EU REGULATIONS

After two recent medical mishaps—failure by EU regulatory authorities to detect irregularities in breast implants[1] in 2010 and defective hip implants[2] in 2012—the public lost confidence in not only the European Commission but also in the medical device industry as a whole. Consumer claims of the industry emphasizing profit over patient safety began to surface, with many also expressing concerns that the EU regulatory process was failing to minimize unnecessary patient risks.

As a result of these events and the public's response to them, the European Commission made a call to action, in 2012, to strengthen its Medical Devices Directive (MDD)—regulations for the manufacture and distribution of medical devices within the European Union.[3] The commission is hopeful that such updates, which include a recertification process for medical devices already on the market and stricter premarket approval and postmarket assessment processes for new products, will reestablish patient confidence in the EU regulatory approval process and in the effectiveness of the system.

Although the addition of new medical device regulations was proposed back in September 2012,[3] they have not yet been fully implemented across the European Union. This cover focus intends to summarize the updated directives and the timeline for their implementation and to help surgeons and industry alike decipher how such directives will affect the practice of medicine, the research and development of new products, and the availability of new devices.

One of the biggest questions people who work in the ophthalmology sector have is: **Will innovation stay in Europe?** Experts who have contributed to this cover focus seem to think it will, as long as there is a balanced approach to EU regulation and manufacturers fully understand and uphold the current regulations.

– Laura Straub, Editor-in-Chief

1. Pips breast implant scandal: Regulator warned years earlier. May 15, 2012. The Telegraph. http://www.telegraph.co.uk/health/...../Pips-breast-implant-scandal-Regulator-warned-years-earlier.html. Accessed January 5, 2015.
2. Faulty medical implants investigation: Patients' health put at risk by unscrupulous EU regulators. The Telegraph. October 22, 2012. http://www.telegraph.co.uk/news/health/news/9626756/Faulty-medical-implants-investigation-Patients-health-put-at-risk-by-unscrupulous-EU-regulators.html. Accessed February 13, 2015.
3. Proposal for a regulation of the European Parliament and of the Council on Medical Devices. September 26, 2012. European Commission website. http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf. Accessed January 6, 2015.