



UK HEALTHTECH REGULATORY SURVEY

ABHI AND THE HEALTHTECH INDUSTRY

The Association of British HealthTech Industries (ABHI) is the leading health technology (HealthTech) industry association in the UK. We are a community of over 330 members, from small UK businesses to large multi-national companies.

We champion the use of safe and effective medical devices, diagnostics and digital health technologies. The work of our members improves the health of the nation and the efficiency of the NHS.

The HealthTech industry makes a vital contribution to economic growth in our country. The industry employs over 138,100 people across 4,140 companies, mostly small and medium sized enterprises (SMEs). The industry is generating a turnover of over £27.6 billion and has achieved employment growth of greater than 5% in recent years.

ABHI's members account for approximately 80% of the value of the sector as measured by sales to the NHS. As the most highly

regarded universal healthcare system in the world, the NHS in turn is dependent on technology produced by the industry to enhance the efficiency of services and drive continuous improvement in their delivery.

HealthTech is accordingly an engineering-based industry, characterised by rapid, often iterative product design and development. It is one of two distinct subsectors of the broader Life Sciences, with evidence, regulatory and adoption needs that differ significantly from those of the other, biopharmaceuticals.

CONTEXT

The development of the UK sovereign HealthTech regulatory system offers a once in a generation opportunity to support the growth of a sector that provides many of the solutions necessary to improve patient outcomes and facilitate the necessary transformation to more sustainable models of health and care delivery. The potential benefits from the growth of the industry for the UK health and care system, clinicians patients and the economy are vast.

To support such growth, the Life Sciences Vision rightly calls out the need to ensure the development of a best in class regulatory regime and the tests enshrined in the Medicines and Medical Devices Act¹ set out the parameters for us to do so. In addition, whilst ABHI has continually advocated against divergence from previous arrangements for divergence's sake, we have also maintained that, though the vast majority of technical standards (80% and growing) are harmonised globally, the processes that support the regulations could potentially be streamlined. We welcomed the Benefits of Brexit paper, that outlined a collaborative, trust-based approach, as seizing that potential.

With a regulator such as the MHRA, that has a globally recognised reputation for pragmatic and forward-thinking

approaches, and with the right and urgent action, we maintain the UK can capitalise on the opportunities that exist to advance the health and wealth of its citizens.

However, our window to do so is closing. Not only does the deadline of July 2023 for transition to new sovereign regulations still remain in legislation, providing an entirely avoidable cliff edge for the current system, and representing a serious and significant risk to patient access to technology, but a recent survey of Health Tech companies shows growing concern for the long-term future of UK regulations and a lack of confidence in the country as a place to invest and innovate.

We must act immediately to prevent both.

¹Tests enshrined in Medicines and Medical Devices Act: The safety of medical devices; **b.** The availability of medical devices; **c.** The likelihood of the United Kingdom being seen as a favourable place in which to **i.** carry out research relating to medical devices, **ii.** develop medical devices, or **iii.** manufacture or supply medical devices. Ambitions of the Life Sciences Vision: **a.** Build on the UK's world class science and research capabilities – making the UK the best place in the world to trial and test products at scale; **b.** Make the NHS the country's most powerful driver of innovation – through the development, testing, and adoption of new technologies; **c.** Create an outstanding business environment for Life Science firms – which supports company growth, innovation, and investment;

INNOVATION AND INVESTMENT

Whilst, crucially, industry maintains confidence in the UK to protect patient safety, the primary objective of any regulation, data show that the UK has fallen behind both the EU and US as an attractive place to do business or to promote the development of innovation. **Three quarters of the Health Technology industry currently believe that the UK will no longer be seen as a priority internationally.**

The expected impacts on patient access to life saving and enhancing Health Technology are increasingly significant with **one in five products expected to be removed from the market over the next five years and one in ten companies halting all innovation activity. 67% of the HealthTech industry expects a delay in bringing innovation to the UK, rising to 86% in those manufacturing in vitro diagnostic medical devices.**

