BIA submission:
Priorities for Budget 2020

January 2020

UK BioIndustry Association

Summary

The UK is in a position to lead the world into a new age of technological advances, from gene-editing therapies that could permanently cure disease to genetically modified bacteria that could rid the world of plastic waste. The Government's focus on R&D and the life sciences sector can deliver these public benefits and build a self-sustaining innovation-based economy by harnessing our competitive advantages with smart policy decisions in the upcoming Budget.

The BIA and our members stand ready to work with the new Government to unleash the UK's research and innovation ecosystem and strengthen the business environment to allow entrepreneurs and innovative SMEs thrive. Under this government, the life sciences sector can drive a decade of renewal.

The Government has proven and effective policy levers ready at its disposal to maintain the pipeline of bioscience innovation and show positive progress is being made in building an innovation-led economy. While new R&D programmes and structures are created, programmes like the Biomedical Catalyst can be re-funded and immediately announced and deployed, and then evolved over time to meet the Government's priorities. Evidence shows this sector-specific scheme results in UK-based economic activity within year, and significant science and business progression within three years[1].

The Budget also provides an opportunity to reassure the UK's biotech SME community that a damaging R&D tax credit cap proposed by the previous government that would fundamentally undermine the sector will not be introduced or, if it is, amended to avoid impacting genuine companies. A wider review of R&D tax credits should allow the Government to bring forward positive and welcome updates to the scheme, as outlined in the Conservative manifesto, to ensure it better matches scientific research in the 21st Century. With other pro-innovation measures such as the UK Patent Box, the tax regime is a positive force for attracting global investment into early-stage and scaling companies.

As the UK life sciences SME sector matures, scale-up capital is becoming more critical, and a lack of it is holding back growth and global expansion. The Conservative's announcement of a £200m life sciences scale-up fund prior to the General Election was a welcome measure to address this and should be confirmed and preferably made more ambitious to ensure the British Business Bank can effectively address the scale-up challenge.

A strong research and innovation base and a scaling life sciences industry presents a real opportunity for the UK to capture value through a new high-value manufacturing industry. Strategic investments are needed now to secure UK capabilities in viral vector manufacture and attract inward investment in medicines manufacturing facilities. The BIA developed and supports the proposals submitted by the Medicines Manufacturing Industry Partnership (MMIP) to deliver this.

World-leading life sciences R&D needs to be supported by a world-leading regulator and rapid patient access to innovative medicines. The UK's influential and progressive regulatory expertise is a unique and

[1] IPSOS Mori (2019), *Biomedical Catalyst impact evaluation*: https://www.gov.uk/government/publications/biomedical-catalyst-impact-evaluation

powerful asset for securing the UK's position in the global life sciences industry, which can be cost-effectively achieved through modest funding for new functions of the MHRA targeted to enable academia and SMEs to get free access to advice and regulatory information from the MHRA .

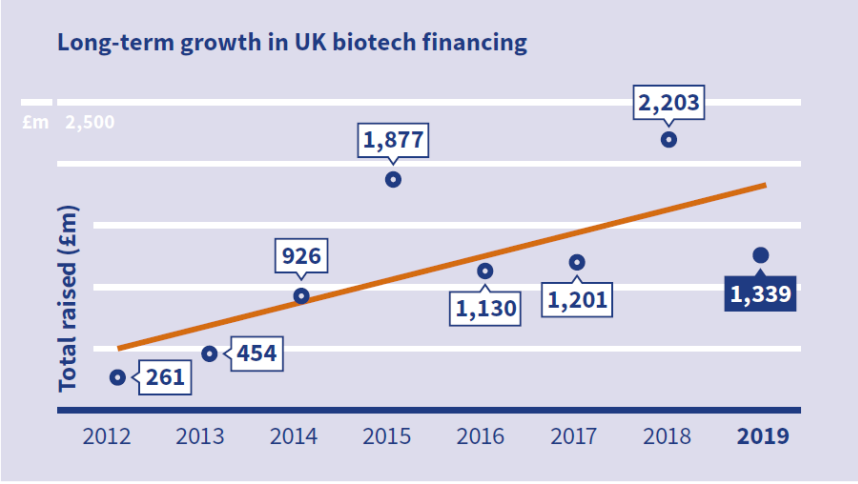
To fully deliver on its objectives, the Early Access to Medicines Scheme (EAMS), must include a reimbursement package so that there is not a financial disincentive for involvement; this is particularly important for SMEs that do not have existing revenues. The Government should commit to improving EAMS through offering a minimal-bureaucracy and rapid reimbursement package for companies taking part in the scheme.

