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Current regulations shape the use of AI in healthcare and more are on the horizon. **Gayle Curry**, partner at Mills & Reeve, discusses what they mean for healthtech companies



How can healthtech companies get ahead of AI regulation?

AI is being deployed in health and care and is set to play an increasingly important role in the move from analogue to digital. Companies that can get ahead of regulations will have a competitive advantage.

We see AI being used to improve efficiency in hospitals and bed/place management and also in the diagnosis and treatment of disease like cancer and heart disease, in some cases more effectively than clinicians.¹ The government recently announced a trial to use AI tools in routine screenings to catch breast cancer early.² The 'C the Signs'³ tool can be used alongside GP appointments and uses AI to predict any cancers that the patient is at risk of developing and recommends referrals. AI tools can also analyse data to predict outcomes and improve care quality. For example, the NHS is rolling out an AI tool⁴ which predicts patient's risks of falls and monitors potential virus symptoms, then flags healthcare staff who can intervene to reduce hospitalisations.

How AI regulations are expected to apply

As exciting new AI tools are emerging, regulations are being developed with different jurisdictions taking different approaches.

The UK government is taking an enabling pro-innovation stance, having published its AI Opportunities Action Plan earlier this year.⁵ The government has so far prioritised a sector-specific approach, which will be implemented by existing regulatory bodies and through existing laws.

In contrast, the EU AI Act which came into force last year aims to prevent potential risks associated with

AI from materialising. It classifies AI according to risk level, with medical devices (which can include AI software) classed as high-risk. Most provisions will be implemented from 1 August 2026. It is likely that many healthcare uses of AI will be classified as 'high-risk'. Even if AI tools are classified as 'low risk', there are transparency obligations to consider.

The EU AI Act sets out a series of obligations for high-risk AI systems.⁶ High-risk AI systems must be consistently accurate and robust, and resilient to cybersecurity risks. Developers must put in place risk management systems with regular reviews and updates and ensure regular testing. AI systems will need technical documentation demonstrating compliance. There are requirements for data governance and management practices. AI systems must be trained on data which meets quality standards, to prevent biases in data. There are also requirements for AI systems allowing automatic data logging. Beyond automated processes, high-risk AI systems need to be overseen by humans and appropriate oversight measures need to be implemented.

AI regulations have been welcomed as a necessary framework for responsible use of AI which prioritises patient safety and builds public trust.⁷ Increasing clarity on regulation helps healthtech companies to plan ahead.⁸ However, some have expressed concern over the risk that regulation will slow innovation. For example, MedTech Europe voiced concerns that the EU Act's human oversight requirements could have a negative impact on the benefit-risk ratio of medical devices.

It will be challenging for healthtech companies to understand how different regulations work together and apply to their products. Input from specialist

advisors will likely be needed, which will create a higher barrier to entry for startups.

Navigating AI regulations

Early planning is critical for healthtech companies looking to continue to develop and launch innovative AI products. The first step is to consider whether technologies will fall within scope of legislation and, in the EU, whether they are high-risk. Companies can then focus on identifying their compliance strategy. Healthtech companies can start developing their internal governance systems and ensuring that data used for training is reliable and compliant. They can also make any changes to their quality management and prepare and deliver training to their employees.

NOTES

- 1** <https://www.imperial.ac.uk/news/249573/new-ai-tool-detects-13-more/>
- 2** World-leading AI trial to tackle breast cancer launched – GOV.UK
- 3** An AI support tool to help healthcare professionals in primary care to identify patients at risk of cancer earlier - Cancer digital playbook – NHS Transformation Directorate
- 4** NHS England » Nationwide roll out of artificial intelligence tool that predicts falls and viruses
- 5** <https://www.gov.uk/government/publications/ai-opportunities-action-plan>
- 6** See EU AI Act, Chapter III: High-Risk AI Systems, Section 2 Requirements for high-risk AI systems Regulation – EU – 2024/1689 – EN – EUR-Lex
- 7** <https://www.digitalhealth.net/2023/06/value-of-regulation-continues-to-rise-as-ai-and-health-technology-booms/>
- 8** Regulation in healthcare: will AI law impact innovation?, Zühlke