Medicines & Healthcare products Regulatory Agency

Windsor Framework agreement on the supply of human medicines in Northern Ireland

Explainer

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Introduction

The Windsor Framework secures the long-term stability of medicines supply to Northern Ireland, ensuring that medicines will be available in the same packaging across the UK. This means that new UK-wide arrangements for medicines come into effect on 1 January 2025 . It is important that you take action now to be ready.

This document explains the main changes that these new arrangements will introduce and what you need to do to prepare. It should be read in conjunction with the other Medicines and Healthcare products Regulatory Agency (MHRA) guidance on the Windsor Framework, including the UK-wide licensing guidance and labelling and packaging guidance.

What is the Windsor Framework?

On 27 February 2023, the UK and EU announced a new agreement, known as the Windsor Framework, which introduced new arrangements in place of the original Northern Ireland Protocol. The new arrangements will make the supply of medicines to the UK market simpler and easier.

For medicines, the Windsor Framework brings novel medicines under the UK licensing regime operated by the UK's MHRA. Previously, the European Medicines Agency (EMA) and the European Commission (EC) were responsible for approving novel medicines for supply in Northern Ireland under a process known as the "EU Centralised Procedure".

This meant different licensing procedures and separate licences were in place for these medicines to be supplied to Northern Ireland, which created a risk of fewer medicines being available in Northern Ireland than in Great Britain. Different procedures and separate licences gave rise to different labelling and packaging requirements, which risked discontinuation of supply to Northern Ireland if companies chose not to maintain two different labels and packs for Great Britain and Northern Ireland.

In addition, the EU's Falsified Medicines Directive (FMD) safety features requirements for packaging, barcoding and scanning applied to Northern Ireland but not Great Britain. Under an existing derogation agreed in April 2022, medicines can move through Great Britain without complying with requirements to verify and decommission FMD unique identifiers on packs until 31 December 2024. After this date, without the Windsor Framework these FMD requirements would have applied in full for Northern Ireland. This arrangement was not sustainable and would have created a disproportionate burden in the supply chain and a further risk to Northern Ireland supply.

Safety of medicines for patients is a central concern for us. There are a range of UK safety measures in place which prevent falsified medicines entering the legal supply chain and reaching patients. These will remain in place.

The Windsor Framework addresses the risks set out above and the UK has put in place legislation to ensure that the same medicines are available at the same time, in the same packs and on the same legal and regulatory basis right across the UK.

Regulatory changes for medicines under the Windsor Framework

From 1 January 2025 new rules in the UK for product licensing, labelling, and FMD will be in place. This also means that from 1 January 2025, the MHRA will be the only authority approving medicines for the UK market.

The new arrangements for medicines make the following key changes:

- Removes EU licensing processes in relation to Northern Ireland for novel medicines (i.e. those that were authorised under the EU Centralised Procedure). Medicines authorisations granted by the EC will no longer be valid in Northern Ireland.

- Removes any requirement for EU Falsified Medicines Directive packaging, labelling and serialisation barcode for medicines in Northern Ireland.

- Requires all medicines placed on the UK market to be labelled ‘UK Only’, indicating they are not for sale in the Republic of Ireland or other EU countries.

All medicines will be under the jurisdiction of the MHRA, regardless of their authorisation route. The MHRA has existing powers to authorise these medicines for Northern Ireland, either through a UK-wide licence (in practice this is used in most cases), or a Northern Ireland-specific licence.

The main change to medicines licensing is that licences will be UK-wide. Companies will therefore no longer need to apply for separate licences for Great Britain and Northern Ireland to market the same novel medicines across the whole UK.

Categorisation of licences after 1 January 2025

Currently, licences are differentiated geographically into UK-wide, Great Britain-only and Northern Ireland-only licences, with all UK-wide and Northern Ireland licences subject to EU law because EU requirements apply in Northern Ireland. As a result of the Windsor Framework, medicines will generally be licensed on a UK-wide basis.

Given that where EU law applies is therefore no longer inferable directly from the geographic scope of a licence, to be clear about which rules apply to each product, medicines will be classified into one of two categories – category 1 and category 2. Section 1.1 below explains how this will work.

Category 1 medicines will be licensed in accordance with UK-law only. For Category 2 medicines, some EU regulations (as already amended in April 2022 by Directive (EU) 2022/642)) will continue to apply after 1 January, ensuring that Northern Ireland will continue to have dual market access to both the UK Internal Market and the EU Single Market. All existing exemptions for UK medicines, such as those related to the location of the Marketing Authorisation Holder (MAH) and batch testing, will continue to apply regardless of whether the medicine falls within Category 1 or Category 2. The MHRA will remain the competent authority and regulate medicines for the whole of the UK.

Medical devices

There are no changes to the regulation of medical devices. See guidance on the regulation of devices in Northern Ireland. For medicine-device combination products, the medicines element will follow the medicines arrangements as set out in this document. UK-wide authorisations for combination products which contain co-packaged medicines and medical devices will need to continue to follow the EU legislation for medical device components.

Summary of key elements

Patients in Northern Ireland will be able to access the same medicines in the same packs, with the same labels, as the rest of the UK.

The MHRA, as UK regulator, will be responsible for licensing all medicines on the market in Northern Ireland under a UK-wide licence. Unless a company decides to only apply for a licence in Northern Ireland, there will be a single marketing authorisation for the whole UK called a Product Licence (PL), which replaces separate licences for Great Britain and Northern Ireland.

All medicinal products (whether new or already on the market) will fall into one of two categories – Category 1 and Category 2.

All medicines for the UK market must carry a ‘UK Only’ label or sticker, showing they are only for sale within the UK and not in EU countries. Products already on the market in older packaging may remain until the date of their expiry.

The EU Falsified Medicines Directive (FMD) safety features will no longer apply in Northern Ireland. UK medicines will not display features included for the purposes of compliance with FMD. 2D barcodes and serial numbers remain permitted but must not be recognised by the European repositories system, and any such code present would need to be fully removed or covered. Anti-tamper packaging continues to be encouraged.

MHRA Windsor Framework Hub

Visit our MHRA Windsor Framework Hub for further information and resources on the Windsor Framework.

1. UK-wide licensing

As a result of the human medicines arrangements in the Windsor Framework, UK-wide licences can be issued for all types of medicinal products from 1 January 2025, avoiding the need for Great Britain and Northern Ireland specific licences.

