Artificial intelligence and machine learning have the power to transform healthcare in an era of stretched resources and overstretched staff. But as the technological developments accelerate, healthcare providers need also to be aware of the risks and regulation surrounding their use, explain **Sharon Lamb**, partner, and senior associates **Pilar Arzuaga** and **Bella North** from McDermott Will & Emery UK LLP

AI in healthcare

The recent publicity around ChatGPT and similar technologies has highlighted the power and potential of Artificial Intelligence (AI) to transform society. In healthcare, the benefits of AI-powered technology are already well recognised. In the US, the FDA has already approved more than 500 AI and machine learning (ML) medical devices and the software framework in the UK and EU is well established.

Use cases for AI is wide, ranging from radiology and diagnostics to care delivery. In trials and drug discovery, AI can accelerate identification of chemistry, molecule design and testing reducing the cost of bringing new medicines to market.

AI software – a medical device

In the UK, software with a medical purpose including AI is regulated as a medical device and the developer must certify that the AI is safe to use and performs in the way it is intended to work.

Depending on the risk class, clinical investigations, clinical evaluations, and performance studies are required.

The current law assumes that software design is 'locked' at the time of certification. Any substantial changes may mean a new certification.

But AI and ML are not static tools. One benefit of AI is the ability to change and learn from real world use. Certifying new changes would be cumbersome and expensive for developers.

International regulators are grappling with the balance between allowing AI to change and learn while remaining safe.

One solution is the concept of a pre-determined change control plan (PCCP).

In 2022, the UK published its consultation response on the regulation of AI as part of new medical device legislation. This indicated permitting PCCPs for AI, which would specify intended changes and how these would be implemented from the outset.

Some respondents to the consultation also proposed that the UK look to follow the FDA protocols, on changes to software algorithms. In April 2023, the FDA issued draft guidance for PCCPs for AI and ML enabled device software functions which sets out information to be included in a PCCP.

One concern is that AI or ML algorithms are at risk of bias, particularly where the data derives from usage across a small population subset.

Bias is not a new problem or specific to AI in healthcare, but reports indicate that medical device manufacturers may lack access to data on ethnicity, gender, and other data exposing some patient groups to unsafe risks. The need for high-quality data as part of clinical evidence is therefore essential.

At the same time, developers and users of AI must comply with data privacy law and guidance – careful thought is needed for the use of data to develop AI and ML.

EU and UK – a different approach?

The speed of AI developments has led to public debate about how to control AI. There are also concerns about the ability of AI to intrude on individual's privacy and human rights.

Governments are taking different approaches to regulation with a risk that a patchwork of laws develops across the world.

This is seen by the different approaches adopted by the EU and UK.

In the EU, a harmonised approach is proposed in new draft law, the AI Act.

The AI Act proposes regulation based on a 4 tier risk system. AI posing unacceptable risk would be banned. High risk AI would require a CE certification and additional compliance. Limited risk AI would be subject to transparency obligations.

The medical device industry is concerned the AI Act, which designates medical devices as high risk, adds another regulatory burden and uncertainty.

The AI Act was proposed in 2021, ahead of public awareness of the potential and risks of AI so many say the law is already out of date and needs to be changed before implementation.

In contrast, the UK in March 2023, proposed a more flexible framework for AI regulation. The policy recognised that AI is already embedded in healthcare, from drug discovery and biological analysis to software.

The UK proposes no new AI law and a de-centralised approach with differ-

ent regulators, such as the UK Information Commissioner's Office (ICO) and MHRA developing their own guidance based on central principles including safety, fairness and redress.

Some critics say this hands-off approach ignores the dangers to society.

It's also questionable whether divergence from the EU is practicable. Any developer accessing the EU market will need to comply with the EU rules so that the stricter EU rules become de facto gold-standard.

The AI will see you now?

Although AI algorithms are regulated as medical devices, there have also been questions about the role of the CQC.

In 2022, the CQC reviewed the use of ML for diagnostics and noted that most ML suppliers would not need to register with the CQC, but that a few may need to become registered providers if they deliver clinical activity. Developers will be concerned if there is a confusing, double layer of regulation.

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Healthcare providers need to be aware that tools used with patients may be regulated software and consider the risk that doctors who have used publicly available tools throughout their education, may use AI to support the care of patients.

Providers are recommended to adopt AI policies, which should include data protection analysis, training, risk assessment and controls for the safe deployment of technology.