

BIA submission: Priorities for the Autumn Budget September 2018



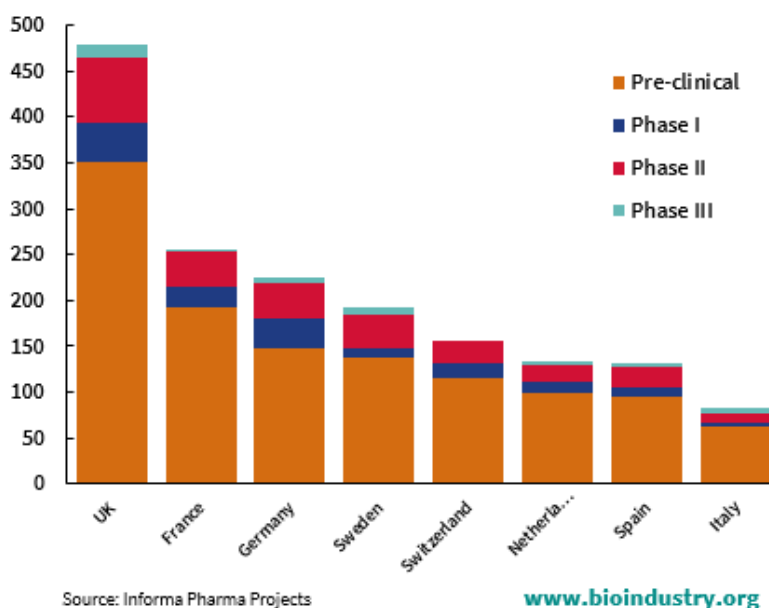
Key points

- Reaching the government's stated target of spending 2.4% of GDP on R&D, raising productivity, and making the UK the best place in world to do business requires an ambitious fiscal policy. The challenges of Brexit add further urgency and importance to this agenda
- The government is making welcome progress with a number of recent initiatives, which have strong support from the life sciences sector, including:
 - Sector specific Innovate UK grant funding, which is a proven effective mechanism for supporting innovation in businesses, especially the Biomedical Catalyst
 - EIS/VCT changes are having impact on VC investment, changes will need to bed in but the government should remain open to further improvements
 - The creation of British Patient Capital and the fund of funds programme within the British Business Bank holds great potential to invigorate the UK's VC market
 - 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
- The BIA proposes the following fiscal policies to strengthen the business environment in the UK to support the government's and sector's shared aims:
 1. Allow pre-revenue SMEs to surrender R&D Allowance losses arising on capital expenditure for up-front cash credits to promote investment in R&D facilities to anchor clinical manufacture in the UK and address the competitive advantage offered by other territories such as Ireland and Singapore
 2. Provide grants for manufacturing investments to allow the government to target tax-payers' money to create jobs in line with the industrial strategy and "place" agenda
 3. Address failures in the R&D Tax Credits to better reflect 21st Century life sciences R&D, notably the purchase of data for R&D purposes
 4. Update the HMRC list of eligible foreign institutions for R&D Expenditure Credits to underscore the government's commitment to global collaboration
- Start-ups and SMEs are sometimes unable to offer competitive salaries – relative to more established companies – to attract individuals with the right skills. The BIA would welcome a HM Treasury-led review of this issue to identify what fiscal policy levers the government has available to it to support smaller early-stage companies.

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. As shown in figure 1, the UK far outpaces other European countries for the number of products in clinical and pre-clinical development and is well positioned to benefit from the next wave of innovative new treatments if the business environment is optimal.

Figure 1. Products at each stage of development, 2017



An independent analysis by PwC estimated that the sector contributed £30.4 billion to the economy in 2015 and supported 482,000 jobs¹. The sector sustains high-quality jobs across the UK, with two-thirds outside London and the South East², and its workers are twice as productive as the UK average³. Furthermore, the sector invests more in R&D than any other in the UK (£4.1 billion in 2016⁴). Beyond the benefits of better health outcomes for patients, improved living standards, and rewarding high-value jobs spread across the UK, this competitive advantage can support long-term sustainable economic growth across the whole country and help reach the government's target of 2.4% of the UK's GDP being invested in R&D by 2027.

The BIA and our sector is grateful for the sustained support it has received from the government, most notably through the Life Sciences Sector Deal 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 Industrial Strategy Challenge Fund. EIS and VCT changes are having an impact on venture capital (VC) investment but the recent changes will need time to bed in; however, the government should remain open to further improvements. The creation of the

¹ PwC (2017), commissioned by ABPI, BIA, BIVDA and ABHI, *The economic contribution of the UK life sciences industry*: https://www.abpi.org.uk/media/1371/the_economic_contribution_of_the_uk_life_sciences_industry.pdf

² HM Government (2017), *Strength and opportunity 2017*: <https://www.gov.uk/government/publications/bioscience-and-health-technology-database-annual-report-2017>

³ PwC (2017), commissioned by ABPI, BIA, BIVDA and ABHI, *The economic contribution of the UK life sciences industry*: https://www.abpi.org.uk/media/1371/the_economic_contribution_of_the_uk_life_sciences_industry.pdf

⁴ Office for National Statistics (2017), *Business enterprise research and development, UK: 2016*: <https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment/2016> [Note the figure given is for the pharmaceutical sector and does not capture all areas of life sciences R&D]

£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. And 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 management⁵, UK pension funds are well placed to be significant patient investors in UK innovation.