In summary, the BIA urges the Government to use this Budget to:

- Rapidly re-fund and deploy the Biomedical Catalyst to maintain the pipeline of bioscience innovation
- Commit to work with the innovative life sciences industry to unleash British science
- Ensure SMEs are protected and supported through R&D tax credit reforms
- Commit to and expand the £200m life sciences scale-up fund
- Establish the UK as a location for the next generation of medicines manufacturing
- Ensure UK SMEs can make full use of the UK's influential and progressive regulatory expertise through funding new functions of the MHRA
- Reimburse medicines taking part in the Early Access to Medicines Scheme

Introduction

The UK is globally recognised as a world leader in the life sciences. The size and success of the UK life sciences cluster is second only to the Boston and San Francisco Bay Area clusters in the United States. In 2019, UK biotech SMEs raised £1.3bn in equity finance[2], an increase of over 400% from 2012 when the Conservative-led Government published the first strategy for UK life sciences and launched the Biomedical Catalyst. UK companies account for a quarter of all biotech venture capital investments in Europe. However, this was a fall of 40% in 2018 and, as the graph below shows, 2019 could potentially signal a plateauing or even the start of a decline.



[2] BIA and Informa Pharma Intelligence (2020), *Global and growing: UK biotech financing in 2019*: https://www.bioindustry.org/resource-listing/global-and-growing---uk-biotech-financing-in-2019.html

The UK life sciences sector invests more in R&D than any other, £4.5 billion in 2018[3] and has two-thirds of its employment outside London and the South East[4]. The North West is the third most concentrated area for life sciences jobs. Pioneering efforts by Eli Lilly in the early 80s resulted in large scale production of recombinant insulin and human growth hormone there, and the past decade has witnessed significant investments, including Allergan's Biologics R&D Centre of Excellence. Elsewhere, Ipsen manufactures Botox in Wrexham and Fujifilm Diosynth Biotechnologies manufacture complex biological molecules in Stockton-on-Tees. Our sector's heritage shows that when done well, investments in bioscience can deliver long-term prosperity in local regions and play a key role in narrowing the productivity gap.

The BIA and our sector are grateful for the sustained support it has received from Conservative governments, most notably through the Life Sciences Sector Deals as part of the Industrial Strategy, and the Patient Capital Review. Sector-specific Innovate UK grant funding has proven an effective mechanism for supporting innovation in businesses, especially the Biomedical Catalyst and the Industrial Strategy Challenge Fund. Enterprise Investment Scheme (EIS) and Venture Capital Trust (VCT) changes are having an impact on venture capital (VC) investment; the government should remain open to further improvements. The expected review of Entrepreneurs' Relief must involve extensive public consultation and be careful to not impact extremely important Enterprise Management Incentive (EMI) share options, which most biotech start-ups and SMEs find essential for attracting and retaining employees at all levels.

The creation of the £2.5bn British Patient Capital fund and the fund of funds programme within the British Business Bank also holds great potential to invigorate the UK's VC market. In addition, the Government's commitment to address the barriers to pension funds investing patient capital to support the UK's innovative SME community is welcome and requires continued focus. With £2.2 trillion under management[5], UK pension funds are well placed to be significant patient investors in UK innovation. Finally, the announcement of the Innovative Medicines Fund in the Conservative manifesto shows that the Government is committed to ensuring NHS patients benefit from the latest medical innovations.

