in Northern Ireland until the expiry or dispensing of those medicines, whichever comes first, and do not require ‘UK Only’ labelling.

Wholesalers must continue to remain vigilant regarding the licence conditions of products that they procure or supply and segregate these according to destination market, and should establish procedures to safeguard against the supply of non-compliant medicines to Northern Ireland. Where a company identifies that PLGB goods which are not compliant with MHRA guidance have been supplied to Northern Ireland in error, this should be documented within their quality management system and notified to: gdpinspectorate@mhra.gov.uk (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-

framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework)

5. Further information

For further information, please use the following contacts:

- For any enquiries about FMD and the Safety Features not covered by published guidance, please email fmd.safetyfeatures@mhra.gov.uk
- If you are a manufacturer and have a query regarding the compliance of your packaging, or any other FMD GMP specific question, please email FMD.GMPenquiries@mhra.gov.uk
- For any GDP FMD enquiries, please email the GDP inspectorate at gdpinspectorate@mhra.gov.uk
- For any enquiries about pharmacy or dispensing operations, please contact the General Pharmaceutical Council (GPhC) at info@pharmacyregulation.org (https://www.gov.uk/government/publications/medicines-eligible-for-northern-ireland-mhra-authorised-route)
- For enquiries about veterinary medicines, please contact Veterinary Medicines Directorate - GOV.UK (www.gov.uk) (https://www.gov.uk/guidance/contact-vmd)

Veterinary medicines do not require ‘UK Only’ to be included on the label and are subject to an arrangement until the end of 2025 which enables veterinary medicines authorised or approved in the UK, or which are moved via Great Britain, to continue to be placed on the market in Northern Ireland.

- For anything else, please email our Customer Services Centre at info@mhra.gov.uk or telephone 020 3080 6000

Footnote 2

Article 5:

Specific rules for the labelling of medicinal products as referred to in Article 1(1)

Medicinal products as referred to in Article 1(1) shall bear an individual label that complies with the following requirements:

- (a) it shall be attached to the packaging of the medicinal product in a conspicuous place in such a way that it is easily

visible, clearly legible, and indelible; it shall not in any way be hidden, obscured, detracted from, or interrupted by any other written or pictorial matter or any other intervening material;

- (b) it shall state the words ‘UK Only’.

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1. Subject to the UK providing written guarantees to the European Commission as provided for in Article 8 of EU Regulation 2023/1182 and following the entry into force and application procedure provided for in Article 14.
2. Footnote 2
3. Including the HMR 2012 as amended by [SI name] and Regulation (EU) 2023/1182