

Government – Department for Business, Energy and Industrial Strategy (BEIS) – Written evidence (LSI0111)

Introduction

In the Industrial Strategy Green Paper¹, Government welcomed initial work on early sector deals, including from Professor Sir John Bell on life sciences.

Six years on from the first Life Sciences Industrial Strategy (2011) and in the context of EU exit, this was a helpful time to take stock. Sir John has convened the sector to develop an industry-led Life Sciences Industrial Strategy (LSIS), bringing together the diverse elements of the sector (pharma, medtech, biotech, digital health, diagnostics, SMEs, charities and the NHS). The LSIS demonstrates the UK's existing strengths in life sciences, the areas where we are internationally competitive and the opportunities of the future. It builds on the Accelerated Access Review and the work of the Office for Life Sciences. At its head is a vision to ensure that the UK remains a top tier global hub for life sciences.

Recommendations have been developed under the themes of:

- **Science** – Building on UK strengths in science, including improving clinical trial capabilities
- **Growth** – Growing manufacturing capability; and the commercialisation of science and access to patient capital
- **Infrastructure** – Recommending that Government, local partners and industry work together to ensure the right infrastructure (e.g. transport, housing) is in place to support the growth of life sciences clusters and networks.
- **NHS** – Building on the Accelerated Access Review (AAR) to embrace cost-effective innovations for patients.
- **Digital** – Supporting collaboration with real-world evidence, de-personalised health data and data hubs.
- **Skills** – Ensuring the UK has the talent and skills to underpin future life sciences success

The strategy also includes a flagship proposal for a **Health Advanced Research Programme** (HARP) where industry, charities, NHS and Government collaborate on ambitious, long-term projects to transform healthcare.

The publication of the strategy on 30th August marked the start of negotiations on a Sector Deal between Government and the life sciences sector. Government welcomed the life sciences story of the sector so far and is now working with Sir John and others to develop an ambitious sector deal.

Science and Innovation

¹ https://beis.gov.uk.citizenspace.com/strategy/industrial-strategy/supporting_documents/buildingourindustrialstrategygreenpaper.pdf

1. How can investors be encouraged to invest in turning basic life science research into new innovations in treatment? Why has investment been lacking in this sector?

Early stage life science companies can face difficulties in accessing funding to develop their products and technologies through discovery and preclinical research to proof of concept stage. This is particularly the case where the development of new treatments may require substantial capital investment to bring products to market. Investors may be reluctant to support life sciences products as the development cycle is long compared to venture capital cycles.

The Biomedical Catalyst programme was introduced to specifically bridge this funding gap. It involves a partnership between Innovate UK and the Medical Research Council and is focused on SMEs to deliver a high-growth pipeline of innovative companies capable of tapping into a global healthcare market. So far, £250m has been awarded to 186 companies and 132 university ventures, which has been matched by ~£150m of private finance. Portfolio companies' subsequent fundraising and licensing fees etc. exceed £1bn.

Developers, particularly those in small and micro-enterprises, face challenges in finding the critical facilities and expertise they require to develop innovative therapies. To address these issues a network of Catapult Centres has been established to play a key role in supporting the innovation landscape, enabling SMEs to access the support needed to bring products and services to market for the first time. The health Catapults consist of Cell and Gene Therapy Catapult, and Medicines Discovery Catapult along with the National Biologics Manufacturing Centre under the High Value Manufacturing Catapult. The broader Catapult family also offers a great opportunity for innovation in health and life sciences with the Digital and Future Cities Catapults exploring the urbanisation of health and wellbeing and the creation of new markets.

Government has also taken general measures to help developers of high-risk, innovative technologies access investment, such as introducing the Enterprise Investment Scheme and the Seed Enterprise Investment Scheme. HMT is currently undertaking a review of the factors needed to encourage more patient capital, with input from Sir Damon Buffini's industry group. The review aims to strengthen the UK further as a place for growing innovative firms to obtain the longer-term 'patient' finance that they need to scale up, building on current best practices. Most recently, Secretary of State for Business, Greg Clark, announced £197m over four years under the Industrial Strategy Challenge Fund to support leading edge healthcare projects that will develop first-of-a-kind technologies for the manufacture of medicines, that will speed up patient access to new drugs and treatments, anchor this cutting-edge manufacturing in the UK, drive jobs and build on the exporting strengths of the UK's biopharmaceutical sector.