The overarching aim is to prevent disruption to supply and ensure all medicines are available at the same time and on the same basis across the whole of the UK.

This chapter explains the arrangements for introducing UK-wide licences and what companies need to do to prepare. It should be read in conjunction with the UK-wide licensing guidance and other relevant MHRA guidance.

1.1 Product categorisation

This section sets out the two categories that will exist for medicines from 1 January 2025, and how medicinal products will be placed in each category.

The Windsor Framework changes the regulation of novel medicines, formerly within the scope of the EU Centralised Procedure – such that matters relating to their marketing authorisation will come under UK law.

This means that, as now, medicinal products have different rules for authorisation depending on whether or not they would have fallen within scope of the EU Centralised Procedure. To be clear which rules apply for UK authorisations, all medicinal products that are licensed on a UK-wide basis will receive a new product classification – either Category 1 or Category 2.

Each application and existing authorised product will be assigned to either of the following categories:

- **Category 1:** Medicines that previously fell within the mandatory or optional scope of the EU's Centralised Procedure will be designated as 'Category 1'. Category 1 includes generic, hybrid or biosimilar products of Category 1 reference products which have been authorised by the MHRA or centrally by the EU regardless of whether the centralised procedure was used for the generic, hybrid or biosimilar application in the EU (see section 4.1 of the UK-wide licensing guidance). The rules for this category largely mirror those for medicines presently covered by GB only licences (these have a PLGB prefix). Category 1 products will be authorised by the MHRA in accordance with UK law on a UK-wide basis.

- **Category 2:** All products that do not fall within the scope of Category 1 will be Category 2 products (see section 4.2 of the UK-wide licensing guidance). The rules

for this category largely mirror those for the medicines presently covered by a UK-wide licences (these have a 'PL' prefix). Category 2 products will be authorised by the MHRA in accordance with UK law and applicable EU law on a UK-wide basis.

No action by MAHs is required for this categorisation process to take place. For authorised products, this will happen automatically prior to 1 January 2025.

The MHRA will publish a list of Category 1 products authorised prior to 1 January 2021, which when ready can be accessed via the UK-wide licensing guidance. Section 4 of the UK-wide licensing guidance provides further details of the basis on which a product's category will be assigned.

1.2 Existing licences

Existing GB product licences (PLGBs) will become UK-wide product licences on 1 January 2025. This means that the territorial scope of these existing licences will be changed from GB only to UK-wide, as outlined below. Licence numbers, including the prefix, will remain unchanged.

1.2.1 PLGB licences

All current PLGB licences will automatically become valid for the whole of the UK from 1 January 2025. There may be some rare circumstances where a PLGB is cancelled by either the Marketing Authorisation Holder (MAH) or the MHRA by 31 December 2024 due to the existence of a PLNI for the same product (see section 1.2.2 below).

However, in the vast majority of circumstances, for MAHs who have a PLGB licence for a specific product, no action is necessary for this transition. It is important for MAHs to also follow the requirements for medicine labels, leaflets, and packaging, as set out in chapter 2.

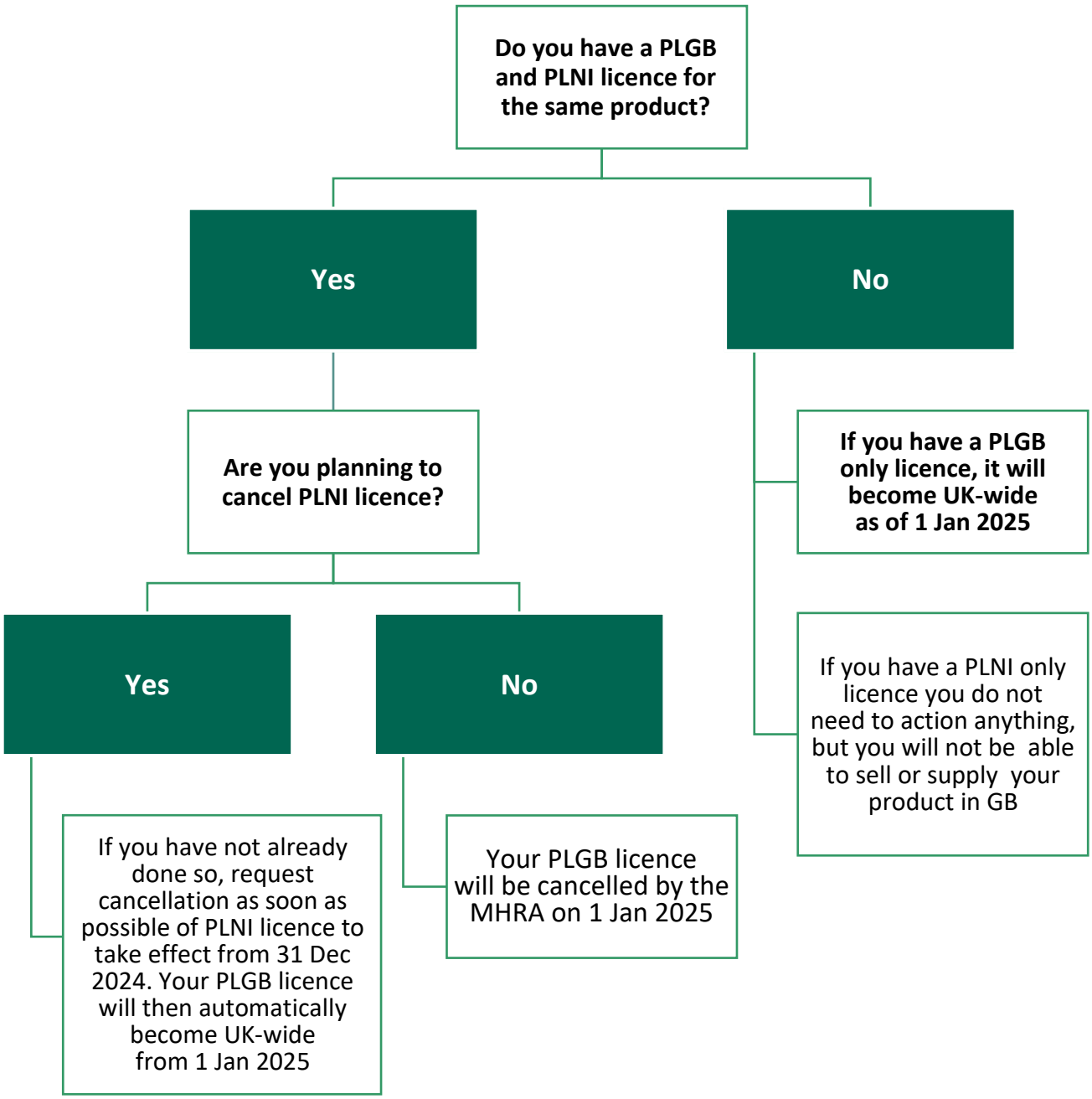
1.2.2 PLNI and PLGB licences for the same product

