Volume 6, No. 3 | May–June 2023

The Journal of Robotics, Artificial Intelligence & Law

fastcase FULL COURT PRESS

RAIL
The Journal of Robotics, Artificial Intelligence & Law
Volume 6, No. 3 | May–June 2023

THE JOURNAL OF ROBOTICS, ARTIFICIAL INTELLIGENCE & LAW (ISSN 2575-5633 (print) /ISSN 2575-5617 (online) at $495.00 annually is published six times per year by Full Court Press, a Fastcase, Inc., imprint. For customer support, please contact Fastcase, Inc., 729 15th Street, NW, Suite 500, Washington, D.C. 20005, 202.999.4777 (phone), or email customer service at support@fastcase.com.

Publishing Staff
Publisher: Morgan Morrissette Wright
Production Editor: Sharon D. Ray
Cover Art Design: Juan Bustamante

Cite this publication as:

The Journal of Robotics, Artificial Intelligence & Law (Fastcase)

A Full Court Press, Fastcase, Inc., Publication

Editorial Office

711 D St. NW, Suite 200, Washington, D.C. 20004
https://www.fastcase.com/

POSTMASTER: Send address changes to THE JOURNAL OF ROBOTICS, ARTIFICIAL INTELLIGENCE & LAW, 711 D St. NW, Suite 200, Washington, D.C. 20004.

Articles and Submissions

Direct editorial inquiries and send material for publication to:

Steven A. Meyerowitz, Editor-in-Chief, Meyerowitz Communications Inc., 26910 Grand Central Parkway, #18R, Floral Park, NY 11005, smeyerowitz@meyerowitzcommunications.com, 631.291.5541.

Material for publication is welcomed—articles, decisions, or other items of interest to attorneys and law firms, in-house counsel, corporate compliance officers, government agencies and their counsel, senior business executives, scientists, engineers, and anyone interested in the law governing artificial intelligence and robotics. This publication is designed to be accurate and authoritative, but neither the publisher nor the authors are rendering legal, accounting, or other professional services in this publication. If legal or other expert advice is desired, retain the services of an appropriate professional. The articles and columns reflect only the present considerations and views of the authors and do not necessarily reflect those of the firms or organizations with which they are affiliated, any of the former or present clients of the authors or their firms or organizations, or the editors or publisher.

QUESTIONS ABOUT THIS PUBLICATION?

For questions about the Editorial Content appearing in these volumes or reprint permission, please contact:

Morgan Morrissette Wright, Publisher, Full Court Press at mwright@fastcase.com or at 202.999.4878

For questions or Sales and Customer Service:

Customer Service
Available 8 a.m.–8 p.m. Eastern Time
866.773.2782 (phone)
support@fastcase.com (email)

Sales
202.999.4777 (phone)
sales@fastcase.com (email)
ISSN 2575-5633 (print)
ISSN 2575-5617 (online)

AI Regulation in the UK: The New Government Approach

Huw Beverley-Smith, Paige Izquierdo, and Charlotte H N Perowne*

In this article, the authors discuss a recent announcement explaining how the UK Medicines and Health products Regulatory Agency will regulate software and AI medical devices in the United Kingdom.

The UK Medicines and Health products Regulatory Agency (MHRA) has published its Guidance, Software and AI as a Medical Device Change Programme—Roadmap,[1] setting out how it will regulate software and AI medical devices in the United Kingdom by balancing patient protection and providing certainty to industry.

Background to the Reforms

The MHRA initially announced the Software as a Medical Device (SaMD) and Artificial Intelligence as a Medical Device (AIaMD) Change Programme in September 2021, designed to ensure that regulatory requirements for software and AI are clear and patients are kept safe. This builds on the broader reform of the medical device regulatory framework detailed in the government response to consultation on the future regulation of medical devices in the United Kingdom, which recently saw its timetable for implementation extended by 12 months to July 2024.

The proposed changes are a response to a healthcare system that is under severe strains from competing demands on limited resources and a post-COVID-19 backlog and the need to update existing medical device regulations given that many products coming to market today were largely conceptual or aspirational when the regulations were originally drafted.

The Roadmap's Aims

The MHRA's principal stated aim is for the Change Programme to protect patients and the public, while enabling the United

Robotics, Artificial Intelligence & Law / May–June 2023, Vol. 6, No. 3, pp. 219–221.

ISSN 2575-5633 (print) /ISSN 2575-5617 (online)

Kingdom to be recognized internationally as a home of responsible innovation for SaMD and AIaMD for a global market. To accomplish this, the MHRA is focusing on safety (without compromising on functionality), clarity, and streamlining processes for manufacturers and driving international harmonization. The MHRA intends to work with other national regulators through the International Medical Device Regulators Forum (IMDRF) and key domestic partners, as well as data protection offices in order to fully consider the processing of personal data as part of the reforms.

A further aim is the MHRA's desire to develop existing work addressing health disparities in medical devices, understanding that software and AI should perform equally across all populations and meet the needs of diverse communities.

Work Packages

In addition to secondary legislation, many of the intended changes will be implemented through regulatory guidance.

The original roadmap published in 2021 established 11 work packages (WPs) indicating the way ahead for the MHRA and other stakeholders, although only eight are included within the updated roadmap. This is due to some packages (Innovative Access, SaMD Airlock, and Mobile Health and Apps) having been included within or spread over multiple other WPs. Each WP targets a different objective within the reforms and proposes specific deliverables addressing each issue.

The WPs relating to SaMD address Qualification, Classification, Pre-market Requirements, Post-market Surveillance, and Cyber Security of Medical Devices.

At a high level, the WPs specifically relating to AIaMD can be summarized as:

- *AI Rigour*. Ensuring products achieve the appropriate level of safety for their purpose. By the end of 2022, the MHRA aims to produce (1) a document summarizing how "good machine learning practices" link to responsibilities in the existing 2002 Medical Device Regulations, and (2) guidance to help identify, measure, manage, and mitigate bias to improve the representativeness of data.

- *Project Glass Box (AI Interpretability)*. Improving transparency and trustworthiness of AIaMD for healthcare professionals and patients, including ensuring AI models are sufficiently transparent.
- *Project Ship of Theseus (AI Adaptivity)*. Promoting adaptability of AIaMD and improving change management processes. The MHRA intends to produce a paper breaking down the existing change management issues and how regulation can tackle these challenges.

Looking Ahead

It remains to be seen whether the Change Programme will result in (1) a significant and sustainable improvement to patient results and healthcare, and (2) SaMD and AIaMD innovation that sets the United Kingdom apart, rather than merely aligning with other jurisdictions.

One foreseeable difficulty will be for the MHRA and the government to ensure that all the guidance (and legislation) keeps pace with not only the technology but also the needs of manufacturers in such a rapidly developing area. Approaching this through regulatory guidance rather than the legislative process makes sense given the need to update the guidance quickly and flexibly. However, this will not always provide the necessary certainty and the guidance will still require regular review.

Businesses placing SaMD and AIaMD on the market should track the roadmap's progress and keep in mind wider regulatory reforms relating to AI products.

Notes

* The authors, attorneys based in the London office of Faegre Drinker Biddle & Reath LLP, may be contacted at huw.beverley-smith@faegredrinker.com, paige.izquierdo@faegredrinker.com, and charlotte.perowne@faegredrinker.com, respectively.

1. https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap.