Medical devices matter

It was a long time coming, but the new rules regulating medical devices will make a real difference to patient safety, writes **Mairead McGuinness**

Mairead McGuinness (IE) was Parliament's EPP group shadow rapporteur on the medical devices regulation

When the breast implant scandal broke in 2012, there was an outcry from the public and rightly so. How could such a shocking thing happen, that a manufacturer of a medical device (breast implant) would knowingly use a harmful substance in their products, without any concern for the health of women who would receive these implants? Clearly this was a criminal act and the question we had to ask was, why was this activity not detected in our regulatory system? And how could it continue for so long impacting on thousands of women in many EU member states and beyond our borders? It was a question that the European Parliament demanded answers to. That pressure for action pushed the European Commission to act and bring forward a new medical devices regulation. Before the new regulation could be agreed, we needed immediate action and the Commission drew up and implemented an action plan to tighten up controls on the system. The action plan revealed cracks in the system which needed to be addressed, including a tightening up on notified bodies and the need for unannounced inspections.

Work on the regulation has taken a great deal of time. Perhaps it has taken too long, but in the process of negotiating between Commission, Council and Parliament we have managed to come up with concrete steps to improve patient safety - which has to be our core concern. Trust and confidence of patients in the healthcare system is vital, so any damage done to the reputation of the medical devices sector damaged that essential trust in the system and our work aimed to restore that vital level of trust. Medical devices are wonderful. The industry that produces them is incredibly innovative and many of us, our family and friends have come in contact with medical devices. For a lot of people these devices, like heart stents or hip replacements, improve the quality of lives. In many cases, these devices save lives. So we were also conscious in our work not to impose overly complex and unnecessary bureaucracy on the industry. We did not want a regulation which dampened the ability of the industry to continue to innovate and develop devices, but we did want to ensure that devices placed on the market were safe and rigorously assessed.

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And so I, and others who worked on this file, were happy that in April of this year the European Parliament adopted the regulation that will enter into force by mid-2020. As one of the MEPs very closely involved, I believe that our work will lead to greater security for patients. The work was incredibly detailed and technical and the proof of the effectiveness of our work over four and a half years will only be known after mid-2020. I am acutely conscious that we must continue to monitor the work on implementing the regulation. With any file going through the House there are always highs and lows during negotiations – and this file was no different. However throughout the intense discussions the overarching goal of achieving and adhering to the highest standards in patient safety guided our work. The efforts of our staff must be recognised as the file involved many long hours of pouring over technical details in order to get things right.

For many of the stakeholders in the sector this will require increased resources right along the supply chain, from the Commission itself, down to the notified bodies and member states' competent authorities. The role of member state authorities is absolutely vital in the correct implementation of the new regulation. Getting safe products onto the marketplace is important, but so too is post market surveillance and follow up. This means that if a problem arises there must be rapid notification of the incident and rapid recall, if that is what is required. Sadly with the PIP breast implant scandal, there was poor coordination of reporting of problems, which resulted in the faulty implants being on the market for too long before action was taken.

The introduction of an unique device identification under the new regulation will allow devices to be traced rapidly. Overall the new rules demonstrate how the EU can effectively respond in the interest of its citizens. It may take some time, but even though the regulation will not be fully implemented until 2020, already our work is making a difference as the industry gears up for the new rules. The attention to detail on this file was crucial in guaranteeing that scandals like the PIP breast implant one, do not occur again. Rules and laws do not stop criminal activity. However, our new medical devices rules should mean that anyone attempting to take shortcuts will be caught red handed and before their actions damage the health of citizens. This is of course cold comfort for anyone who was affected by faulty devices in the past. But for the future, I believe our work will make a real difference.★

MEDICAL TECHNOLOGIES CAN KEEP PEOPLE HEALTHY, WRITES **SERGE BERNASCONI**

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THOUGHT LEADER

Today's healthcare systems are not fit for the future. The model that delivered steady gains in life expectancy through the 20th century will not be able to serve the ageing population and the rise of chronic diseases we have today. It's time for a rethink. Let's start by looking at what we want from our health systems. For me, healthcare should help us to live longer, healthier lives; allowing us to be socially and economically active and independent for as long as possible. Achieving these benefits for people will also avoid, wherever possible, the need for high-cost care and the cost of advanced disease.

Medical technologies are a central part of the solution to our shared problem. Representing around seven per cent of total health spending, they can deliver better value for every euro spent on health. From prevention to diagnosis and cure, technologies inform and enable care at every step of the pathway. Let me give you three ways in which medical technologies can enable the change we need. First, we need to focus on the value we deliver to patients. This means providing outcomes that matter to patients; interventions that improve their quality of life and make healthcare more convenient. I'm talking about faster and more accurate diagnosis; more homecare solutions, supporting people in self-managing their chronic condition, including tele-monitoring services; less invasive surgical procedures; as well as technologies that can prevent deterioration and speed up recovery time.

Second, technology can drive efficiencies in the whole system. It is estimated that up to 30 per cent of health spending is wasted. By identifying the most successful treatment options through accurate diagnosis, or providing care at peoples' home medical technology solutions can trigger smarter investment in health. The third big benefit of embracing the value of medical technologies is the wider socio-economic impact that flows from a healthy and active population. Think of the economic gains we enjoy when people are fit for work and less reliant on social supports.

New methods incentivise such beneficial solutions. For example, procurement is an important area for medical technologies as 70 per cent to 80 per cent of medical technologies are purchased through tenders. The EU Procurement Directive, updated in 2014, provides a framework for combining price with quality elements. Progressive procurement bodies now aim to incentivise technologies and services that deliver high value for money from a holistic point of view. We must also look to modernise payment schemes. The traditional 'fee-for-service' regime is not delivering optimal care in the most efficient way. Rather than activity-based funding, payment can be linked to outcomes and value. The medical technology industry is engaging in this debate and aims to play a constructive role.

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As we get to MedTech Week, it's time for all of us to consider how to make healthcare more sustainable. I would be more than pleased to hear your view and enter a dialogue about how we all could contribute to positive change.

Serge Bernasconi is the Chief Executive Officer of MedTech Europe