Medtech in an era of new technology and regulation

Digital technology and artificial intelligence are bringing about major changes in the way healthcare is practised. At the same time, new EU legislation on the regulation of medical devices is coming into force in 2020 which promises to dramatically change the way companies develop and bring their products to market.

The dual challenges of technology and new regulation were the subject of a conference in Basel, Switzerland on 24 to 25 October, organised by the industry association Medtech & Pharma Platform. The meeting was attended by stakeholders from the medical technology, pharma and information technology sectors, as well as regulators and patient advocates. How will these dual challenges be met?

For a start, the new technologies, notably digitalisation, were identified as the main disruptors within healthcare systems today. The issue is about data and how this is collected and used. The digitalisation of existing medical technologies, the development of new diagnostics, and the broad availability of mobile and wearable sensors are all leading to an unprecedented quantity of healthcare data. Some of the biggest challenges facing the system are integrity and proper analysis of collected data, validated feedback to patients or physicians if applicable, and individual privacy and data protection rights.

Artificial intelligence (AI) is expected to help people manage data and augment the quality and operational efficiency of healthcare. However, to positively impact healthcare, the developers of AI need to take the needs of the end-users, namely patients and healthcare professionals, into consideration. Similarly, quantum computing can transform healthcare by improving the speed and accuracy of data analysis and enable currently intractable problems to be addressed. While quantum computing is still in the research stage, its potential commercial applications for healthcare are diverse, including drug development, diagnosis and risk and supply chain management.

At the conference, panellists agreed that one of the big regulatory events of 2020 is the coming into force of the EU Medical Devices Regulation (MDR) on 26 May, which will dramatically reshape the European landscape for medical devices as well as products combining devices and pharmaceuticals. There was concern that the new requirements for clinical data, rigorous post-market oversight, and the scope of the regulation pose obstacles to compliance. The estimated industry-wide cost of MDR compliance has been put at between 4% and 7% of a company's revenue in a European market worth over $100 billion.

Accordingly, MDR is predicted to substantially affect device manufacturers and innovation in the sector. While larger manufacturers are expected to reduce their portfolios by approximately 30%, some small manufacturers could close due to a lack of available resources to cope with the increased requirements. Moreover, the limited number of MDR-designated notified bodies is expected to delay new device launches and result in the removal of some devices from the market. Notified bodies are the organisations designated by EU member states to assess the conformity of devices with safety and performance requirements.

In making these assessments, panellists took note of the legislative background. The MDR amends *Directive 2001/83/EC* on the Community code relating to medicinal products via Article 117. This article stipulates that a marketing authorisation application (MAA) for a medicinal product with an integral medical device must include evidence of the conformity of the device with the MDR, either by a CE certificate, Declaration of Conformity, or if the device has not been certified, a notified body's opinion on the device's conformity to relevant General Safety and Performance Requirements (GSPRs). However, currently there is no guidance available which details the notified body's expectations and the documentation required for this opinion, nor do we have any information about its expected content. To accelerate patient access to innovative products, the European Medicines Agency (EMA) is reviewing whether it would be possible for companies to submit their MAAs to the agency first, followed by the notified body's opinion within a defined timeframe. Manufacturers are also discussing with the authorities the concept of a 'platform application' in which only one notified body opinion would be required for a device which is used with several medicinal products. Uncertainties also affect medical devices for which the notified body is obliged to seek clinical evaluation consultation with a competent authority or an expert panel, as detailed in Article 54. For example, expert panels to evaluate products such as infusion pumps, which are classified as Class IIb under Rule 12, do not yet exist. The EMA is currently preparing implementation guidance for devices within the scope of Rule 14, related to devices which incorporate, as an integral part, an ancillary medicinal product and Rule 21, related to substance-based devices which are absorbed by, or locally dispersed in, the human body.

Furthermore, the strongly growing electronic-health / mobile-health sector is expected to be impacted by the MDR via the introduction of classification Rule 11 for software as a medical device. Due to stricter classification rules, the majority of standalone software will be up-classified from Class I to Class IIa or higher, requiring the involvement of a notified body for conformity assessment.

Several presenters emphasised that manufacturers should study the new regulatory requirements as early as possible during product development and communicate with their notified bodies to ensure MDR compliance. The interface between the new technology and the new EU law is complex, but it is also full of opportunities.

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