The rest of this submission is focused on the key policies that could be announced at the upcoming Budget to support the life sciences sector and strengthen the business environment for entrepreneurs and SMEs.

Policies to strengthen the business environment

To enable the life sciences sector to increase its R&D investment further, develop new technologies faster and create more jobs across the country, the Government must create a business and innovation-friendly environment. Budget 2020 will be a key opportunity to do this and enable the sector to increase its global competitive advantage. In this submission we set out five key priorities for the life sciences sector that could be implemented at the Budget:

- Rapidly re-fund and deploy the Biomedical Catalyst to maintain the pipeline of bioscience innovation
- Commit to work with the innovative life sciences industry to unleash Britain's scientific potential
- Ensure SMEs are protected and supported through R&D tax credit reforms
- Commit to and expand the £200m life sciences scale-up fund

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3 Office for National Statistics (2019), *Business enterprise research and development, UK: 2018*: https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment/2018#pharmaceuticals-remains-the-largest-product-group-performing-rd [Note the figure given is for the pharmaceutical sector and does not capture all areas of life sciences R&D]

4 DHSC and BEIS (2019), *Bioscience and health technology sector statistics 2018*: https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2018

5 OECD (2018), *Pension funds in figures:* http://www.oecd.org/daf/fin/private-pensions/Pension-Funds-in-Figures-2018.pdf

- Ensure UK SMEs can make full use of the UK's influential and progressive regulatory expertise through funding new functions of the MHRA
- Reimburse medicines taking part in the Early Access to Medicines Scheme

Rapidly re-fund and deploy the Biomedical Catalyst to maintain the pipeline of bioscience innovation

The Government has rightly said it will prioritise investment in industries of the future where the UK can take a commanding lead, such as life sciences[6]. Sector-specific funding streams provide long-term consistency and assurance to researchers and investors that the Government is committed to delivering targeted support for the sector, that funding will be available to their company in the future, and that the grant application will be reviewed by industry experts.

Many British bioscience SMEs benefit from the Biomedical Catalyst, a competitive grant funding programme run by Innovate UK. In 2019, an independent analysis from IPSOS Mori[7], commissioned by Innovate UK and the Medical Research Council (MRC), showed that the Biomedical Catalyst generates £4.72 in public and business value for every £1 invested by government. The study also showed that the programme leverages over £5 of private investment per £1 of public expenditure. As such, the programme outperforms other public funding programmes, which on average leverage £1.40 of private investment from every public £1.[8] The Biomedical Catalyst therefore provides the new Government with a ready-made vehicle for rapid and efficient investment in life sciences to demonstrate its support for the sector from the outset.

Key statistics on the Biomedical Catalyst:

- Companies in receipt of Biomedical Catalyst grants increased their R&D investment by 93%, which will help the Government reach its target of raising UK R&D investment to at least 2.4% of GDP by 2027.
- Grants increased employment in companies by 11-15% over 3-5 years, equivalent to creation of up to 330 jobs.
- The 150 companies funded by the Biomedical Catalyst raised as much as £710m in additional VC after receiving the grant. This suggests the grants leveraged £3.99 to £5.09 private investment per £1 of public grant.

The programme was last refilled in 2016 with £100m, which has now been fully committed, meaning no further projects will be funded until the Government commits new funding. This will create a chasm in the bioscience innovation pathway and R&D investment, which will hamper both the Government's ambition to make the UK a global hub for life sciences and reach its 2.4% target. The Biomedical Catalyst can be re-funded, announced and deployed rapidly to avoid this, and reformed over time to meet government priorities as it develops its R&D funding plans. Its branding could also be updated if a fresh vision needs to be communicated; it is the sector-specific nature of the programme, not its name, that is key to its success.

