Tech Me Up!

AI webinar series

by TaylorWessing

Session #5

From the White Paper to the AI Safety Summit – what is the UK's regulatory position on AI?

Victoria Hordern, Alison Dennis, Clare Reynolds and Lulu Freemont (Miltown Partners) I November 2023

Speakers

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Patchwork of UK regulators relevant to AI

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'Horizontal': remit spans across multiple sectors

EHRC, as the UK equalities watchdog, has made **tackling discrimination** in AI a major strand of its strategy.

Equality and Human Rights Commission

ICO's remit over **data protection and information rights** aspects of AI, including issues such as fairness, bias, transparency and automated decision-making.

ICO. Information Commissioner's Office

CMA responsible for **competition and consumer** law implications of AI, including whether use of AI poses risks to market competition.

CMA Competition & Markets Authority

DRCF

Digital Regulation Cooperation Forum (DRCF). Brings regulators together with responsibilities for digital regulation, including to conduct research. Preparing to Pilot a DRCF "AI and Digital Hub" to support digital innovators

'Vertical': sector specific remit

Not an exhaustive list!

MHRA Regulating Medicines and Medical Devices

MHRA regulates **medicines, medical devices and blood components** in the UK. Includes regulating use of AI in medical devices. medicines, clinical trials etc.

Healthcare

FCA FINANCIAL CONDUCT AUTHORITY

BANK OF ENGLAND PRUDENTIAL REGULATION AUTHORITY

Bank of England

FCA regulates conduct of **FCA-authorised firms** in the UK, including their use of AI. Bank of England also has an interest in AI implications, including use by firms supervised by the Prudential Regulation Authority (PRA).

Financial Services

Ofcom

Ofcom responsible for overseeing use of AI by **communications services providers** in the UK.

Communications

GAMBLING COMMISSION

Gambling Commission regulates use of AI in **gambling products/games**, including the potential for consumer harm.

Gambling

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Exploring regulatory themes in life sciences & healthcare (LSH) and financial services (FS)

Regulatory snapshot: Life Sciences & Healthcare

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Key initiatives on AI and Medical Devices

- **July 2020** Cumberledge Review
- **August 2022** Equity in medical devices independent review
- **September 2021- June 2022** Consultation and Government Response on future regulation of medical devices in the UK
- **October 2021 - Good Machine** Learning Practice for Medical Device Development: [10] Guiding Principles (with FDA and Health Canada)
- **October 2023** Predetermined Change Control Plans for Machine Learning Enabled Medical Devices: [5] Guiding Principles (with FDA and Health Canada)

Key themes

- Existing regulations relevant to use of AI MDs – product liability, MDR, GDPR.
- Equipping regulators to cope with the unique challenges of AI: training data sets, on-going independent development, or simply understanding how they work.
- HCPs – training them to: use AI-enabled products effectively – issue of trust and understanding.

Key principles relevant to regulating AI in life sciences

- Can help to reduce inequalities in healthcare provision if biases are not built-in or introduced over time.
- Continued real-world monitoring necessary to ensure on-going safety and performance as well as trust.
- Use of pre-determined change-control plans.

Key questions

1. Level of explainability needed for a) regulators; b) consumers; and c) HCP users
2. How to maintain cybersecurity – incredibly important for medical devices and is challenged by AI-enabled cyber-attacks.
3. How to operate regulatory sandboxes to not over-burden product development.

Regulatory snapshot: Financial services

Key initiatives on AI

Launch of AIPPF

- October 2020
- Bank of England and FCA launched the AI Public-Private Forum (**AIPPF**), to further dialogue on AI between public and private sectors

Discussion Paper 5/22

- October 2022
- Joint Discussion Paper DP5/22 on AI and ML
- Looks at existing regulatory framework application to AI, risks, opportunities etc.

AIPPF Final Report

- February 2022
- Private sector wants regulators to have a role in supporting the safe adoption of AI in UK FS.

Feedback Statement 2/23

- October 2023
- Joint Feedback Statement FS2/23 on AI and ML
- Summarises responses to DP5/22, but does not include policy proposals

Other initiatives

- 2019 and 2022 Joint Surveys on the use of AI and ML in FS.
- 2021 Report by Alan Turing Institute, commissioned by the FCA.
- PRA SS1/23 on model risk management principles for banks.
- FCA 'Implementing Technology Change' Paper.

