



The Evolving UK Regulatory Landscape for the Life Science Sector Post-Brexit



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The Evolving UK Regulatory Landscape for the Pharmaceutical Sector Post-Brexit

Introduction

The pharmaceutical sector has experienced significant change in the regulatory landscape over recent years as a result of the UK withdrawing from the European Union, and further changes are expected in the near future. Whilst Brexit came into effect on 31 January 2020, the transition period ended on 01 January 2021 and further amendments to various regulations continue to be made. The aim of this article is to provide an overview of some of the key milestones, challenges and opportunities which have arisen over recent months and years as well as a look towards what can be expected going forward.

Brexit and the Northern Ireland Protocol



As part of the Brexit deal, a trading arrangement named the Northern Ireland Protocol was agreed between the UK and EU and came into force on 01 January 2021 following the end of a transition period. The Northern Ireland Protocol exists to ensure that progress made in the 22 years since the Belfast (Good Friday) Agreement is secured in the future. For the Protocol to work, it was important that it was implemented in such a way that protected the interests of the whole of the UK and the EU. Under the terms of the Protocol, Northern Ireland remained bound by EU single market rules in a number of areas such as product requirements and safety, including chemical and medicinal safety. In addition, new checks on goods crossing the border were introduced. ^(a)

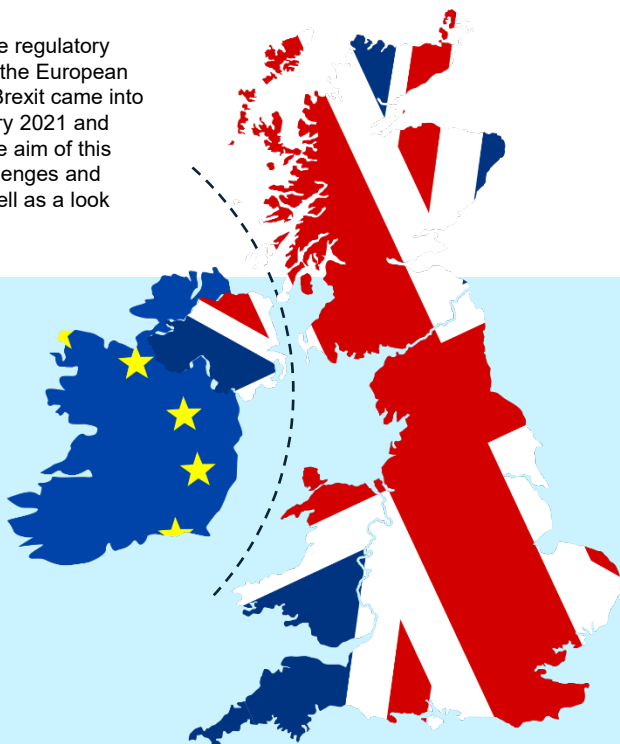


Figure 1. Map to indicate border between Great Britain and Northern Ireland

Impact of the Northern Ireland Protocol on the Pharmaceutical Sector

At present, goods are checked in Northern Ireland on arrival. Goods can be moved into the Republic of Ireland once checked. Goods moved by businesses from Northern Ireland to the UK market are moved with unfettered access. Northern Ireland continues to uphold the EU's falsified medicines directive (FMD), however, the UK does not. This directive prevents falsified or fraudulent medicines from entering the EU market. Manufacturers must continue to place a barcode on each of the product packs and log crucial product information on the relevant EU database. Furthermore, the Protocol does not allow the UK in respect of Northern Ireland to:

The majority of medicines available in Northern Ireland continue to be sourced from Great Britain. A medicine may be subject to different Market Authorisations (MAs) in Northern Ireland and Great Britain and therefore have different labelling requirements. Since the Northern Ireland market is relatively small, this can result in a disproportionate cost for MA holders to comply with the requirements of two different MAs and produce different packages and labels for Northern Ireland compared to Great Britain. This has resulted in supply shortages for a large number of medicines in Northern Ireland. Official batch release by the UK in respect of Northern Ireland is not recognised in the EU. ^(b)

- 01 Participate in the decision-making and decision-shaping of the Union.
- 02 Act as the leading authority for assessments, examinations, and authorizations
- 03 Act as reference Member State or trigger referrals.

