BHTA Brief 2024: UK Med Tech Regulation – Open-Source for Maximum Gain

The British Healthcare Trades Association (BHTA) calls for the UK government to resource the Medicines and Healthcare products Regulatory Agency (MHRA) to create a world-leading medical device regulatory regime. The UK faces a fragmented regulatory landscape that jeopardises the med tech industry. The BHTA calls for:

-- Open-Source Regulation for Safe & Effective UK Med Tech, with five "must-have" characteristics:

1. *Responsive*
2. *Clear*
3. *Equitable*
4. *Transparent*
5. *Harmonised*

New UK med tech regulations must deliver access to safe and effective medical devices, overseen by a world-leading authority, in the form of MHRA. After the UK's exit from the EU, there is now no single law, regulation, or market-access route for UK medical devices. Medical device companies in the UK face a tangled landscape of inter-related laws, regulations, and processes (each with its own timelines, risks, and costs) against which corporate decisions must be made[1]. These challenges are putting £13.5bn of UK Health Tech[2] at risk, as companies prioritise more stable and defined markets.

Adopting the recommendations outlined here could yield safer, better med tech for patients, enhanced economic returns in the life sciences sector, and increased inward investment to UK plc.

Laura Squire, MHRA Chief Healthcare Quality and Access Officer, said recently[3], "our priority is patient safety, and we know we need to work in partnership with our stakeholders to achieve that." Plans for international recognition have recently been published and MHRA have detailed proposals for the balance of UK medical device regulations, which will hopefully become clear over the next year. It is essential that Government support and resource MHRA appropriately to continue this vital work – and it is equally important that MHRA partners with industry.

Recommendation – Open-Source Regulation for Safe & Effective UK Med Tech: Via MHRA, Government should deliver a world-leading medical device regime; this can only be achieved via open-source regulation and engaging meaningfully with stakeholders to develop UK laws, regulations, and market-access routes.

New UK Med Tech Regulation – Five Must-Haves

The new UK med tech regime – law, regulation, and guidance – should be:

Responsive

- Capacity and capability: MHRA must be supported by Government to urgently build both the organisational and systemic resources to ensure safe and effective UK medical device regulation. The UK must operate in a global market context.
- Tactical innovation champion: MHRA must continue to partner meaningfully with industry and trade associations at the highest levels as it transitions to a sovereign regulator.
- Strategic innovation enabler: MHRA must partner with industry and trade associations at the working level to fulfil its stated strategic goal to "deliver UK innovation focussed legislation"[4].

[1] For more, including a UK medical device journey infographic, please see the BHTA Guide to Medical Device Registration.
[2] Sectoral Systems of Innovation and the UK's Competitiveness: The UK MedTech Sector, Professor James Moore Jr. and Yunus Kutlu, *Imperial College London*, London: June 2023.
[3] See Med Tech Regulatory Reform: The first steps towards a new framework for medical devices in the UK, *MHRA*, 13-Feb-24.
[4] MHRA Corporate Plan 2023-26, p. 11, Point 3.9.

Clear

- Strategic: the MHRA Corporate Plan 2023-26 sets good direction and this must be refreshed regularly with policymakers, industry, and other regulators to remain relevant.
- Guided by a detailed roadmap, with milestones for progress: regular meetings between MHRA and trade associations/industry partners should provide opportunities for updates and input.
- Communicate straightforward, clear regulatory guidance: MHRA should partner with key stakeholders to develop and publish guidance.

Equitable: Regulation and market-access should be equitable, regardless of company size and operational model. MHRA must demonstrate:

- Market-access benchmarking: to ensure UK regulation and domestic assurance avoids excessive requirements or expense compared to other global regulators.
- Information protocols: to build/maintain compatible data-sharing agreements with global regulators.
- Real-world vigilance: to develop risk-guided and proportionate approaches – e.g. pre- and post-market surveillance; incident-reporting; quality-management systems – that avoids undue burden on SMEs.

Transparent: MHRA should, as part of its commitment to a Science Strategy[5] and evidence-based decision-making[6], establish open-source regulation, including:

- Evidence registry: to show how and via what processes it develops regulatory policy.
- Dispute-resolution mechanism: including medical device classification questions.
- Emerging-regulation sandboxes: like its new AI Airlock, to allow multi-stakeholder debate of novel technologies, and to develop regulatory reasoning, rationale, and expectations for future regulation.

Harmonised: As outlined in the MHRA Corporate Plan 2023-26 and the UK Government's 2021 Life Sciences Vision, MHRA must place UK medical device regulation in a global market context. MHRA should establish regular reporting mechanisms to show follow-through on plans to:

- Partner: broaden and deepen partnerships with other global regulators.
- Contextualise: ensure UK conformity assessment maximises the potential for global mutual recognition (via, e.g., Medical Device Single Audit Program).
- Level-up: advance UK interest globally (via, e.g., the International Medical Device Regulators Forum).
- Streamline: secure UK participation in integrated platforms and pathways that reduce regulatory burden and time to market for innovative treatments and technologies (via, .e.g., the Innovative Licensing and Access Pathway and Innovative Devices Access Pathway).

Benefits to Government

In addition to better collaboration and cooperation between MHRA and the Health Tech sector, adoption of open-source UK med tech regulations along the lines of these five recommendations stands to deliver the following:

- Maximise potential of the Life Science Sector, an identified "key driver" of 21st-century UK growth
- An evergreen 25% rate of return on every public £1 invested in medical research; 2.5 jobs supported in other parts of the UK economy per every 1 life-sciences job[7]
- Safer, better, more modern, and innovative care and quality of life for UK patients
- More inward investment and reversal of the alarming UK life-science decline (c. 7k manufacturing jobs lost and production down 29% since 2009[8])

[5] MHRA Corporate Plan 2023-26, p. 11, Point 3.1.
[6] MHRA Corporate Plan 2023-26, p. 11, Point 3.4.
[7] Source: https://www.amrc.org.uk/Handlers/Download.ashx?IDMF=cd2e22ec-7fc4-4c44-b682-9e7ad5a50f37
[8] Source: https://www.ons.gov.uk/economy/economicoutputandproductivity/output/datasets/indexofproduction