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Your guide to the latest updates

Windsor Framework Regulations & Labeling:

What you need to know

What You Need to Know About the New Windsor Framework Regulations

In the wake of Brexit, the regulations on medicinal products are undergoing significant changes. It is crucial for companies involved in the manufacturing and distribution of these products to the UK to keep well-informed in order to ensure compliance and avoid potentially expensive recalls and penalties.

It was recently announced by the UK government that new labeling and packaging requirements would be introduced for medicinal products for human use as part of the Windsor Framework Agreement. Here's a breakdown of what these regulations mean, who they will affect, what steps companies need to take to comply and the best approach to minimize the time and money spent.

Understanding The New Windsor Framework Regulations, Who They'll Affect And What Steps to Take

Overview of the new Windsor Framework Regulations

The Windsor Framework stands as a post-Brexit legal agreement between the European Union and the United Kingdom, designed to fine-tune the operation of the Northern Ireland Protocol. Initially announced on February 27, 2023, both parties formally adopted this framework on March 24, 2023, and took effect on October 1, 2023. If you sell products in the UK then you'll need to be aware of what the regulations entail.

As part of the agreement, there have already been major labeling changes for businesses producing goods intended for sale in Northern Ireland and Great Britain. The agreement requires "not for EU" labels on certain goods from Great Britain that don't meet EU standards. These labels are being phased in over three years, **starting with meat and fresh dairy products in October 2023, all other dairy products in October 2024, and composite products, fruit, vegetables, and fish in July 2025.** While originally required only for goods intended for sale in Northern Ireland, the UK Government has decided to implement these labels in Great Britain as well, starting in 2024. As a result, organizations are now having to make mass changes to their product packaging in order to stay compliant.

Furthermore, in January 2024, the UK Government outlined intentions for revisions to enhance the framework's efficacy and adaptability to evolving circumstances. These revisions include a crucial change to labeling and packaging requirements, aimed at ensuring the seamless supply of medicines into Northern Ireland. Effective from January 1, 2025, all medicinal products on the UK market must be labeled as 'UK Only'. This means they cannot be sold in the EU unless they are classified as 'specials' and comply with EU rules and conditions.

Who will be affected?

These regulations will impact industries involved in the production, distribution, and sale of medicinal products for human use. This includes pharmaceutical companies, manufacturers, distributors, and retailers operating in the UK market.

Key Changes and Requirements

Here's the five key points in the Windsor Framework you should be aware of:

1

'UK Only' label:

From January 1, 2025, all packaging for UK medicinal products must prominently feature a 'UK Only' message. This message must be clearly legible and can be presented anywhere on the outer packaging. It can be an additional label until June 2025 but after that, the message must be on the main product label or packaging.

2

Disapplication of FMD Requirements:

The EU Falsified Medicines Directive (FMD) requirements will no longer apply in Northern Ireland from January 1, 2025. This means the two-dimensional barcodes and serialization numbers will no longer be required but the MHRA will expect other anti- tamper devices to remain on all medicine packaging.

3

Stickering:

A temporary measure allows the application of 'UK Only' stickers until June 30, 2025, after which the message must be printed directly onto the main product label or packaging.

4

Notification Process:

Companies must notify the MHRA of any artwork changes by December 31, 2024. Various notification processes are available, including regulatory opportunities, self- certification, and self-certification without initial eCTD.

5

Early Release to Market:

Updates to labeling and packaging can begin before January 1, 2025, for UK-wide Product Licenses and GB Product Licenses. The MHRA will continue to allow manufacturers to supply medicines in legacy EU packaging until 31 December 2024.

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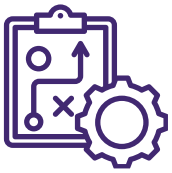
Steps You Need to Take Now

The new labeling and packaging regulations for medicinal products represent a significant shift in the industry. By understanding these changes and taking proactive steps to comply, companies can navigate the transition smoothly while continuing to supply safe and effective medicines to consumers in the UK market. Here are five steps to ensure you're not caught out by the Windsor Framework changes and to ensure your company is compliant in advance of the deadlines.

Your 5 steps to compliance...

1. Review Current Packaging

Assess existing packaging to determine if updates are needed to comply with the 'UK Only' labeling requirement.



2. Plan for Changes

Develop a timeline for implementing necessary updates, considering the deadlines outlined in the guidance.

3. Submit Notification

Choose the appropriate notification process and submit any artwork changes to the MHRA by December 31, 2024.

4. Implement Changes

Once approved, update packaging accordingly, ensuring compliance with the new regulations.

5. Monitor Compliance

Regularly review processes to ensure ongoing compliance with regulatory requirements.

You can find more information on the action you need to take on the UK government's official website.

How End-to-End Labeling and Artwork Management Software Can Help

When it comes to making mass label and artwork changes in line with new requirements, often with very little time to spare, using the right software is crucial to ensure you're keeping compliant and meeting deadlines. The evolution of global commerce demands efficiency, accuracy, and agility, all of which are facilitated by modern digital solutions. Utilizing cloud-based platforms ensures global collaboration, instant updates, and enhanced security, while automation and AI drive accuracy, speed, and compliance.

