



Developers and Manufacturers

The MHRA established the independent [National Commission into the Regulation of AI in Healthcare](#) in September 2025, bringing together global AI leaders, clinicians and regulators to advise on how the regulatory framework should evolve to be **Safe, Fast and Trusted**.

Industry has been central to this work. Through the Commission's Technology Working Group, sector roundtables, the Call for Evidence and wider [research and engagement](#), developers and manufacturers were clear about the changes needed to support the safe and effective use of AI in healthcare.

The Commission's report [Recommendations for a future regulatory framework](#), published in September 2026, responds directly to these priorities. The Government has now accepted the recommendations and will take a coordinated, cross-government approach to implementation.

What this means for you: supporting responsible innovation, greater clarity to innovate, invest and grow

- 1 A clearer and more proportionate route to market**
Greater certainty about classification, evidence requirements and the regulatory pathway your product will follow.
- 2 Regulation that supports safe updates and faster improvement**
Clearer approaches to product changes and updates, helping beneficial improvements reach patients while maintaining appropriate safeguards.
- 3 Real-world evidence that supports adoption and growth**
Stronger evidence of how products perform in practice to support improvement, procurement, investment and growth.
- 4 A stronger route from regulation to adoption**
Better alignment between regulatory and healthcare assurance requirements, reducing unnecessary duplication and supporting adoption.
- 5 Clearer responsibilities across the product lifecycle**
Greater clarity about the safeguards required for safe deployment and who is responsible for putting them in place.



**Read the
full report**



What this means for you



The UK's existing regulatory framework provides a strong foundation for patient safety but was not designed for AI systems that are adaptive, probabilistic, multi-use, and capable of ongoing change after deployment. Improvement should therefore focus on risk-based adaptation, clarity, and proportionality rather than wholesale replacement of existing regulation.

Industry Organisation

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A clearer and more proportionate route to market

Healthcare AI covers everything from administrative support to technologies that materially influence diagnosis and treatment. Different products create different levels of risk, so they should not all face identical expectations.

The National Commission recommended clearer guidance on when AI needs to be regulated as a medical device, how products should be classified and what evidence will be expected. Requirements should reflect the product's intended purpose, level of autonomy, deployment setting, uncertainty and potential consequences if it does not perform as expected.

Clearer distinctions on when a product qualifies as a regulated medical device could provide more proportionate routes for lower-risk technologies while focusing stronger evidence and scrutiny on higher-risk clinical applications. It could also support a competitive environment that recognises investment in quality, evidence and responsible development.

The National Commission also recommended that UK based manufacturers are supported to scale up by being able to sell their devices across the world whilst manufacturers from other countries are supported to bring promising devices to the UK.

To realise this, the MHRA will need strong partnerships with other medical device regulators and advance international harmonisation with their regulatory regimes where appropriate, so UK manufacturers have streamlined routes to other markets whilst enabling patients in the UK to benefit from the world's most promising innovations.

What this could mean for you: earlier certainty about the pathway your product will follow, helping you plan development, evidence generation, investment and routes to international markets more confidently and use resources where they add the most value.



AI is not a homogeneous sector and regulation needs to be risk proportionate and clearly differentiate between risks that apply only to a subset of AI medical devices versus those that may apply across all AI and all medical devices.

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Systems used for administrative or low risk support raise different regulatory considerations from those that materially influence diagnosis, treatment, or clinical decision making.

UKAI Life Sciences Working Group

[Insights from UKAI 's Call for Evidence response](#)

Regulation that supports safe updates and faster improvement

AI products may be updated regularly and, in some cases, can change in ways that traditional medical technologies do not. Manufacturers need to understand which changes can be made within an existing authorisation, and which require further assessment.

The National Commission recommended clearer approaches to managing product updates, including predetermined change control plans (PCCPs). These could allow manufacturers and regulators to agree in advance which changes could be made within defined boundaries, and what testing, monitoring and safeguards would be needed.

For example, a tool that helps clinicians assess scans could be updated to identify an additional finding after targeted testing, provided the change remains within its intended purpose. More significant changes would continue to receive the level of scrutiny their risks justify.

Where appropriate, carefully controlled routes could also allow promising technologies to be deployed while further evidence is collected in real-world settings. For example, a product could first be authorised within a limited or staged scope, with safeguards and transparent reporting. It could then progress towards full authorisation if it meets agreed safety and performance requirements.

What this could mean for you: greater ability to plan product development and release beneficial updates without unnecessary stop-start processes, while maintaining confidence that meaningful changes are being assessed appropriately.



Post-market surveillance must move from reactive incident reporting to a proactive, lifecycle model proportionate to AI risk and capability.

Industry Organisation

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By adopting a PCCP framework, MHRA can help streamline regulatory processes, shorten innovation cycles, reduce “stop-start” adoption, and still protect patients.

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Real-world evidence that strengthens your commercial case

Authorisation remains an essential milestone, but healthcare providers, professionals and investors increasingly need to understand how a product performs in ordinary care settings, across different organisations and patient populations.

