



17 October 2024

# Windsor Framework: continued preparations for implementation

We wrote on 8 August 2024 and asked you to complete a questionnaire to share how you were progressing with the labelling updates required as part of the implementation of the Windsor Framework.

Today we are sharing some further advice to support you in achieving compliance by 1 January 2025. We are also running a repeat questionnaire open until the end of October; further details are given below.

**You must notify the MHRA of updated artwork requirements as soon as possible. If you have concerns about reaching compliance with the updated labelling required as part of the Windsor Framework. We will seek to work with and support MAHs if they are experiencing unforeseen challenges.**

We remind MAHs that you do not need to wait for MHRA approval of self-certification submissions to proceed with the packaging updates.

This message includes:

1. Sharing approaches for preparedness
2. Implementation issues
3. [October DHSC questionnaire](#) for marketing authorisation holders
4. Save the date: [October MHRA Windsor Framework webinar](#)
5. Further information

## 1. Sharing approaches for preparedness

Respondents to the August questionnaire have shared approaches for managing completion of their submissions and preparations in advance of the implementation of the Windsor Framework. Some examples which may help you prioritise your notifications over the coming months.

- Products currently on the market can be prioritised while products not currently on sale can be completed at a later date after 1 January 2025. Updated labelling for a product only needs to be notified before a new batch is QP certified in 2025, it does not have to be done by 31 December if no new batch is planned until later.
- Some companies do not need to complete submissions at this point due to the volumes of stock currently on the market.



- Some respondents have shared that they have released sufficient surplus stock to cover the first three months of the year to act as a buffer in the case of any delays to applying the 'UK only' labelling.

## 2. Implementation issues

We strongly encourage companies to contact us to discuss concerns they may have regarding the implementation of the labelling updates required as part of the Windsor Framework. We appreciate there may be unforeseen circumstances that could prevent compliance by 1 January 2025 – we are only able to help when we know specific details relating to a product or portfolio. We have supported several companies to reach a compliant pathway and we urge those with concerns to contact us.

If you are concerned about reaching compliance by 1 January 2025 please contact us at [partnerships@mhra.gov.uk](mailto:partnerships@mhra.gov.uk), and include 'WF implementation' in the subject line of your email.

If you have more general questions about the labelling, such as how to add the 'UK-only' label or how to make your notification to the MHRA, please contact us at [patient.information@mhra.gov.uk](mailto:patient.information@mhra.gov.uk).

## 3. October DHSC questionnaire for marketing authorisation holders

DHSC is continuing to monitor industry preparedness for the implementation of the Windsor Framework on 1 January 2025. Please spend a few minutes completing this questionnaire so that we can better understand the progression of industry preparedness and facilitate a smooth transition.

**Please complete the questionnaire via the link below by 5pm Friday, 1 November:**

[October DHSC Questionnaire](#)

## 4. Save the date: October MHRA Windsor Framework webinar

On **Wednesday, 23 October** we will be hosting another industry webinar designed to help you understand the main changes that the implementation of the Windsor Framework for medicines will introduce and what you need to do to ensure you are ready.

You can register for the October webinar [here](#), and a recording of the Windsor Framework webinar held in September has been published and can be found [here](#).



**Registration for October MHRA Windsor Framework webinar closes tomorrow, Friday, 18 October – [sign up to secure a space](#).**

## **5. Further information**

Full details on how to present 'UK Only' on your packaging and options for submitting updated mock-ups to the MHRA can be found in our [labelling and packaging guidance](#). It should be read in conjunction with the [UK-wide licensing guidance](#) and other relevant [MHRA guidance](#).

Further information on the Windsor Framework labelling requirements can be found in our extensive [Q & A document](#).