Although investing in enterprise labeling and artwork management software can be costly, with regulations changing constantly and more updates expected to come off the back of Brexit, organizations will likely be required to make more mass changes in the near future and having the ability to make changes quickly and accurately is paramount.

On the other hand, relying on traditional methods or outdated software lacking cloud, automation, or AI capabilities can lead to significant drawbacks. Manual processes often result in inefficiencies, errors, and delays, hindering time-to-market and increasing costs. Moreover, without the agility and scalability provided by cloud-based solutions, businesses risk falling behind in adapting to regulatory changes and market trends, ultimately compromising their competitiveness and market positioning.

In today's fast-paced environment, the consequences of using traditional methods or outdated software are far-reaching. Without the automation and intelligence afforded by modern solutions, businesses may struggle to meet regulatory requirements, leading to compliance issues and potential fines. Additionally, the lack of real-time collaboration and updates inherent in non-cloud solutions can impede communication and decision-making, slowing down workflows and inhibiting innovation. Ultimately, failure to embrace the right labeling and artwork software may result in missed opportunities, decreased efficiency, and diminished competitiveness in an increasingly digital and dynamic marketplace.

Don't underestimate the power of using the right labeling and artwork software.

When it comes to making potentially tens of thousands of changes, you need a platform that'll ensure you're getting it right first time, every time.

Bob Tilling, VP of Global Sales at Kallik

Making Mass Changes Quickly and Accurately With Veraciti™

Global Digital Transformation

Total Regulatory Confidence

Reduced Time to Market

In light of the significant regulatory changes in the medicinal product industry, companies must streamline their processes to ensure compliance while maintaining efficiency. This is where Kallik's innovative software, Veraciti™, emerges as a crucial tool for businesses navigating the complexities of label and artwork management. Wondering where to start with making so many changes and concerned about getting them done by June 2025? Veraciti™ is the answer to your problems.

We sat down with our labeling and artwork expert, Bob Tilling, VP of Global Sales, to run through some of Veraciti™'s key tools and functions that streamline making mass changes like this without compromising on accuracy and compliance.

Update 10,000 labels in just

14 days

with Veraciti™ versus six months with conventional methods

Designed specifically to help complex, highly regulated enterprise organisations

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Making it Simple With Veraciti's™ 'Where Used' and Automatic Artwork Generation Tools

'Where Used' Function For Complete Regulatory Confidence

The 'Where Used' function is a key feature in helping to maintain compliance. It can identify specific assets and recognize every artwork or label where they have been used previously. With ever-changing regulations, this makes the process of making bulk changes to icons, images, and phrases seamless, both facilitating and accelerating the process of achieving regulatory compliance. This is paramount to organizations looking to make mass changes to their product packaging ahead of the implementation of the latest Windsor Framework Regulations.

> *"Kallik's 'Where Used' function enables us to search and locate artwork files, logos and phrases impacted by regulatory changes at the touch of a button."*
>
> MARY KAY
> Emma Polman,
> Creative Business Packaging Manager

"Veraciti's™ ability to quickly and accurately locate all the impacted labels or artworks is a game changer in accelerating changes and identifying errors early on to prevent any sudden discoveries after printing that may have you becoming non-compliant," Bob Tilling explained.

Kallik's recent collaboration with a Danish multinational medical device company underscores the remarkable efficiency achieved with Veraciti™. Facing the daunting task of updating and approving 90,000 product labels to comply with European Union Medical Device Regulations (EU MDR), the company accomplished this feat in just 25 weeks with Veraciti™, without requiring additional resources. This rapid change management, facilitated by Veraciti™'s digital platform, exemplifies the indispensable role of automation in ensuring compliance while minimizing time and resource expenditure.

Automatic Artwork Generation (AAG) For Rapid Speed-to-Market

Veraciti™'s unique Automated Artwork Generation (AAG) tool dynamically assembles the chosen pre-approved content. By using intelligent pre-approved templates to automatically generate the artwork or label, the need for human input is removed, reducing the risk of errors as well as rapidly decreasing project completion times. Labels or artworks can be created within seconds rather than days or weeks.

Increasing Speed-to-Market and Reducing Costs With Label Templates

Additionally, Kallik's work with global consumer goods corporations illustrates the substantial cost savings achievable with Veraciti™ thanks to its intelligent label or artwork templates. By transitioning from manual alterations, which incurred significant expenses, to a cloud-based automated service, the manufacturers reduced artwork costs by 60-70%. This drastic reduction, amounting to potentially millions of pounds saved over the contract term, underscores the tangible return on investment offered by Veraciti™'s label templates and streamlined processes.

So how is it possible to achieve this? Veraciti's™ templates are pre-designed formats that are used as a basis for creating labels or artwork for various products, packages, or documents. These templates typically include placeholders for variable information such as product names, descriptions, barcodes, pricing, and other relevant details. Label or artwork templates are far more efficient, accurate, and compliant than relying on graphic design software such as Adobe Illustrator or Adobe InDesign driven by an artworker.

