Into the unknown

Product liability post-Brexit: Sarah Moore & Stuart Warmington discuss what the post-Brexit 'new world' might look like for product regulation in the UK

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IN BRIEF

▶ What might the post-Brexit 'new world' look like for product regulation in the UK? Can the UK's domestic regulator alone keep us safe? And what legal challenges will be created?

Irrespective of whether the words of this title trigger *Frozen 2* flashbacks, or not, they pose a crucial question in the context of post-Brexit product liability.

On 31 December 2020, we moved out of the Brexit transition period, and into, well, the unknown, with respect to the network of institutions and agencies across the EU that have worked alongside our domestic regulator—the Medicines and Healthcare Regulatory Authority (MHRA)—to protect patients and consumers from unsafe medical products.

The UK entered the European Economic Community, the predecessor to the EU, in 1973. A year prior, Sir Harold Evans at the *Sunday Times* had broken the story of the Thalidomide tragedy. Evans's reporting exposed the UK as a 'Wild West' in which poorly tested drugs, with limited safety data, could be provided to the public at large, including pregnant women.

What followed was the creation of a regulatory infrastructure, through statute and agency, to ensure that the British public would be better protected from untested and unsafe medical products. This infrastructure was nurtured and grown—just as the UK forged its identity as a member of the EU. Consequently, the UK's modern history of drug and device regulation, from the 1970s onwards, has been developed as part of a European project.

Now, on the other side of the transition deadline and in the context of an unprecedented global pandemic, our MHRA must stand alone for the first time in almost 40 years—tasked with safeguarding the UK market from unsafe medical products.

What might this post-Brexit 'new world' look like for product regulation in the UK? Can the MHRA alone keep us safe? And what legal challenges will be created?

Before 2020, products and devices entering the UK were subject to approval by a network of European checks and balances: from the well-known CE mark denoting conformity with EU safety standards, to the deep bench of pan-European experts scrutinising product safety and health risks at, for example, the European Medicines Agency (EMA), and the European Commission's Scientific Committee for Health and Emerging Health Risks (SCHEER).

This well-developed infrastructure has fallen away, and our MHRA stands alone. Starkly, in 2019 the EMA closed the doors on its London headquarters and relocated to Amsterdam after 24 years in the capital, confirming that: 'As of 1 February 2021, no one representing, appointed by or nominated by the UK can participate in any EMA scientific-committee or working-party meetings, or in the Agency's Management Board'.

Post-Brexit changes in infrastructure will be matched with changes in the UK's legislative architecture: in May 2021, the EU's new Medical Devices Regulation (MDR) will be implemented, but will not form part of the UK's retained EU law.

Instead, during February 2021, the UK enacted the Medicines and Medical Devices Act 2021 (MMDA 2021) which, among a range of powers, permits the amendment of the Medical Devices Regulations 2002, SI 2002/618. Introducing the Bill for its second reading, Matt Hancock said: 'it gives us the means to depart from EU rules and regulations in future, moving at a faster pace, …. as an independent, self-governing nation' and 'will ensure that we strike the right balance between capturing the benefits of innovation without compromising patient safety'.

Exactly where that balance will be found, and the long-term shape of medicine and medical device regulation in the UK, remains to be seen. What is clear is that, as set out in MMDA 2021, s 1, the government is intending that the newly created role of an independent patient safety commissioner (PSC) will play a part. This new statutory position is a direct response to the second recommendation of the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Cumberlege. The PSC's core duties will include promoting patient safety and ensuring that patients' views are heard.

Listening for wider input is also at the heart of the government's 'call for evidence' announced last week, which, it is intended, will seek to modernise the UK's product safety laws for the first time in 30 years.

Shelving the crystal ball for a moment; towards the end of 2020, we were given an encouraging preview of how the MHRA's newly independent, non-European persona, might look.

In October 2020, months ahead of mainland Europe, the UK made the decision to trigger an emergency clause in the Human Medicine Regulations 2012, SI 2012/1918. This permitted the MHRA to issue temporary authorisation for mass-population rollout of the Pfizer/BioNTech vaccine. Had the UK still been a member state, we would likely have been subject to the same vaccine supply contracts and delays in authorisation that are reflected in the divergent vaccination statistics as at March 2021, with some 30% of the UK now having received at least one vaccination jab, in contrast with just 8% across the EU.

It is of course also important to remember that the history of product liability is littered with examples in which it has taken the more cautious interventions of other regulatory agencies to raise the alarm on harmful products. Historic examples include thalidomide, the articular surface replacement (ASR) hip (both blocked by the US regulator); and more recently, the proactive interventions of the French regulator, the ANSM, around breast implants including PIP, and Allergan.

The pressure on our 'newly single' MHRA, in the context of a global pandemic, to move at pace to approve novel products post-Brexit, has never been greater.

It is to be hoped that, just as some 40 years ago the thalidomide tragedy was a catalyst for the first raft of medicines regulation as we entered the EU, the UK can now work to forge new international relationships—because, if the pandemic shows us anything it is that, even post-Brexit, no healthcare regulator can afford to be an island. **NLJ**

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