Medicines & Healthcare products Regulatory Agency

14 May 2024

Getting ready: Windsor Framework labelling changes

We would like to thank those marketing authorisation holders (MAHs) for the good progress they have made so far in submitting their updated packaging artwork, as we prepare for the Windsor Framework's commencement on **1 January 2025**.

We are conscious, however, that there are still many outstanding. We estimate that there are approximately 19,000 marketing authorisations that need to be updated and so far, we have received 3,950 submissions from 317 MAHs, which represents about 20.7% of the total to be updated.

We are now asking you to start making your submissions as soon as possible. This will help avoid a surge of applications in the last quarter of 2024 and ensure readiness in advance of 1 January 2025.

As set out in section 9 of our labelling and packaging guidance, there are a number of submission routes available, as well as the opportunity to make bulk applications to assist with updating your packaging by the end of the year.

In addition to keeping track of the rate of updated artwork submissions, the Department for Health and Social Care will be surveying MAHs during the summer to understand how you are managing your readiness. You can expect to receive these surveys via the usual channels.

Labelling: What is required?

As you are aware, from 1 January 2025, all new packs placed on the market must display a clearly legible 'UK Only' label to preclude onward movement of these medicines into any part of the European Union, while ensuring medicines use the same packaging and labelling across the UK.

As set out in guidance, any stock in existing packaging already placed on the market (i.e. released by a Qualified Person (QP) in Northern Ireland and GB in accordance with the relevant rules in Northern Ireland or GB), can continue to be supplied to patients until the date of their expiry in the relevant territory for which the product was valid for supply prior to 1 January 2025.

EU Centrally Authorised Products (CAPs) will no longer be valid in Northern Ireland from 1 January 2025 and corresponding PLGBs will automatically become valid for the whole of the UK as UK-wide licences. This will mean that there will be a period of overlap where QP released packs that are EU CAPs will be present in the supply chain.

Where there is divergence in the product information between the EU CAP and the UK-wide MA, it is the responsibility of the MAH to manage the introduction of new packs, which are aligned with the UK-wide MA, into the supply chain as soon as possible. This should be done in line with timelines for the introduction of product information updates via a variation. MAHs will be required to update the electronic Medicines Compendium (eMC) accordingly but will only need to communicate with healthcare professionals where there is significant divergent safety information.

Further information

We would encourage you to make use of our extensive Q & A document which addresses the common queries we receive on Windsor Framework labelling requirements.

Full details on how to present ‘UK Only’ on your packaging and options for submitting updated mock-ups to the Medicines and Healthcare products Regulatory Agency (MHRA) can be found in our labelling and packaging guidance.