II - The future of post-Brexit regulation

Attracting investment and protecting patients with smart regulation

The recent Independent Medicines and Medical Devices Safety Review, or Cumberlege Review, identified systemic failures in patient safety, emphasising the importance of strong regulation of medicines and medical devices to reduce the risk of avoidable harm.

It details the harrowing experiences of patients treated with three type of medicines and devices (i.e. Primodos, sodium valproate, and pelvic mesh devices). The lack of appropriate channels for reporting adverse incidents and zero post-manufacture surveillance on device safety experienced in these cases require a strengthening and rethink of how existing regulation is actually implemented.

Regulatory change in this area is already on the table due to Brexit. The Medicines and Medical Devices Bill 2019-20 is moving apace through Parliament, but in its current form will not provide the necessary prioritisation of safety. Changes to the Bill, including strengthening the role of the MHRA, are needed to provide much needed safeguards, as well as to ensure opportunities for scientific and regulatory innovation.

The UK needs to remain a desirable place to develop and market medicines and medical devices post-Brexit. The Medicines and Medical Devices Bill addresses this by requiring that any new regulations have regard for the "attractiveness" of the UK in relation to these activities. However, since no definition of "attractiveness" is provided in the Bill, there is a real and present danger that, in its current form, this may be detrimental to patient safety. Unamended, the application of this requirement is open to interpretation, leaving the question as to how this interacts with patient safety unanswered.

Although it is contained within the Bill, patient safety is not explicitly prioritised. Given the findings of the Cumberlege Review, a failure to make safety the primary concern would call into question the strength of commitment by the Government to building a fit-for-purpose regulatory regime for medicines and medical devices.

One of Review's recommendations is for the strengthening of the role of the MHRA. It recommends that it take on the role of a licensing authority for medical devices, akin to its role in medicines, and that it creates and controls a medical device registry. Whilst the current Bill includes powers to create a medical device registry, it would be controlled by NHS Digital (the Health and Social Care Information Centre in the Bill), not the MHRA. This risks making the regulatory landscape even more disparate, decentralised, and disconnected than it already is, as yet another body takes on a governance role.

The MHRA has a wealth of experience working with various European organisations, including the European Medicines Agency. Post-Brexit the Authority will take over much of the European Medicines Agency's remit in relation to pharmacovigilance. There is a strong argument to be made for greater central oversight over medical devices.

Brexit provides the potential to restructure devices regulation to enable tighter domestic oversight concentrating regulatory oversight and enforcement for both areas in the one agency. There is an opportunity for the role of the MHRA to be strengthened with regards to both medicines and devices in order to ensure patient safety.

The Medicines and Medical Devices Bill could facilitate this, as well as providing some much-needed regulatory clarity. However, it does not do so in its current form. The opportunity to remedy this should be taken as the Bill enters the next stages in its passage through Parliament.

Dr Laura Downey, Dr Rachael Dickson, Professor Muireann Quigley and Professor Jean McHale

University of Birmingham

"Changes to the Bill, including strengthening the role of the MHRA, are needed to provide much needed safeguards, as well as to ensure opportunities for scientific and regulatory innovation."