Spring Spending Review

Association of British HealthTech Industries (ABHI) Submission, February 2025

Spending Review Submission: Unlocking the Potential of UK HealthTech - Executive Summary

His Majesty's Government has been clear about the need to embrace and deliver its Growth Mission, and the Department for Health and Social Care's 'Three Shifts'. ABHI recognises the need for prioritisation to meet these challenges and build an NHS Fit for the Future, with the HealthTech sector at the heart of reforms. However, the scale of challenge is great, and the urgency with which action is needed is acute.

With combined economic and regulatory headwinds impacting the HealthTech sector, the UK risks a reduction in inward investment, and risks innovative companies removing products from the UK market or withdrawing from the market altogether[i] – each of which will impact on growth in the UK economy, as well as a reduction in life saving and life enhancing innovations in the NHS.

Without support for the sector, the challenges faced by Government and the NHS will continue, and meeting the ambitions of the Growth Mission and the Three Shifts will be impeded.

ABHI recommends a clear focus in support for the sector, including:

- The integration of priorities through the 10-Year Health Plan, Life Sciences Sector Plan, Industrial Strategy, NHS Innovation and Adoption Strategy and Spending Review, and each of their respective delivery mechanisms to ensure success;
- Strong regulatory signal for the sector through the implementation of international reliance, indefinite recognition of CE marking;[ii]
- A commitment around partnership and communication with the sector, to drive meaningful collaboration around joint aims and objectives; and
- Support for innovators from R&D right through to deployment, to deliver economic growth and help transform the NHS and deliver better patient outcomes.

ABHI Proposals for Spending Review (Spring 2025)

1. **Recognition of regulatory approvals by the FDA, EU, and other trusted jurisdictions as sufficient to grant UKCA approval.**

   The single most impactful change for the sector would be for the Government to deliver an effective and efficient model of international recognition (IR) within our regulatory framework.[iii] *This incentivises companies to invest in NHS clinical trials and ensure that the choice of clinical trial participants reflects the UK population. Experts consulted during the development of this proposal said this would also encourage North American and Asian companies to establish their European operations in the UK.*[iv]

2. **Specific R&D tax credits for clinical trials conducted with the NHS.**

   The UK has fallen from 4th to 10th globally in the number of large clinical trials conducted, and this measure will restore the UK's competitiveness in clinical trials. More trials will bring more cash to the NHS and boost corporate recruitment of HealthTech specialists in the UK.[v]

3. **Changes to Capital Gains Tax (CGT) and Enterprise Management Incentive (EMI) rules to reward employees of high-risk early-stage companies such as those in HealthTech.**

   These employees generally have lower cash earnings and higher share-based remuneration than comparable roles in established companies. Without a lower tax rate for share based incentives in high-risk private companies, experienced managers and engineers are discouraged from taking jobs with entrepreneurial innovative companies.[vi]

4. **Deliver a funding package to support the delivery of the 10-Year Health Plan, NHS Innovation and Adoption Strategy, and the Life Sciences Sector Plan, including exploring how the collective financial burden on HealthTech SMEs may be mitigated.**

   By fully supporting and funding the work of the 10YHP, NHS Innovation and Adoption Strategy, and the LSSP, HM Treasury can support the growth and success of the sector. This is a prime opportunity at a moment when the NHS needs structured reform, and accompanying funding to repair broken services, provide better outcomes for patients and deliver economic growth for the country. However, to miss this opportunity will mean stunted growth, a hampered life sciences sector, and an NHS stuck in the status quo.

5. **Reforming NHS procurement processes to place more emphasis on value.**
   Whilst the world's largest single-payer health system could act as the greatest enabler for the sector, its procurement system instead acts as a barrier to growth. It continues to focus on price rather than value in procuring HealthTech. Almost a quarter of companies are removing products from the market because the price the NHS is prepared to pay was below cost. It also has increased burden through ineffective application of social value questions in tenders.[vii]

6. **Create a fit for purpose adoption pathway, reducing duplicative activity, rewarding and supporting innovation and creating funding flows that support front line adoption.**
   The Innovation Ecosystem Programme (IEP) stands out from previous, similar, initiatives, in that it was done by the NHS for the NHS. The stumbling block in almost all the previous

exercises was the lack of engagement of the operational service. Funding and support should be provided to implement and deliver the IEP in conjunction with the 10YHP and the LSSP.

