

**From the President**  
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**Via email:** [futuredevicesregulations@mhra.gov.uk](mailto:futuredevicesregulations@mhra.gov.uk)

To whom it may concern,

The Academy of Medical Sciences welcomes the opportunity to contribute to the MHRA's consultation on the future regulation of medical devices in the UK. We are supportive of the MHRA's intention to enhance patient and public safety through improving the regulatory framework for medical devices, with an aim to enable early access for safe, effective and innovative medical products.

Regulatory agencies like the MHRA have a vital role in ensuring that medical products that reach the market are properly and proportionately evaluated for safety and efficacy. This includes accompaniment with appropriate information to support patients and doctors in decision making about how and when to use medical devices.

The Academy's 2017 working group report on evaluating the safety and effectiveness of medicines included several recommendations that are also directly relevant to the regulation of medical devices.<sup>1</sup> We believe that by adopting these recommendations, regulators can ensure the risks and benefits of medical devices are conveyed to users in an effective manner.

To minimise the possibility of patients and healthcare professionals being misled by spurious claims about medical devices, the MHRA should work with medical device companies and the public to improve accessibility of benefits and risks conveyed in medical device packaging. The success of global initiatives such as The Drug Facts Box developed in the United States could be adapted for use with medical devices in the UK, having had demonstrable benefit in enabling individuals to make improved judgements about medicines.<sup>1,2</sup>

Additionally, a user-friendly repository similar to NHS Choices could be created for medical devices, offering patients and doctors an easily accessible point of reference to find detailed information such as ingredient/component parts, benefits and risks, and when a user should consult a healthcare professional.<sup>1</sup>

These issues need to be considered especially with the rising prominence of emerging technologies in the realm of diagnostics, such as software as medical device (SaMD) and genetic testing. Despite being considered as low-risk, further requirements are necessary

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<sup>1</sup> Academy of Medical Sciences (2017). ['Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines'](#)

<sup>2</sup> Schwartz LM & Woloshin S, (2013). *The Drug Facts Box* PNAS, **110;14069-14074**

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to ensure the implications and significance of results from new diagnostics are described clearly to patients.

Upon clinical evaluation, we agree that devices claimed to have equivalency to an already established safe device must be 'entirely equivalent'. This is to avoid a situation where a product with consecutive equivalency claims has characteristics very different from the original equivalent product and reaches patients without proper assessment of potential risks.

Clinical investigation plans and reports for general medical devices should have a consistent and comprehensive approach to safeguard health and welfare of participants. Especially, provisions should be in place to assure vulnerable populations and subjects are appropriately protected through suitable means of informed consent. Additionally, the exclusion of certain populations - such as pregnant or breastfeeding women - from participation in a clinical investigation must be reported and adequately justified. Ideally clinical investigations should include patients and users from a diverse range of backgrounds to identify possible variation in safety and efficacy amongst different groups. Where this is not possible, the manufacturer must use the clinical investigation report to highlight the groups for which safety and efficacy data of their product is unclear.

Products that do not possess an intended medical purpose as stated by the manufacturer (e.g. cosmetic implants) currently fall outside the scope of UK medical devices regulations. However, there is a need to ensure products with a similar risk-profile to medical devices are suitably regulated and users are educated about their risks. For example, in the case of dermal fillers, in 2019 doctors and MPs called for tighter regulation due to a significant rise in the number of patient complaints from their procedures.<sup>3</sup> EU legislation currently considers all dermal fillers to be medical devices under Regulation (EU) 2017/745.<sup>4</sup> Therefore, lacking other suitable regulatory oversight, expanding the MHRA definition of 'medical device' to incorporate such products and requiring their registration will enhance safety of patients as well as keep the UK in line with international best practice.

We welcome the MHRA's ambitions to set up a world-leading regulatory framework for SaMD and AI as/in a medical device (AIaMD) to deliver on its promise for transforming healthcare. Fundamental algorithms that make up software and AI are not perfect and may have a propensity to impart bias based on the datasets they are trained.<sup>5</sup> MHRA should encourage involvement of public and patients in the development of SaMD/AIaMD to reduce such risks and improve efficacy.<sup>6</sup> In addition, frequency and types of mistakes of algorithms should be objectively quantified to deduce an associated risk that can be conveyed before use. Like IVDs, conformity of SaMD should be based on scientific validity, analytical and clinical performance data.