Whilst some of these concerns are not limited to the UK, and are being seen across the EU more generally, the opportunity for the future UK system to be seen as truly innovate and pro-

innovation has not yet been realised. Only **17% of companies believe that the UK is taking an ambitious approach in the development of a sovereign system, and only one in 10 companies foresee the UK developing a best in class regulatory regime.**

The data provide a number of explanations for this increasing loss of confidence, including constrained capacity, with **19% of companies unable to engage early with their Approved Body on new technologies.** This is compounded by a dramatic rise in costs. 90% of companies have seen their regulatory costs increase over the last 12 months, and for **20% the increase has been by over 50%, and these companies now feel it is too costly to continue developing and bringing innovation into the UK.**

RECOMMENDATIONS

To ensure that the UK regulatory system builds on its long-standing and hard-earned favourable reputation, continues to protect patient safety, and becomes a driver of growth and innovation, ABHI calls on the UK government to urgently act to:

- › Reduce ongoing uncertainty by;
 - Immediately providing the legislative amendments for transitional arrangements committed to within the Government's UKCA consultation response.
 - Working with industry throughout the development of the UK system to ensure that aligned messaging on reassurance can be provided even whilst the longer term uncertainty remains.
 - Providing a comprehensive UK roadmap of activities and milestones to develop UK regulatory infrastructure.
- › Overcome capacity constraints and reduce the cost burden by:
 - Limiting costs for the designation of Approved Bodies.
 - Prioritising the development of domestic assurance routes that will allow recognition of approvals in other, trusted jurisdictions such as those within the Medical Device Single Audit Programme (MDSAP) and ACCESS consortium. This would also allow the reduction of the scope of operations for our own Assessment Bodies.
- › Provide both the resource and political impetus to MHRA to increase UK regulatory ambition and enable the development of systems such as those based on the principles of Outcome Based Cooperative Regulation (OBCR).
- › Ensure appropriate focus and support for the development of innovative technologies by:
 - Developing an ambitious Innovation Devices Assessment Programme (IDAP) that supports clinical need, availability and choice.
 - Developing new support programmes for HealthTech clinical investigations and performance studies.