Does the research base have the necessary infrastructure to be world-leading?

The UK has a world-leading research infrastructure, including the National Institute for Health Research (NIHR). NIHR created a comprehensive health research system, integrated within the NHS, to drive faster translation of basic science discoveries into tangible benefits, with the commitment to provide

significant levels of sustained, long-term funding (over £1bn annually) to support this system. NIHR has been widely recognised as having transformed the health research environment in the UK. Together with the Medical Research Council, which supports basic/discovery science, research charities and the life science industry, NIHR helps make the UK among the best places in the world to develop and launch innovative medicines, technologies and diagnostics.

The Department for Business, Energy and Industrial Strategy is delivering on the long-term science capital commitment of £6.9bn between 2015-2021 to support the UK's world-class research base. The Department's capital investments in life sciences include up to £150m to create a Dementia Research Institute, a £350m investment in the Francis Crick Institute, and £100m investment in the Rosalind Franklin Institute (RFI). The UK Research Partnership Investment Fund (UKRPIF), which is managed by HEFCE working with the Devolved Administrations, provides funding to HEIs for research infrastructure. Established in 2012, UKRPIF has allocated over £680m to 43 projects, leveraging over £1.65bn of private co-investment. 17 of the 43 projects have been life sciences orientated.

The Medical Research Council (MRC) provides funding for research through a range of response mode and strategic investments. The MRC funds research across the entire spectrum of medical sciences, from fundamental laboratory-based science to clinical trials and welcomes high-quality investigator-led research proposals in all areas of research relevant to human health.

Furthermore better use of information and data has the potential to transform health and care for everyone. Data sharing is essential to support the provision of quality and safe patient care, to underpin the planning and funding of services and to support research. In a recent speech at the NHS England Expo, Simon Stevens highlighted the opportunity of "exploiting the unused comparative advantage that the NHS has with the anonymised clinical data at [its] disposal." Improved use of healthcare data (used legally, securely and appropriately) would have multiple benefits. Patients would receive more accurate diagnoses and more personalised advice, care and treatment; there will be improved, up-to-date care records; reduced bureaucracy will free up NHS staff time for patient care. For researchers and innovators they will be able to undertake faster, more accurate and cheaper research and development; identification of new therapeutic targets will be enabled; there will be better evidence of the true value and effectiveness of medicines and technologies to support adoption and uptake across the health system; and the ability to better develop, test and deploy new technologies in health and care. In the sector's Life Sciences Industrial Strategy, Sir John Bell made recommendations about the use of data and the development of data infrastructure. Government is now considering the proposals, working with Sir John on what may be taken forward in a sector deal.

2. Why has the UK underperformed in turning basic research in the life sciences into intellectual property? What needs to be done to address this historic weakness in the UK and grow new companies to commercialise new research and related technologies in the life sciences?

The UK is already world-class at developing inventions and concepts at our universities: the World Economic Forum evaluation ranks the UK 2nd for the quality of scientific research institutions, and the Global Innovation Index 2016 showed the UK at 3rd in 2017. We are doing better than ever before at collaborating with businesses and at turning research into intellectual property: total knowledge exchange income and IP income have both been rising, with an increase in total income from knowledge exchange activity of 6.2% from £3.9bn in 2013-14 to **£4.2bn** in 2014-15². There has been an annual increase of 18.5% in **IP income**, from £131m in 2013-14 to **£155m** in 2014-15.³ University income from business has also risen consistently in recent years⁴, and the UK compares well internationally, generating similar levels of patents, spin-outs, and income from industry in proportion to research spend as the US.⁵ Though the UK has an excellent record in creating businesses, many of them face barriers to scaling up. The Government's Industrial Strategy green paper identifies one part of the challenge as improving access to finance for businesses looking to grow.

The Government is already undertaking a number of activities to create an environment in which the commercialisation of research, across all sectors, can flourish. The policy framework includes the **Research Excellence Framework**, creating incentives for universities to deliver impact, from their research, and working with UKRI to increase the Higher Education Innovation Funding by £40m p/a to strengthen universities' knowledge exchange and commercialisation capabilities.

