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Brexit
Pharma Artwork:
Challenges & Solutions

By: Suzanne Ivory
Global Quality Director

Brexit

Brexit has brought with it a raft of concerns for businesses in the pharmaceutical industry that operate in the UK and EU. With a vast array of legislation under scrutiny, possibly to be completely torn up and re-written, there is understandable concern among the regulatory community on just how to deal with this unprecedented challenge.

The pharmaceutical industry relies on an EU-wide framework to legally trial, manufacture, distribute, and sell products throughout the Union. That framework may have to undergo great change in order to accommodate a new, post-Brexit reality. Drilling down further, we will see the real impacts that this regulatory shift may have on the pharma artwork process.

The EMA has stated there are "considerable uncertainties" [1] surrounding exactly what will be contained in any transitional arrangement. On the other side, the MHRA have promised to keep regulations in line with EU legislation as much and as quickly as possible, even in the "doomsday" scenario of no all-encompassing transition agreement being agreed to. (so called "Hard Brexit") [2].

This difference in language alone presents a uniquely challenging scenario for regulatory professionals in pharma. Below, we lay out some specifics surrounding the artwork portion of this scenario, what outcomes to expect and how to prepare for a new post-Brexit reality.

Key Facts

✓ **Mark the date: 30 March 2019.**

This is when the UK will formally cease being a member of the European Union.

✓ **Change in regulatory bodies.**

The MHRA will take over from the EMA as the sole provider of regulations and guidelines within the UK.

✓ **You may need an entirely new set of marketing authorisations.**

This means that both Centralised Procedure licensed products and Mutually Recognised Procedure products will have to receive completely new authorisations to sell from and to the UK.

The Regulatory & Artwork Challenge

The UK is a very important market for pharmaceuticals. With a healthy

internal market, high level of investment in research, and its role as an English speaking gateway to the rest of the European market, it is an attractive place to do business. Many large companies base themselves in the UK for just that purpose and use it as the in Union state for their "Marketing Authorisation Holder" (MAH). In fact, just over 1/3rd of Centrally Authorised Products on the EU market are made by UK based companies. [3]

However, with Brexit looming, this might no longer be an option and change may be necessary. The EMA has warned that "MAH holders will need to act sufficiently in advance to avoid any impact on the continuous supply of medicines…" [1]. The impetus here would be to transfer the MAH for your Centralised Procedure products to a country in Union.

Moving your MAH involves a series of checks and screenings, following strictly defined timelines, in order to meet standards set by the EMA. This must be an entirely separate legal entity and therefore, a new company. From an artwork perspective this would require a change of address across all products that need to transfer to the new MAH.

When talking about Mutually Recognised Procedure, the endpoint is the same. The MAH equivalent in this case, the Reference Member State, would also have to shift to inside the EU. This creates a situation where the following items might have to undergo artwork changes:

- ✓ Containers
- ✓ Secondary packaging
- ✓ Foil packs
- ✓ Shared packs (which may have to be split)

This is a huge headache for any company, approaching the level of a total rebrand in terms of percentage of products that will need to be updated, alongside the movement of MAH to a new, in Union location. The ability to track changes, organise new data and ensure processes are able to deal with this disruption is the baseline for keeping your artwork correct and consistent.

That's Where Perigord Can Help

At Perigord, we have over 20 years of experience in dealing with artwork for regional and global pharma companies. Our expertise and background gives us the strongest possible grounding to address the challenges that Brexit brings to you.

Here is just some of what we can do for you:

01 Artwork Services – Getting it right, first time, on time

Get your products aligned with your new MAH rapidly with no compromise in quality. Our artwork teams have deep knowledge of the UK & EU regulatory environment, combined with complete focus RFT and lead time targets set by you. They are specifically equipped to help you manage the increased volume of artwork changes that may result from Brexit.

02 GLAMS Software Platform – Industry best practice in a box

Brexit demands change. Our Global Labelling and Artwork Management System (GLAMS) makes change easy with configurable industry best practice workflows, full validation provided by us, audit trails and reporting. GLAMS doesn't disrupt what you do either – just helps you do more with frictionless implementation and integration.

03 Knowledge Process Outsourcing – Let our knowledge work for you

Challenges like Brexit can bring your pain points into sharp focus. Our total artwork and process experts work right alongside you to relieve that pain. Remove approval bottlenecks. Improve artwork turnaround times. Integrate closer with your clients. Find your best practice process with us. The Perigord KPO team excels in mapping out your path to success. We fine tune a solution with the right people, in the right place to help you manage costs and improve KPIs.

Get In Touch Today

Our 20 years of experience in the UK, EU and the US pharmaceutical markets ensures that we can anticipate and meet any challenges Brexit poses to your artwork. Stay ahead of your Brexit challenges.

Get in touch with us today to discuss how Perigord can provide you comprehensive artwork cover and peace of mind when dealing with Brexit: mark.ennis@perigord-as.com

Stay Ahead Of Your Brexit Challenges

References:

[1] Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500226603.pdf

[2] MHRA update to pharmaceutical companies on exit preparations. https://www.gov.uk/government/news/mhra-update-to-pharmaceutical-companies-on-exit-preparations

[3] EMA Survey to Industry: Key Figures. http://www.ema.europa.eu/ema/images/Brexit_survey_figures.jpg