The Windsor Framework

A live webinar discussing the regulatory impact to your marketed products

10th December 2024

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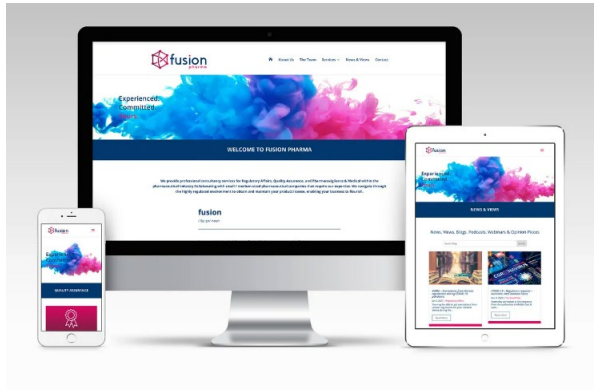
Fusion Pharma Limited

Fusion Pharma are Regulatory Affairs Experts

We offer a bespoke consultancy service to our clients
to obtain and maintain their product licences

Blogs and opinion pieces



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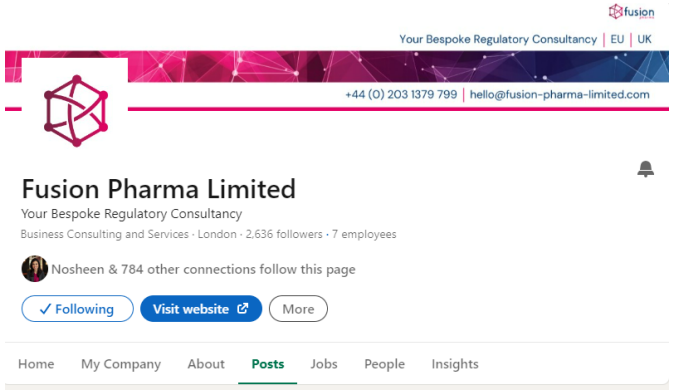

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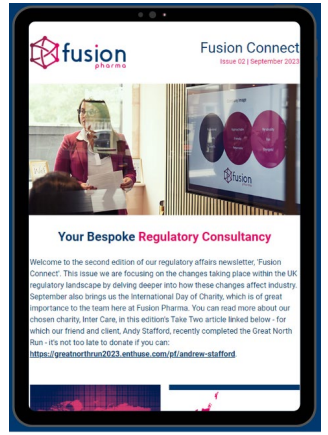

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The Windsor Framework:
The regulatory impact to your marketed products

We will cover…

- A quick recap on the background of the Windsor Framework
- Impact to Marketing Authorisations
- Submission requirements and artwork updates
- How to manage shared packs
- Falsified Medicines Directive (FMD)
- Supply of existing stock
- Taking advantage of Health Authority flexibilities
- Project planning and how to avoid large write off costs or being out of stock
- Latest updates - PV requirements, material updates
- Final thoughts, key guidance and resources

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The Windsor Framework: Recap on the background

2016

UK Vote to Leave EU

UK formally left in 2020

Transition period starts (EU law)

2021

Transition Period Ends

EU law no longer applies to GB

EU law continues to apply to NI

'*The Northern Ireland Protocol*' in place

2023

Windsor Framework Announced

Amends and replaces the Northern Ireland Protocol and brings NI back into the UK trade laws

2025

Windsor Framework Applies

All measures will commence on 1st Jan 2025

Regional explanation

United Kingdom (UK)
England
Northern Ireland
Scotland
Wales

Great Britain (GB)
England
Scotland
Wales

Ireland (IE)
A separate country and remains part of the EU

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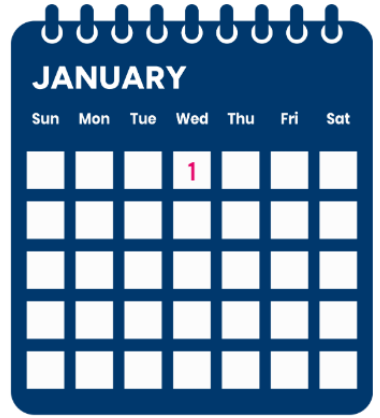
The Windsor Framework: Measures commencing 1st Jan 2025



- **All new medicines for the UK market will be authorised by the MHRA**
- **All outer packaging* must state 'UK Only' and can only be distributed/sold within UK**
- **The Falsified Medicines Directive (FMD) will not apply to NI**
  (Anti-tamper devices should remain on packaging)

Summary of the impact to Marketing Authorisations:

- All new medicines for UK market will be authorised by the MHRA, these will have 'PL' prefix and be UK-wide
- All PLGB licences will automatically become valid UK-wide (the prefix will not (currently) change to PL)
- Companies will no longer be able to hold both a PLGB and a PLNI (see submissions slide for actions)
- Companies can continue to apply for a 'PLNI' through the MR/DC Procedure (only valid in NI)
- NI licences currently part of the CP will automatically be withdrawn from the CP (there is no action needed to withdraw)
- Existing UK-wide licences granted through MR/DC (where UK(NI) is a CMS), can remain part of the procedure unless there are UK specific changes, at which point UK(NI) will need to withdraw from the procedure

* Outer packaging could be carton or label (depending on whether the medicine has secondary packaging)

The Windsor Framework: Submission requirements and artwork updates

Ahead of making artwork changes (to add UK Only), the MHRA must be notified, by one of the following submissions

1) **Any regulatory variation (except TIAs)** *implementation within 6 months of approval*

   Note – if you are marketing the product, depending on manufacturing runs, this may not be appropriate to use now!

2) **Self-certification with eCTD** *implementation any time between submission and 1st Jan 2025*
3) **Self-certification without eCTD** *implementation any time between submission and 1st Jan 2025*

   Note - the cut off for submitting without eCTD is 31st Dec 2024. An updated sequence including the artwork must be submitted by 31st Dec 2025 within another procedure or self-cert.

Artwork updates – addition of 'UK Only'

Must be clearly visible and at least 7-point font, printed anywhere on outer packaging

From 1st Jan, companies will no longer be able to hold both a PLGB and a PLNI for the same product

- Inform RMS of intention to withdraw NI as a CMS from the DCP/MRP
- Submit a request to MHRA by 30th Sept 2024 to cancel the PLNI (effective 31st Dec 2024)
- If you don't do this, the MHRA will cancel the PLGB on 1st Jan 2025

'Stickering'

'UK Only' can be applied as a non-easy peel sticker until **30th June 2025.**

Stickering **must** be carried out by the secondary packaging site named on the MA.

Application of the sticker must be applied **before QP release.**

Submission is still required, as described, and should confirm the **name of the MIA holder** performing the stickering.

Following 30th June, updated labelling can be submitted at next regulatory opportunity.

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The Windsor Framework: Implementation

QPs / Quality

Link to our 'Windsor Framework for QPs' webinar

Reminder of what we are trying to achieve:

MHRA guidance states all outer packaging must state 'UK Only' and can only be distributed/sold within UK from 1st Jan 2025

Can the updates be implemented before 1st Jan 2025? It depends…

- PL products (UK wide packs) can be updated/released before 1st Jan but must continue to have FMD if going to Northern Ireland
- PLGB (GB packs) can be updated/released before 1st Jan – with 'UK Only' and FMD can be disapplied
- PLNI (NI packs) can only be updated/released to market with 'UK Only' from 1st Jan (FMD to be disapplied also)
- EU market packs shared with NI – you could remove UK/NI before 1st Jan but you won't be able to supply to NI

Additionally, implementation timelines depend on the type of submission that made the change:

- If submitted via Art 61(3) – implementation upon submission (not approval), or before next batch released after 1st Jan (depending on above)
- If submitted within an ongoing variation – must wait until approval received and implement within 6 months, or within next batch released after 1st Jan

**** If you have concerns regarding implementation contact the MHRA at partnerships@mhra.gov.uk ****

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The Windsor Framework: How to manage shared packs

What is a shared pack…

Packaging that is shared with another market(s), and which presents administrative details for all markets sharing the pack

MHRA position

- From 1st Jan 2025, all new packs QP released to the UK market must state 'UK Only' and FMD will not be permitted
- Therefore packs going to GB, UK or NI cannot be shared with any EU markets

HPRA position

- Shared packs with UK will no longer be possible since the UK pack must state 'UK Only'
- After 1st Jan 2025, IE packs shared with NI, GB, UK can be supplied to the IE market (*these cannot be distributed to NI, GB, UK*)
- Packs should be updated to remove NI, GB, UK at the next opportunity

EMA position

- EMA's Q&A document states the MAH should update the product information to align to revised QRD template in any upcoming regulatory procedure affecting the annexes. If there is no opportunity within 36 months a dedicated Art 61(3) should be submitted.

QPs / Quality

After 1st Jan 2025 you can continue to release packs with UK/NI info to EU until the pack is updated.