The NIHR research infrastructure is also critically important in providing the resources, support and facilities that the NHS needs to conduct first-class research across the full pathway of discovery science to evaluation. NIHR recognises the key role of intellectual property assets in driving innovation, in addition to a range of associated activities such as fostering a culture of invention and effective industry collaboration. This in turn supports the commercialisation of new research and related technologies to help grow new companies (including SMEs).

As previously noted, the availability of early-stage finance to support innovative firms to start up and begin to grow has increased significantly. But there remains less investment in the long-term capital needed for our most innovative companies to scale up and become the mid and large companies of the future. HMT's review of the factors needed to encourage more patient capital, with input from Sir Damon Buffini's industry group, is now underway and published a detailed consultation document on 1 August 2017.

²http://www.hefce.ac.uk/media/HEFCE,2014/Content/Pubs/2016/201619/HEFCE2016_19.pdf, p.14

³ As above, p.9

⁴ Total income from **collaborative research** increased by 9.9% during 2014-15, from £1,144m to **£1,257m**, and **contract research** income increased by 1.5%, from £1,192m to **£1,210m**. Although IP income from licensing and equity has grown, they remain a consistently small share (£155m in 2014-15) compared with collaborations with industry and others more generally on consultancy, contract research and collaborative research which have grown from £2.2bn in 2009-10 to just under **£3bn in 2014-15** ([HE-BCI 2014-15](#), figure 2 on p.6).

⁵ Comparison of performance of knowledge exchange activity in HEIs for the US, UK and Japan suggests that the UK performs quite well. The UK generates similar levels of patents and spinouts per £1 of research, and a higher percentage of industrial research income ([HE-BCI annual report](#), p.35).

3. What can be done to ensure the UK has the necessary skills and manpower to build a world class life sciences sector, both within the research base and the NHS?

For the UK to remain the most productive G7 science and research base and increase its economic growth, it is vital to create a strong STEM workforce. We must draw on all our available talent, improve diversity in the STEM workforce, and inspire more young people to study STEM subjects. Through the UK's Industrial Strategy, this Government is committing £170m of capital funding to the creation of Institutes of Technology to deliver higher technical education in STEM subjects. In implementing these plans, Government wants to address regional skills imbalances to help spread economic growth and opportunity throughout the UK.

BEIS is making a series of interventions to raise awareness and interest in STEM careers amongst young people, including under-represented groups in the STEM workforce, and those that influence pupils' subject choices at school. To ensure a strong cadre of talented individuals to deliver the Industrial Strategy, BEIS will invest £300m from the National Productivity Investment Fund to increase the number of highly skilled researchers and develop the talent needed for a thriving and innovative economy. This includes £90m for 1000 new PhD places and £210m for fellowships for early and mid-career researchers and innovators. In addition, the Rutherford Fund, a £100m investment over four years, will attract the brightest minds to the UK and help maintain the UK's position as a world-leader in R&D. The Rutherford fund includes £50m from the from the National Productivity Investment Fund specifically ring-fenced for fellowship programmes to attract global talent and over £50m of existing international funds to support fellowships that attract researchers to the UK from emerging research powerhouses like India, China, Brazil and Mexico.

The NIHR is the UK's largest funder of research training, providing over £100m a year of training funding to support researchers in all disciplines and at all levels, enabling trainees to acquire skills which are also of benefit to industry. Through NIHR, collaborations with industry to identify skills gaps and to support development of specialist skills required; have contributed to the creation of a research environment which adds to the UK's international competitiveness as a place to undertake clinical research: it is developing a cadre of researchers equipped to work at the university/NHS/industry interface and to go on to lead collaborative research between HEIs, the NHS and industry.