7. **Utilising the UK's international strength to support trade and investment.**
   There is a significant opportunity for government to work with Trade Associations and other international organisations to increase the support HealthTech companies are receiving on trade within Industrial Strategy. ABHI proposes a Global Export Programme that prioritises the sector's needs and delivers a simplified framework of export services. Such an initiative could be led by industry, in partnership with government to drive economic growth.[viii]

Realising the Potential of HealthTech

HealthTech is a hidden gem of the UK economy. It contributes £13bn Gross Value Added (GVA, equal to biopharma) thanks to the UK's strengths in medical innovation- but its potential remains barely tapped. Growth in UK HealthTech is limited by shortages in capital and skills, partly because HealthTech investment has been damaged since Brexit by uncertainty about regulatory arrangements.[ix]

The HealthTech sector – as a key plank in the Life Sciences sector – is poised to play a key role in delivering benefits for the NHS and for the UK economy, particularly in line with the Chancellor of the Exchequer's ambitions for growth, and supporting the development and delivery of the 10 Year Health Plan, the Life Sciences Sector Plan and the Industrial Strategy.

The potential of HealthTech is very considerable, but it requires very different consideration from other parts of the Life Sciences sector. It is incredibly diverse, with a large number of companies, the vast majority of which are SMEs. The pace of iteration is also very rapid. For example, pharmaceutical products tend to iterate over a period of 10-12 years, whilst for traditional HealthTech this figure is typically 12 -18 months. For those technologies that rely on algorithms based on AI and deep learning, iteration will be almost instantaneous with each new data input.

The UK boasts a particularly vibrant small business HealthTech community, with SMEs accounting for approximately 85% of the 4,465 of the companies here[x], alongside significant R&D and manufacturing capabilities across a variety of subsectors such as wound care, orthopaedics, genomics and in-vitro diagnostics (IVDs). The UK HealthTech sector is also highly innovative, with it accounting for one in every twelve of UK patent applications in 2021 submitted to the European Patent office annually.[xi]

The UK has significant strengths in clinical research, regulatory expertise, and a thriving ecosystem for health technology innovation. Industry data demonstrate the UK is ranked above the EU and US for its research environment, and in its ability to evaluate technologies for their effectiveness and value for money. The research environment is bolstered by the fifty universities which are research-active in HealthTech, and institutions such as the National Institute for Health Research (NIHR) and the National Institute for Health and Care Excellence (NICE) are globally renowned.

The NHS is also recognised globally as the largest single-payer health system and has a brand of quality associated with it that allows companies to accelerate their export activity if they can demonstrate that they have significant adoption in their home market.

The OLS's 2024 paper, entitled *Unlocking the Potential of UK HealthTech*, made several comments and recommendations around how to unleash the UK HealthTech sector to support the NHS and patients, as well as the sector and the wider UK economy.[xii]

It noted that 'the sector Gross Value Added showed a 19% compound annual growth rate between 2016-2020 for MedTech (which adopts a narrower definition than HealthTech)'. It also noted that 'the geographical spread of the UK HealthTech sector goes beyond London and the Golden Triangle', and that it 'exhibits significant diversity and a substantial presence throughout the country. While the South East region leads in employment, turnover, and the number of HealthTech sites, SME HealthTech businesses are dispersed evenly across various UK regions'.[xiii]

Together, we need to provide opportunities to innovate at all levels of the NHS; build a framework to attract inward investment through the 10YHP and the LSSP; and embrace the change needed in the NHS to deliver a more sustainable service and better outcomes for patients, through changing the demand curve.

Crucially however, the Government should also consider the sectors' impact beyond its direct growth. The appropriate use of HealthTech can enable the "three shifts" required in the NHS, while reducing long-term costs and improving broader economic productivity through better health of the general population.

For example, newer technologies such as quantum, genomics, AI, 3D printing and robotics underpin exciting and important developments in prevention, earlier and more accurate diagnosis and precision medicine. More traditional HealthTech continues to enable high-quality, cost-effective care for millions of NHS patients every day. More effective use of green technologies, both existing and developing, such as novel materials and circular solutions would also help the NHS to reduce its environmental impact.