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6 UK Government (2019), The Queen's Speech 2019: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/853886/Queen_s_Speech_December_2019_-_background_briefing_notes.pdf

7 IPSOS Mori (2019), *Biomedical Catalyst impact evaluation*: https://www.gov.uk/government/publications/biomedical-catalyst-impact-evaluation

8 HM Government (2019), 'Queen's Speech 2019: background briefing notes': https://www.gov.uk/government/publications/queens-speech-2019-background-briefing-notes

As part of this, UKRI's Budget must be renewed with a real-terms increase to ensure the continuity of the funding ecosystem.

Commit to work with the innovative life sciences industry to unleash Britain's scientific potential

The current strength of the UK's life sciences sector is the result of a continuous and supportive industrial strategy delivered by successive governments. However, the world does not stand still, and neither should research and innovation policy. The Government's commitment to the fastest ever increase in public R&D spending and to developing new R&D funding plans therefore represents a new and welcome approach to investing in science and innovation. The BIA stands ready to work with the Government to unleash the UK research and innovation ecosystem.

This will involve establishing new funding programmes and evolving existing ones. We have consulted widely and taken a whole-system approach to develop recommendations to ensure new initiatives effectively support entrepreneurs and companies at the cutting edge of research and innovation[9]. The programmes and agencies should:

1. **Balance responsive and challenge-led programmes** - to allow all types of innovation to thrive
2. **Sector-specific** - to provide long-term consistency and assurance to researchers and investors
3. **Grants, not loans** - to ensure it pays to start and grow innovative companies
4. **Maintain a variety of funding streams** - to support the varied needs of life science SMEs
5. **Unbureaucratic and informed by the needs of the sector** - to ensure SMEs are consulted, the right areas are funded, and the best use of scientists' time

These principles can provide a framework for system change driven by the academic and industrial research community in collaboration with government to develop a new approach to investing in research and innovation. The sector enjoys the existing Life Sciences Council as a formal arena for industry-government dialogue. The Council should be fully engaged and have a formal role in the evolution of the UK's overarching research and innovation policy.

Ensure SMEs are protected and supported through R&D tax credit reforms

The UK's tax system is globally competitive and encourages entrepreneurs to start and grow companies. In particular, R&D tax credits attract global investments and support innovative SMEs. However, as the way R&D is conducted in the 21st Century continues to evolve, so too must the tax regime to remain relevant and supportive to innovators.

Former Chancellor Philip Hammond proposed amending the SME tax credit scheme to make it more restrictive by linking payments to payroll size. Although targeted at preventing abuse by foreign companies, this proposal could fundamentally undermine the UK's biotech SME sector because many companies use a business model involving outsourcing R&D to reduce capital risk. Biotech companies in the UK and around the world have evolved a lean and efficient business model, which utilises a network of specialist companies, complemented by universities and hospitals, each contributing to a specific part of the R&D process. This 'virtual biotech' model has evolved to manage the risk associated with biotech R&D programmes but is also more efficient than the traditional 'large pharma' R&D model and creates more

[9] BIA (2019), *UK life sciences: Catalysing investment and growth*: https://www.bioindustry.org/resource-listing/uk-life-sciences---catalysing-investment-and-growth.html

stable employment in UK regions. It is vital for the future of the sector that the Government ensures that anti-abuse measures, such as the PAYE cap proposed by the previous Government, do not impact genuine SMEs and harm the growth of the life sciences sector. This can be achieved through a suitable test, based on intellectual property management and group structures, to identify non-fraudulent companies and exempt them from the cap.

We welcome new Conservative Party manifesto commitment to increase the R&D Expenditure Credit rate and to review and expand the tax credit scheme. This review is an opportunity to update the scheme so that core R&D activities including data generation and acquisition (including specifically for life sciences the Clinical Study Reports of clinical trials), analysis and storage costs are included in eligible costs. This would also send a clear global message that the UK is open for business and committed to maintaining its globally competitive tax system.