From 1 January 2025, it will not be possible to simultaneously hold a UK-wide and a PLGB or PLNI licence for the same product. This is to ensure that the regulation of each product is clear. If a MAH has both a PLNI and a PLGB for the same product and wants to retain UK-wide authorisation, the PLNI must be cancelled. This will allow the existing PLGB to be converted to a UK-wide licence on 1 January 2025.

Consequently, the MHRA requested MA holders of PLGB and PLNI licences for the same product to submit a request by 30 September 2024 to cancel the PLNI to **take effect on 31 December 2024**. The MAH should also inform the Reference Member State (RMS) of its intention to withdraw Northern Ireland as a Concerned Member State (CMS) from the MRP/DCP.

The MHRA will co-ordinate the cancellation of the PLNI and the conversion of the PLGB to a UK-wide marketing authorisation (MA). If the PLNI has not been cancelled the MHRA will automatically cancel the PLGB with effect from 1 January 2025. This means that only the PLNI will be valid from 1 January 2025.

Management of licences process



MAHs must also comply with labelling and packaging requirements needed on these licences detailed in chapter 2 below.

1.2.3 PLNI-only licences

Where a MAH only holds a PLNI and subsequently applies for a UK-wide licence, the PLNI will need to be cancelled prior to the granting of the UK-wide MA. The MHRA will co-ordinate these actions. The MAH should inform the RMS of its intention to withdraw Northern Ireland as a Concerned Member State from the MRP/DCP. MAHs must also comply with labelling and packaging requirements.

1.2.4 Existing UK-wide licences granted through the MRP/DCP

Existing UK-wide licences that were granted through Mutual Recognition Procedure (MRP) or Decentralised Procedure (DCP) prior to EU Exit (31 January 2020), where Northern Ireland remains a CMS in the EU procedure, can continue to be managed in alignment with the EU procedure. Should UK-specific changes be required in the future which do not align with the EU procedure, Northern Ireland will have to be withdrawn from the procedure. The existing UK-wide licence will then be managed as a standalone authorisation.

1.3 New applications

Any new application for a medicinal product authorisation must be for a UK-wide licence or a NI only licence. MAHs will no longer have the option to apply for a licence that is limited to GB only (PLGB). New Marketing Authorisation Applications (MAA) will receive a UK-wide licence that is valid across the entire UK and the marketing authorisation (MA) number will start with ‘PL’.

The MHRA will only accept an application for a PLNI licence through an MRP/DCP, but the scope of such a licence will be strictly limited to Northern Ireland. It will not be possible to seek a new UK-wide licence which is aligned with an MRP/DCP. It will also not be possible to simultaneously hold a PLNI licence and a UK-wide licence for the same product, so a PLNI should only be sought where an MAH does not wish to supply to GB or hold any other licence in the UK for the same product.

1.3.1 New applications for generics

Reference Medical Products (RMPs) and comparator products

Generic, hybrid or biosimilar applications must cite a Reference Medicinal Product (RMP). The RMP is the existing innovator medicine that has been authorised for at least 8 years. Currently a generic, hybrid or biosimilar application must cite a RMP which has been authorised for at least 8 years in both UK and EU when submitting an application for a UK wide generic, hybrid or biosimilar. This will no longer be necessary. All applications for these UK-wide licences from 1 January 2025 should cite products with a UK licence as the RMP.

The use of European Reference Products in applications for UK-wide generics, hybrids and biosimilars will no longer be possible for applications submitted from 1 January 2025.

Valid UK-wide RMPs will include:

- All eligible existing products with UK-wide licences including PLGB licences which through the conversion process described above will become UK-wide licences from 1 January 2025.

- All new and innovative medicines which will be licensed UK-wide by the MHRA.

The Data and Marketing Exclusivity Periods (DME) refer to the time from authorisation of a new medicinal product before applications for generic, hybrid and biosimilar versions of that medicine can be applied for and subsequently marketed:

- For UK-wide generic, hybrid and biosimilar applications the DME period will start from the date of the authorisation of the UK product used as the RMP.

- Where the UK RMP is a product that was converted (grandfathered), from an EU CAP to a PLGB following EU-Exit, the start of the DME which was in effect on 31 December 2020 will apply – as it does now.

- For PLNI applications authorised through the MRP/DCP, the DME periods relevant to the cited ERP will apply.

The current GB position on the use of international comparator products for bioequivalence and therapeutic equivalence studies will be extended to cover the whole of the UK from 1 January 2025. In summary, comparator products generally should be sourced from the UK. However, if the comparator product is not sourced from the UK market, the applicant should provide evidence that an international alternative is representative of the UK RMP. For further information, see guidance on the suitability of RMPs for generic or hybrid applications and international comparator products.

1.4 Regulatory compliance for category 1 and 2 products

The following table summarises different aspects of regulatory compliance for UK-wide licences and how these apply to category 1 and category 2 products. For further details about each compliance area, the links within the table will direct you to relevant guidance.

Category 1 products will be either converted from present GB licences or are existing UK-wide products. The rules for this category largely mirror those for the present PLGB medicines category.

Category 2 products will overwhelmingly be current UK-wide products. The rules for this category largely mirror those presently in place, though for new applications there are certain changes consequential to the Windsor Framework – for example for reference medicinal products.