With support for the life sciences and HealthTech sectors, the UK could:

- Strengthen investment flows into UK HealthTech companies from domestic and overseas investors through tax and regulatory incentives, alongside measures to address skills shortages.
- Boost investment by UK HealthTech through tax and regulatory incentives to fund clinical trials in the UK.
- Increase the attractiveness of the UK for HealthTech companies by providing a collaborative framework for the adoption of HealthTech by the NHS.
- Boost exports through a programme of overseas customer engagement events supported locally by the Department of Business and Trade (DBT).

However, the UK's tax and reporting burden also continues to grow. ABHI has identified 30 separate areas where costs to businesses are increasing, straddling employment, property and assets, energy and manufacturing, transport and reporting. As HealthTech manufacturing processes are people intensive, UK SMEs are particularly exposed to these changes. One medium sized, family-owned company is facing an additional £1m increase in employment taxes resulting from the October budget, alongside ever-increasing regulatory costs. The company provides 300 UK jobs and is having to explore offshoring manufacturing. Inheritance tax changes also present the real possibility of the family being forced to sell the business in the future to a private equity firm, impacting both the growth and innovation it can support.

Regulatory Environment

Many of our members of all sizes cite regulatory approval as their biggest challenge.[xiv] The transition from EU to UK specific regulations has amplified some long-standing issues and introduced new concerns. The effect of the complex regulatory environment is that time to market/revenue for new products/services is extended and the cost of development projects increases.

The recognition of, or reliance on, regulatory approvals from trusted jurisdictions will save both the regulator and the industry duplicating vast amounts of constrained resource. Indeed, the single greatest thing, by a substantial margin, the UK Government can do to support HealthTech is deliver an effective and efficient model of international recognition (IR) within our regulatory framework.[xv]

In our recent annual survey, IR was identified as 'likely to considerably improve attractiveness' by four times as many companies, compared to any other ongoing or developing initiative in any other policy area by the UK Government. In addition, 84% of respondents to the 2021 Consultation on the future regulation of medical devices in the United Kingdom, were in favour of an alternative route to market which utilises approvals from other countries signifying the support for IR coming from a cross section of the industry, healthcare professionals, institutions and public and patients who responded.[xvi]

With 68% of the sector declaring IR will 'actively increase the attractiveness of the UK', there is an opportunity to potentially support the growth of, or attract investment from, over 3,000 companies.[xvii]

Current arrangements limit the ability of the UK Government to performance manage and improve the system. Companies are currently facing extended timelines for approvals and increasing costs. Recent ABHI data reported costs could be over 700% higher in the EU, and timelines 150% longer than the US. However, UK Government has no power through MHRA to set targets for timelines and costs for approvals.[xviii]

Simultaneously, MHRA is currently consulting on increasing costs further by adding a £16+ million bill on the sector for post-marketing surveillance, in addition to the fees the sector already pays directly to Approved Bodies. MHRA is also consulting on increasing the fees the Approved

Bodies pay to the Agency for designation, which will inevitably also be passed onto the sector. The current system is leading to ever-increasing costs, extended delays and is drastically impacting the attractiveness of the UK market. However, there is an opportunity, post-Brexit, to think again about how we want our system to function.

On regulatory reform, ABHI is asking for Government to:

1. **Accept certain non-UK approvals of HealthTech products by:**
   a. Accepting all FDA approvals and clearances supported by appropriate assurances and including post-market surveillance.
   b. Matching the automatic and indefinite recognition of CE approved goods that is affordable to other sectors.
   c. Extending trusted jurisdictions beyond those already identified in the statement of policy intent (EU, USA, Canada, Australia) to include, for example, those under the scope of the Medical Device Single Audit Programme.

2. **Shift the focus of UK regulatory resource towards post-market surveillance to support innovation**:
   Where possible, the UK should be looking to the post-market surveillance process to build confidence and avoid burdensome and duplicate processes in the pre-market phase (i.e. for approvals). As a universal, single payer system serving a diverse population, the NHS has the potential to lead the world in generating real-world evidence collected in post-market surveillance.