At the heart of template technology lies its ability to automatically resize text, scale barcodes, and adapt images. This not only ensures that all products within a brand maintain a uniform look and feel, enhancing brand identity, but with strict regulations on ingredient lists, warnings, and usage instructions, templates in conjunction with Automatic Artwork Generation (AAG) can generate consistent, compliant labels or artworks in seconds. With the power of templates, you can rest assured your labels or artwork include all necessary regulatory information, ensuring compliance with local and international standards.

> Brian Cannon, Senior Project Manager at **Teleflex**
>
> *As a major medical device provider operating worldwide, teams working across all of our sites and facilities will be involved with the labeling process at some point, meaning standardised control and processes were simply non-negotiable for future success. The implementation of Veraciti from Kallik has comfortably provided us with that central control and management identified as the keystone of our Global Labeling System.*

Avoiding Errors With Veraciti's™ Cascade

When identifying and making mass changes to labels and artworks, it's often the case that the user information document may also need updating. Ensuring accuracy and consistency across all components and packaging levels is paramount. Veraciti™'s Cascade feature offers a solution that empowers artworkers and designers to work on user documentation while minimizing the risk of errors.

What's unique about Cascade is it flags up to the user if only 9 out of 10 pieces of content have been used so corrective action can be taken.

If someone edits any of the items either intentionally or by mistake then the system will tell them and highlight the item in red to show that a mistake might've been made here.

This makes it almost impossible to create errors, which is crucial when you're short on time and trying to make hundreds, or even thousands, of changes to documents.

Bob Tilling
VP of Global Sales at Kallik

'Cascade' Function For Complete Accuracy

Cascade provides artworkers and designers with full control over how label or artwork assets are utilized. This level of control is crucial for maintaining brand consistency and adhering to regulatory requirements. By streamlining approved content directly into Adobe InDesign or Illustrator, Cascade ensures that all approved elements are seamlessly integrated into the design process.

One of the key benefits of Cascade is the assurance of accuracy. With content locked down to prevent unauthorized changes, artworkers and designers can have 100% confidence that the content used in the design is accurate and compliant with regulatory standards. Moreover, Cascade offers flexibility without compromising on accuracy. While artworkers and designers retain creative control over layout and appearance. If an asset such as a phrase or symbol is not placed in the document the user gets a warning to remind them there is still content to be added to the document. This balance between flexibility and control allows for innovative design while safeguarding against errors in content usage.

As pharmaceutical recalls due to packaging errors continue to plague the industry, the importance of robust label and artwork management cannot be overstated. With Veraciti™, companies can mitigate these risks, ensuring compliance, reducing costs, and ultimately safeguarding both consumers and the environment. In an era where precision and efficiency are paramount, Veraciti™ emerges as an indispensable asset for businesses navigating the evolving regulatory landscape of the medicinal product industry.

It’s Time to Make the Switch

In conclusion, the impending changes brought about by the new Windsor Framework Regulations demand swift action from companies involved in the manufacturing and distribution of medicinal products. With the deadline of January 1, 2025, rapidly approaching, businesses must start making necessary changes to their labels and artworks as soon as possible.

Understanding the intricacies of these regulatory changes and the steps required for compliance is essential. From reviewing current packaging to submitting notifications to the MHRA by December 31, 2024, companies must take proactive measures to ensure adherence to the 'UK Only' labeling requirement and other key provisions outlined in the guidance.

Fortunately, Kallik's innovative software, Veraciti™, offers a comprehensive solution to streamline the process of making bulk changes to labels and artwork with intelligent, automated tools that will revolutionize your labeling and artwork process.

As we approach the deadline for the implementation of the new regulations, there is no time to waste. Companies must act now to adapt to these changes and safeguard their operations. Considering the complexities involved, it may be beneficial for businesses to consult with one of Kallik's experts to explore how Veraciti™ can help streamline their compliance efforts.

In this rapidly evolving regulatory landscape, proactive measures are key to success. By leveraging the capabilities of Veraciti™, companies can navigate the challenges posed by the new Windsor Framework Regulations with confidence, ensuring the continued supply of safe and effective medicines to consumers in the UK market. Streamline, scale, and standardize your labeling and artwork process with Kallik. Contact us to learn more about what we can do for your business by emailing enquiries@kallik.com or calling +44 (0) 1827 318100.

End-to-end Enterprise Labeling & Artwork Management Software

At least a 70% reduction in cycle times

45 production sites live within a year

100% compliant: No FDA recalls due to labeling for 5 years

System implemented and live within 8 weeks

$12-$15 million savings annually

90,000 products updated, approved and printed in 5 months

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Speak to us today

Ready to transform your labeling and artwork processes? Gain total regulatory confidence, enable scalable and standardised global operations, and reduce your time to market with Kallik. Contact us today to schedule a demonstration.

www.kallik.com

enquiries@kallik.com

+44 (0) 1827 318100

Book a demo