Please rank the following markets against the following attributes

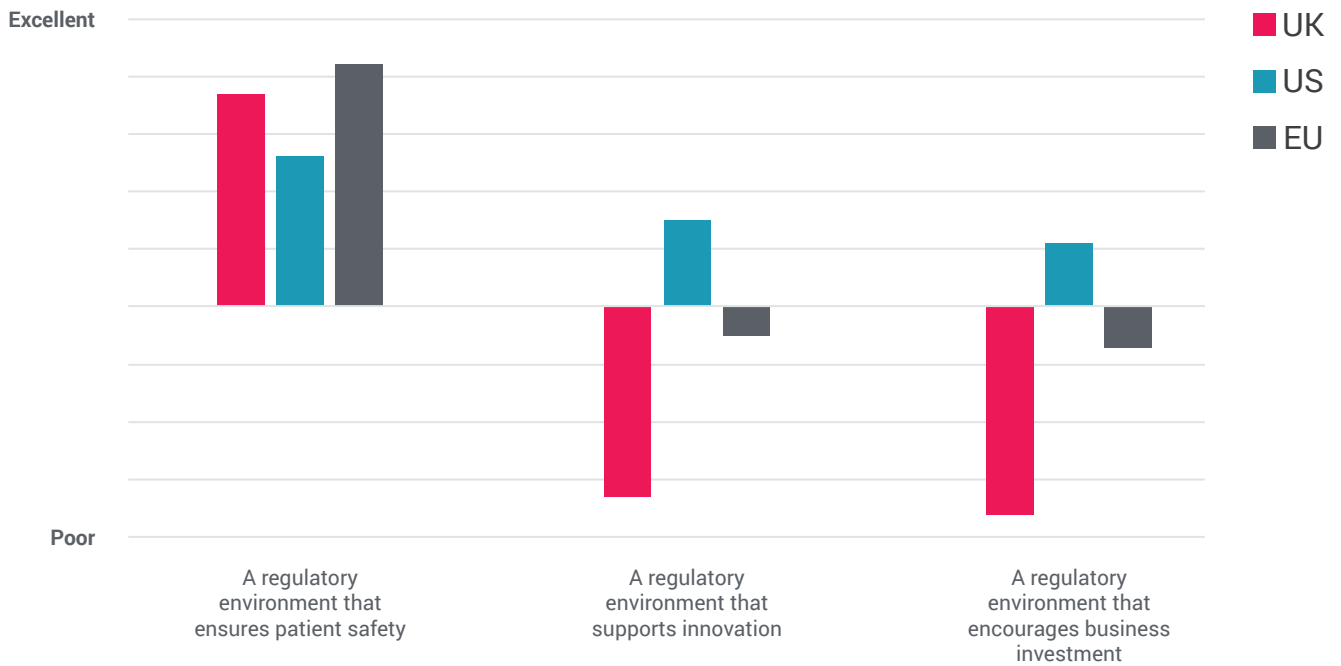


Chart uses numerical averages assigned to depict strength of positive and negative sentiments from the below table.

UK	1. Poor	2	3.	4	5. Excellent
A regulatory environment that ensures patient safety	1.89%	9.43%	22.64%	49.06%	16.98%
A regulatory environment that supports innovation	22.64%	28.30%	37.74%	11.32%	0.00%
A regulatory environment that encourages business investment	26.42%	30.19%	30.19%	11.32%	1.89%
US					
A regulatory environment that ensures patient safety	0.00%	9.62%	36.54%	48.08%	5.77%
A regulatory environment that supports innovation	5.88%	9.80%	39.22%	39.22%	5.88%
A regulatory environment that encourages business investment	3.85%	15.38%	46.15%	25.00%	9.62%
EU					
A regulatory environment that ensures patient safety	0.00%	1.92%	30.77%	51.92%	15.38%
A regulatory environment that supports innovation	5.88%	23.53%	50.98%	13.73%	5.88%
A regulatory environment that encourages business investment	9.80%	25.49%	37.25%	23.53%	3.92%

The UK recently published its response to the consultation on the future regulation of medical devices in the United Kingdom. Following this publication and subsequent engagement with the MHRA and UK Conformity Assessment bodies, to what extent do you feel the UK will:

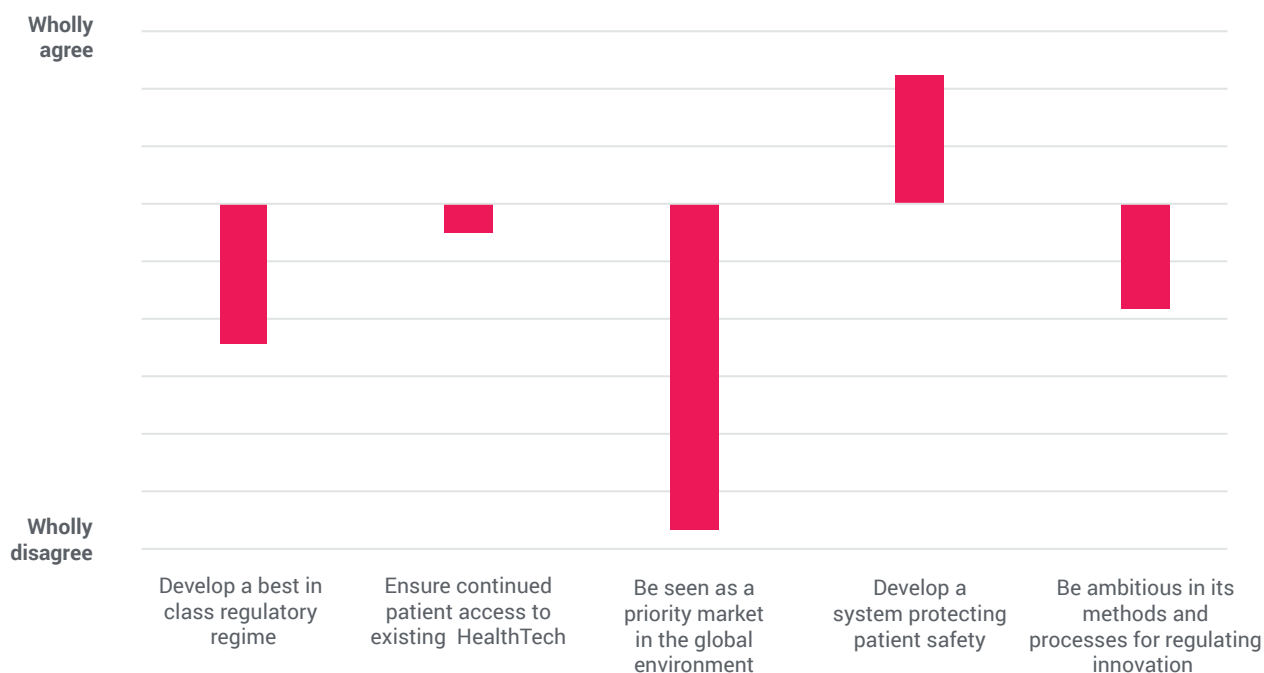
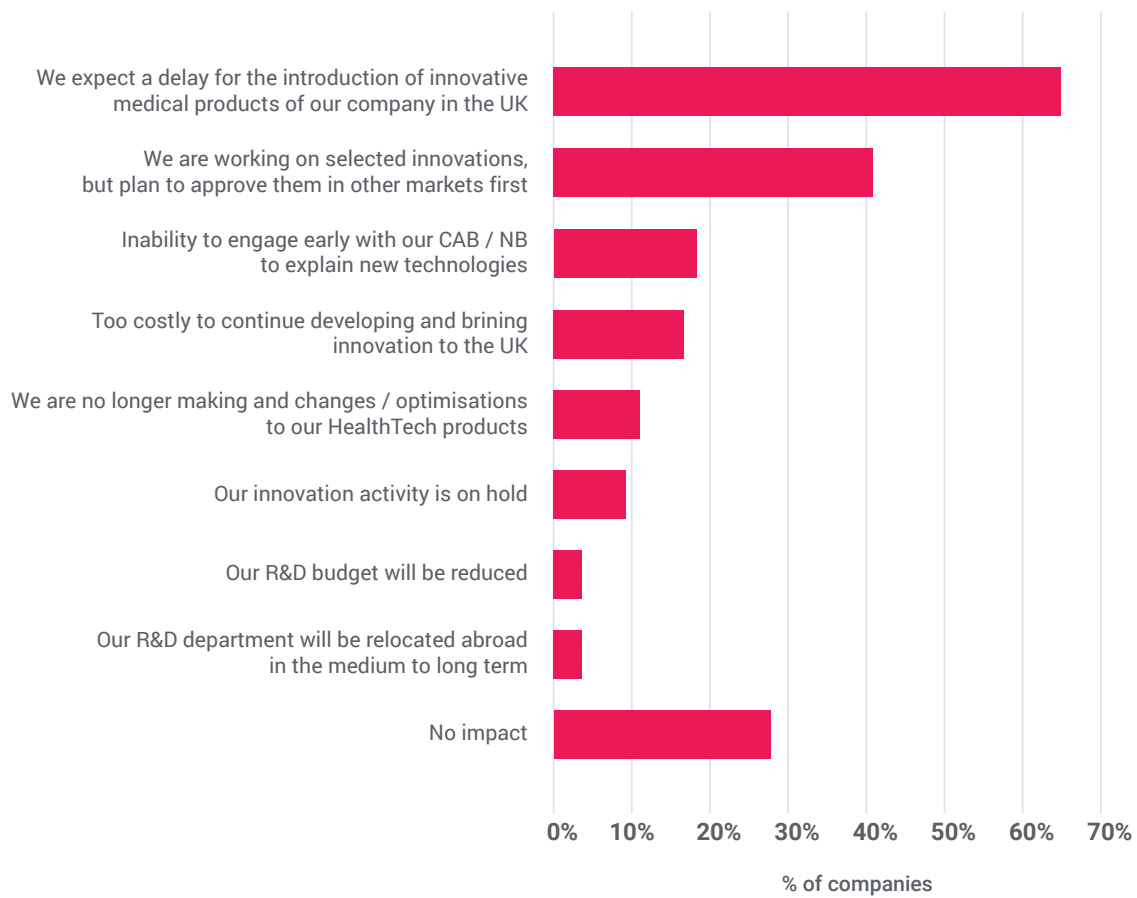


