Feedback to Department for Digital, Culture, Media & Sport, and the office for Artificial Intelligence

Policy paper - Establishing a pro-innovation approach to regulating AI

22 September 2022

Introduction

MedTech Europe welcomes the opportunity to provide feedback to the Policy paper: Establishing a pro-innovation approach to regulating AI, published on 20 July 2022.

MedTech Europe embraces the UK government's goal of creating a pro-innovation approach to regulating Artificial Intelligence (AI) in the United Kingdom. As the European voice of the medical technology industry, it is our view that regulatory intervention needs to drive innovation and growth, all while respecting sectoral specificities. MedTech Europe supports the development of AI regulatory systems underpinned by internationally aligned principles, such as the AI Principles developed by the Organization for Economic Cooperation and Development (OECD)[1], adopted in May 2019, to which the UK government actively contributed[2]. AI regulation based on globally harmonised principles, definitions, and standards, will provide the basis for legal certainty and consistency for manufacturers, developers, and regulators alike, as well as for society at large.

In the following sections, MedTech Europe elaborates on its views on the questions posed by the UK Secretary of State for Digital, Culture, Media, and Sport:

What are the most important challenges with our existing approach to regulating AI? Do you have views on the most important gaps, overlaps or contradictions?

Whilst we strongly support the sector-specific approach taken by the UK government, there is a potential challenge of lack of coordination between the different regulators within the same sector that will have to regulate AI in their respective areas of responsibility.

MedTech Europe believes that it is essential that regulators within the same sector work together to provide joint guidance, for example, to inform AI-enabled medical product development and deployment. The scope, scale and complexity of the expertise required to regulate AI and monitor compliance with those requirements effectively will require collaboration and common capability-building amongst those regulators. With respect to the UK regulation of AI, we believe that technical guidance, developed with input from stakeholders, will help reduce regulatory uncertainty and increase investment in AI-enabled medical technologies. We, therefore, commend the Medicines and Healthcare products Regulatory Agency (MHRA) for adopting the

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[1] OECD, Recommendation of the Council on Artificial Intelligence, AI Principles Overview https://oecd.ai/en/ai-principles (May 2019)

[2] OECD, Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0449, https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449#adherents (May 2019)

Good Machine Learning Practice (GMLP) Principles in collaboration[3] with the US FDA and Health Canada. To foster innovation and investments in AI in the medical technology sector, UK regulators should build on the GMLP principles and clarify regulatory expectations with respect to the design, development and validation of AI. Such guidance should set feasible expectations that can be deployed in a risk-based fashion to ensure products are technically sound. Such guidance should cover topics including 1.) A framework for assessing the relationship between the quality of the datasets and regulatory assessment of safety and effectiveness, 2.) recommendations to assess the performance of algorithms across training, test cycles, and approaches for retraining and recalibration of datasets over time, 3.) the change control process (which should include a risk/benefit assessment), and 4.) considerations regarding transparency, both in terms of meaning and practical application.

There are situations where current regulatory paradigms may not be fully optimised for certain types of AI. For example, different regulatory approaches may be needed for static versus dynamic (continuously learning) AI/machine learning (ML) systems. From our perspective, any new regulatory guidance should be risk-based and focused on these unique aspects of AI/ML-enabled technologies.

To that end, alignment with international principles such as those from the OECD[1] and the International Medical Device Regulators Forum (IMDRF)[4] should be considered to promote patient safety, foster innovation, and encourage access to advanced healthcare.

[Do you agree with the context-driven approach delivered through the UK's established regulators set out in this paper? What do you see as the benefits of this approach? What are the disadvantages?](#)

As a representative of a significant share of the medical technology sector, MedTech Europe welcomes the UK government's recognition that regulation of this technology should be context-based, coherent, proportionate, and adaptable, as well as pro-innovation and risk-based, all the while sufficiently reflecting the sectoral nuances within which it is deployed.

AI-embedded medical technologies are not by default 'high-risk', and we appreciate regulatory interventions that recognise this fact. As laid out in the new pro-innovation approach, regulators should focus on applications of AI that result in a real, identifiable risk to patients to foster innovation. Rather, AI-integrated medical technologies serve as an additional source of information assisting healthcare professionals in their tasks, e.g., diagnosis, therapy, treatment, etc. Even if AI-embedded medical technologies can be applied to patient-facing devices, healthcare professionals (HCP) are ultimately responsible for the final decision regarding patient diagnosis, treatment, and care. The "risk" posed by AI-embedded medical technologies should consider this fact. MedTech Europe welcomes the approach to allow sectoral regulators to set out and evolve the detailed regimes for AI, as the current work of the MHRA on Software and AI as a Medical Device is referenced. We believe that this is a critical piece of work for the medical technology sector. We

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[3] MHRA, FDA, Health Canada, Good Machine Learning Practice for Medical Device Development: Guiding Principles https://www.gov.uk/government/publications/good-machine-learning-practice-for-medical-device-development-guiding-principles/good-machine-learning-practice-for-medical-device-development-guiding-principles (27 October 2021)
[4] IMDRF, Machine Learning-enabled Medical Devices: Key Terms and Definitions https://www.imdrf.org/sites/default/files/2022-05/IMDRF%20AIMD%20WG%20Final%20Document%20N67.pdf

recommend that the principles outlined in the policy paper are incorporated in this work, particularly a pro-innovation, international outlook jointly with a lighter touch approach whilst still providing clarity through appropriate guidance.