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<sup>3</sup> The Guardian (2019). [Plastic surgeons call for tougher UK rules on dermal fillers | Plastic surgery | The Guardian](#)

<sup>4</sup> EUR-Lex (2020). [Regulation \(EU\) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices](#)

<sup>5</sup> Academy of Medical Sciences (2017). [Response to the House of Commons Science and Technology Committee inquiry into algorithms in decision-making](#)

<sup>6</sup> Academy of Medical Sciences (2018). [Our data-driven future in healthcare: People and partnerships at the heart of health related technologies](#)

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Implementing a risk categorisation (I, II, III, IV) for SaMD similar to that of the International Medical Device Regulators Forum will harmonise with international practice and help clarify to manufacturers the additional evidence requirements for SaMD that may be needed beyond those in place for other medical devices.

Where security is concerned, SaMD manufacturers should be required to ensure robust protection against external interference which may damage integrity of software algorithms or compromise the privacy of personal data.<sup>7</sup> Dialogue between software developers and regulators should be firmly established throughout the design process to ensure software is thoroughly appraised.<sup>8</sup>

Additionally, clinical evidence for a medical device should be updated throughout the lifetime of that device wherever possible. This is especially pertinent in the case of AI powered tools, where software updates or modifications to an algorithm may alter how it works. Regulation should be appropriately flexible to accommodate such iterative changes.

To ensure clarity and patient safety for medical devices, we support the MHRA's intention to replace the current guidance for post-market surveillance with a more stringent system. Requiring a clear and comprehensive plan to collect field incident data and user feedback should ensure potential serious incidents are reported and dealt with promptly.

We welcome the MHRA's intention to become a 'sustainability pioneer' and support the proposals to require that manufacturers complete an environmental and public health assessment. As the Academy's recent working group report with the Royal Society outlined, the NHS emits around 5-6% of the UK's total greenhouse gas emissions and medical equipment accounts for around 10% of NHS total carbon emissions.<sup>9</sup> Introducing waste management responsibilities into the medical device supply and reducing the environmental impact associated with a device will buttress the aim of the NHS to reach net-zero by 2045. Furthermore, it complements national healthcare sustainability initiatives such as the NHS Ocean initiative.

The MHRA and the Academy have a shared goal in ensuring that patients have timely access to safe and effective healthcare products and new, potentially life-saving innovations. We support the plans to develop criteria for 'Innovative MedTech', which can access an alternative quicker route to market. As suggested in the consultation, this should be based on scale of impact and size of manufacturer, appreciating the regulatory difficulties small and medium sized enterprises (SMEs) face.

However, we also acknowledge that streamlined regulatory processes may have limited impact on public health if other stages of innovation pathway, including the adoption of innovation in healthcare, are not also optimized.<sup>10</sup> Therefore, partnering with the

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<sup>7</sup> Academy of Medical Sciences (2018). [Our data-driven future in healthcare: People and partnerships at the heart of health related technologies](#)

<sup>8</sup> Academy of Medical Sciences (2017). [Response to the House of Commons Science and Technology Committee inquiry into algorithms in decision-making](#)

<sup>9</sup> Academy of Medical Sciences & The Royal Society (2021). [A healthy future – tackling climate change mitigation and human health together](#)

<sup>10</sup> Academy of Medical Sciences (2021). [Letter to All Party Parliamentary Group on Access to Medicines and Medical Devices](#)

National Institute for Health and Care Excellence (NICE) and other key healthcare partners will be critical to establish end to end oversight.

In conclusion, we applaud the ongoing efforts of the MHRA to comprehensively improve the regulatory framework for medical devices as outlined in the consultation, and to incorporate views from a wide range of stakeholders, especially patients/public. We would be happy to expand on the points in our response or provide further evidence as requested and we look forward to remaining engaged with the MHRA's work in this area.

Yours sincerely,



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