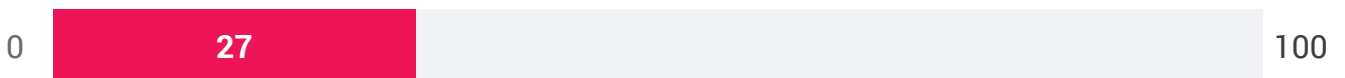
Chart uses numerical averages assigned to depict strength of positive and negative sentiments from the below table.

	1. Wholly disagree	2	3. Neither agree or disagree	4	5. Wholly agree
The UK will develop a best in class regulatory regime	12.96%	31.48%	42.59%	12.96%	0.00%
The UK will ensure continued patient access to existing HealthTech	7.55%	30.19%	28.30%	32.08%	1.89%
The UK will be seen as a priority market in the global environment	41.51%	32.08%	18.87%	5.66%	1.89%
The UK will develop a system protecting patient safety	3.77%	13.21%	33.96%	35.85%	13.21%
The UK is being ambitious in its methods and processes for regulating innovation	15.09%	22.64%	45.28%	15.09%	1.89%

The UK regulatory environment has now been in transition for many years, first through the European transition from MDD to MDR, and now as we prepare for UKCA. Has this impacted your innovation activity in the UK?



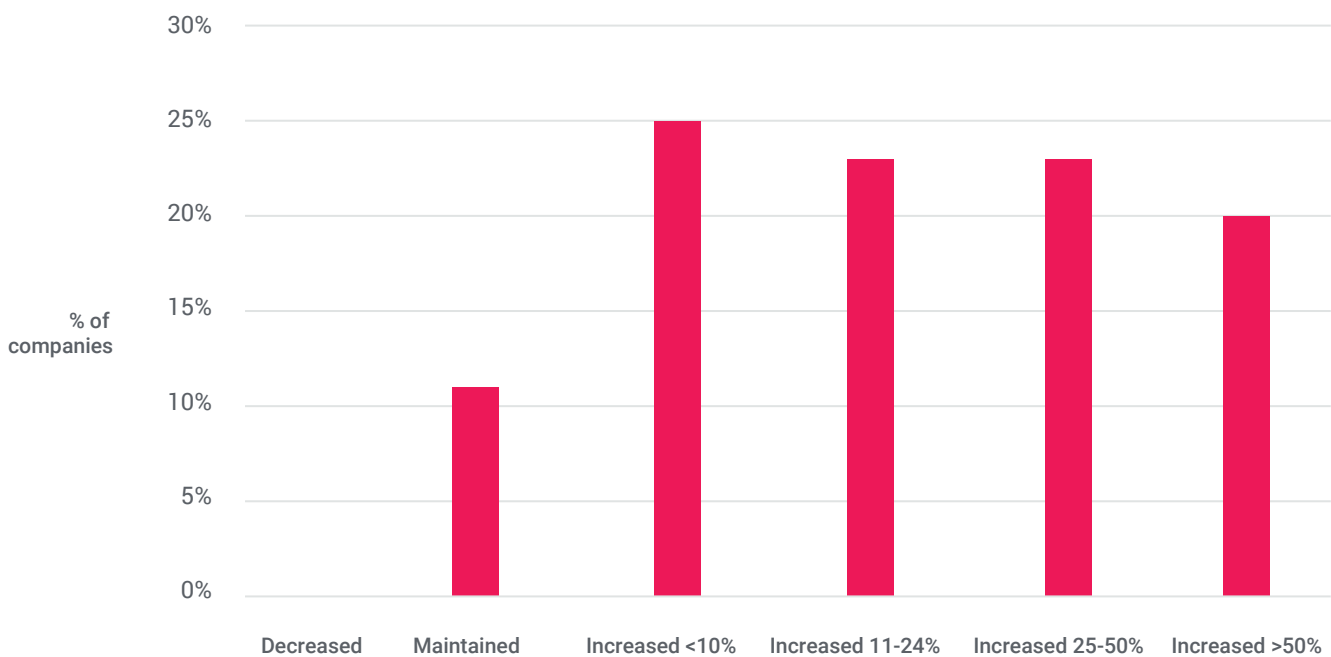
Industry confidence that there is enough capacity to meet the current transition timelines (current proposed transition times of 3-5 years after the date of application (currently set for June 2023))