Table 1 – Regulatory compliance: Applicable product categories

Compliance area	Category 1	Category 2
Pharmacovigilance	UK requirements only*	UK and EU requirements as applicable
Location of Qualified Person for Pharmacovigilance (QPPV)	UK or EEA	UK or EEA
Territory where applicant for marketing authorisations must be established	UK or EEA	UK or EEA
Reference Medicinal Products (RMP) for generic/hybrid application	RMP must have a UK MA. Data and Market Exclusivity period starts on date of UK/ GB authorisation; or original EU authorisation for converted EU MAs.	RMP must have a UK MA. Data and Market Exclusivity period starts on date of UK/ GB authorisation including for cases originally authorised through EU mutual recognition or decentralised procedures.
Comparator product for Bioequivalence or Therapeutic Equivalence Testing	UK product or supported by data in UK guidance on comparator products	Comparator product for Bioequivalence or Therapeutic Equivalence Testing
Requirement to add 'UK Only' label on packaging	Requirement applies	Requirement applies
Falsified Medicines Directive (for applicable products)	EU requirements disapplied	EU requirements disapplied
Paediatric requirements	UK requirements apply	UK and EU requirements apply
Orphan designation and rewards	UK regulations apply	Not applicable
Good Manufacturing Practice (GMP)	The Good Manufacturing Practice Directive has not been altered by the Windsor	The Good Manufacturing Practice Directive has not been altered by the Windsor

	Framework. EU GMP applies in respect of Northern Ireland; and the EU GMP, modified by Schedule 2A of the Human Medicines Regulations applies in respect of Great Britain.	Framework. EU GMP applies in respect of Northern Ireland; and the EU GMP, modified by Schedule 2A of the Human Medicines Regulations applies in respect of Great Britain.
Location of Qualified Person (QP) – batch certification	The responsibilities of the QP (and RPi) are not altered by the Windsor Framework.	The responsibilities of the QP (and RPi) are not altered by the Windsor Framework.
Pharmacopeial standards	Compliance with Pharmacopeial standards has not been altered by the Windsor Framework. European Pharmacopoeia and British Pharmacopoeia standards apply.	Compliance with Pharmacopeial standards has not been altered by the Windsor Framework. European Pharmacopoeia and British Pharmacopoeia standards apply.

1.5 Summary of key changes from 1 January 2025

New applications	All new national applications for medicine approvals will receive a UK-wide licence and MAs will have the prefix 'PL' in the licence number. Learn more
New applications for generics	• **Reference Medicinal Products (RMP):** All new generic, biosimilar and hybrid applications must cite UK-wide licence as a reference product. • **Data and Marketing Exclusivity (DME) periods:** The start date of DME periods will be the date of authorisation of the UK product. Learn more
Existing GB Product Licences (PLGBs)	• You will no longer be able to apply for a licence that is valid only in Great Britain (known as PLGBs) after 31 December 2024. • Existing PLGBs will automatically be converted to Product Licences that are valid for the whole of the UK. Medicines will retain the same licence number (including the prefix 'PLGB'). Learn more

Existing NI Product Licences (PLNIs)	• If you only hold a PLNI and subsequently seek UK-wide authorisation, the PLNI will need to be cancelled before the UK-wide licence can be granted. • Where you are involved in EU procedures that include Northern Ireland as a Concerned Member State (CMS), you must notify the Reference Member State (RMS) to withdraw Northern Ireland as a CMS from the procedure. This must occur before the cancellation of the PLNI and the granting of the new UK-wide licence. Learn more
Existing UK-wide licence not connected to MRP/DCP	No change to territorial scope – remains UK-wide Learn more
Existing UK-wide licence where NI is a CMS in MRP/DCP	Can continue to be managed in alignment with the MRP/DCP procedure unless or until such a time as the MHRA requires UK-specific changes, at which point NI will need to be withdrawn from the MRP/DCP Learn more
Holding a PLNI and PLGB for the same product	• You will no longer be able to simultaneously hold a UK-wide licence and a PLGB or PLNI for the same product. • MAHs with existing PLGB and PLNI for the same product will need to cancel the PLNI in order for the existing PLGB to be converted UK-wide. Learn more

Further information

View guidance on UK-wide Licensing for Human Medicines

2. Labelling and packaging requirements

The introduction explained that the packaging for all licensed medicines placed on the UK market from 1 January 2025 must include the wording ‘UK Only’. This is to prevent onward movement of UK medicines into the EU.

This chapter gives more detail about the regulatory action that needs to be taken by UK-based suppliers or distributors of medicines.

If you have not already done so, you should submit your updates to labelling artwork as soon as possible to ensure your products are compliant on the implementation date of 1 January 2025. If using the self-certification submission route, you do not need to wait for approval to implement the proposed change once you have submitted your artwork updates to the MHRA (see sections 2.2 and 2.3 below).

2.1 Applying ‘UK Only’ to packs

The requirement to apply the wording ‘UK Only’ to all new packs for licensed medicines placed on the UK market (i.e. certified by a Qualified Person (QP)) on or after 1 January 2025, applies to all marketed products regardless of legal classification, i.e. Prescription Only Medicines (POM), Pharmacy (P) medicines and General Sales List (GSL) medicines. When applying ‘UK Only’ to your packs, this must be in line with Article 5 of EU Regulation 2023/1182 and following requirements must be met:

- ‘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 should 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.

Stock in existing packaging that has been QP-certified in Great Britain and Northern Ireland prior to 1 January 2025 can continue to be supplied to patients in the relevant territory until the date of expiry of the medicine. This will help support a smooth transition to the new arrangements.

UK Herbal (THR) and Homeopathic (HR) medicinal products

Products authorised through the Traditional Herbal Registration scheme (THR) and the Homeopathic registration scheme (HR) in the UK are not obligated to carry a 'UK Only' label on their packaging, as they fall outside the scope of the Windsor Framework. However, companies do have the option to apply the 'UK Only' label if they wish to maintain consistency. If they do so, the guidelines for label application should be followed.

2.2 Submitting artwork changes

The MHRA's regulatory responsibility is to have oversight of all medicines supplied to the UK market, this includes approval of changes to UK labelling and packaging to ensure all packs supplied to UK patients meet UK requirements. This regulatory requirement is set out in Regulation 267 of the Human Medicines Regulations 2012.

From July 2023 the MHRA has offered three possible submission routes for making updates to packaging artwork, to give maximum flexibility to companies. Companies could submit through:

1. **Any regulatory opportunity:** Labelling notifications can be submitted as part of any other regulatory procedure (except a Type IA variation) so long as it is by 1 January 2025.

2. **Self-certification:** Submit a separate self-certification notification specifically for the Windsor Framework artwork change. Provided the changes are in line with the guidance, you can implement the proposed changes once the application has been submitted rather than wait for formal approval. The MHRA is also permitting bulk submissions of up to 25 licences per bulk.

3. **Self-certification without initial Electronic Common Technical Document (eCTD):** A labelling notification made with a PDF mock-up of updated artwork by 31 December 2024. Followed by provision of the updated eCTD as part of another regulatory submission by 31 December 2025.

In order to meet the regulatory implementation deadline of 1 January 2025, for release of packaging that includes the 'UK only' label, **from November 2024 it is recommended that companies only use the self-certification options 2 or 3** to make their remaining artwork submissions. For further information on the notification process, please see section 9 of the labelling and packaging guidance.

2.3 Flexibilities that can be applied

While all submissions for updates to new packaging artwork **must** be made by the 31 December 2024, there is flexibility in implementation:

- The ‘UK Only’ wording can be applied via a sticker (which should comply with the requirements listed in 2.1 and not be an ‘easy peel’ label) for a limited period of 6 months, to 30 June 2025.

- For self–certification submissions where the only changes to the labelling and/or leaflet are to implement the Windsor Framework:

    ✓ the proposed changes can be implemented once the submission is made rather than wait for formal approval.

    ✓ the usual six-month period between submission and implementation of the updated artwork is waived. Where companies would normally need to implement artwork changes 3-6 months after MHRA approval, for the Windsor Framework related changes the updated cartons can be implemented at any time before 1 January 2025.

- Updated packaging for PL and PLGB packs can be released to market ahead of 1 January 2025.

2.4 Export packs

As ‘UK Only’ must be present on the outer packaging of all medicine packs supplied in the UK, these words will appear on export packs where this is the authorised UK pack. The inclusion of ‘UK Only’ on packaging does not mean that goods cannot be exported to 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 Department of Health and Social Care (DHSC) export ban list.

Acceptance of these packs is up to the individual country receiving them and will depend on their own requirements. Packs produced solely for export do not require the ‘UK Only’ wording.

The MHRA also requires that any company exporting medicines should show proof that they have followed both UK laws and the laws of the country receiving the medicines.

2.5 Summary of actions to take now

Labelling changes to packs released before 1 January 2025	Updates to packaging for PLs and PLGBs can be made and released to their respective markets ahead of 1 January 2025. Further information for QPs is set out in section 5.2 below. Learn more

Submitting artwork updates	Companies must notify the MHRA by 31 December 2024 before implementing new artwork changes. Notification can be through: 1. any appropriate regulatory opportunity; 2. self-certification; or 3. self-certification without an initial Electronic Common Technical Document (eCTD). Companies should start making their submissions as soon as possible to ensure readiness in advance of 1 January 2025. From November 2024, it is recommended that companies only use the self-certification options 2 or 3 for submission of their updated labelling. Learn more

Implementation flexibilities	For self-certification submissions where the only changes to the labelling and/or leaflet are to implement the Windsor Framework, companies can do the following: ● the proposed changes can be implemented once the submission is made rather than wait for formal approval. ● the usual six-month implementation period is waived – the updated cartons can be implemented at any time before 1 January 2025. Learn more

Using stickers	Stickers can be used to apply ‘UK Only’ wording for a limited time of 6 months (until 30 June 2025). Learn more

Further information

- View guidance on Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework
- View Q&A document on labelling and packaging of medicinal products

3. Disapplication of the EU Falsified Medicines Directive in Northern Ireland

The introduction explained that a key change made by the Windsor Framework is that the EU Falsified Medicines Directive (FMD) safety features requirement will no longer apply in Northern Ireland from 1 January 2025. This chapter gives more detail on what this means and what companies need to do.

3.1 Background

Following the UK's departure from the EU, the European FMD safety features requirement no longer applies in Great Britain but currently still applies in Northern Ireland until 1 January 2025, when the Windsor Framework arrangements on human medicines takes effect.

The FMD introduced a verification system, consisting of unique bar codes on packs which are scanned at various points including before they are dispensed to the patient. A temporary derogation on the full application of FMD packaging, barcoding and scanning requirements in Northern Ireland was due to expire at the end of 2024, which could have caused disruption to the supply of medicines when it ended. The disapplication of FMD in Northern Ireland resolves this issue.

3.2 Disapplying the Falsified Medicines Directive

The FMD system will be disapplied UK-wide from midnight 31 December 2024 and the UK repository will no longer be accessible. For products to be supplied in the UK from 1 January 2025, any safety features that were added to comply with the FMD, meaning any barcode that can be recognised by the EU verification system, must be removed or covered up (see also section 6 of the published labelling and packaging guidance).

Under UK law, MAHs 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; and

- a serial number of any format.

We continue to encourage companies to use anti-tamper packaging for all medicines.

Access to Medicines Verification System

From midnight 31 December 2024, the UK National Medicines Verification System (NMVS) will no longer be available. This will remove the risk of companies uploading to the repository in error.

Should a company become aware of circumstances where goods have been, or could be uploaded to the 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) should be reported in the usual way via the Yellow Card reporting system.

QPs should have mechanisms in place to ensure that medicinal packs meet the requirements of FMD disapplication, as set out in this chapter and the guidance listed below.

Enterprise resource planning (ERP) software systems

Companies should note that when the NMVS is no longer available, ERP software systems will lose their connection which may result in error messages. You may therefore wish to notify your ERP system provider of this forthcoming change.

Further information

- View section 6 of guidance on Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework
- View section 3.2 of guidance for Wholesalers and Manufacturers Following Agreement of the Windsor Framework
- View guidance on Disapplication of Falsified Medicines Directive Safety Features: Requirements for Parallel Imports

4. Parallel imports

The UK parallel import licensing scheme allows a medicine authorised in a European Economic Area (EEA) Member State to be marketed in the UK, as long as the imported product has no therapeutic difference from a specific cross-referenced UK authorised product. Parallel Import Licences (PLPIs) are subject to different regulations in the Human Medicines Regulations 2012 from non-parallel import products.

This chapter explains the new arrangements for parallel imports under the Windsor Framework and what companies need to do now to prepare.

4.1 Parallel importation of Centrally Authorised Products (CAPs)

Following EU exit, two separate processes are in place for parallel imports of Centrally Authorised Products (CAPs) into the UK. Parallel Import Licences (PLPIs) allow the imported products to be marketed in GB only and Parallel Distribution Notices (PDNs) (i.e. notice letters from the EMA) must be obtained before placing a centrally authorised product on the market in Northern Ireland. PLPIs for non-CAPs may be valid UK-wide.

