

REGULATORY INTELLIGENCE

A Comprehensive Analysis of the Windsor Framework to Support Marketing Authorization Holders

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The Windsor agreement, announced in February 2023, signifies a pact between the European Union and the UK. This accord emerged due to the intricacies stemming from the initial Northern Ireland Protocol, which had been a source of economic and societal challenges since its implementation following Brexit. The primary aim of this new framework is to address the concerns of Northern Ireland, given its distinct position within the European market. It entails substantial modifications to the text and provisions of the original Protocol. While the focal point of the agreement revolves around the movement of goods across borders, it encompasses a broad spectrum of activities, including the authorization of medicines, which will be the central theme of this article.

Understanding the Windsor Framework

Based on the Protocol, EU pharmaceutical law applies to and in the UK in respect of Northern Ireland only, as of 1 January 2021. The original Protocol mandated adherence to all EU regulations and authorisation requirements for medicines, including novel drugs such as innovative cancer treatments, thereby necessitating approval from the European Medicines Agency (EMA) rather than the UK's Medicines and Healthcare products Regulatory Agency (MHRA) for the Northern Ireland market. However, this arrangement failed to acknowledge that the predominant flow of medicines to Northern Ireland is from Great Britain, with medicines provided for the whole UK market.

To address these issues, the EU already introduced amendments to its regulations allowing MHRA to authorise generic drugs under a unified license for the entire UK. Currently, most products not covered by the EU centralized procedure are already eligible for UK-wide authorization by the MHRA. Furthermore, the introduction of the Northern Ireland Medicines Authorization Route (NIMAR) by the UK, in conjunction with existing procedures, ensured uninterrupted medicine supply to Northern Ireland.

Despite these measures, concerns persisted regarding the long-term solution and implications of the EMA's role in licensing of innovative medicines. This uncertainty, compounded by the need for Northern Ireland drugs to comply with various EU labelling standards, posed the risk of discontinuations if companies were unwilling to maintain separate labelling for Great Britain and Northern Ireland. Recognizing the unsustainability of this situation, the agreement addresses these issues, providing a viable solution moving forward.

Regulatory Shifts: From EU to UK

Per the agreement, the responsibility of approving all medications for the entire UK market will be transferred to the MHRA. This consolidation will facilitate the distribution of various medicines in single packs, under a single license covering the entire UK, ensuring a stable and enduring supply of medicines to Northern Ireland.

In terms of providing innovative treatments to patients, Northern Ireland will be reintegrated into a regulatory framework exclusive to the UK, thereby eliminating the involvement of the EMA.

These measures will commence on 1 January 2025. Consequently, post this date, new medications intended for the UK market will undergo authorization by UK regulatory authority, and UK packaging will need to display a 'UK only' label to be permitted for distribution, including in Northern Ireland. Such products will be exclusively available in the UK market and will not be accessible in Ireland or elsewhere within the EU.

Interim Licencing Rules

Until the Windsor framework is implemented, the Centrally Authorized Products (CAPs) bridging mechanism remains operational. This means that decisions made by the European Commission (EC) regarding the approval of new Marketing Authorizations (MAs) within the centralized procedure will continue to be applicable for Northern Ireland, in alignment with EU legislation.

MAs issued by the EC for CAPs do not extend to Great Britain (GB), necessitating a separate national application for GB. Consequently, in scenarios where simultaneous applications are made to both the EMA and the MHRA, the MHRA may grant an MA for a medicinal product prior to its approval in the EU. In such instances, under the CAP bridging mechanism, companies will be permitted to supply a GB licensed product (PLGB) to Northern Ireland for a duration of six months or until the EC grants authorization for a CAP in Northern Ireland, or rejects the product's application, whichever occurs first.

This measure aims to ensure equal access to medicinal products for patients in Northern Ireland concurrently with those in other regions of the UK. The CAP bridging mechanism is part of an EU legislative package for medicines passed in April 2022.

Ensuring Compliance

To legally implement the Windsor framework, the EU has adopted the “Regulation No 2023/1182” in Jun 2023.

- The supporting document *“Questions and answers to stakeholders on the implications of Regulation (EU) 2023/1182 for centrally authorised medicinal products for human use”* was published in Jan 2024, addressing the specifics details and logistics of the implementation.
- From the UK side, several important documents were also published. *“UK-wide licensing for human medicines”* (Sep 2023) aims to describe all types of licences that will be applicable following the implementation in Jan 2025.
- *“Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework”* (Jul 2023) provides detailed instructions on the new labelling and packaging requirements.

Each MAH needs to perform an analysis of the above-mentioned documents and ensure that depending on their specific scenario, the proper actions are taken in a timely manner.

Conclusion

While the framework doesn’t directly affect pharmacovigilance rules, the changes in the licencing system can result in different pharmacovigilance requirements. Starting 01-Jan-2025, the MHRA will be able to license centrally authorised products (CAP) in addition to non-CAP products under one UK-wide regime, EU CAPs will no longer be applicable in the Northern Ireland. Further instructions and clarifications are expected during 2024. In the meantime, the above-mentioned guidance provides useful information on how the current product licences can be transferred into the new system and what the options for MAHs are.

References

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