

Life Sciences Industrial Strategy

WA Health analysis and recommendations
for engagement

Headline Analysis

“This Strategy is a blueprint for investment by Government and the private sector to strengthen and enhance our capabilities in life sciences” Professor Sir John Bell

The long-awaited industry-led report to Government on the life sciences sector was published today (30/08/17).

Prof Sir John Bell, the lead author of the strategy, has been touring the country speaking to companies for months. He highlights the life sciences industry is incredibly productive compared to other UK sectors, and deserves to attract significant investment.

Many have been eagerly awaiting the Strategy, and most will welcome its focus on encouraging more Government investment in key areas – as well as a more favourable fiscal, regulatory and reimbursement environment for life sciences.

The key question now is how the Government will respond, and if the sector can maintain enough momentum to ensure the Sector Deal stemming from this Strategy will have enough ‘bite’ to gain cut-through both nationally and internationally.

There will be questions raised about the amount of funding committed by the Government in announcing the Strategy (£160m in total), and how some of the rhetoric around the Strategy can be realised.

Key Themes

- ▶ **Science:** Maintaining the UK’s strength and international competitiveness.
- ▶ **Growth:** Create an environment that encourages companies to grow in the UK, including expanding life sciences manufacturing.
- ▶ **NHS:** Better collaboration and adoption of innovative treatments and technologies.
- ▶ **Data:** Making the best use of data to support research and patient care.
- ▶ **Skills:** Ensuring the sector has access to talented people to support growth.

Strategy’s Key Recommendations

Investment in science and R&D

- ▶ Create the Health Advanced Research Programme (HARP) to undertake high-risk, large research infrastructure projects.
- ▶ Advancing proposals for increasing genomic testing and screening.
- ▶ The UK should establish a working group to evaluate the use of digital health care data and health systems.
- ▶ Design a translational fund to support the pre-commercial creation of clinically-useable molecules and devices.
- ▶ To support a 50% increase in the number of clinical trials over the next 5 years.

Investment and growth in manufacturing

- ▶ The Government should ensure the UK’s tax environment is internationally competitive.

- Review the eligible costs recognised by the SME R&D Tax Credit and large company RDEC schemes, and consider raising further the RDEC employee limit.
- Attract substantial investment in life sciences manufacturing, including the Government optimising the fiscal environment for manufacturing investment to drive investment in industrial buildings, equipment and infrastructure.
- Consider nationally-available incentives to support capital investment – suggested by industry to be 10-15% of the total capital commitment of a project.
- Government, local partners and industry should work together to ensure the right infrastructure is in place to support the growth of life sciences clusters.
- New processes and approaches need to be developed to allow for more agility and to adapt to new therapeutic and product modalities, and to adapt to the requirements for more personalised or ‘near patient’ manufacturing.
- Accepting in full the recommendations of the Advanced Therapies Manufacturing Action Plan and apply its principles to other life-science manufacturing sectors.

Access to medicines

- Create a forum for early engagement between stakeholders to agree commercial access agreements.
- Create a streamlined access framework with a single clear decision point.
- Deliver a conditional reimbursement approval, for implementation as soon as licensing and value milestones are delivered.
- Multiple criteria should inform the value assessment including a QALY-based, cost-

effectiveness assessment, burden of illness, unmet need and therapeutic breakthrough impact.

- Value assessments should be evolved in the long-term with improved patient outcome measures, affordability and cost management data extending beyond one year timeframes.
- The Strategy also sets out that a new voluntary agreement should be agreed with the ABPI, and that as an overarching principle the next agreement should balance patient access to new medicines with value for money for the NHS and the need to incentivise industry to invest in R&D.
- Government and industry should work together to address lack of comprehensive digitalised prescription data across the NHS and agree an updated measurement along the lines of the annual life science competitiveness indicators report.
- The Strategy states the importance for the NHS to be equipped to agree partnership deals in order to progress a more collaborative environment between industry and the NHS – the commercial team in NHS England could fulfil this role or executed locally by Trusts –
- Put forward parallel processing of MHRA and independent NICE assessments to provide rapid access to Health Technology Assessment evaluations and regulatory approval.
- Also calls for an enhanced ability of the NHS to collaborate locally to reshape and evaluate clinical pathways, as well as system alignment to support consistent adoption and sustainability.
- Recommendations to be taken forward by a subgroup of the Ministerial Industry Strategy Group supported by the OLS and

incorporating existing work being undertaken by NICE, NHS England and industry.