The Windsor Framework means that parallel import products which are CAPs can, from 1 January 2025, be authorised to be marketed across the whole of the UK via a PLPI licence.

All PLPIs with a current GB territorial limitation will be automatically converted to UK-wide authorisation on 1 January 2025. New applications for PLPIs can be made at any time from now. They must comply with all labelling and packaging requirements as set out in sections 4.2 and 4.3 below, and the artwork must be supplied with the application.

4.2 Summary of requirements for PLPI licence holders

All PLPI licences will continue to use the prefix ‘PLPI’ and the licence number will not change. Any inner/outer labels and leaflets containing the prefix ‘PLGB’ must be changed to ‘PL’.

From 1 January 2025, PLPI licence holders must include ‘UK Only’ on their packaging. In line with the requirements outlined above in section 2.1, ‘UK Only’ may be presented anywhere on the outer packaging of the medicine so long as the text meets the requirements set out in section 2.1 above. The application of ‘UK Only’ may be done by either stickering or printing directly on the packaging. A variation will not be required to amend the artwork; this may be changed ‘in-house’ by the company.

As set out in chapter 3, the EU Falsified Medicines Directive (FMD) safety features will no longer apply in Northern Ireland from 1 January 2025. EU FMD safety features will therefore not apply to parallel import licences as set out in section 3.1 above. PLPI licence holders must ensure packs are decommissioned correctly and cannot re-enter the supply chain. Like other MAHs, PLPI licence holders are encouraged to use anti-tamper packaging. See further details in the FMD guidance for parallel imports.

4.3 Early release to market

Ahead of the 1 January 2025 commencement date, updates to PLPI labelling and packaging can start to be made from now and released to their respective UK or Great Britain markets. Packs which have a UK territory and may enter Northern Ireland, must remain compliant with FMD requirements until 31 December 2024.

Further information

- View guidance on UK Parallel Import Licences Following Agreement of the Windsor Framework
- View guidance on Disapplication of Falsified Medicines Directive Safety Features: Requirements for Parallel Imports
- View guidance on Medicines: Apply for a Parallel Import Licence

5. Pharmacovigilance

This chapter covers the changes to the operation of pharmacovigilance activities under the Windsor Framework for medicines authorised in the UK, what they mean, and what companies need to do.

Patient safety is our top priority. One way we achieve this is through the operation of pharmacovigilance requirements and processes. Some areas of EU law continue to apply for medicines, reflecting the fact that Northern Ireland retains access to the EU single market, as outlined in the introduction section.

In general, the pre-Windsor Framework principles for pharmacovigilance for Great Britain continue to apply, with these now being largely applicable on a UK-wide basis. MAHs should ensure they follow the latest pharmacovigilance guidance on the MHRA website for their licence type as there are differences between Category 1 and Category 2 products for some pharmacovigilance activities (e.g. individual case safety reporting).

- **Category 1 products** will be legally required to follow Part 11 of the Human Medicines Regulations, with further pharmacovigilance requirements outlined in Schedule 12A .

- **Category 2 products** will be legally required to follow Part 11 of the Human Medicines Regulations for pharmacovigilance and with further pharmacovigilance requirements outlined in the Commission Implementing Regulation (EU) No. 520/2012.

The pharmacovigilance rules for Category 1 products reflect the present rules for products in the ‘PLGB’ category and the rules for Category 2 products reflect those in the UK-wide ‘PL’ category. Products which are currently authorised under the PLGB category but fall under the definition of Category 2 will need to comply with EU and UK pharmacovigilance requirements from 1 January 2025.

The Windsor Framework guidance on pharmacovigilance listed below confirms the position for all pharmacovigilance activities regulated by the MHRA and the requirements for Category 1 and Category 2 products. This guidance should be used to supplement the MHRA’s existing operational pharmacovigilance guidance. The guidance will also be reflected in the revised Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK MAHs and the licensing authority guidance note, which is due to come into effect on 1 January 2025.

If in doubt, MAHs should contact the MHRA for further information, using the contact details provided in the pharmacovigilance guidance.

Further information

- View guidance on Pharmacovigilance Following Agreement of the Windsor Framework
- View guidance on Pharmacovigilance Procedures

6. Wholesalers and manufacturers

This chapter sets out the requirements for Qualified Persons (QPs), Responsible Persons (RPs) and Responsible Persons for Import (RPis) from 1 January 2025. It should be read in conjunction with guidance for wholesalers and manufacturers following agreement of the Windsor Framework and other relevant MHRA guidance.

As explained in the introduction, from 1 January 2025 the MHRA will authorise all new medicines and medicines in Northern Ireland that currently fall under the scope of the EU Centralised Procedure.

This means that these products:

- can only be sold in the UK and in export markets where it is lawful for them to be placed on the market (i.e. QP certified) or supplied as unlicensed medicines in those markets.

- will however, not be available for sale in Ireland or other EU countries, unless they are supplied through specific regulatory pathways for unauthorised medicines that comply with EU rules and conditions. For instance, they could be supplied as unlicensed medicines that meet EU regulations and conditions – this is a matter for the relevant local regulatory authority.

Wholesalers and manufacturers should take note of the following in preparing for implementation on 1 January 2025:

Releasing goods to UK from Northern Ireland	QP-certified goods in Northern Ireland may be released to the UK without RPi oversight.

Implementation of 'UK Only' labelling prior to 1 January	Updates to packaging for PLs and PLGBs can start to be made from now and released on the market. However, PLGBs may only be supplied to Northern Ireland after 1 January 2025. In the case of PLGB packs, in order for them to be valid for immediate supply to the Northern Ireland market after 1 January 2025, QPs should have mechanisms in place to ensure PLGB packs meet the FMD disapplication requirements (set out in section 6 of the labelling and packaging guidance) and the labelling requirements prior to release.

Anti-tamper devices	Tamper-evident seals can continue to be retained and are encouraged.

Using stickers	Stickers can be used to apply ‘UK Only’ wording for a limited time of 6 months (until 30 June 2025).

Storage of medicines	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. Batches QP certified prior to 1 January 2025 may continue to be stored at appropriately authorised sites in EEA until supply to the UK.

