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From the Northern Ireland Protocol to the Windsor Framework

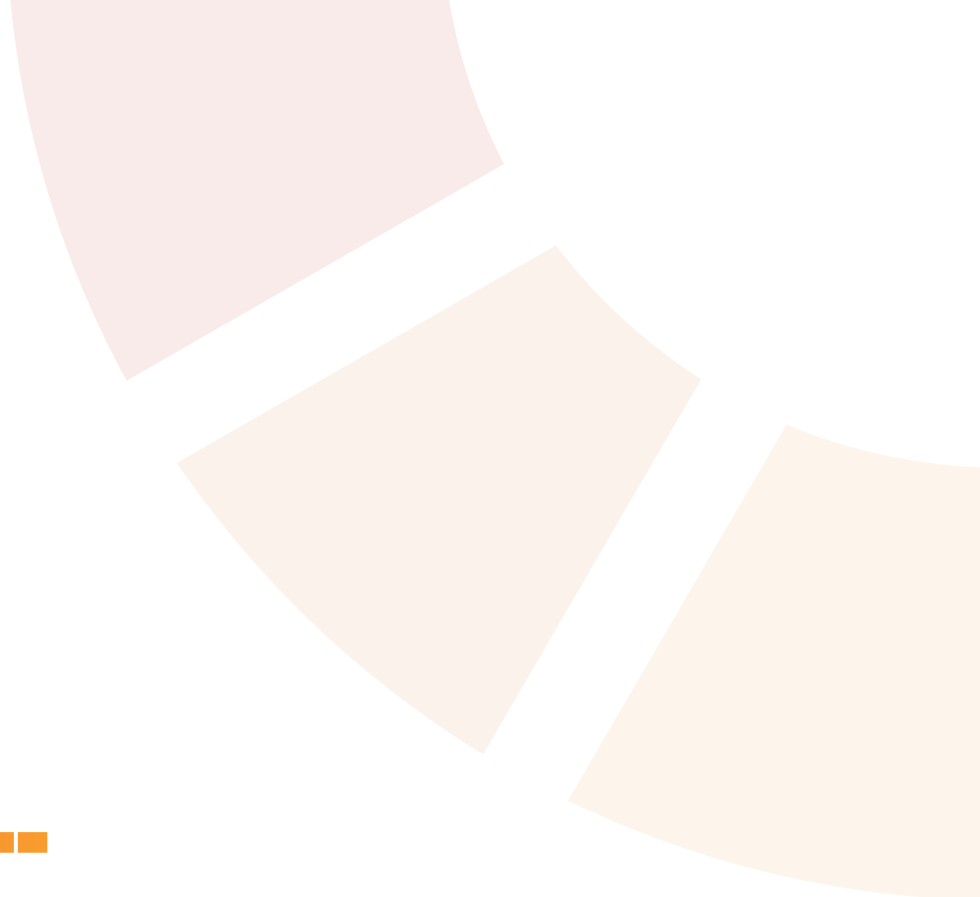
WHITEPAPER



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The United Kingdom’s exit from the European Union on 31 January 2020 necessitated the implementation of the Northern Ireland Protocol to prevent a hard border between Northern Ireland (NI) and the Republic of Ireland. The Protocol ensured alignment with the EU’s regulatory systems in Northern Ireland while the rest of the UK (Great Britain or GB) diverged.

However, regulatory complexities, including dual licensing and compliance with EU laws for NI, created challenges for Marketing Authorisation Holders (MAHs). The Windsor Framework, introduced on 27 February 2023, is set to replace the Protocol, streamlining regulatory processes for medicines across the UK while preserving supply chain stability.

This whitepaper explores the changes introduced by the Windsor Framework, their implications for the pharmaceutical industry, and the steps MAHs need to take to ensure compliance by the implementation deadline of 1 January 2025.

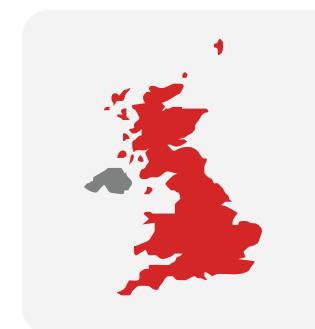
The Northern Ireland Protocol¹, effective from 1 January 2021, was designed to maintain economic stability on the island of Ireland and uphold the Good Friday Agreement². Under the Protocol, NI remained within the EU’s pharmaceutical regulatory framework, while GB operated independently.

At the time of Brexit, the Northern Ireland Protocol meant that Northern Ireland (NI) was still inside the EU’s pharmaceutical regulatory system, whilst the rest of the UK (denoted as Great Britain (GB)) was not. Therefore Marketing Authorisations (MAs) were given different prefixes to differentiate them.