What % of your product portfolio do you intend to continue to supply to the UK market after the five year transition?

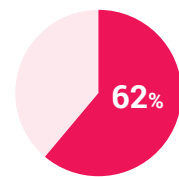
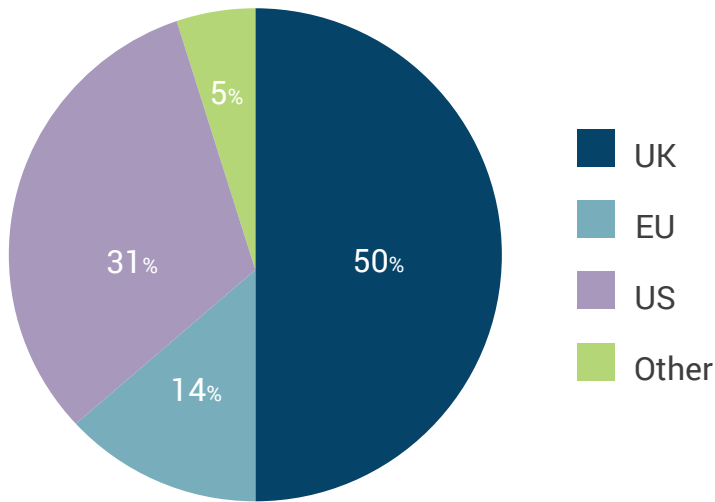


Regulatory cost changes over the last 12 months

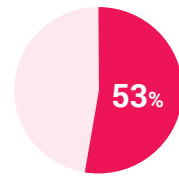


HEALTHTECH REGULATORY SURVEY REPORT BY QUESTION

Company headquartered



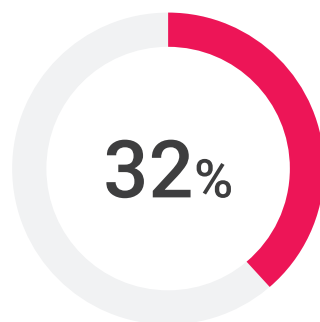
R&D in the UK



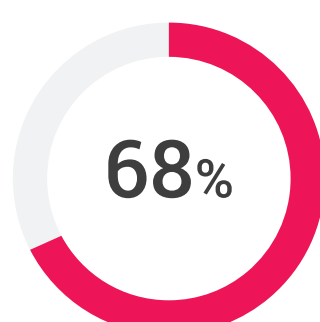
Manufacture in the UK

Breakdown of responses

78 companies



Large



SME



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ABHI

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