Note: for packs shared with non-EMA or HPRA member state, review relevant HA's guidance on releasing packs after 1st Jan

**** PILs and inner packaging can continue to be shared, as long as the content is authorised in all relevant markets ****

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The Windsor Framework: Falsified Medicines Directive (FMD)

Reminder: Since Brexit, FMD no longer applied in GB, from 1st Jan 2025 this will extend to include NI

Until 1st Jan 2025 all products intended for NI must continue to apply FMD

- From 1st Jan 2025, UK companies can retain the 2D barcode (data matrix) on the packaging
- Although **prohibited** from encoding a unique identifier and **uploading** to EMVS (European Medicines Verification System) (from midnight 31st Dec 2024 the UK NMVS will be switched off)
- Companies can continue to encode the 2D barcode with other relevant data such as expiry, batch no. etc.
- Companies *can* remove EMVS encoding before 1st Jan 2025, but won't be able to supply it to NI (until 1st Jan 2025)
- Anti-tamper devices were introduced for POM as part of FMD in 2016 - these are encouraged to remain

**** If upload to EMVS has occurred this must be reported ****

As per FMD Regulation

a unique identifier is a product code which identifies:

- serial number which is a numeric or alphanumeric sequence of a maximum of 20 characters randomly generated
- name of the medicine
- common name
- pharmaceutical form
- strength, the pack size
- pack type
- batch number
- expiry date

This is printed on the pack as
1) 2D matrix, and
2) Human readable code

In summary - we recommend you retain FMD on all applicable packs up until 1st Jan 2025, following this, any batches QP released to UK should not contain EMVS uploaded data. We also recommend against removing the 2D data matrix as may be needed in the future…

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The Windsor Framework: Supply of existing stock

Supply of non 'UK Only' packaging to GB / NI / UK:

- Any stock QP released prior to 1st Jan 2025 can continue to be supplied to market until expiry
- The territory for which this stock was QP released to prior to 1st Jan 2025 continues to apply for these products, therefore:
  - PL (UK-wide) products can continue to be supplied UK-wide
  - PLNIs can only be supplied to NI
  - PLGBs can only be supplied to GB
    - unless on the NIMAR list, or
    - unless the pack has already been updated with 'UK Only'

*These packs **can** be distributed to Northern Ireland after 1st Jan 2025*

Supply of shared packs

- Shared packs QP released before 1st Jan 2025 can continue to be supplied to all the markets they were released for

NIMAR

The Northern Ireland MHRA Authorised Route

This will still be in place following 1st Jan 2025

We have a number of webinars if needed

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The Windsor Framework: Health Authority flexibilities

MHRA

- All joint packs QP released prior to 1st Jan 2025 can remain on the GB, UK, NI market until the date of their expiry
- Submissions can be made in several different ways
- Artwork for products with a 'PL' and a 'PLGB' licence number can be updated immediately
- Mandatory text 'UK Only' can be applied as a sticker until 30th June 2025
- NIMAR remains in place following 1st Jan 2025 – reach out to MHRA if you suspect you may need this beyond 1st Jan 2025
- Bridging mechanism – companies can supply GB product to NI for 6 months, or until approved (applies until 31st Dec 2024)

HPRA / EMA

- All shared packs QP released prior to 1st Jan 2025 can remain on the market until date of expiry
- All shared packs with UK, NI, GB **not** stating 'UK Only' **and** adhering to EU regulatory requirements including FMD, can continue to be placed on the market after 1st Jan 2025 - these **cannot** be QP released or distributed within UK after 1st Jan 2025
- Shared packs can be updated to remove UK, NI, GB after 1st Jan 2025 at the next opportunity

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The Windsor Framework: Impact to Pharmacovigilance (PV)

The MHRA issued guidance that will be in operation from 1st Jan 2025 – in addition to existing guidance on PV procedures

In summary:

- You need to understand the licence type of each of product and how it will change from 1st Jan – this determines the changes (if any)
- For PV considerations the Windsor Framework changes covers only those products which fall under the mandatory scope of the Centralised Procedure
- Therefore the MHRA have split products into two categories, Category 1 and Category 2
- There is detailed guidance to help you determine which category your products are (we have also summarised this in our blog)
- The MHRA will publish a list of existing Category 1 products before the end of 2024
- There are differences in PV responsibilities depending on your product's category
- Read through our blog which goes through this in much more detail, and…

Exciting collaboration announcement!

