Medicines & Healthcare products Regulatory Agency

8 August 2024

Getting ready: Windsor Framework implementation

We wrote on 14 May 2024 to remind you of the requirement to update packaging artwork in line with Windsor Framework requirements, to ensure your products are compliant on the implementation date of 1 January 2025.

We are still awaiting a number of artwork submissions. If you have not submitted your notification of updated packaging artwork, please do so as soon as possible.

This message includes:

1. Changes to labelling: What is required?

From 1 January 2025, all new packs placed on the market (Qualified Person (QP) certified) must display a clearly legible 'UK Only' label to prevent onward movement of these medicines into any part of the European Union (EU). All UK medicines will use the same packaging and labelling across the UK.

Any stock in existing packaging already placed on the market prior to 1 January 2025 (i.e. released by a QP before that date), can continue to be supplied to patients in the relevant territory until the date of their expiry. Please see the labelling and packaging guidance for further details.

2. How to submit your artwork

As set out in section 9 of our labelling and packaging guidance, there are three ways to submit your new artwork, including a way to make bulk applications, but you must do so by 31 December 2024.

1. **Any regulatory opportunity:**
   Use any available regulatory opportunity to submit the artwork change in conjunction with another application, such as a variation (except Type 1A variations).
2. **Self-certification:**

Submit a separate self-certification notification specifically for the Windsor Framework artwork change to be registered and tracked through the MHRA's regulatory management system. Provided the changes are in line with the guidance, you can implement the proposed changes once the application has been submitted rather than wait for formal approval.

3. **Self-certification without initial Electronic Common Technical Document (eCTD):**
   MAHs can initially submit artwork changes without an updated eCTD sequence by 31 December 2024, and then have until 31 December 2025 to submit an updated eCTD sequence.

Further information can be found in the Q & A document addressing common queries about Windsor Framework labelling requirements.

3. Falsified Medicines Directive disapplication

From 1 January 2025, the EU Falsified Medicines Directive (FMD) will no longer apply in Northern Ireland. For information on encoding of pack information and barcodes under UK law, please see the labelling and packaging guidance.

In line with this, the UK FMD national medicines verification system (NMVS) 'SecurMed' is closing and there will be no access to this system after 11pm on 31 December 2024. Manufacturers, wholesalers, dispensing points, and their respective software suppliers should take appropriate steps to prepare for this change. This is set out in section 6 of the labelling and packaging guidance.

Packs placed on the market before 1 January 2025 with FMD information uploaded to the repositories system can continue to be supplied. Verification or de-commissioning of these packs from 1 January 2025 will not be required.

4. DHSC Survey for Marketing Authorisation Holders

The Department for Health and Social Care (DHSC) is monitoring industry readiness for 1 January 2025, and requests that you complete a survey so that they can understand this better. We would appreciate if you could spend a few minutes completing this survey.

Please complete the survey via the link below by 5pm Friday, 16 August:

https://forms.office.com/Pages/ResponsePage.aspx?id=MIwnYaiRMUyMH-9N6Jc6HD4QyYKkMCZNq6NaMVbBhotUNkpMS0cxQjNXSjZCVVlFWjZHSllaODZCTi4u

5. Save the date: MHRA Windsor Framework industry webinar

On **Thursday, 19 September** we will be hosting a 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 will have the opportunity to submit your questions in advance. An invitation with further details will be shared in due course.

6. Further information

Further information on the Windsor Framework labelling requirements can be found in our extensive Q & A document.

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.