Batch releases of joint packs (QP release)	Any batches of joint labelled UK/IE medicines which are QP certified for the IE/UK markets before 31 December 2024, can remain on the market until the expiry date of these medicines.

Inspections	Inspections will be conducted against Windsor Framework and Human Medicines Regulations 2012 requirements from 1 January 2025.

Batch release (QP certification) from 1 Jan 2025 for UK	QP can only certify for batch release products which contain ‘UK only’ on the pack and have FMD disapplied (where applicable).

Batch release (QP certification) from 1 Jan 2025 for EU	Northern Ireland-based QPs may continue to release goods for EU markets.

6.1 When products are ‘on the market’

A product is considered to be ‘on the market’ once it has received QP certification. This ensures that QP certified products can remain in circulation until their expiry date without requiring ‘UK Only’ labelling, so long as they are placed on the market before 1 January 2025. Some example scenarios are given below:

- Medicines manufactured and QP certified for the UK before 1 January 2025, then stored in a UK warehouse ahead of onward distribution, can be released to the market in their original packaging, as they were placed on the market before this date.

- Medicines held in the EEA before 1 January 2025 that have been QP certified for the UK can be imported into the UK for distribution in their existing packaging without ‘UK Only’ labelling, as they were placed on the market before this date.

- Medicines manufactured in the EU and imported into the UK before 1 January 2025, but not yet been QP certified, cannot be distributed further without the ‘UK Only’ label.

6.2 Northern Ireland MHRA Approved Route

The Northern Ireland MHRA Authorised Route (NIMAR) provides for the lawful supply of Prescription Only Medicines, authorised for supply to Great Britain only, to Northern Ireland, where there is unmet clinical need. The NIMAR list will remain in force after 1 January 2025 to continue to facilitate the supply of packs into Northern Ireland in the event of the unlikely situation where there are no other authorised medicines available.

For further information regarding inclusion on the NIMAR list, please contact the Department of Health and Social Care (DHSC).

6.3 Supply of stock released before 1 January 2025 in existing packs

Any stock in existing packaging already placed on the market in Northern Ireland and Great Britain can continue to be supplied to patients in the relevant territory until the date of their expiry, provided it is in accordance with the relevant rules in Northern Ireland or Great Britain (i.e. released by a QP up until that date) and they are not repackaged or relabelled.

This means that until the expiry date of the pack:

- PLGB packs released before 1 January 2025 and listed on NIMAR can be supplied in their existing packaging to both GB and Northern Ireland.

- PLGB packs released before 1 January 2025, but not listed on the NIMAR, can continue to be supplied in their existing packaging to GB only.

Type of Licence	**Territory for supply of packs released pre-1 January 2025 in existing packaging**
UK-wide MA	UK-wide until expiration date
PLNI	NI only until expiration date
PLGB on NIMAR list	UK-wide until expiration date
PLGB not on NIMAR list	GB only until expiration date

6.4 Exporting and importing medicinal products

As explained in section 2.5, medicines featuring ‘UK Only’ on their packaging may continue to be exported. The relevant considerations for QPs and RPis are that:

- ‘UK Only’ livery does not prevent export of goods where local legislation allows, including into the EEA as unlicensed medicines.
- Both UK and EU livery medicine imported to Great Britain require RPi oversight.
- UK and EU livery medicine imported to Northern Ireland does not require RPi oversight.
- All UK medicines may freely circulate in the UK market once QP certified and released.

Further information

- View guidance for Wholesalers and Manufacturers Following Agreement of the Windsor Framework
- View guidance on Sourcing Medicines for the UK Market

7. Control testing of biological medicines

The requirement for control testing of biological medicines is set out in the Marketing Authorisation through the application of the ‘batch testing condition’. Currently there are different processes for Great Britain and Northern Ireland. For Great Britain, the MHRA’s National Institute for Biological Standards and Control (NIBSC) issues all certifications while for Northern Ireland, EU Official Control Authority Batch Release (OCABR) certifications are also valid for some products, in addition to NIBSC certificates.

From 1 January 2025, biological medicines (Category 1) will be licensed on a UK-wide basis under UK law. This means that the NIBSC will certify biological medicines on a UK-wide basis, and all batches for sale or supply in the UK will require NIBSC certification. There will be exceptions however for batches that were manufactured and certified by a country with whom the UK has a Mutual Recognition Agreement in place (batches manufactured and released in Switzerland or Israel).

Current processes that are specific to Northern Ireland will no longer apply in the following instances:

- EU OCABR certificates issued after 31 December 2024 will no longer be automatically accepted for batches for Northern Ireland, however evidence of previously obtained OCABR batch certification may still be considered for all UK batches, including batches destined for Northern Ireland. Please contact us at ControlTesting@mhra.gov.uk to discuss specific arrangements for your product. If OCABR certificates are accepted, NIBSC certificates will usually be issued without laboratory batch testing by the MHRA.

- The waiver procedure for products for Northern Ireland whose OCABR certificate was issued in a different EEA State to that in which the batch was manufactured will be revoked.

- Products supplied from Northern Ireland to Great Britain will no longer require confirmation that a NIBSC certificate is available before supplying a Great Britain wholesaler or other authorised person in Great Britain.

Certificates valid from 1 January 2025

Certificate type	Scope of validity
NIBSC	Valid for batch release UK-wide
Country with an MRA	Valid for batch release UK-wide

EU OCABR	May be accepted as proof for independent laboratory testing in exceptional circumstances as determined by the MHRA. NIBSC certification required for batch release UK-wide.

Further information

- View guidance for Manufacturers on Independent Control Testing (Batch Release) for the UK
- View guidance on Applying to Release a Vaccine or a Blood Product to Market

8. Advertising and promotion

This chapter explains what is changing for advertising and promotion of medicinal products, and what companies will need to do to prepare.

From 1 January 2025, the default authorisation of all medicines will be UK-wide, medicines therefore can also be advertised UK-wide. Since PLGBs will automatically be transitioned to UK-wide licences from 1 January 2025, these products can be advertised UK-wide.

At present, some UK-wide advertisements aimed at Persons Qualified to Prescribe or Supply may list in the statutory particulars a PLGB number (for Great Britain) and an EU number (for Northern Ireland). From 1 January 2025, the PLGB number will cover these UK-wide advertisements, and the EU number will no longer apply to the territory of Northern Ireland. Companies will need to phase out the EU number from UK advertisements over time.