Note

- a) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950601/Northern_Ireland_Protocol_-_Command_Paper.pdf
- b) <https://www.gov.uk/government/publications/the-northern-ireland-protocol>

What is the Windsor Framework?

The Windsor Framework was formally adopted on 24th March 2023. The framework puts in place a new legal and constitutional framework that restores the balance needed to uphold the Belfast (Good Friday) Agreement.

Key aspects of the framework include:



Restoration of the smooth flow of trade within the UK internal market

Removing unnecessary red tape and checks for movement of goods



Safeguarding Northern Ireland's place in the Union

A large number of EU laws will no longer apply which will be replaced by UK rules e.g. medicine supply

What does the new deal change in practice?



The Windsor Framework still fully preserves access for Northern Ireland businesses to the EU market, alongside their full unfettered access to the whole UK market.

Under the new framework, goods will be split into two different lanes i.e. the Green Lane and the Red Lane. Goods, such as medicines, destined for Northern Ireland from Great Britain will go into the 'Green Lane' and will require no checks, duties or unnecessary paperwork, with only ordinary commercial information required. Medication destined for the Republic of Ireland and the EU will go into the 'Red Lane' and the normal checks will be carried out.^(d)

According to the terms of the agreement, the UK Medicines & Healthcare Products Regulatory Agency (MHRA) will be able to grant a single UK-wide approval for all medicines, including those that fall within the scope of the EU's centralized procedure. This means that all drug approvals granted by the MHRA will therefore automatically be valid in Northern Ireland. This will enable pharmaceutical companies to produce a single pack which will be valid across all four constituent countries of the UK. Northern Ireland will be reintegrated back into a UK-only regulatory environment and the role of the European Medicines Agency (EMA) will be removed. This is in response to calls from industry for more stability and certainty, which in turn provides reassurance to patients and clinicians in Northern Ireland. The provisions of the EU Falsified Medicines Directive (FMD) will no longer apply in Northern Ireland. This means there will be no need for separate packs of medicines for Great Britain and Northern

Ireland which will reduce work and cost requirements associated with checking that product packs comply with the FMD in Northern Ireland.

The new rules mentioned in the Windsor Framework will go hand in hand with appropriate safeguards to ensure that UK authorised medicines do not enter the market of any EU Member State. Individual packs of all medicines placed on the Northern Ireland market should therefore bear a label indicating "UK only". The UK should continuously monitor their placing on the Northern Ireland market and the Commission will be able to unilaterally suspend the new rules in case the UK does not comply with its obligations. These measures will commence on 01 January 2025.^(e)

Note
c) <https://www.bbc.co.uk/news/explainers-53724381>
d) <https://www.gov.uk/government/publications/the-windsor-framework>
e) <https://www.gov.uk/government/news/windsor-framework-medicines-announcement>



One downside of the Windsor framework is that Northern Ireland will no longer have access to medicines that are approved by the EU and not the UK. However, there are other, alternative, collaborative regulatory submission strategies (see section titled 'The European Commission Decision Reliance Procedure (ECDRP)' below), which can be considered instead.

Following the solutions agreed between the UK and the EU, The European Commission has published a proposal for a Regulation to reflect these solutions.^(f) This Regulation would suspend the application of certain aspects of EU pharmaceutical law in Northern Ireland. Unless specifically modified by the proposed Regulation, EU law on medicines will continue to apply to and in Northern Ireland. This will mean MA holders will be required to comply with EU rules relating to, amongst other things, the manufacture and distribution of medicines and pharmacovigilance when supplying medicines to Northern Ireland. The proposed Regulation will preserve the recognition of Great Britain quality control testing and Qualified Person (QP) release for the Northern Ireland market. This will enable medicines to be "imported" to Northern Ireland from Great Britain by a wholesale dealer authorisation holder without the need for a manufacturing authorisation.

Both the proposed EU Regulation and the Windsor Framework are silent on the application to Northern Ireland of the decentralised procedure (DCP) and mutual recognition procedure (MRP). It therefore appears that the current position could continue, i.e. that the UK may be named as a Concerned Member State in respect of Northern Ireland with a separate MA required for Great Britain. However, in order to make supplies to the UK easier, pharmaceutical companies have the option to decide to apply for a whole-UK authorisation rather than include Northern Ireland in a DCP or MRP.

A grace period has been introduced for veterinary medicines. This means that veterinary medicines will not immediately benefit from the same UK-wide approvals as human medicines. The grace period introduced by the Windsor Framework will allow for veterinary medicines that are authorised and approved in the UK, or moved via Great Britain, to be placed on the market in Northern Ireland until the end of 2025.

The next steps will be for the UK and EU to take steps to transpose the provisions of the Windsor Framework into law. The Commission's proposed EU Regulation modifying the application of the EU medicines regulatory framework to Northern Ireland will need to be adopted by both the European Council and the Parliament. Further clarifications is required in terms of what companies should do in the meantime and around medical devices.

The Stormont Brake

The Windsor Framework introduces a 'Stormont Brake'. Under the previous deal, some EU laws still applied in Northern Ireland and politicians at Stormont had no way of influencing them. The Stormont Brake will allow the Northern Ireland Assembly to object to new EU rules but would only be reserved for 'significantly different' rules.

The European Commission Decision Reliance Procedure (ECDRP)

The ECDRP has been extended to 31 December 2023.^(g) Until this date, where a Committee for Medicinal Products for Human Use (CHMP) positive opinion has been received, organisations can continue to submit their ECDRP Marketing Authorisation Application (MAA) or variations to MHRA. MHRA will continue to review these applications via the current ECDRP process.

From 1 January 2024 organisations can apply to MHRA through their new international recognition framework (IRF), which will have regard for decisions already made by the European Medicines Agency and certain other regulators. This may include the United States Food and Drug Administration and Japan's Pharmaceuticals and Medical Devices Agency, though no formal confirmation has yet been announced. This means applications with a CHMP positive opinion received after 31 December 2023 will be eligible. The aim is to extend the countries whose assessments will be taken into account, increasing routes to market in the UK.

The MHRA will communicate who these additional regulators are and publish detailed guidance about this new framework in due course, including any transition arrangements for applications received under existing frameworks.

Note

- f) https://commission.europa.eu/system/files/2023-02/COM_2023_122_1_EN_ACT_part1_v2.pdf
g) <https://www.gov.uk/guidance/european-commission-ec-decision-reliance-procedure>



Voluntary Pricing and Access Scheme (VPAS) – Impact on the UK Commercial Environment

The rapid rise in revenue tax stipulated through the existing Voluntary Pricing and Access Scheme (VPAS) and the fallback Statutory Scheme has created what some may refer to as an unfavourable commercial environment in the UK. As such, the UK is currently missing out on investment opportunities in the fields of manufacturing and research. Similarly, clinical trial numbers are falling, and there is a real risk that NHS patients will be forced to wait for, or not get access to, medicines which are available in Europe. In 2021 the VPAS rebate led to companies paying approximately 5% of their revenue back to the NHS. In 2022, this rebate rose to 15% and in 2023 to 26.5%. Some view this rise as unsustainable. WPI Strategy suggests that sustaining such high rates for another five years would result in economic scars, with a total loss of £50bn to UK GDP by 2058.^{(h)(i)}

It has become apparent that the VPAS is challenging for the pharmaceutical industry and that changes to the current form are required when it concludes at the end of 2023. The Association of the British Pharmaceutical Industry (ABPI) has proposed a new Voluntary Scheme for Pricing, Access and Growth (VPAG) which would deliver a sustainable approach to medicines provision whilst also maximising the potential of the UK life sciences industry as an engine for growth.^(j)

Note

- h) <https://www.abpi.org.uk/value-and-access/uk-medicine-pricing/voluntary-scheme-on-branded-medicines/>
- i) <https://www.abpi.org.uk/publications/false-economy-how-nhs-medicine-procurement-threatens-the-uk-s-life-sciences-growth-engine/>
- j) <https://www.abpi.org.uk/media/news/2023/march/abpi-sets-out-new-proposals-to-support-the-nhs-and-economic-growth/>

The proposal has four key areas:

- Restoring an internationally competitive commercial environment for life sciences;
- Supporting UK clinical research and R&D;
- Ensuring rapid patient access and uptake of new medicines;
- And improving population health and productivity through health innovation.