UK-wide MA: a product licensed by the MHRA, across the whole of the UK (England, Wales, Scotland and Northern Ireland)

MAs with a PL prefix



GB MA: a product licensed by the MHRA that covers Great Britain only (England, Wales and Scotland)

MAs with a PLGB prefix



NI MA: a product licensed by the MHRA that covers Northern Ireland only

MAs with a PLNI prefix

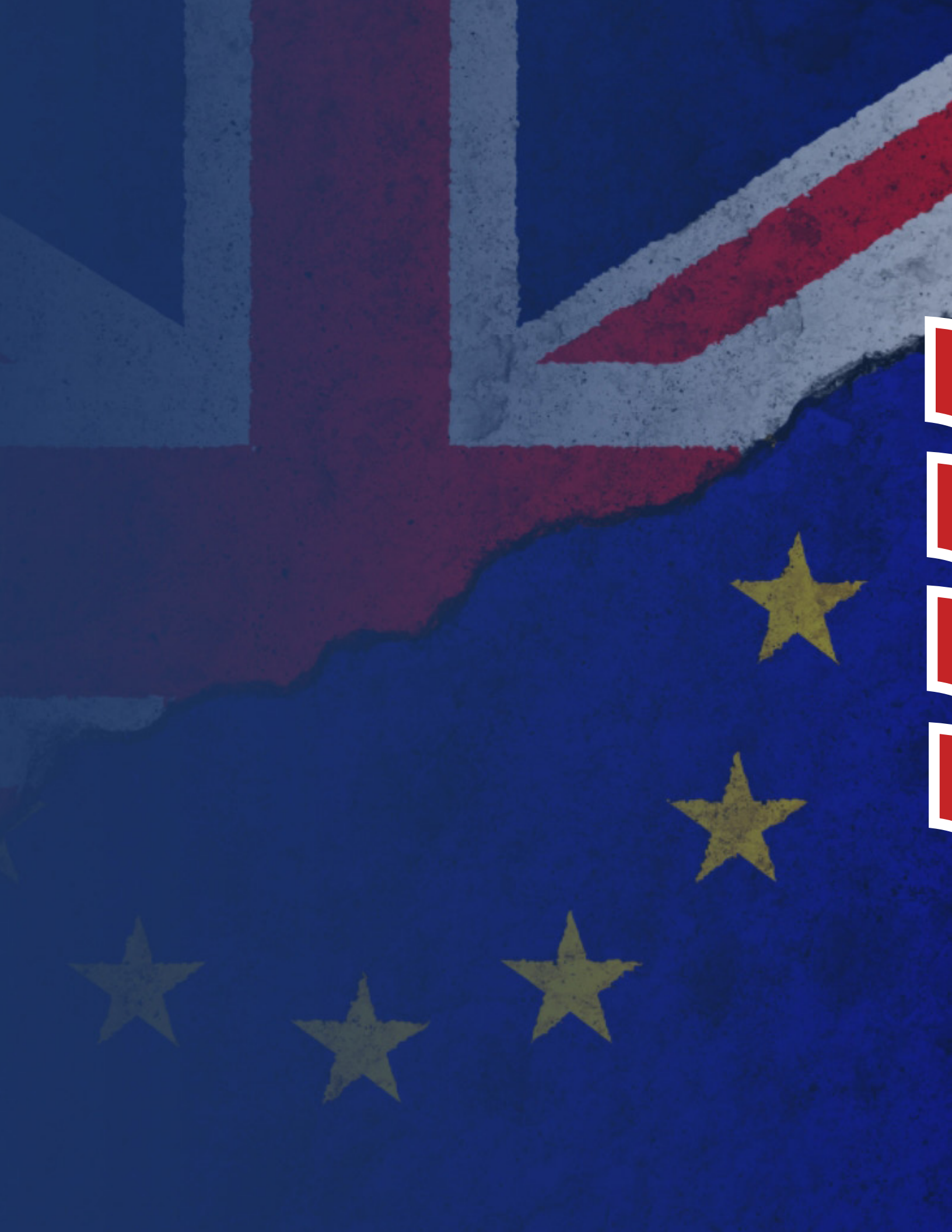
The implementation of the Northern Ireland Protocol meant that there was a change to Centrally Authorised Products (CAPs). GB was no longer allowed to be part of a CAP after Brexit; therefore, the MHRA converted the GB part of a CAP into a UK National MA (with prefix PLGB) by a process called ‘grandfathering’. The NI part remained included in the CAP.

Marketing Authorisation Holders (MAHs) that held CAPs could opt out of this process, but for the majority of CAPs at the time of Brexit, they were grandfathered into PLGBs in order for MAHs to continue to supply the UK. Therefore MAHs now had two licences which were not linked to each other. This added additional cost and complexity for MAHs as any regulatory updates in the lifecycle of the medicine meant that two submissions were now needed – to the EMA for the CAP (including NI) and to the MHRA for the PLGB MA. This could result in divergent opinions as the two agencies were independent of each other and could impose conditions or reject regulatory changes in their relevant territory.