Advertisements for the UK may continue to be combined with a campaign that also may cover Europe, where product indications remain aligned and where there is no other divergent information that may pose a risk to the safety of the UK public. It is companies' responsibility to ensure that any such advertising complies with Part 14 of the Human Medicines Regulations (HMRs), as well as EU requirements. Overall requirements for quality standards must continue to be met; the material must not mislead a UK audience and must be consistent with the UK Summary of Product Characteristics (SPC or SmPC).

In line with overall requirements for keeping promotional material up to date, material that no longer complies with UK law should be withdrawn from use in the UK.

There may be exceptional cases where a medicinal product may only be licensed in part of the UK (i.e. Great Britain or Northern Ireland). In these exceptional cases, a product may only be advertised in the territory where it is licensed: UK-wide licensing will be prohibited and current requirements for Great Britain or Northern Ireland territory-specific advertising and promotion will remain, as outlined in the MHRA Blue Guide.

Further information

- View guidance on Advertising and Promotion Following Agreement of the Windsor Framework
- View MHRA Blue Guide on the Advertising and Promotion of Medicines in the UK

Annex A – Glossary of terms

Term	Definition
CAP	**Centrally Authorised Product:** A medicine with a single marketing authorisation issued by the European Commission (EC) and valid across the European Union (EU).
CP	**Centralised Procedure:** The EU-wide procedure for the authorisation of medicines, where there is a single application, a single evaluation and a single authorisation throughout the EU. Only certain medicines are eligible for the centralised procedure.
CMS	**Concerned Member State:** An EU member state in which an application has been submitted for authorisation of a medicine through the mutual recognition or decentralised procedure. The assessment of the medicine is led and co-ordinated by another member state called the Reference Member State.
DCP	**Decentralised Procedure:** The procedure for authorising medicines in more than one EU Member State in parallel. It can be used for medicines that do not need to be authorised via the centralised procedure and have not already been authorised in any EU Member State.
EC	**European Commission:** An executive branch of the European Union, responsible for proposing legislation, implementing decisions, upholding the EU treaties and managing the day-to-day business of the EU. An EC decision is a legally binding decision issued by the EC at the end of a regulatory procedure, such as a marketing authorisation application or arbitration procedure.
EMA	**European Medicines Agency:** An agency of the EU responsible for the scientific evaluation of medicines and supervision of pharmaceutical products for use in the European Union.
FMD	**Falsified Medicines Directive:** An EU Directive which seeks to prevent falsified medicines entering supply chains, including through the use of safety features to be included on packs of prescription medicines. The EU FMD ceased to have effect in Great Britain from 31 December 2020.
GSL	**General Sales List:** A list which specifies those medicinal products which can be sold with reasonable safety without the supervision of a pharmacist, for example in a supermarket.
ICSR	**Individual Case Safety Report:** A document providing information related to an individual case of a suspected side effect due to a medicine. This includes technical information on MHRA specific additional requirements to incorporate when submitting electronic reports, between marketing authorisation holders and the MHRA.

MA	**UK-wide Marketing Authorisation:** A product licensed by the MHRA, across the whole of the UK.
MAA	**Marketing Authorisation Application:** An application made to a licensing authority for approval to market a medicine.
MAH	**Marketing Authorisation Holder:** The legal entity that holds the marketing authorisation.
MHRA	**Medicines and Healthcare Products Regulatory Agency:** The regulator for medicines, medical devices and blood components for transfusion in the UK.
MRP	**Mutual Recognition Procedure: A European authorisation route resulting in a recognition of an authorisation already granted by another member state.**
NIBSC	**National Institute for Biological Standards and Control**: A centre of the MHRA that acts as the UK's Official Medicines Control Laboratory, responsible for independent regulatory testing of biological medicines as required by UK law.
NIMAR	**Northern Ireland MHRA Authorised Route:** A mechanism that allows a medicine licensed by the MHRA in GB to be supplied to Northern Ireland on an unlicensed basis, where no licensed alternative is available.
OCABR	**EU Official Control Authority Batch Release:** A system of control and release of immunological medicinal products (e.g. vaccines) and human blood derived medicinal products (e.g. clotting factor, immunoglobulin, albumin) by national authorities, referred to as OMCLs (Official Medicines Control Laboratories), carried out independently from the manufacturers before marketing. Each batch of these products is controlled and if the batch is compliant with the specifications in the approved marketing authorisation it is granted an EU OCABR certificate.
P	**Pharmacy Medicines:** Medicines that do not require a prescription but which must be sold or supplied only in a registered pharmacy, hospital or health centre by or under the supervision of a pharmacist. The packaging gives information on dosage.
PLGB	**Great Britain (GB) Product Licence:** A product licensed by the MHRA that covers GB only as the territorial application.
PLNI	**Northern Ireland (NI) Product Licence:** A product licensed by the MHRA that covers Northern Ireland only as the territorial application.
PLPI	**Parallel Import Licence:** A licensing scheme which lets a medicine authorised in European Economic Area (EEA) Member State be marketed in the UK, as long as the imported product has no therapeutic difference from the cross-referenced UK product.

POM	**Prescription Only Medicine:** Medicines that may be sold or supplied only from a registered pharmacy, or hospital or health centre under the supervision of a pharmacist, in accordance with a prescription issued by a doctor or dentist.
QP	**Qualified Person:** Assures the quality of medicines. A QP must certify every batch of a medicine before release to the EU market. Article 51 of Directive 2001/83/EC defines the duties of the QP and more information can be found in the Orange Guide.
RMS	**Reference Member State (RMS):** The regulatory authority of an EU member state that is responsible for coordinating the evaluation of a marketing authorisation application (MAA) for a medicinal product in a mutual recognition procedure or decentralised procedure.
RP	**Responsible Person:** The central person within a Licence Holder's operations, ensuring compliance with the conditions of the licence and ensuring the quality of the medicinal products handled.
RPi	**Responsible Person (import):** The central person within a Licence Holder's operations, ensuring that batches of authorised medicines imported from countries on a list have been appropriately certified prior to being placed on the Great Britain market.
SmPC or SPC	**Summary of Product Characteristics:** A document describing the properties and the officially approved conditions of use of a medicine. Summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively.
UK-wide MA	**UK-wide Marketing Authorisation:** A product licensed by the MHRA, across the whole of the UK before 1 January 2025.