4. How does the UK compare to other countries in this sector, for example Germany and the United States?

The UK has some core strengths in this sector that allow it to compete globally: its strong science and university base are particularly important in this respect:

- The UK has three of the top ten universities globally, according to the Times Higher Education League tables for 16/17, and also places six institutions in the top 20 for pre-clinical and clinical subjects.⁶

⁶ Times Higher Education, 2017. *World University Rankings 2016-2017*. Available at:

- The World Economic Forum evaluation ranks UK 2nd for the quality of scientific research institutions, and the Global Innovation Index 2016 showed the UK at 3rd in 2017.
- The UK is home to key institutions, such as the Francis Crick Institute and The Wellcome Trust, as well as pioneering projects like UK Biobank and the 100,000 Genomes Project.
- This helps make the UK an attractive place to invest: in 2016 the UK had the second highest number of life sciences FDI projects behind USA. The UK is the leading destination in Europe for foreign direct investment in health and life sciences projects: more than £9bn of private sector inward investment in life sciences in the UK has been committed in the last 5 years, supporting 23,500 jobs.
- The UK does well in terms of research productivity: In 2015, for example, UK public life science R&D spend was \$76 per capita compared to \$109 in Germany and \$159 in the US⁷; yet produced 185 life science publications per million people; compared to 66 in Germany and 121 in the US.⁸
- The NIHR, carrying out world-leading science within a universal NHS, is a globally unique environment for life sciences research and innovation. The NIHR ecosystem, working within and as a part of the NHS, represents the most integrated clinical research system in the world and is a significant global competitive advantage for the UK.

There are however areas where the UK could do more to compete with global rivals and Government is taking action to address this:

- The UK Government currently spends less on life sciences R&D than competitors, although research productivity is nonetheless twice as great as that in the US and almost three times greater than in Germany. The Government has set out its vision to meet R&D investment of 2.4% of GDP within ten years and 3% in the longer-term. Going forward, this ambition will be an important part of the HMG Industrial Strategy and will require a concerted cross-government approach.
- Government is already taking action to increase R&D investment, announcing in the 2016 Autumn Statement a further £4.7bn by 2021 – the largest increase by any government since 1979. By the end of this Parliament, the government will invest an additional £2bn a year in

<https://www.timeshighereducation.com/world-university-rankings/2017/world-ranking>. Times Higher Education World University Rankings Overall & by subject: clinical, pre-clinical and health 2016-17
https://www.timeshighereducation.com/world-university-rankings/2017/subject-ranking/clinical-pre-clinical-health#!/page/0/length/25/sort_by/rank/sort_order/asc/cols/stats

⁷ NIH; UK Government; AMRC; Förderatlas DFG; Federal Statistical Office (includes charity, government and EU funding [for Germany and UK])

⁸ 2015 filtered by country and region and by life sciences e.g., ((Boston AND United States) AND ("2015/01/01"[Date – Publication]: "2015/12/31"[Date – Publication])). Weighting is by H index of journal
 Source: Pubmed, Elsevier Scopus.

research and innovation, including the new Industrial Strategy Challenge Fund.⁹

- In 2016 China and the USA made up over half of all global life science IPOs (56%), the UK had 4% of all global life science IPOs (ranked 7th), similar to India and Japan (5% and 3% respectively). HMT's Patient Capital Review notes that the UK performs well in financing start-up firms but young, innovative UK firms that are growing are less likely to receive the investment they need to scale up than businesses based in the US. The Review, with input from Sir Damon Buffini's industry group, aims to strengthen the UK further as a place for growing innovative firms to obtain the longer-term 'patient' finance that they need to scale up, building on current best practices.

Industrial Strategy (Qs 5-9)

5. What can be learnt from the impact of the 2011 UK Life Sciences Strategy? What evidence is there that a strategy will work for the life sciences sector? How can its success be measured against its stated objectives?

6. Does the strategy contain the right recommendations? What should it contain/what is missing? How will the life sciences strategy interact with the wider industrial strategy, including regional and devolved administration strategies? How will the strategies be coordinated so that they don't operate in 'silos'?

7. What opportunities for small and medium sized enterprises (SMEs) are there/should there be in the strategy? How can they be involved in its development and implementation?

8. Where should the funding come from to support the implementation of the strategy?

9. How do the devolved administrations and city regions fit into the strategy? Scotland has its own life sciences strategy, how will the two interact?

