Building a Brighter Future
for Injured People

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National Commission into the Regulation of AI in Healthcare
C/o PPSE Team
MHRA
10 South Colonnade
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30 January 2026

By email only: Engagement@mhra.gov.uk

Dear Sir/Madam,

Call for evidence - National Commission into the Regulation of AI in Healthcare

APIL is grateful for the opportunity to respond to the Medicines and Healthcare products Regulatory Agency's call for evidence on the regulation of AI in healthcare.

We are only responding to question six of the call for evidence regarding the current legal framework for establishing liability in healthcare AI tools. We appreciate that AI technology will be transformative and will drive change in the health care system but we believe the existing product liability framework is insufficient to adequately handle AI-related disputes.

While the Consumer Protection Act 1987 is in principle equipped to deal with new technologies (with the state-of-the-art defence), it is extremely challenging for a consumer to litigate against a well-resourced manufacturer in a product liability claim due to the unlevelled playing field. These challenges are further intensified where the index product involves AI and other complex modern technologies.

The increasing use of software and emerging technologies such as AI in products makes claims even more complex and challenging for consumers to pursue. We are concerned that with the introduction of new AI products, injured people will have to pursue complicated, costly international claims against, for example, foreign-based software developers when something goes wrong, with inadequate routes to redress in the UK courts.

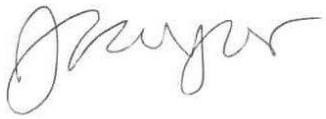
The National Commission should not consider the regulation of AI in healthcare in isolation. We note that the Law Commission is currently reviewing the Consumer Protection Act, including in relation to digital products and emerging technologies such as AI, to determine what law reform might be required to ensure that the product liability regime is fit for purpose. We believe the conclusions from the review must be considered in the context of the regulation of AI for healthcare products to avoid tensions in the legislation.

The UK Jurisdiction taskforce is also consulting on a draft legal statement on liability for AI harms. The taskforce's view is that the CPA will apply to products with integrated AI functions (the taskforce gives an example of a fridge with integrated computer vision which can recognise ingredients placed within it and their expiration dates) but will not apply to AI systems supplied as pure software e.g. a large language model chatbot unless the Law Commission's review proposes legislative change. The statement also proposes that when medical professionals use devices/tools with integrated AI, for example, a scanner that uses

AI analysis, their duty of care to the patient under review is likely to remain.[1] It would be helpful for the National Commission into the Regulation of AI in Healthcare to consider the jurisdiction taskforce's statement and any outcomes from their consultation.

We hope our comments prove useful.

Sincerely,



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[1] UK Jurisdiction Taskforce (UKJT) Consultation on the Legal Statement on Liability for AI Harms under the private law of England and Wales, page 29