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ABHI's Statement of the PIP Implant Matter

ABHI (the UK's medical technology industry association) notes with great concern the media reports that the French firm Poly Implant Prothèse (PIP) may have violated the regulations by utilising unauthorised industrial-grade silicone in some of its implantable products and by allegedly falsifying or withholding documents. If these, or other allegations are confirmed, ABHI strongly condemns PIP's activities. The alleged offences are the result of serious fraud.

Many millions of medical devices are utilised across the EU everyday with few reports of failure. It is crucial to the future development of healthcare that innovative technologies are made available at the appropriate time. In order to do this Europe has to maintain an effective regulatory framework that not only ensures patient safety and outcomes but also allows for the timely access of new medical devices to market.

Over the last couple years and entirely unconnected with this case, the medical device regulatory system has been undergoing fundamental review and reform of its Directives to combat these issues and proposals for a revision are imminent. While ABHI supports the key aspects of the current regulatory model, it recognises that reform is necessary to strengthen and evolve appropriate and proportionate regulation that balances patient safety and innovation. Manufacturers, the Commission and National Authorities also recognise the need to update the system and in turn are working toward enhancing the legal framework to allow more homogeneous and comprehensive implementation across all EU Member States, including more efficient vigilance and market surveillance systems.

No regulatory system can wholly guard against all fraudulent acts and abuse.