ABHI STATEMENT ON ICIJ INVESTIGATION

Over the last few days stories in the media have sought to portray our industry as unethical, poorly regulated, and likely to place commercial interests above those of the patients we serve.

Rather than a comprehensive look at both the challenges and the achievements of an industry that touches almost every human life, these stories ignored the life-changing, and often life-saving solutions delivered to millions of people worldwide.

Life today would be unimaginable without medical devices. From catheters and syringes, to MRI scanners and patient monitoring devices, technologies are essential to the delivery of modern healthcare. In 2017 alone, the NHS conducted nearly 200,000[1] hip and knee replacement procedures, implanted over 60,000[2] cardiac devices and provided nearly 400,000[3] cataract operations.

We should never discount any patient's experience. But by magnifying the stories of only a few individuals, investigators overlooked the overwhelmingly positive experiences of millions of others. We take seriously all reports of unexpected or unwanted events, and whilst no effective medical treatment can ever be completely without risk, a continual drive to improve technologies and care delivery is a fundamental part of our work.

Comparison to pharmaceuticals is not helpful. Products that are pharmacologically derived and work systemically, have very different evidence and regulatory requirements from those which are physically engineered and have a localised therapeutic effect. 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 medical technologies into health systems.

Industry is committed to continually improving regulation, and the transition to the new Medical Device Regulation (MDR) in Europe, builds on what is already a robust framework that has served patients well for almost 30 years. MDR brings into it 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.

Every day we deliver safe, effective products. Millions of people benefit from them to live healthier, more productive and independent lives.

Sources

1 National Joint Registry, 15th Annual Report
2 ABHI analysis of market data
3 National Ophthalmology Database Audit 2017, The Royal College of Ophthalmologists