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Post-Brexit Windsor Framework: Start Submitting ‘UK Only’ OTC Medicines Packs To MHRA

by David Ridley

OTC medicines manufacturers operating in Great Britain or Northern Ireland must add a “UK only” label to outer packaging to prevent their OTC products being exported into any part of the European Union. This new packaging artwork can be submitted to the MHRA anytime from now but must be submitted prior to 31 December 2024, advises Jenson R+.

Manufacturers should start submitting their “UK only” labelling changes to the MHRA to meet post-Brexit regulatory changes, advises consultancy Jenson R+.

A consequence of the Windsor Framework, signed earlier this year, marketing authorization holders (MAHs) of current UK, Great Britain or Northern Ireland product licenses must add a “UK only” label to outer packaging to prevent their OTC medicines being exported into any part of the European Union.

“The Windsor Framework sets out the long-term arrangements for the supply of medicines into Northern Ireland,” commented Jenson R+ regulatory manager Ben Smith. “It will ensure that medicines can be approved and licensed on a UK-wide basis and provides for the disapplication of EU Falsified Medicines Directive (FMD) requirements for medicines marketed and supplied in Northern Ireland.”

“For OTC medicines,” Smith told HBW Insight, “as the FMD does not apply for this category of medicines, the required update will be to add ‘UK only’ to the outer packaging. This new packaging artwork can be submitted to the MHRA anytime from now but must be submitted prior to 31 December 2024.”

Any stock in existing packaging already placed on the market in Northern Ireland and Great Britain can continue to be marketed until 31 December 2024, or their expiry date, depending on which comes first, he added.

Implementation

Smith said that companies can place the 'UK only' label anywhere on the outer packaging of the medicine, as long as the label is “conspicuous and clearly legible, at least 7-point font and in line with Article 5 of EU Regulation 2023/1182, current MHRA expectations and best practice guidance.”

“The ‘UK only’ statement can be applied via a sticker for a limited period of six months, to 30 June 2025,” Smith advised. “However, after this date, stickering will not be accepted, and ‘UK only’ must be printed directly onto the packaging.”

“The application of a ‘UK only’ sticker will need to be done prior to certification by a Qualified Person (QP),” he noted. “The stickering must be completed by the site named on the Marketing Authorization (MA) prior to QP Certification.”

Notification

There are two ways in which companies can notify the MHRA of artwork changes before the 31 December deadline.

“Firstly, MAHs can utilize any available regulatory opportunity, except Type 1A variations, to submit the artwork change in conjunction with another application, such as a variation,” Smith said. “No additional fee would be required for the artwork change.”

“MAHs choosing this route of submission must ensure that the cover letter and form include a statement that the labelling has been updated in accordance with the Windsor Framework requirements.”

For this option, Smith advised that MAHs should wait until they receive formal approval for the procedure before implementing the updated artwork.

Self-Certification

Companies can also submit a separate notification specifically for the artwork change to be

tracked through the MHRA's regulatory management system.

"For this option," Smith said, "MAHs can implement the proposed changes once the application has been submitted rather than wait for formal approval, provided the changes are in line with the guidance."

"The usual implementation timeline of six months does not apply to this change and companies are able to implement updated cartons at any time as long as this is before the 1 January 2025 deadline."

Mock-Up

MAHs who initially wish to apply the 'UK only' statement by means of a sticker will need to provide an updated mock-up of the outer packaging to the MHRA, indicating where this will be placed on the carton, Smith explained.

"There is no need to register an updated mock-up when the 'UK only' label is subsequently printed directly on the pack" Smith said. "Updated labelling may be provided at the next regulatory opportunity."

Where more than one set of labelling is approved on a license, for example, own-label suppliers or a product marketed under more than one name, Smith said that all labelling components must be updated in a single submission. "This may be via either of the options above," he noted.

Landmark Agreement

Signed earlier this year, the landmark Windsor Framework, which agrees that medicines will require no checks or paperwork when exported from Great Britain for sale in Northern Ireland and establishes the MHRA as having UK-wide responsibility for all drug approvals, was welcomed by the UK consumer healthcare industry.

"We congratulate the UK and EU Governments on this very positive outcome which will help to secure the supply of medicines to Northern and Ireland and the UK and secure the huge contribution our sector makes to healthcare in the UK," commented UK industry association, PAGB, CEO Michelle Riddalls. (Also see "*UK Industry Welcomes Post-Brexit 'Windsor Framework' For Northern Ireland*" - HBW Insight, 2 Mar, 2023.)

"This agreement shows that the parties have been listening to and prioritizing our sector's concerns," Riddalls continued. "Great progress has been made over recent years to avert many of the issues which could have prevented medicines being supplied to Northern Ireland. This has been possible because of the expert voice of the sector being heard and a constructive attitude being adopted by both sides."