Significant progress has been made since the 2011 UK Life Sciences Strategy. This includes:

- **Investment in science & growth industries:** 100k genomes project, UK Biobank, The Francis Crick Institute.
- **Catapults:** Precision Medicine, Cell & Gene Therapy, Medicines Discovery, High Value Manufacturing
- **Academic Health Science Networks:** Established in 2013 to spread innovation at pace and scale
- **Test Beds:** real world sites for evaluating 'combinatorial' innovations

⁹ <https://www.gov.uk/government/publications/autumn-statement-2016-documents/autumn-statement-2016>

- Improving access for patients to innovative medicines, devices and diagnostics through the **Early Access to Medicines Scheme** and the **Accelerated Access Review**
- **R&D tax credits & Patent Box**
- **The Biomedical Catalyst** to target high growth companies (£250m grants awarded; a further £100m funding announced at Autumn Statement in 2016)
- Supporting local clusters, e.g. **Health North, £137m response to NIC's Oxford-Milton Keynes-Cambridge study recommendations**
- **Regional Growth Fund and Advanced Manufacturing Supply Chain Initiative funding awards of £91m in last Parliament**

The UK sector is strong and continues to grow, building on this progress: with over 5,100 companies, nearly 235,000 employees and £63.5 bn turnover in 2016.¹⁰ This compares to around 4,500 firms, employing 165,000 staff, with an annual turnover of over £50bn in 2011.¹¹ It also provides products which the NHS and over 65 million UK patients rely on every day. The UK is the leading destination in Europe for foreign direct investment in health and life sciences projects: more than £9bn of private sector inward investment in life sciences in the UK has been committed in the last 5 years, supporting 23,500 jobs. There were health and life science exports of £30.7bn in 2016, c.11.4% of UK manufacturing exports, compared to £25.8bn in 2014.

Industrial strategies of the past – and in other countries - have recognised that driving productivity growth is key to increasing prosperity. We want to develop on this approach with Life Sciences, building on strengths and targeting efforts to boost productivity, whilst also learning important lessons from what has gone before. Government has always looked to work closely with the UK's highly productive and world-leading sectors. In the context of increasingly mobile international investment and the UK's exit from the European Union, this partnership between the Government and the life sciences sector is more important than ever.

Sir John Bell's Life Sciences Industrial Strategy 2017

Sir John Bell's strategy¹² has been developed following extensive engagement with the sector, including with SMEs and the Devolved Administrations. The Strategy includes a specific section on SME support, growth and retention. It also outlines how the recommendations align with the work underway in the Devolved Administrations on their own Life Sciences Strategies and how the LSIS has been developed in a way that complements and builds on that activity.

The publication of the strategy on 30th August marked the start of negotiations on a Sector Deal between Government and the life sciences sector. Government is now working with Sir John and others in the sector to consider the strategy in more detail and specifically what action can be taken forward in partnership

¹⁰ <https://www.gov.uk/government/publications/bioscience-and-health-technology-database-annual-report-2016>

¹¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf

¹² <https://www.gov.uk/government/news/sir-john-bell-to-unveil-industry-led-proposals-to-build-uks-status-as-world-leader-in-life-sciences>

between Government and industry. As set out in the Green Paper, agreement of a sector deal is not necessarily about Government providing additional funding; rather it should involve the sector recommending actions to transform their sector and ways in which the Government can support this, for example by helping align government policies around a sector or ensuring existing sources of funding are used most effectively.

One example of this, demonstrating early progress on the sector deal, is the Industrial Challenge Strategy Fund announcement made by Greg Clark, Secretary of State for Business, Energy and Industrial Strategy at the launch of the LSIS on 30th August. In April 2017, **£197m was announced for cutting edge healthcare and medicines over 4 years** and at the LSIS launch, Greg Clark set out how a portion of this fund would be targeted at five major projects across three priority areas for LSIS, including innovation in medicines manufacturing, vaccines development and manufacturing, and advanced therapies treatment centres. Beyond this, it would not be appropriate to prejudge the outcome of sector deal discussions.

Once agreed, the sector deal will include an implementation plan, with metrics, governance and oversight arrangements to ensure that success can be measured against objectives.

