MHRA Stakeholder Survey on Medicines and Medical Devices Legislation

Written evidence submitted by The Health Tech Alliance

Section 3: Operation of the Regulations

Q: How well do you think the current legislation protects public health? (Please select the option that best reflects your view)

Option C: Somewhat effectively - there are noticeable gaps or areas for improvement

The Health Tech Alliance (HTA) sees that the current legislation offers a foundation for safeguarding public health, as the regulatory framework ensures that new products are subject to scrutiny and that patient safety remains a primary concern. However, there are also notable gaps in the framework that undermine the effectiveness of current legislation. Regulatory requirements, while essential for safety, often face lengthy approval and delayed timelines, which can have a significant impact on innovative diagnostics, medical devices and digital health tools. There are also unclear regulatory timelines for mechanisms that are intended to facilitate urgent patient access, which can further delay the availability of critical products.

Moreover, there are inconsistencies in the application and scrutiny of legislative exemptions (such as through the Health Institution Exemption) which can further increase the risk to public health.

Q: In your experience on a scale of 1 to 10, how effectively do the regulations work in practice? This refers to the clarity, enforceability, consistency, and practical impact of the regulations in achieving their intended outcomes

On a scale of 1 to 10, the HTA rates the effectiveness of regulations at a 6.

The UK regulatory framework is robust and well-established in principle, and the MHRA has made significant progress in supporting regulatory compliance, including through the publication of guidance.. However, some Members still face challenges with interpreting the legislation. For example, there are notable gaps in the guidance, particularly around innovative diagnostics, medical devices and digital health tools, which can mean companies are uncertain about how to interpret or implement requirements.

It would be useful for the MHRA to expand the scope and accessibility of its guidance to improve regulatory clarity and consistency, as well as introduce clear and measurable benchmarks for compliance and enforcement of regulations.

Q: Have you encountered any issues, blockers, or areas of ambiguity when using the Regulations?

Yes; members of the HTA have encountered a range of challenges and ambiguities when navigating the currently regulatory environment.

The evolving requirements for UKCA marking has led to uncertainty among industry and created more regulatory burden, leading to repeated changes to product labelling, packaging and documentation. This has resulted in delayed certifications, registrations and product launches in the UK, which has on occasion led some companies to deprioritising the UK as a launch market. The UK-specific labelling requirements, particularly for medical devices, has also led to greater complexity in the supply chain.

In addition to this, there is a lack of alignment between different authorities on borderline product classification, which results in diverging classifications and, at times, creating conflicting regulatory

requirements. To help overcome these challenges, the MHRA should consider issuing a more comprehensive and unified framework with clear requirements.

Q: Are there any particular areas of the regulation which you consider impose unnecessary or excessive regulatory burdens?

Yes; HTA members have expressed concern about the administrative and regulatory burdens.

Firstly, the requirement for companies to repeatedly register medical device importers, as well as renew licences through the MHRA, consumes significant resources and is perceived as an unnecessary regulatory burden. Implementing perpetual licences, where ongoing reporting or withdrawal obligations would suffice, would be a more efficient approach and reduce unnecessary bureaucracy.

The need for distinct labelling for the UK market also significantly impacts the industry by adding greater cost and complexity for manufacturers and distributors, which in turn can result in higher prices or reduce product availability for UK patients. Moving away from this and transferring this information to accompanying documentation or electronic labelling would alleviate the pressure on industry.

Q: How do UK regulations compare with those of other regulators or international comparators (e.g., EU, FDA)?

The UK's regulatory environment shares several similarities with that of the EU and FDA systems, but also presents distinct challenges. The FDA provides clearer timelines and a single registration pathway, whereas the UK's approach, particularly around UKCA marking and dual registration requirements, can be complicated and slow. The lack of recognition in the UK for international conformity standards can also increase the regulatory duplication and cost, which can be discouraging to global manufacturers and encourage them to deprioritise the UK market.

The UK's consultation process for introducing new legislation and regulations is well established, and members value the opportunity for stakeholder input. However, the frequency and complexity of amendments can create a fragmented regulatory landscape.

Section 4: Structure of the Legislation

Q: On a scale of 1 to 10, how clear, well-structured, and easy to navigate do you find the Legislation and are there any overlapping, duplicative or outdated provisions?

On a scale of 1 to 10, the HTA rates the legislation at a 6 for how clear, well-structured and easy to navigate.

While the core regulatory framework is logically structured, and the MHRA's online resources are generally clear, the proliferation of amendments are challenging to navigate, particularly when exclusions have applied during the post-Brexit period. This fragmented landscape makes it difficult for stakeholders to maintain a comprehensive and up-to-date understanding of requirements, especially for companies operating across both the UK and EU.

Establishing a single reference point that consolidates all relevant legislation, amendments and guidance will help improve transparency, reduce ambiguity, and support greater industry compliance.

Q: Do the regulations strike an appropriate balance between flexibility to address new technologies and emerging public health issues and robust regulatory oversight, and is the current allocation between what is set in legislation versus what is provided in supporting guidance appropriate?

Option C: Neither agree nor disagree

The current allocation of detail between legislation and supporting guidance is not optimal. There is too much technical detail embedded in primary legislation, making it difficult to update in response to emerging technologies or new guidance. We would suggest that the technical detail is reserved for guidance instead. Simultaneously, guidance is sometimes misaligned with legislative requirements. For example, UKCA requirements and post-market surveillance obligations are set out in law, but lack sufficient practical guidance, whereas the obligations for combination products and importers are described in guidance but need clear statutory underpinning. In order to enable the regulatory system to adapt and support innovation without compromising patient safety, there is a need for a more balanced approach, where legislation sets out high-level principles and guidance provides operational detail.

Section 5: Streamlining

Q: What is your view on the extent to which the legislation should be streamlined? (Please select the option that best reflects your view.

Option D: Significant changes – the legislation would benefit from a major simplification and restructuring

Q: What impact, if any, would streamlining the legislation have on you or your organisation?

Option A: It will have a very positive impact.

Q: In your opinion, would the benefits of streamlining the legislation outweigh any potential Downsides?

Yes; the HTA supports the simplification and restructuring of the current legislative framework, providing that any changes are accompanied by comprehensive, practical guidance to help industry comply with new requirements.

Streamlining legislation would reduce administrative burdens, facilitate faster access to innovative devices and diagnostics, and make the UK a more attractive market for global innovators by reducing compliance costs. Embracing international reliance and recognising trusted overseas approvals would help to speed up access to products for UK patients, and reduce the regulatory burden on companies.

Section 6: New Regulations Made Under the Medicines and Medical Devices Act (MMDA)

Q: Have you had experience of interacting with the new regulations and which ones?

The Heath Tech Alliance (HTA) has had experience interacting with the following new regulations

1. The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021
2. The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023
3. The Medical Devices (Amendment) (Great Britain) Regulations 2023
4. The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023

Q: How well do you think the new regulations are operating, and have you encountered any issues or concerns in their implementation?

Option B - the regulations are working effectively.

In general, the new regulations operate effectively and are delivering intended outcomes. However, the HTA would also welcome improved communication and advanced notices regarding changes, particularly those with financial implications, such as fee increases or new charging methodologies.