Going further to include a 'facilities credit' – allowing claims on capital R&D investment – will encourage the UK's innovative industries to invest in the equipment and buildings required to capture the full benefits of our world-leading science base. Currently, the R&D Allowances only benefit profit-making companies, and thus are an ineffective incentive for most life science businesses in the UK that are in the R&D phase and pre-revenue. In our sector, this facilities credit would drive greater investment, and anchor clinical and then commercial manufacture in the UK, delivering jobs and exports for years to come. Companies could surrender tax losses to claim this tax credit to reduce the cost to the exchequer.

Commit to and expand the life sciences scale-up fund

As the UK life sciences SME sector matures, scale-up capital is becoming more critical, and a lack of it is holding back growth and global expansion. UK companies are increasingly looking to the US public markets for capital or being sold to larger business before their full potential can be captured, adding a further pull to move operations across the Atlantic, to the possible detriment of the UK science base.

The Conservative's announcement of a £200m life sciences scale-up fund prior to the General Election was a welcome measure to address this. Crucially, it could provide the British Patient Capital fund with the in-house expertise to expedite investment in the life sciences sector.

The commitment should be confirmed at the Budget and preferably made more ambitious to ensure the British Business Bank can effectively address the scale-up challenge in the life sciences. We anticipate that a £1bn+ fund is required to provide the scale to support companies as they grow and meet demand in the short to medium-term. Greater life sciences expertise is also required within the Bank, and a focussed mission on actively addressing the deficiencies in the UK private and public equity finance ecosystem.

Establish the UK as a location for the next generation of medicines manufacturing

New classes of medicines, including cell and gene therapies, have emerged in recent years, transforming outcomes for patients. The UK has already played a major role in the development of these advances; there are 70 companies developing such therapies in the UK with 25 manufacturing sites and already three unicorn companies[10]. The BIA, working through Medicines Manufacturing Industry Partnership (MMIP), has

[10] BIA and Alliance for Regenerative Medicine (2019), *Leading innovation: the UK's ATMP landscape*: https://www.bioindustry.org/resource-listing/leading-innovation.html

developed a suite of policies to capture the full value of advanced therapies for the UK economy. These address a number of key issues.

Skills - The UK will require a highly trained workforce developed through technical apprenticeships, university degrees and cross sector training courses. Following a recommendation in the MMIP Advanced Therapies Manufacturing Taskforce, Cell and Gene Therapy Catapult has recently presented Government a comprehensive programme of training initiatives, validated by industry, to address the skills gap over the term of this parliament totalling over £80m. The BIA supports this measure. By establishing new apprenticeship courses, specialist training facilities and industry-informed degree courses, the Government can ensure the next wave of medicines manufacturing benefits people across the UK through well-paid and rewarding jobs. The existing clusters of life sciences economic activity in the North West and North East shows that this investment would contribute to the regeneration of towns in those regions.

Highly specialised components - There is a global shortage of the key components used in the manufacture and delivery of gene therapies, notably viral vectors. This is most acutely impacting early-stage clinical trials and is holding back the rate at which research can be translated into clinical and financial value. Worse still, in order to fulfil the viral vector manufacturing requirements, promising UK research, largely funded by the UK taxpayer, is being forced to seek supply from outside of the UK. Not only is public investment therefore being used to support economic growth overseas but, once offshored, larger scale commercial manufacturing contracts associated with later phases of development seldom return to the UK. The BIA therefore supports the business case developed by the industry and academia to setup three funding streams over a three-year period (2020-2023) totalling over £50m to establish this capability in the UK. With support there is the realistic prospect of major new modern medicines manufacturing being built in the next two years outside London and the South East. If this support is not delivered in this Budget, this opportunity will be lost to the US.