NHS procurement and collaboration

10. How can public procurement, in particular by the NHS, be an effective stimulus for innovation in the Life Sciences Sector? Can it help support emerging businesses in the Life Sciences sector? (from NHSE)

Public procurement has significant potential to stimulate the life sciences sector. The NHS uses a range of public procurement models underpinned by frameworks to buy healthcare products and services. Organisations like NHS Supply Chain, Crown Commercial Services, regional procurement hubs and G-Cloud operate frameworks on behalf of the public sector. These frameworks allow products and services to be bought on a national scale and deliver greater value for money for the NHS. There are however some significant challenges faced by innovative life sciences technologies when engaging with public procurement frameworks:

1. Frameworks are often driven on reducing cost in the short term rather than looking at the longer view. Innovative healthcare products and solutions are often more expensive in the short term than their incumbent meaning they fail the affordability test.
2. Frameworks by their nature are locked down, in some cases for up to 5 years making the introduction of new innovation difficult. This can be a major challenge to new companies who are essentially locked out of the market for the duration of the framework.
3. New products and solutions are often hampered by the fact that they may be the only solution or provider on the market. This places additional procurement challenges, for example if the value is over the OJUE threshold a full tender is required even if there is no viable competition.

This can be time consuming and costly presenting another barrier to the uptake of a new innovation.

Public procurement can provide an effective stimulus to the market but more work needs to be done to make processes more flexible and amenable to new innovation. NHS England and Department of health are looking at how central procurement can be improved to speed up the adoption of new innovations linked to tariff. On a national scale Cabinet Office is developing the Future Operating Model (FOM) which will supersede many existing healthcare framework providers. The intention of the FOM is to move away from short term unit cost to look at system wide efficiencies and savings.

11. How can the recommendations of the Accelerated Access Review be taken forward alongside the strategy? Will the recent changes to the NHS England approval process for drugs have a positive or negative effect on the availability of new and innovative treatments in the NHS? How can quick access to new treatments and the need to provide value for money be reconciled? (from NHSE)

Lord O'Shaughnessy has indicated that government sees the Accelerated Access Review (AAR) as a key step in delivering the strategy. In responding to the AAR, government and its partners will set out plans for implementation. As a first step, government recently announced up to £86m to support innovators and the NHS in overcoming barriers to getting new, innovative technologies to patients.

NICE and NHS England recently consulted on, and implemented, changes to the NICE technology appraisal process which aim to provide quicker access for patients to the most cost-effective new treatments (through the introduction of a new 'Fast Track Appraisal'); more flexibility in the adoption of technologies into the NHS which are cost effective but have a high budget impact (through the introduction of the 'Budget Impact Test'); and greater clarity for patients and companies about the level at which treatments for very rare conditions will receive automatic funding (through the introduction of a clear funding level for the Highly Specialised Technologies programme).

These changes address, in part, the challenge of introducing new products more quickly into the NHS, while maintaining a rigorous assessment of a treatment's clinical and cost-effectiveness, and providing an opportunity to trigger commercial discussions for those products likely to pose a significant affordability challenge to the NHS.

12. How can collaboration between researchers and the NHS be improved, particularly in light of increased fiscal pressures in the NHS? Will the NHS England research plan help in this regard? How can the ability of the NHS to contribute to the development of and adopting new technology be improved? (from NIHR)

In 2005 the Department of Health's health research strategy, 'Best Research for Best Health', set the course for the creation of the NIHR with its vision 'to improve the health and wealth of the nation through research'; integrating a health research system into the health care delivery system so that the two would become interdependent and synergistic. Since it was established, the

NIHR has transformed health research in the UK. It has increased the volume of applied health research for the benefit of patients and the public, developed and supported the people who conduct and contribute to applied health research, and driven faster translation of basic science discoveries into tangible benefits for patients and the economy. NIHR has a strong focus on collaboration, mandating partnership directly through its research infrastructure funding schemes: whether this be single NHS/University partnerships for the NIHR Biomedical Research Centres or multiple partners with the NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) which are hosted by a single NHS organisation, acting on behalf of a collaboration of local providers of NHS services and NHS commissioners, a University(ies), other relevant local organisations.

NHS England's research plan outlines a number of commitments to foster collaboration between researchers and the NHS by improving the NHS's ability to facilitate research and supporting the recruitment of patients into trials. The Department of Health is working with NHS England to encourage closer collaboration between the NIHR infrastructure and the wider NHS innovation landscape, including Academic Health Science Networks (AHSNs) sponsored by NHS England.