The National Commission recommended monitoring matched to the risks and uncertainties of individual products. This could include real-world studies, meaningful performance reporting, monitoring for changes or drift and clearer tracking of products and software versions. For example, recording which version of an AI tool was used in a patient's care could help identify whether a change in outcomes is linked to a particular product update.

Better information-sharing between manufacturers, healthcare providers and regulators should also make it easier to identify emerging issues, learn across different sites and act consistently.

Strong real-world evidence both demonstrates safety and can help responsible companies show that their technology is reliable, works across different settings and delivers outcomes that healthcare organisations and patients value.

What this could mean for you: an evidence base that supports product improvement, procurement, investment and growth, while reducing uncertainty for potential customers and partners.



A proportionate, clearly articulated Post-Market Surveillance framework is therefore critical to supporting both patient safety and timely, sustainable adoption of AI health technologies.

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[Call for Evidence response](#), page 4.



The export case strengthens when products have demonstrably performed under the UK's governance and monitoring discipline.

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A stronger route from regulation to adoption

Regulatory authorisation is one step in the lifecycle of a product. That lifecycle also includes developing protocols, assessing evidence, setting out controls such as cybersecurity safeguards, and clearly explaining the requirements for safe use to those who use or deploy the technology.

The National Commission recommended clearer and more navigable pathways, with better alignment between regulatory processes and healthcare provider assurance. For example, a public-facing journey map could show developers which guidance, organisations and requirements are relevant at each stage.

This means you could plan your evidence and assurance work earlier. Evidence requirements should be coordinated and aligned between regulators, rather than unnecessarily recreated for every organisation considering the same product.

Better access to independent information about clinical effectiveness and value, together with a clearer NICE pathway, could also help healthcare organisations make more informed and consistent decisions. For example, existing evidence could be brought together or, where useful, products designed for the same purpose could be independently compared. This would help providers judge which product best fits their needs.

Regulatory reform cannot determine procurement or reimbursement by itself. It can, however, provide a stronger and more reusable foundation for evaluation, adoption and wider deployment.

What this could mean for you: less duplication after authorisation, a more credible route to adoption across multiple healthcare organisations, and a clearer understanding of where your product could bring the most value to the health system.



A faster, safer route from evaluation to routine adoption is not merely a regulatory win; it is an economic growth strategy

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Clearer responsibilities across the product lifecycle

The development and use of AI products can involve several organisations, including an Underlying model developer, device manufacturer, healthcare provider and end users. The National Commission recommended clearer allocation of responsibilities between those involved.

In pre-market submissions, you would be required to clearly set out the conditions needed for safe deployment of a tool, including when this depends on actions outside the product itself. This may include user training, cybersecurity controls and routes needed for escalating concerns. This means explaining which safeguards your product needs in the setting where it will be used, and which depend on the provider or its staff. This would be supported by MHRA guidance on best practice of risk controls, including published examples showing what good practice looks like.

Explicit allocation of responsibilities for delivering required risk controls should also be reflected in your contract with the deploying organisation and tailored to different contexts. For example, if you need information from a healthcare provider to monitor your product after it is introduced, the contract could set out what information they will share and who will act if a problem is found. This should take into account what each organisation controls, the information available to it and its ability to prevent or address a problem.

What this could mean for you: safeguards tailored to your product and where it is used, with clearer agreement about who is responsible for putting them in place. This could give you greater certainty when planning deployment and help make the UK a more attractive place to develop and deploy healthcare AI.



Responsibility should be shared based on who controls what across the AI lifecycle, with clear duties for each party and shared duties where collaboration is essential.

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Standardised contractual and clinical protection arrangements, covering monitoring responsibilities, update obligations, reporting routes and remediation, would support clearer allocation of responsibilities across manufacturers, commissioners and providers and enable safer adoption.

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Enabling innovation and supporting industry

The National Commission's recommendations, which are being taken forward by government, aim to give developers and manufacturers clearer, more proportionate routes to market, greater certainty about evidence and product updates, and clearer responsibilities across the product lifecycle. That could help you plan development and investment, make beneficial improvements to your product and understand the safeguards needed for its safe use.

Industry helped shape this work through involvement in working groups, the Call for Evidence, sector roundtables and wider research and engagement. The message we heard was clear: you need to understand which requirements apply to your product, what evidence and safeguards you need to meet them, how updates will be assessed and what it will take to move from authorisation towards use in healthcare.

Clear and credible safeguards can give healthcare organisations, professionals and patients confidence to adopt beneficial technologies. Stronger real-world evidence and better alignment between regulation and healthcare assurance could also help you show providers and investors the value of your product and make a stronger case for adoption across more healthcare settings.



This is about creating a future healthcare system that is increasingly tech-enabled but always people-centred.

Professor Alastair Denniston, Chair
Professor Henrietta Hughes, Deputy Chair



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The Commission's overall vision