Key themes

- Many existing regulations relevant to use of AI (cross-sectoral & FS-specific)
- Various benefits of AI acknowledged, but also risks.
- Challenges to adoption include lack of clarity around how rules apply to AI.
- AI also used by supervisory authorities directly (RegTech, SupTech).

Key principles relevant to regulating AI

- Regulation needs to be proportionate and conducive to facilitating safe and responsible AI adoption.
- Technology neutral, where appropriate.
- Approach needs to be context-specific, pro-innovation & risk-based, adaptable.
- Competition aspects also need to be considered.

Key questions

1. Whether AI can be managed through extensions/clarifications to the existing regulatory framework, or is a new approach needed?
2. How to mitigate AI risks while facilitating beneficial innovation?
3. Is there a role for technical, and indeed global, standards?

Avoiding harm to the consumer / patient as consumer

- Existing consumer protection laws.
- Work by the CMA, e.g. review of competition and consumer protection in AI foundation models.
- Where personal data processed, obligations under UK data protection law apply.

Life sciences & healthcare (LSH)

- Medical devices are regulated products: consumers trust the CE or UKCA mark. Manufacturers submit technical documentation to regulators. Regulators review for potential consumer harms.
- Basic principle for medical devices of safety and efficacy extends to any AI within the device.
- Human factors: consider the user in the design of the medical device, which includes placing trust in a device where not situationally relevant.
- Regulatory sandbox: AI-Airlock to allow safe early access to AI for patients and the healthcare system.
- Continue to use harmonised standards for risk assessments: ISO 14970.

Financial services (FS)

- Principles 6 (*Customers' interests*), 7 (*Communication with clients*), 9 (*Customers' relationships of trust*) & 12 (*Good outcomes for retail customers*) all relevant to AI.
- New Consumer Duty: Firms should be able to monitor, explain and justify if AI models result in differences in price and value for different customer cohorts.
- Vulnerable Customer Guidance (pre Consumer Duty), especially relevant to financial exclusion.
- FS2/23: Industry agrees consumer outcomes should be a key focus on regulation and supervision, especially ensuring fairness and other ethical dimensions.
- FS2/23: Respondents considered consumer harms associated with AI mostly originate from the data.

Fairness / Bias

- Discriminatory decisions made using AI systems could be a breach of the Equality Act 2010 – protects individuals from discrimination on basis of 9 protected characteristics.
- EHRC primary responsibility for upholding equality and human rights laws in the UK.
- Where personal data processed, obligations under UK data protection law apply.

Life sciences & healthcare (LSH)

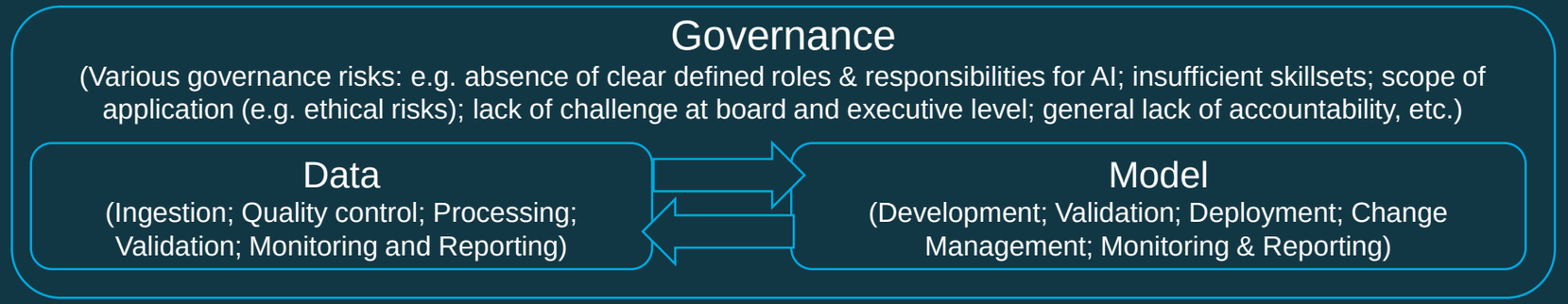
- For regulated products such as medical devices, the obligation to minimise bias - already in EU MDR/ IVDR.
- Principle of "inclusive innovation" – medical devices should serve the needs of diverse communities.
- ISO/ IEC TR 24027 Information Technology – AA – Bias in AI systems and AI aided decision making.
- UK: undertaken the Equity in medical devices: independent review.
- Participate in the **STANDING Together** project:
  - STANdards for Diversity, INclusivity and Generalisability
- Once HCP users start to use the systems: **automation bias** creeps in.