Improving data

- Establish 2-5 regional innovation hubs providing data across regions of 3-5m people – with a suggestion a focus could be molecular diagnostics, cardiac or digital health.
- Create national registries of therapy-area specific data across the NHS in England – to be created and aligned with the relevant charity.
- Health care system to build on the standards set out by the NDG and CQC and set out a national approach to rapidly and effectively establish studies for the generation of real-world data.
- ePrescribing should be mandatory for hospitals.
- NHS Digital and NHS England should set out clear and consistent national approaches to data and interoperability standards and requirements for data access agreements.

Investing in skills and access to talent

- Develop and deliver a reinforced skills action plan across the NHS, commercial and third sectors based on a gap analysis of key skills for science.
- The Government should establish Institutes of Technology to provide technical training, particularly in digital and advanced manufacturing.
- A migration system should be established that allows rapid recruitment and retention of highly skilled workers from the EU and beyond.

Regulation

- Focus should be on alignment with the EU in order to deliver the best decision-making for patient safety.
- UK should seek to continue to operate within the wider EU framework of medical device assessment.
- For medicines licensing it suggests continued involvement of the MHRA in the review of dossiers and joint scientific deliberations.
- The Strategy states that developing an innovative regulatory approach to emerging technologies outside of the EU would not be worth pursuing if it jeopardised the UK's participation in the EU systems and processes. Report concludes that UK market is too small to stand alone from a larger decision-making bloc.
- Outside the EU we should attempt to maintain the current balanced approach to data sharing regulations.

Next Steps

“The proposals here and in the sector deal are designed to be thought about in that longer-term context”
Professor Sir John Bell

Now that the strategy has been published the aim is to establish a joint programme of delivering it between industry, NHS and Government. This delivery programme will be agreed and overseen through the upcoming Life Sciences Sector Deal – anticipated later this year.

The Strategy is meant to spark a conversation between industry and Government as to who is prepared to invest what, to achieve a Sector Deal.

The Sector Deal will include an agreed implementation plan, setting out clear milestones and timescales. Each part of the Sector Deal will be overseen by an industry and Government lead, reporting to an oversight board.

Initial Stakeholder Reactions

“We look forward to working with Government and other partners to implement these recommendations – including through a sector deal with the bio-pharmaceutical industry and a voluntary agreement on UK medicines policy between industry and the Department of Health.” Mike Thompson, Chief Executive of the ABPI

- Headline reactions have thus far been positive, praising the scope of the report and its commitment to retaining the importance of the sector in post-Brexit Britain.
- Of particular focus for the ABPI was using the NHS’s ability to use health data in research and development to develop new treatments in closer cooperation with industry, and on the voluntary agreement on a new UK medicines policy between industry and the Department of Health.
- Chief Executive of the Institute for Cancer Research, Professor Paul Workman, said that life sciences being the first sector to receive an industrial strategy recognised the strength of the industry. In welcoming the government’s pledge to support what he called “basic science”, Mr Workman cautioned this would only continue if the UK had the chance to attract the best and brightest in the world.
- The ICR looks forward to “hearing more about the Government’s plans for ensuring the UK continues to be a beacon for skilled scientists from within the EU and beyond.”

- The Association of British Health Industries welcomed what the report meant for MedTech’s role in the British economy.
- They particularly welcomed the focus on high levels of sustained NHS collaboration, and called for the recommendations of the Accelerated Access Review to be implemented immediately.
- As with other organisations, the ABHI called for continued convergence with the EU-wide regulatory system post-Brexit.
- Government has also responded to the report, with both Health Secretary Jeremy Hunt and Business Secretary Greg Clark accompanying Sir John Bell during his announcement and penning a joint article in The Times.
- The Government pledged £160 million in order to support the life sciences sector as part of today’s announcement, and have also emphasised the need for better collaboration between industry and the NHS.

“The fact the life sciences are the first to have an industrial strategy recognises the strength of the sector’s collaborations between industry and academia.” Professor Paul Workman, Chief Executive of the Institute for Cancer Research.

For more information or advice, please contact WA Health on: health@wacomms.co.uk or 020 72229500