**ABHI REGULATORY POSITION PAPER**

Patient safety is of paramount importance to the HealthTech industry. However, no effective medical intervention is completely without risk, and explaining the potential risks as well as the expected benefits, is an important part of the informed consent process ahead of any procedure.

Manufacturers, regulators and healthcare professionals work continually to minimise these risks, whilst simultaneously delivering advances in patient care that benefit millions of people every day. Nearly all of us will use a HealthTech product in our lifetime, and the effectiveness of regulation is highlighted by the fact that serious adverse events are rare.

Regulatory approval for medical devices is provided by the CE marking process, and is overseen, in the UK, by the Medicines and Healthcare Products Regulatory Agency (MHRA).

For a product to gain approval, it must demonstrate the necessary quality, safety and performance attributes. Robust post-market surveillance and vigilance ensure that products are continually monitored once in clinical use, a process which contributes to iterative improvements and increased patient safety.

The legislation that currently governs regulation, the Medical Device Directive, is currently being replaced by a new Medical Device Regulation (MDR), which will be fully implemented by May 2020. MDR brings an increased emphasis on post-market surveillance, the publication of clinical follow-up plans, and an ongoing commitment to real-time updating of risk/benefit considerations. In addition, the new Eudamed database will provide a comprehensive summary of safety and clinical performance. These requirements will ensue the continued long-term safety of devices.

Conformity assessments are conducted by third party organisations called Notified Bodies. Their role is to audit manufacturers annually to ensure that compliance to standards and regulations is being maintained. Furthermore, Notified Bodies undertake regular, un-announced audits.

Comparisons to the regulation of pharmaceuticals are not appropriate. Products that are pharmacologically derived and work systemically, have very different evidence and regulatory requirements from those which are physically engineered and have localised therapeutic effects. The iterative nature of device development and the consequently short timelines involved, user variability and the potential to be truly disruptive to care pathways, all demand a separate approach to approval, assessment, funding and the managed introduction of devices into health systems.