



FPM Consultation Response to MHRA's National Commission into the Regulation of AI in Healthcare's call for evidence

Launched by the Medicines and Healthcare products Regulatory Agency (MHRA) on 26 September 2025, the National Commission into the Regulation of AI in Healthcare brings together global AI leaders, clinicians and regulators to advise the MHRA on the development of a new regulatory framework for AI in healthcare, to be published in 2026.

In December 2025, the National Commission opened its call for evidence. FPM submitted its response (below) to the Commission on 2nd February 2026.

Questions

Question 1: Which of the following best describes your view about the need to change the UK's framework for regulating AI in healthcare?

- *No change: The framework should be maintained as is*
- *Minor adjustments: The current framework works but requires small changes*
- ***Significant reform: The current framework requires substantial changes***
- *Complete Overhaul: The overall framework should be replaced entirely*
- *Unsure*

Question 2.1: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Safety and Performance Standards

- *Strongly disagree*
- ***Disagree***
- *Neither agree or disagree*
- *Agree*
- *Strongly agree*

Question 2.2: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Data Privacy and Data Governance

- *Strongly disagree*
- ***Disagree***
- *Neither agree or disagree*
- *Agree*



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- *Strongly agree*

Question 2.3: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Transparency

- *Strongly disagree*
- *Disagree*
- *Neither agree or disagree*
- *Agree*
- *Strongly agree*

Question 2.4: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Requirements for clinical evidence

- *Strongly disagree*
- *Disagree*
- *Neither agree or disagree*
- *Agree*
- *Strongly agree*

Question 2.5: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Post Market Surveillance

- *Strongly disagree*
- *Disagree*
- *Neither agree or disagree*
- *Agree*
- *Strongly agree*

Question 3: How would you rate the current framework's impact on innovation?

- *Too restrictive (stifles innovation)*
- *Somewhat restrictive (creates some barriers)*
- *About right (balances safety and innovation)*
- *Somewhat loose (lacks necessary controls)*
- *Too loose (risks patient safety)*

Question 4: How might the UK's framework for regulation of AI in healthcare be improved to ensure the NHS has fast access to safe and effective AI health technology?

A new category should be added to the Medical Devices regulation that regulates AI. It should specify the required evidence-generation, technical, assurance and conformity standards that must be met.



Question 5: How should the regulatory framework manage post-market surveillance for AI health technologies?

The new category should also specify the post-marketing surveillance standards that must be met.

Question 6: Which statement best reflects your view on the current legal framework for establishing liability in healthcare AI tools?

- *Sufficient: existing laws (eg. Medical negligence, Product Liability etc) can adequately handle AI-related disputes*
- *Gaps exist: existing laws work for most cases but leave uncertainty in some scenarios*
- *Insufficient: existing laws are unfit for AI*
- *Unsure*

Question 7: How could manufacturers of AI health technologies, healthcare provider organisations, healthcare professionals, and other parties best share responsibility for ensuring AI is used safely and responsibly?

AI manufacturers should be required to conform with this new category of medical device.

Healthcare providers should be required to only procure and deploy AI that conforms to the required standards for the intended use.

Healthcare professionals should be required to only use appropriately procured and deployed AI for the intended use in the intended way according to the manufacturers requirements.

Question 8: In the event of an adverse patient outcome where an adverse patient outcome involved an AI tool, where do you think liability should lie?

It depends on where the fault or error lies.

If the AI tool did attain or maintain the technical, assurance or conformity standards then the manufacturer should be held liable.

If the healthcare provider did not procure an appropriate tool, or deploy it appropriately, then they should be held liable.

If a healthcare professional did not use the tool for the appropriate use or according to the manufacturer instructions, then they should be held liable.