Do you agree that we should establish a set of cross-sectoral principles to guide our overall approach? Do the proposed cross-sectoral principles cover the common issues and risks posed by AI technologies? What, if anything, is missing?

MedTech Europe supports the UK government's development of cross-sectoral principles to guide this regulatory approach. Overarching high-level principles represent important foundational pillars to underpin the UK government's forthcoming legislative intervention. We recognise the UK government's cross-sectoral principles[5] reflecting the OECD AI Principles[1]. We are pleased to see that the UK foresees these principles to be tailored to the distinct characteristics of AI, where the relevant and responsible regulators would interpret, prioritise, and implement them **within their respective sectors and domains.** The involvement of stakeholders, including the medical technology industry, in this sectoral implementation is essential to delivering innovative medical technologies.

Do you have any early views on how we best implement our approach? In your view, what are some of the key practical considerations? What will the regulatory system need to deliver on our approach? How can we best streamline and coordinate guidance on AI from regulators?

MedTech Europe encourages working interactively with the industry and other stakeholders within each sector in developing guidance to ensure a harmonised approach. Transparent and unambiguous regulatory responsibilities of sectoral agencies for the respective products that fall within their scope need to be established, such as the MHRA for the medical technology industry. Additionally, the number of responsible agencies and bodies needs to be kept to a minimum and set reporting lines and delineated responsibilities between them. Sufficient staffing and an adequately skilled workforce need to be ensured at all levels. Lastly, technical standards and, as far as possible, international consensus standards should be used to define the technical level of "AI requirements" while refraining from referring to technical details in legislation, avoiding any potential misalignment with **international consensus standards** applicable to each sector.

Do you anticipate any challenges for businesses operating across multiple jurisdictions? Do you have any early views on how our approach could help support cross-border trade and international cooperation in the most effective way?

It is of paramount importance that AI regulatory systems do not digress substantially in terms and definitions employed, the proportionality of market access requirements, and cooperation. MedTech Europe encourages

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[5] Ensure that AI is used safely; Ensure that AI is technically secure and functions as designed; Make sure that AI is appropriately transparent and explainable; Embed considerations of fairness into AI; Define legal persons' responsibility for AI governance; and Clarify routes to redress or contestability https://www.gov.uk/government/publications/establishing-a-pro-innovation-approach-to-regulating-ai/establishing-a-pro-innovation-approach-to-regulating-ai-policy-statement#a-new-pro-innovation-approach

the UK government to continue its well-established track record of leading international alignment and cooperation in technology innovation and regulation. The definition of Artificial Intelligence is a worthwhile example here, and the OECD proposes an effective, representative, and accurate definition of AI[6].

MedTech Europe believes that failure to reach a sufficient level of international regulatory alignment in AI, and its related basic principles, may prompt global market distortions, with subsequent impacts on international trade and investment. It is paramount that manufacturers and developers of innovative AI systems are presented with appropriate levels of regulatory certainty as they navigate global markets with their own unique national and regional regulatory systems. Divergences stemming from respective design and development requirements will lead to fragmented quality of products entering national and regional markets. Worse still, it may represent regulatory trade barriers.

In few sectors are such issues so critical to society as in the medical technology and healthcare sector, where international health systems rely on the retention and procurement of innovative medical technologies for effective diagnosis and treatment and remote patient monitoring across the globe. MedTech Europe, therefore, urges the UK government to continue its constructive role at international fora to promote international regulatory alignment on current and emerging technology issues, such as AI, in accordance with the OECD AI Principles[7] and IMDRF.

Led by MedTech Europe, with the support of ABHI and BIVDA

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices, and digital health. Our members are national, European, and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services, and solutions.
www.medtecheurope.org.

About ABHI

ABHI is the UK's leading industry association for health technology supporting the HealthTech community to save and enhance lives. HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth.
www.abhi.org.uk

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[6] OECD AI Principles Overview – AI terms and concepts: *An AI system is a machine-based system that can influence the environment by producing an output (predictions, recommendations, or decisions) for a given set of objectives. It uses machine and/or human-based data and inputs to (i) perceive real and/or virtual environments; (ii) abstract these perceptions into models through analysis in an automated manner (e.g., with machine learning), or manually; and (iii) use model inference to formulate options for outcomes. AI systems are designed to operate with varying levels of autonomy.* https://oecd.ai/en/ai-principles
[7] OECD AI Principles – International co-operation for trustworthy AI (Principle 2.5) https://oecd.ai/en/dashboards/ai-principles/P14

About BIVDA

BIVDA is the national industry association for the manufacturers and distributors of IVD products in the UK and we currently represent more than 95% of the industry and over two hundred organisations ranging from British startup companies to UK subsidiaries of multinational corporations.
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