Fusion Pharma and ADAMAS will unpick the MHRA's new PV guidance and review all areas impacted in a new joint webinar

ADAMAS

Register now

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The Windsor Framework: Update to Promotional Materials

The PMCPA issued guidance 7th November 2024 for

Is summary:

- Reminder – from 1st Jan 2025, all PLGB licences will become UK-wide, and, EU licence numbers will no longer apply to NI
- Prior to this, your prescribing information (PI) for GB and NI may have been combined or separate
- All UK-wide materials with an EU licence number should be updated since this licence number is no longer applicable to the UK
- There is a grace period to update these materials until 31st December 2025, provided that:
    - The PI is otherwise accurate
    - The PI is updated at the next opportunity (before 31st December 2025)
    - The MA Holder can still be contacted from the address in the PI
- If the above cannot be met, the company should withdraw/amend promotional materials by 15th Jan 2025
- If your MA is only licenced for NI or GB, the material should be updated to state “For GB (or NI) health professionals only”

**** Communicate these requirements and plans to update internally cross all impacted departments****

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The Windsor Framework:
Project planning and avoiding large write off costs / out of stock

Should have already…

- Raised a change control (this impacts many functions, not just Regulatory)
- Reviewed what was done last time (initial Brexit changes, if relevant)
- Communicated internally with key stake holders – artwork houses, manufacturing, global regulatory colleagues…
- Considered what other changes may need to be made e.g. SAP, SKU changes, new barcodes, SOPs, are you 'stickering'…
- Reviewed artwork lead times and planned inline with manufacturing runs ready for next batch released after 1st Jan 2025
- Reviewed if EU markets currently relying on GB stock – assess impact / plan
- If applicable, assessed if it is commercially viable to have an IE only pack or a NI only pack
- Reviewed any if there has been any divergence between an EU CAP and equivalent PLGB, since significant differences may require communication to HCPs
- Completed DHSC questionnaire
- Informed RMS of intention to withdraw NI as a CMS from the DCP/MRP (if applicable)
- Submitted a request to MHRA to cancel the PLNI effective 31st Dec 2024 (if applicable) – if you haven't they will cancel the equivalent PLGB
- Informed DHSC of potential shortages though DASH portal
- Updated SOPs where there is an impact to systems

**** If you haven't done any of the above you may have some issues – reach out and we can advise ****

**** The MHRA / DHSC want to know if shortages are likely or if you have any issues implementing the measures****

Project planning is key!

Based on the guidance and flexibilities, you need to devise the best regulatory strategy depending on your licence type and shared pack status.

Project team should include:

Cross-functional PM
Regulatory
Quality
Supply Chain

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The Windsor Framework: Project planning continued

Now it is time to…

- Ensure all packs are ready for implementation for next batch released after 1st Jan 2025
- Plan updates to EU shared (outer) packs that have UK, GB or UK(NI) included
- Update relevant SOPs to ensure ‘UK Only’ is added to new product launches
- Plan subsequent submissions to MHRA to include eCTD and/or mock ups, if applicable
- Meet with PV to discuss and plan any impact to ways of working (+ register interest to our joint PV webinar)
- Review prescribing information and promotional materials for updates required, plan these updates according to the guidance
- Decommission NI licences that won’t exist form 1st Jan 2025:
    - No action for CPs, these will happen automatically
    - If applicable, withdraw from MR/DC procedure
    - Ensure your regulatory records are up to date on local and global systems, archive where relevant
    - Read through Datapharm’s guidance on eMC NI for awareness

The Windsor Framework: Final thoughts

- **Infuriating!!**
- **However, short term pain with long-term benefits by reducing complexity in Regulatory, Supply Chain, QA**
- **The MHRA / DHSC want to know if shortages are likely or if you have any issues implementing the measures**

Continue your regulatory intelligence:

Websites	Sign up to Health Authority email notifications Sign up to Fusion Pharma Newsletter
LinkedIn	Follow Health Authority pages for announcements Follow Fusion Pharma for interpretation of new guidance
Trade Associations	Join calls and read updates if your company is a member (e.g. ABPI, PAGB, BIA, EMIG)

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Key Guidance and Resources

This presentation has been compiled through our understanding and interpretation of guidance from the MHRA, HPRA and EMA, as well as reviewing updated from ABPI, Datapharm and the DHSC. Links to published guidance are included below.

MHRA's Windsor Framework Hub
The Windsor Framework (UK Government announcement)

MHRA Windsor Framework Hub

MHRA guidance on UK-wide licensing

MHRA guidance on labelling and packaging

MHRA NIMAR

MHRA Pharmacovigilance guidance

HPRA Brexit updates

HPRA Q&A

EMA Brexit Q&A

Datapharm's guidance on eMC NI

PMCPA promotional material guidance

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We hope you have found this presentation useful

We have taken the time to prepare this presentation as we are passionate about the role we play in raising the profile of Regulatory Affairs within the pharmaceutical industry. If you have any queries, comments or suggestions please reach out to us

hello@fusion-pharma-limited.com

While the information in this article is considered to be true and correct at the date of publication, changes in guidance and/or experience may impact on the accuracy of the information. Please refer to the relevant guidance for the latest information.

If you feel you require a more in-depth discussion, we offer a fully confidential free 30 minute consultation

Contact us and we will book in as many calls as we can on a first come first serve basis

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