Financial services (FS)

- FCA, PRA & BoE subject to public sector equality duty, including having due regard to need to eliminate discrimination under the Equality Act.
- Various existing requirements relevant to fairness and bias, inc: (i) Vulnerable Customer Guidance; (ii) Consumer Duty; (iii) Product Intervention & Product Governance Sourcebook.
- I.e. Discriminatory decisions by AI systems could breach Equality Act and/or the FCA's Principles or rules and be subject to action from the FCA.
- FS2/23 suggests respondents would like more clarity on practical interpretation of Equalty Act and Consumer Duty in context of AI, including through use of metrics.

Role of Governance

- Good governance essential for safe & responsible adoption of AI.
- Governance underpins effective risk management and spans entire AI lifecycle:



Life sciences & healthcare (LSH)

- UK will have a reliance model for medical devices. "Trust" other regulators for safety, efficacy, bias, human factors etc. Regulation on a "refusal" basis – otherwise, acceptance.
- UK regulation of medical devices: sandbox approach to get ahead of other regulators and to allow a collaborative approach to development in the UK.

Financial services (FS)

- Principles-based approach to governance, plus specific requirements relevant to AI (e.g. recordkeeping).
- Accountability key. E.g. Under Senior Managers & Certification Regime (SM&CR), who is accountable for AI, Operations, Risk, or new AI SMF? What constitutes "reasonable steps" at each stage of the AI lifecycle?
- Lack of understanding at senior management and board level could contribute to ineffective governance.
- New certification for AI one possibility given complexity.

Diagram based upon Figure 1 (Stages of AI lifecycle) in DP5/22 – 'Artificial Intelligence and Machine Learning', October 2022

Validation and verification in the AI value chain

- Risk mitigation and allocation across the AI value chain raises further challenges.
- "Trust but verify". Technology service providers might find that certain compliance obligations on deployers of AI systems might flow down the AI value chain.
- Role of industry standards

Life sciences & healthcare (LSH)

- Validation and verification is part of the process for regulating software as a medical device (SaMD)
- NHS and other HCPs will need to "skill-up" to handle, build confidence (but not over confidence) in AI devices and technologies and make appropriate judgements.
- HCPs will need to be trained on how to use, when to/ not to trust the output of AI devices and systems. Will IFUs for professional users need to include information to support this?
- HCPs to be enlisted as part of the on-going quality processes? Maintaining curiosity.

Financial services (FS)

- Framework for operational resilience and outsourcing: expectations may provide a useful basis for managing certain AI risks, e.g. consider backup and remediation actions before AI model put into production.
- Industry technical standards can help establish common best practice, and complement the regulatory system. E.g. standards on data-quality could be useful.
- Use of third-party models and data raised by industry as an area where more regulatory guidance would be helpful. Data and model providers could emerge as potential 'critical third parties' under DP3/22.

Sessions 2023 – Overview

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#1	Between Regulation and Innovation: AI regulation in the EU, UK and worldwide	**11 July I 6 pm CEST** Fritz Pieper (DE), Christopher Jeffery (UK), Michael Tan (China), Liisa Thomas (Sheppard Mullin)
#2	Who owns the output? Generative AI Intellectual property considerations	**25 July I 6 pm CEST** Adam Rendle (UK), Xuyang Zhu (UK), Gregor Schmid (DE), Marc Schuler (FR), Cristina Villasante (ECIJA)
#3	The autopilots fault? Who is liable when AI fails?	**8 August I 6 pm CEST** Fritz-Ulli Pieper (DE), Katie Chandler (UK), Philipp Behrendt (DE), Travis Norton (Bureau Veritas)
#4	AI, lawful bases, transparency and fairness: How to thread the GDPR needle	**12 September I 5 pm CEST** Paul Voigt (DE), Mareike Gehrmann (DE), Chris Jeffery (UK), Benjamin Znaty (FR), Fabrizio Sanna (Orsingher Ortu)
#5	**From the White Paper to the AI Safety Summit – what is the UK's regulatory position on AI?**	**08 November I 5 pm CET** Victoria Hordern (UK), Alison Dennis (UK), Clare Reynolds (UK), Lulu Freemont (Milltown Partners)
#6	**AI at work – taking the "Human" out of Human Resources?** Register now →	**15 November I 5 pm CET** Paul Callaghan (UK), Roxane Davey (UK), Bart Hunnekens (NL), Dr. Christian Maron (DE), Ian Carleton Schaefer (Sheppard Mullin)

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