3. **Train students in relevant disciplines in regulatory affairs:**
   Fewer than half the biomedical engineering undergraduate programs in the UK offer training in regulatory affairs. Making this more widespread is an easy win for the supply of qualified personnel for industry, Approved Bodies and the MHRA. There is a global shortage in HealthTech regulatory skills, so the planned reform of the Apprenticeships Levy into a 'Growth and Skills Levy' should prioritise this. The deliverable here is more capacity at Approved Bodies (Abs) to bring the best innovations to the NHS and patients sooner.

Adoption and Spread of HealthTech

ABHI also recommends taking a more integrated approach, adopting a centralised 'passporting' approach to information governance approval, where companies/technologies are approved once at a national level.

The NHS is recognised as the largest buyer of health technologies in the UK, with annual spending exceeding £10 billion. However, current procurement strategies have increasingly shifted toward cost optimisation, prioritising supply base reduction and the selection of the lowest-cost products. While this approach may offer short-term financial savings, there is growing concern that it could undermine patient outcomes and product quality.

Many innovative HealthTech solutions that offer superior clinical benefits, improved patient experiences, and longer-term cost savings are being marginalised due to their higher initial price. This short-term focus on cost rather than value risks discouraging the adoption of breakthrough medical technologies and limiting patient access to the most effective treatments available.

Whilst the UK HealthTech ecosystem has tremendous strengths in innovation and early-stage research, supported by infrastructure such as the NIHR, IUK and a plethora of funding bodies and charities, gaps arise in translation, adoption and spread.

Funding support specifically falls off in the translational research phase and is an area that capability was rated behind the US and EU in our recent industry survey. Crucially, the likelihood of adoption could help to pull technologies through this phase. However, it takes on average 17 years for a new HealthTech device to go from successful clinical trial to adoption by the NHS. Given the pace of technological advances designed to improve patient health outcomes and, in many cases, improve NHS productivity, this has consequences on the quality of care that can be delivered in the NHS, and on workforce efficiency.

Many initiatives have aimed to overcome these challenges with varying degrees of success. One however that the HealthTech sector remains optimistic for is the Innovation Ecosystem Programme (IEP).[xix] It stands out from previous, similar, initiatives, in that it was done by the NHS for the NHS. The stumbling block in almost all the previous exercises was the lack of engagement of the operational service. This element, we believe, is particularly important for HealthTech versus the Life Sciences more broadly. HealthTech has traditionally been developed by close collaboration between industry and the clinical community, a relationship that remains vital for adoption and spread, especially where innovation leads to changes in clinical practice, location of care delivery, or diagnosis earlier in the patient pathway.

In the short term, the CSEP/ABHI report '*A sector strategy to transform the economic and societal benefits of UK HealthTech'* that provides a methodology for how deliver a HealthTech industrial strategy, recommends six immediate key actions to professionalise adoption in the UK.

1. Ensure there is a framework for the adoption of innovation by the NHS in partnership with the sector,
2. Protect time for innovation within clinical timetables while enabling joint posts to allow NHS clinicians to work with industry,
3. Appoint Board level Chief Innovation Officers in all NHS organisations and provide the resource and mechanisms to ensure innovation is managed and measured, in part through the CQC well-led framework,
4. Centralising some activities that currently lead to unnecessary duplication of work by both the NHS and HealthTech,
5. Bring NHS savings targets in line with wider HMG productivity initiatives i.e. moving from a one-year time horizon to five-years,
6. Amend Innovation Adoption Initiatives to encourage innovations that improve NHS productivity.[xx]

Moreover, procurement processes should be reformed to foster greater collaboration between the NHS and HealthTech companies, particularly startups and SMEs that often struggle to navigate complex NHS purchasing structures. Establishing dedicated NHS innovation accelerators in partnership with industry bodies, universities, the NHS and Government would also enable faster testing and validation of emerging HealthTech solutions.

It is also important that Health Innovation Networks (HINs) are retained, supported and resourced to provide support for the NHS and innovators to improve the adoption of technologies equitably across ICS and regional areas, and more generally across the country.