In order to meet the needs of patients and the NHS, industry progress in these key areas is essential. ABPI proposes a fixed rebate rate of 6.88% levied across all eligible NHS medicine sales paid by the pharma companies. This would deliver over £1 billion a year to the NHS which is approximately £300 million more than the average amount delivered under the old scheme. To maximise the potential of the UK health and life sciences ecosystem as an engine for innovation-led economic growth, ABPI could agree to an industry-funded 'Investment Facility' worth over £1 billion over five years. The fund could be used to boost NHS clinical trial capacity and delivery, expand UK Genomics capacity, and build the UK capability to use real-world data to improve the speed, diversity and efficiency of recruitment into clinical trials. This would strengthen the UK's ability to attract inward investment in life sciences. The Investment Facility would also fund a Medicines Equity Partnership operating across the four nations of the UK. The Partnership would improve health outcomes and productivity for the whole country by addressing barriers that prevent the timely uptake of new medicines that have been approved by All Wales Medicines Strategy Group (AWMSG), National Institute for Health and Care Excellence and The Scottish Medicine Consortium (SMC).

Another key proposal put forward by the ABPI is for pharma companies to commit to prioritising the UK as an early launch market which means seeking a Great Britain licence on new medicines in their first wave of regulatory filings. This would enable the UK to regain and maintain its position as a 'first wave' country for new drug launches. ABPI is currently working with the government to set the UK back on the road to becoming a global superpower in life sciences.

Summary

The Windsor Framework sets out a long term solution for the supply of medicines into Northern Ireland. It will ensure that medicines can be approved and licensed on a UK wide basis by the MHRA. This will enable medicines to use the same packaging and labelling across the UK. As such, all medicines on the UK market will be labelled as for sale only within the UK.

These measures will come into effect from 01 January 2025. ^(k)
After this date:

- New medicines for the UK market will be authorised by UK authorities, and UK packaging must carry a clearly legible 'UK only' label to be allowed onto the UK market, including in Northern Ireland
- These products will only be able to be sold in the UK, and will not be available on the market in Ireland, or elsewhere in the EU
- Medicines entering Northern Ireland will not display features required under the EU Falsified Medicines Directive (FMD) including 2D barcodes and serialisation numbers that are compliant with the EU FMD Directive
- The MHRA will expect anti tamper devices to remain on all medicine packaging.

Future Implications

Whilst ongoing changes to the regulatory landscape inevitably bring about challenges associated with understanding and navigating new laws, policies and procedures, they do also deliver new opportunities for life science companies.

For example, as a result of the Windsor Framework, smooth flow of trade within the UK internal market will be restored and the UK will be able to re join the EU's £84 billion Horizon Europe scheme (EU's key funding programme for research and innovation).^{(l)(m)} Similarly, initiatives such as those undertaken by ABPI will help to unlock further avenues for business and collaboration in the UK.

How We Can Help

The KPMG Life Science Regulatory Solutions team has expertise in the field of pharmaceutical and medical device regulations and can provide advice in terms of understanding potential implications associated with changing policy landscape. In addition, the team offer strategic regulatory advice to life science organizations throughout key product development stages, from early phase planning to launch and compliance for approved products across critical markets internationally.

Note

- k) <https://www.gov.uk/government/news/windsor-framework-medicines-announcement>
l) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1138989/The_Windsor_Framework_a_new_way_forward.pdf
m) <https://www.dailymail.co.uk/news/article-11799587/Britain-able-rejoin-EUs-84bn-Horizon-Europe-scheme-new-Brexit-deal.html>



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