Revising the regulation of medical devices to protect both safety and innovation

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'Revised legislation that creates the right conditions for safe and innovative medical devices is essential,' according to Neven Mimica, EU Commissioner for Consumer Policy who spoke last week in Brussels about the Commission's proposed revisions to legislation on medical devices and in-vitro diagnostic medical devices.

According to the Commissioner, the proposed revisions succeed in striking the delicate balance between encouraging innovation and protecting patient safety. He noted, 'Our ambition is to establish a framework ... that is flexible enough to reap the benefits that innovation can bring to patients and for the competiveness of the industry.'

Europe will face major challenges to its healthcare systems in coming years. Across the EU, our population is ageing - it is estimated that, in 2060, there will be twice as many Europeans aged 65 or over as there are now. This demographic change increases the prevalence of chronic disease and heaps intense pressure on healthcare budgets. On the other hand, innovation in medical devices has gained pace in recent years. The move towards remote diagnoses is just one example of the tech revolution sweeping our healthcare services.

Although increasingly innovative medical devices have the potential to allow for early disease diagnosis and treatment, keep us healthier for longer and shift care from hospital to home, they bring with them concerns for patient safety. Such anxieties are particularly keenly felt in light of scandals in recent years regarding defective medical products.

In late 2012, following the scandal of defective breast implants produced by the French PIP company, the Commission proposed revised regulations on medical devices and in-vitro diagnostic medical devices. The proposals are intended to extend the scope of legislation and provide greater clarity. The revised legislation would be extended to include, for example, implants for aesthetic purposes. The proposals also provide for stronger supervision of independent assessment bodies by national authorities and clearer rights and responsibilities for manufacturers, importers and distributors, applying also to diagnostic services and internet sales.

Addressing stakeholders and media at a European Policy Centre breakfast briefing in Brussels last week, Commissioner Mimica noted, 'The European Commission proposal on medical devices reflects the rapid pace of scientific progress as well as the need to preserve the highest level of patient safety.' The Commissioner insisted that innovation and safety are in fact 'two sides of the same coin'.

According to Commissioner Mimica, the regulation is also necessary for the EU to adapt to a global market. He noted, 'I have just returned from China where I discussed the Chinese revised regulatory framework for medical devices and the effect of its implementation on the market access for the European medical devices. When we have in mind that the EU and China together represent over a quarter of the world's population, it is easy to recognise the enormous potential of this cooperation for the mutual benefit of our consumers and economies.'

The Commissioner elaborated on how negotiations on the Transatlantic Trade and Investment Partnership with the US would also impact this issue of medical devices: 'I believe that the mutual recognition of quality management system audits can be beneficial for patients and companies on both sides of the Atlantic ... However, the basis should be global standards under the International Medical Device Regulatory Forum and not a single jurisdiction standards.'

In April 2014, the European Parliament confirmed its proposed amendments to the Commission's proposed text. However, Member States continue to consider their position on the proposals despite many days of meetings.

The Commissioner underlined how eager he is to see movement on the issue - the proposals are now almost two-years old: 'Further delays would be prejudicial not only patient safety but also to innovation. Swift access to innovative and life-saving technology is an important aspect of public health ... An uncertain and unpredictable framework does not create a favourable environment for the businesses and the investors.'

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