R&D Tax Credits for Clinical Trials Conducted with the NHS

The UK has historically been a leader in clinical trials, attracting global pharmaceutical and biotech companies due to its strong research infrastructure, skilled workforce, and world-class NHS system. However, in recent years, the country has seen a decline in its standing, slipping from 4th to 10th place globally in terms of large clinical trials conducted. This drop has significant consequences for both the NHS and the broader HealthTech ecosystem. To address this, introducing specific R&D tax credits for clinical trials conducted within the NHS would provide a major incentive for life sciences companies to conduct their research in the UK rather than moving trials to other jurisdictions with more favourable conditions.[xxi]

Increasing the number of clinical trials in the UK will provide several benefits. Firstly, it will bring much-needed revenue into the NHS, allowing hospitals and research institutions to reinvest in medical advancements and patient care. Secondly, it will create new employment opportunities, particularly for specialists in HealthTech, data science, and medical research, making the UK a more attractive hub for top global talent. Strengthening tax incentives will not only help restore the UK's global competitiveness in clinical trials but will also boost innovation, accelerate drug development, and improve patient access to cutting-edge treatments.

Changes to Capital Gains Tax (CGT) and Enterprise Management Incentive (EMI) Rules for Early-Stage HealthTech Companies

Startups and early-stage HealthTech companies play a vital role in driving medical innovation, developing breakthrough technologies, and improving patient outcomes. However, attracting and retaining top talent in these companies remains a significant challenge due to their inherently high-risk nature. Unlike established corporations, startups often lack the financial resources to offer competitive salaries. Instead, they rely on share-based remuneration schemes to compensate key employees, particularly managers and engineers who are essential for growth and innovation. Unfortunately, the existing tax structure does not sufficiently reward employees who take on the risks associated with working in these companies, making it harder for startups to compete with larger firms for talent.

Reforming Capital Gains Tax (CGT) and Enterprise Management Incentive (EMI) rules to offer preferential tax treatment for share-based remuneration in high-risk private companies would encourage experienced professionals to join early-stage ventures. A lower tax rate for stock options and share-based incentives would help offset the lower cash salaries typically offered by startups, making these positions more financially viable for skilled professionals. By implementing these changes, the UK can stimulate entrepreneurial activity, support the growth of its HealthTech sector, and foster a culture of innovation that ensures the country remains a global leader in life sciences and medical technology. ABHI calls for CGT rates to be reduced to pre-budget (October 2024) levels.

Annex

ABHI is the UK's leading industry association for health technology (HealthTech).ABHI supports the HealthTech community to save and enhance lives. Members, including both multinationals and small and medium sized enterprises (SMEs), supply products from syringes and wound dressings to surgical robots, diagnostics and digitally enhanced technologies. We represent the industry to stakeholders, such as the government, NHS and regulators.

HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is the largest employer in the broader Life Sciences sector, employing 154,000 people in 4,465 companies, with a combined turnover of £34.3bn. The industry has enjoyed growth of around 5% in recent years. ABHI's 400 members account for approximately 80% of the sector by value.

References

[i] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[ii] https://www.abhi.org.uk/resource-hub/file/20448
[iii] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[iv] https://www.abhi.org.uk/media/ymcfex5q/final-helthtech_report.pdf
[v] https://www.abhi.org.uk/media/ymcfex5q/final-helthtech_report.pdf
[vi] https://www.abhi.org.uk/media/ymcfex5q/final-helthtech_report.pdf
[vii] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[viii] https://www.abhi.org.uk/media/ymcfex5q/final-helthtech_report.pdf
[ix] https://www.abhi.org.uk/media/ymcfex5q/final-helthtech_report.pdf
[x] https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2020/bioscience-and-health-technology-sector-statistics-2020
[xi] https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2023/04/aac004a-medical-technology-strategy.pdf
[xii] https://assets.publishing.service.gov.uk/media/66f691c7a31f45a9c765edc5/unlocking_the_potential_of_uk_healthtech.pdf
[xiii] https://assets.publishing.service.gov.uk/media/66f691c7a31f45a9c765edc5/unlocking_the_potential_of_uk_healthtech.pdf
[xiv] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[xv] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[xvi] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[xvii] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[xviii] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf
[xix] https://www.england.nhs.uk/long-read/the-innovation-ecosystem-programme/
[xx] https://www.abhi.org.uk/media/ymcfex5q/final-helthtech_report.pdf
[xxi] https://www.abhi.org.uk/media/fvhmxqbi/2024-pulse-of-healthtech-survey.pdf