Browne Jacobson

New regulatory pathways announced for innovative medical technologies and internationally approved medicines

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On 23 May 2023 the Medicines and Healthcare products Regulatory Agency (MHRA) made two significant announcements relating to the implementation of the Government's plans to streamline and fast-track the regulatory approval processes for medical technologies and medicines following Brexit. These were:

1. New regulatory recognition routes for medicines approved in the EU, Switzerland, US, Canada, Australia, Singapore and Japan. The new international recognition framework for medicines will be in place by the first quarter of 2024. This pathway will sit alongside the MHRA's Innovative Licensing and Access Pathway (ILAP), which allows for an accelerated approval process for certain new medicines.
2. A new Innovative Devices Access Pathway (IDAP) that will be launched later in 2023 and operated by the MHRA, NICE, and other partners, including the devolved administrations. The ambition is to create a pathway that supports innovators generate the evidence they need to achieve regulatory approval, heath technology assessment decisions, and patient access in the NHS. Stage 2 of the IDAP implementation will include legislative changes to mirror the accelerated ILAP process for medicines

The IDAP is part of the broader package of reforms to the medical devices regulatory framework that the Government is introducing in a phased approach. This process includes:

- Introducing a new post-market surveillance regime later in the year, which will require proactive patient safety monitoring and increased reporting to MHRA re safety incidents.
- A legislative package of more substantive reforms that are expected to be implemented in 2024, which will include matters such as new alternative domestic routes to market and rules dealing with approved bodies, registration requirements, software as a medical device, clinical investigations and implantable medical devices.

Whilst the new regulatory framework is proceeding more slowly than originally anticipated (and has required an extension to the transitional arrangements for CE marked devices), the announcements are an important step in the implementation process and will accordingly be welcomed by the medical device industry, healthcare providers and patients. If the indicative timescales set out in the various announcements summarised above are adhered to, the next 12 months will be a significant one for the implementation of these various developments. Browne Jacobson's specialist health team is here to answer any questions you may have about the announcements and guide you through the regulatory reforms as these come into force.

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