Investment incentives - The production of the next generation of medicines presents a real opportunity for the UK to capture value through a new high-value manufacturing industry. The BIA continues to support the recommendation in the Life Sciences Industrial Strategy that the UK should set a target of attracting ten large (£50-250m) and ten smaller (£10-50m) commercial-scale manufacturing facilities in the next five years. MMIP recommends the Government establishes a capital finance grants programme to achieve this target. Grants would increase the international competitiveness of the UK to leverage private capital investments. The programme would support 10-15% of the total capital investment, meaning a programme fund size of £60-90m could achieve the lower-ambition range of securing ten £50m and ten £10m private investments in facilities, and £300-450m could achieve the high-ambition range of ten £250m and ten £50m investments. The grants should be available to domestic and foreign companies looking to invest in the UK.

Ensure UK SMEs can make full use of the UK's influential and progressive regulatory expertise

We fully support the aim of the Medicines and Medical Devices Bill outlined in the Queen's Speech to "ensure that the UK remains at the forefront of the global life sciences industry after Brexit, giving patients faster access to innovative medicines and supporting the growth of the domestic sector".

The Medicines and Healthcare products Regulatory Agency (MHRA) is recognised globally for its expertise, and the UK's robust, supportive and innovative regulatory environment is seen as a major draw for global life sciences businesses. As the UK leaves the EU, the MHRA is facing new challenges, not least the loss of funding from the European Medicines Agency (EMA), which the Government has already recognised

through additional funding, which we welcome. As a key player in the EMA system, the MHRA was able to fund its expertise from industry fees. Its funding model will need to change and if the UK is to remain competitive it will need to continue to offer service to SMEs on at least as good terms as the EMA and FDA, so may need further Treasury support.

The Medicines and Medical Devices Bill is an opportunity for the Government to ensure the MHRA has the capability to maintain its influential and progressive voice at the global regulatory level after Brexit and build its capacity to support healthcare innovation in the UK. This will require initiatives across the range of MHRA activities, but for drug discovery and development, should include funding:

- To enable the MHRA to maintain its expert capacity through the transitionary years and invest in the future through, for example, PhD apprentice places
- To enable the MHRA's Innovation Office to maintain its capability without this resulting in additional fees to SMEs, and to allow its work to be expanded to cover influencing of global standards work
- For the MHRA to have a fund to enable it to participate fully in global regulatory events and projects to maintain its leading position and voice

We remain committed to working with the Government as the Bill progresses through Parliament to ensure that it enables the MHRA to continue to be an integral part of the UK's world-leading life sciences sector.

Reimburse medicines taking part in the Early Access to Medicines Scheme

The Early Access to Medicines Scheme (EAMS) was introduced as part of the UK Strategy for Life Sciences to "increase the speed and efficiency of routes to market approval for innovative, breakthrough therapies"[11] Making it a success is key to ensuring the UK's regulatory and licensing system remains internationally competitive and capable of bettering alternative offerings available, particularly in France, Germany and emerging in other markets.

However, since its launch, the benefits of the scheme have not convincingly outweighed the risks and costs of participating for many decision makers in the life sciences industry when deciding where to test and launch an innovative new treatment. This has stymied the scheme, meaning it has not delivered on its full potential. It must be a "no brainer" in the minds of global executives when presented with the case of whether to risk an asset into a scheme in the UK.

To fully deliver on its objectives, EAMS must include a reimbursement package so that there is not a financial disincentive for involvement; this is particularly important for SMEs that do not have existing revenues. The Government should commit to improving EAMS through offering a minimal-bureaucracy and rapid reimbursement package for companies taking part in the scheme.

[11] Department for Business Innovation and Skills (2011), *Strategy for UK Life Sciences*: https://goo.gl/cmE2Da

About the BIA

The BIA is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

Our members include:

- Start-ups, biotechnology and innovative life science companies
- Pharmaceutical and technological companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, IP consultants, IR agencies

We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

For any further information on the contents of this submission please contact Dr Martin Turner, Head of Policy and Public Affairs, by emailing mturner@bioindustry.org