The Department of Health has designated a number of Academic Health Science Centres (AHSCs) which are partnerships of NHS providers / Universities that bring together world-class medical research, education and patient care in order to speed up the translation of new developments in research into benefits for patients. The Centres play an important role in driving economic growth through partnerships with industry, including life sciences companies.

Responsibility and accountability (Qs 13-15)

13. Who should take responsibility for the implementation of the Life Sciences Industrial Strategy and to whom should they be accountable? What should the UK Government's role be? What should the role of the academic, charitable and business sectors be?

14. What is the role of companies within the sector, particularly the large pharmaceutical companies, in the implementation of the strategy? How are they accountable for its success?

15. Does the Government have the right structures in place to support the life science sector? Is the Office of Life Sciences effective? Should the Government appoint a dedicated Life Sciences Minister? If so, should that Minister have UK-wide or England-only responsibilities?

Once agreed, the sector deal will be underpinned by an implementation plan, with metrics, governance and oversight arrangements to ensure that success can be measured against its objectives.

It will be important to ensure that the governance arrangements are appropriately representative of the sector, bringing in organisations from pharma, med tech and digital, representing large and small companies, and charities, working closely with Government and NHS representatives. The

implementation plan will need to include a clear set of milestones with timescales and stretching success metrics with owners, who are held accountable for their delivery.

As outlined above, the life sciences industry is critical both to the UK economy and to UK health. The Office for Life Sciences was established as a joint unit between the Department for Business and the Department of Health to recognise this dual focus and to ensure the life sciences sector is appropriately supported and prioritised across both departmental portfolios. OLS's mission therefore is to "Maximise the UK's strengths in science and research to support the development and adoption of 21st century health and life sciences technology, delivering the best health and care outcomes and increasing wider growth and efficiency."

Brexit

16. What impact will Brexit have on the Life Sciences sector? Will the strategy help the sector to mitigate the risks and take advantage of the opportunities of Brexit?

The EU and UK has long benefitted from shared collaboration across the life sciences sector and as we leave we want to continue to build on the success we have already achieved in research and innovation.

We recognise the importance of a close cooperative relationship between the UK and EU in the life sciences field. As we leave, we intend for this to form a key part of our special partnership with the EU for the benefit of citizens, business and patients in both the UK and EU. Maintaining this close relationship will enable us to achieve our ambitions and improve healthcare for our citizens across the UK and Europe.

Our absolute priority for life sciences during the negotiations is the safety of patients and making sure they have access to the best public health protection. Our aims are ensuring the continuation of safe and effective regulation, research funding and ongoing collaboration with the EU.

17. How should the regulatory framework be changed or improved after Brexit to support the sector?

The Secretary of State for Health and the Secretary of State for Business, Energy and Industrial Strategy have made a clear, public statement of the Government's desire to retain a close working partnership in respect of medicines regulation after the UK leaves the EU.

In this context, the UK would like to find a way to continue to collaborate with the European regulatory framework. We start from the position of having an aligned regulatory partnership and any changes should consider the interests of and the impact on patient and public health. We want to make sure patients in the UK and the EU continue to get rapid access to new and innovative medicines and devices and that the quality, safety and efficacy of those medicines and devices are maintained.

18. To what extent should the UK remain involved with and contribute to agencies such as the EMA post Brexit?

The MHRA has over 30 years of knowledge as lead regulator on over 3,500 medicines on the EU market and currently leads between 20% and 35% of the EMA's licensing and vigilance work. Its expertise in licensing, devices, inspections, batch release and pharmacovigilance is globally recognised and respected. We want to ensure this expertise and our shared experience continues to benefit UK and EU patients. As the Prime Minister has stated, we will put forward proposals for deep, broad and dynamic co-operation. The Secretary of State for Health and Business, Energy and Industrial Strategy have made a clear, public statement of the Government's desire to retain a close working partnership in respect of medicines regulation after the UK leaves the EU. In this context, the UK would like to find a way to continue to collaborate with the European regulatory framework, in the interests of public health and safety.

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