Future Care Capital

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Parliamentary Briefing: Medicines and Medical Devices Bill

House of Lords Second Reading, September 2nd 2020

About Us

Future Care Capital is an independent charity which undertakes research to advance ideas that will help shape future health and social care policy and deliver improved outcomes for individuals in the United Kingdom. We have produced several publications which explore how the UK might better harness the value of healthcare data, including: *Taking Next Steps to Harness the Value of Health and Care Data* (2019); *Research and Commercial Use of Healthcare Data* (2020); and *Health Enterprise amongst Clinicians and Academics in the UK* (forthcoming). Our briefing outlines a number of areas which, we believe, parliamentarians might usefully reflect upon ahead of the Medicine and Medical Devices Bill's second reading in the House of Lords.

Context

As the UK transitions from membership of the European Union (EU), powers to regulate medicines and medical devices are needed to ensure that the Government and pertinent bodies can guarantee their safety and efficacy whilst nurturing innovation in key sectors. *First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review* [July 2020] underlines the need for up to date provisions to reduce the risk of avoidable harm to patients. Meanwhile, the public health emergency continues to shine a light on the value of an ecosystem that is conducive to innovation in primary and secondary care, data-driven technology for population health management as well as in drug discovery and repurposing.

The UK is a leading nation in the development of data-driven technology in healthcare[1], and whilst we welcome the introduction of the Bill and its overarching aims, we wish to ensure that medical devices underpinned by new techniques, including those which are currently classified as 'decision support tools', are provided for within the Bill. Digital advancements are transforming medical devices and the distinction between a device, the software it relies upon and prescribed medical treatments is less clear than was once the case. Moreover, that distinction is not readily reflected in the tiered classes of device which are otherwise useful for understanding the potential impact and risk of harm from individual medical devices. A Bill is needed which goes beyond the provisions enshrined in the Medical Devices Regulations (2002) with this in mind.

The Challenge

At present, more than 500,000 medical devices are thought to have been licensed for manufacture worldwide[2] - many are digital devices and a growing number are data-driven by design. We believe that there are three key challenges when considering the Bill and its implications for the regulation of such data-driven devices:

1. **Guaranteeing patient safety** - we are concerned that unquestioning, over-reliance on data-driven medical devices has the potential to put individuals at risk in the absence of appropriate regulation. Existing data-driven medical devices provide health services directly to patients via their smartphone, remotely diagnose and identify conditions, monitor and recommend treatment on the basis of

[1] According to the official Bioscience and Health Technology Sector Statistics published by the Office for Life Sciences, digital health businesses in the UK comprise the largest number of businesses for all of life science industry and the largest segment in MedTech by employment [August, 2020]. https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2019

[2] Medtech and the Internet of Medical Things [Deloitte, July 2018].

feedback from wearables. In other scenarios, these devices amount to assistive tools for clinicians. Onus is currently placed upon the individual to make appropriate use of such 'decision support tools', rather than developers of devices being required to take clearly defined steps to guarantee patient safety.

2. **The potential for automatic updates to cause harm** - the Bill does not currently define when a data-driven device, as compared with its analogue counterpart, might be said to have substantially changed or updated, and neither does it provide the means to track these changes or updates. By their very nature, many data-driven devices change or 'learn' over time as they are informed by or amass new data. Without the means to monitor these updates, it is currently impossible to assess how many patients might be adversely affected by such changes at any given point in time.

3. **Digital trade, intellectual property and innovation** - the Government has made plain its ambition where boosting digital trade post-Brexit is concerned, but must negotiate new trade agreements with countries that subscribe to an increasingly protectionist approach to intellectual property (as distinct from calls for the 'free flow of data'). Whilst we acknowledge the value of entering into agreements to grow the UK's Digital Health and MedTech sectors, we are concerned that the effect of some provisions in new trade agreements could be to reduce access to and understanding of algorithms which underpin new data-driven medical devices.

The Opportunity

The UK has an opportunity to be a leader in the global medical devices market and, not least, because the NHS affords it significant advantages over other territories where the development, testing and introduction of new devices and therapies is concerned. However, it must not sacrifice patient safety to facilitate product innovation. The Bill should build upon existing international legislation, incorporate explicit reference to 'decision support tools' and the use of *algorithms* in medical devices. The Government should, also, commit to the development of leading-edge provisions pertinent to the deployment and regulation of machine learning and artificial intelligence within the Bill[3]. Crucially, the Bill should guarantee patient safety in relation to data-driven medical devices by requiring access to their technical architecture for the purposes of auditing innovative products as a prerequisite of approval for trial and ongoing use in the United Kingdom[4].

Key Questions

- Does the Government intend to make provisions for 'decision support tools' and the use of algorithms in medical devices now or in the future and, if so, when?
- Does the Government perceive merit in building upon pertinent provisions introduced to safeguard citizens of the European Union and, if not, why?
- If there is an opportunity to learn from other countries, can the Government highlight which nations the UK is looking toward and outline what it thinks we can usefully learn from them?

If you would like to discuss any of the issues raised in this briefing, please do not hesitate to contact: Annemarie Naylor, Director of Policy and Strategy - annemarie.naylor@futurecarecapital.org.uk

[3] For example, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance).
[4] In a similar vein, the Federal Drugs Administration requires pre-market notifications and approval of Class III medical devices prior to deployment in the United States of America.