Another outcome of the NI Protocol was that the EU’s Falsified Medicines Directive (FMD) safety features requirements for packaging, barcoding and scanning applied to NI but not GB. Under an existing derogation agreed in April 2022, medicines could move through GB 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 NI. This would have created a burden in the supply chain and a further risk to supply to NI.

The differences in the requirements between NI and GB, coupled with NI representing a smaller market than GB, meant there were also concerns that MAHs would choose not to supply medicines to NI. Negotiations between the UK and the EU resulted in an agreement to have free movement of medicines between mainland UK (GB) and NI. However, the issue of NI having to follow EU legislation remained.

Announced on 27 February 2023, the Windsor Framework³ addresses these challenges by simplifying regulatory processes and creating a unified system for medicine approvals across the UK. The Windsor Framework introduces new rules in the UK for product licensing, labelling, and the EU Falsified Medicines Directive. It also removes the requirement for the EMA and the EC to approve novel medicines for supply in NI under a process known as the “EU Centralised Procedure”. It will ensure that medicines can be approved and licensed on a UK-wide basis by the MHRA, and medicines can be supplied in the same packs across the UK, including NI.



Key provisions effective 1 January 2025 include:

Removal of EU licensing in relation to NI for novel medicines (approved via the EU Centralised Procedure). Medicines authorisations granted by the EC will no longer be valid in NI.

Removal of the requirement for EU Falsified Medicines Directive packaging, labelling and serialisation barcode for medicines in NI.

All UK medicines will be UK-wide. Companies will therefore no longer need to apply for separate licences for GB and NI in order to supply the same product across the whole UK.

MAHs need to update their packaging to add the words ‘UK Only’, indicating they are not for sale in the Republic of Ireland or any other EU countries.

The implementation of the Windsor Framework on 1st January 2025 also means that the MHRA will be the only authority approving medicines for the UK market.



The MHRA are also introducing a two-category system of reclassifying medicines, which will mean that some medicines will remain subject to certain EU legislation. From 1st January 2025, approved MAs and applications in the UK will automatically be assigned to one of the following categories:

Category 1: Medicines previously within the mandatory or optional scope of the EU’s Centralised Procedure.

- This includes generic, hybrid or biosimilar products of Category 1 reference medicinal 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.
- These medicines are typically those with the prefix PLGB.
- From 1st January 2025, they will become UK-wide and be authorised by the MHRA in accordance with UK legislation only.
- The MHRA have indicated that they will publish a list of Category 1 medicines that were authorised prior to 1 January 2021.

Category 2: medicines that do not fall within the mandatory or optional scope of the EU’s Centralised Procedure.

- These medicines are typically those with the prefix PL.
- From 1st January 2025, they will be authorised by the MHRA in accordance with both UK law and applicable EU regulations which will continue to apply.

The introduction of the two-category system will result in further complexity on MAHs, including for generic companies that obtained MAs based on European reference medicinal products, which fall under category 2.

Prior to 1st January 2025, if a generic company holds a PLGB MA with an EU reference product, there is no requirement to comply with any EU legislation; however, as an EU reference product is category 2, the applicable EU legislation is required, including the Falsified Medicines Directive and certain pharmacovigilance requirements such as submission of PSURs, PASS and safety referrals to the EMA.

Whilst the introduction of a two-category system aims to ensure the continued supply of medicines in the whole of the UK including Northern Ireland, the MHRA has agreed to a number of flexibilities that were advocated by The Association of the British Pharmaceutical Industry (ABPI) and other trade organisations⁴:

- Medicines with ‘UK Only’ on packaging can be released to the GB market (but not NI) before 1st January 2025.
- MAHs can update their medicines through any regulatory opportunity or self-certification.
- Packaging updates can be done through UK-approved repacking sites and the packs are not required to be returned to the original manufacturing site for this to take place.

The Windsor Framework represents a significant shift in the UK's pharmaceutical regulatory landscape, addressing the challenges of the Northern Ireland Protocol while simplifying the approval of medicines and ensuring the long-term stability of medicine supply across the UK, including Northern Ireland. By standardizing packaging and processes, the Framework ensures that medicines will be available in the same packaging across the UK, fostering seamless operations and uninterrupted patient access.

With the 1 January 2025 deadline approaching, Marketing Authorisation Holders (MAHs) must act promptly to update packaging, align regulatory processes, and ensure compliance with the new system. To support this transition, the MHRA has published comprehensive guidance documents, hosted webinars, and launched the MHRA Windsor Framework Hub⁵, providing MAHs with the resources and support needed to navigate these changes effectively. By embracing the Windsor Framework, the pharmaceutical industry can safeguard the continuity and accessibility of medicines for patients across the UK.



References

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