Policies to strengthen the business environment for investment

The UK is in a strong position to capitalise on its strength in life sciences, but to capture the full economic value of our world-leading research base and innovation economy, the government must double-down on efforts to encourage businesses to start, grow, and manufacture in the UK. Fiscal policies are crucial to this and we urge the government to be ambitious and forward-thinking in the Autumn Budget, especially at this time, with Brexit creating significant challenges for industry.

The following policies have been developed by the BIA's Finance and Tax Advisory Committee in consultation with our wider membership to strengthen the UK's business environment at every stage of the value chain. Enacting these policies will send a strong signal to international investors and the domestic sector, helping to achieve our shared ambitions to raise R&D investment to 2.4% of GDP and to make the UK the best place in the world to start and grow a business.

Introduce cash credits for R&D Allowances to stimulate investment in new and innovative medicines manufacture

Despite being recognised as a leading cluster for life sciences R&D, the UK has been largely overlooked as a medicines manufacturing location. This is illustrated by the “second wave” of medicines: large molecule biopharmaceuticals (figure 2), which have seen the highest growth in the medicines sector in the past 20 years and transformed the pharmaceutical industry. The top ten prescribed biopharmaceuticals globally now have combined annual revenues in excess of £50bn. This represents a major manufacturing demand and value but, despite the UK having played a central role in the development of some of these products, none are made here. Manufacturing investments in the past 20 years have largely gone to Ireland, Singapore, Germany and the US where financial incentives and the necessary skills and infrastructure have been available.

The UK has a vibrant bioscience SME sector developing the third wave of medicines, most notably cell and gene therapies (figure 2). It also has the skills and infrastructure to compete for future manufacturing

Figure 2. The progression of medicines innovation



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

investments, but without action to present the most competitive fiscal offer, the UK risks missing out on the economic benefits of manufacturing the third wave.

During drug development, companies need to manufacture small quantities of product for use in the clinical trial stages of medicines R&D. Manufacturing for this R&D purpose is called clinical manufacture and requires significant investment in production equipment. Capital expenditure is currently not covered in the R&D tax relief or cash credit system. However, there is an existing regime of R&D allowances (RDAs) for capital equipment, which is applicable to investments to enable clinical manufacture. This allows 100% tax relief in the year of equipment acquisition but cannot be surrendered for a tax credit. As many UK SMEs are pre-revenue and have tax losses already, accelerated tax relief is of little benefit. The system is therefore in need of reform to incentivise SMEs to invest in new buildings and equipment, which will promote clinical manufacture in the UK but also have much wider benefits for UK innovation and productivity.

Our recommendation is to enhance RDA legislation to create a facility for a company to surrender RDA losses for a discounted cash credit in a similar way to ECAs for energy efficient assets. Crucially, as the measure is based on surrendering losses for an up-front payment, this measure will not have a negative net impact on the Exchequer, and would in fact have a positive impact on the overall economy by stimulating activity. This would be hugely beneficial to R&D-intensive SMEs and increase cash availability to support productivity-boosting investment. Critically, if companies establish clinical manufacture in the UK creating associated new patentable IP, know-how and expertise, it is significantly more likely that they will choose to invest in and locate commercial manufacture here once the product receives regulatory approval.

In our view, a rate of somewhere between 10p-15p/£ for surrendered losses would be sufficient to influence decision making. In order to control the cost of such a measure it could initially be subject to an annual cap, which could be adjusted once there is evidence of the policy working.

RDA credits would be elective and can be limited to SMEs (using the SME definition applied to R&D incentives) as we would not expect large enterprises without the critical need for cash to elect to surrender losses.

Introduce targeted grant awards to anchor commercial medicines manufacturing

Life science manufacturing is spread across the UK and is a significant opportunity for economic growth in regions outside the South East. Whilst much of the UK's life sciences R&D and headquarters are based in the South East, the sector's manufacturing activity is not so dependent on being in the immediate vicinity of the world-class research base found in the triangle, and investment is driven by other business factors such as skills availability, infrastructure and land value. However, the UK's regions are in competition with other countries keen to attract manufacturing.

Since the withdrawal of Industrial Building Allowances and the gradual reduction in capital allowances, the UK is not competitive in attracting investment in larger scale manufacturing. The BIA recognises the cost of reinstating these reliefs. However, in order to address this disadvantage, we propose a package of grants and/or loans to stimulate investment in medicines manufacturing and increase the international competitiveness of the UK for this activity.

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. At an intervention rate of 10-15%, the low-impact scenarios (10 £10m and 10 £50m investments) would need £60-90m public sector finance and the high-impact scenario (10 £250m and 10 £50m investments) would need £300-450m.

Update R&D tax credits to reflect 21st Century life sciences R&D

The small and large business R&D Tax Credit schemes are often cited by BIA members as the most valuable form of innovation support. Tax credits provide a minimal-bureaucracy system that rewards and amplifies companies' own investment in R&D. Continuing them and ensuring they function as intended is critical to maintaining the UK's attractive fiscal environment for R&D investment.

Governments around the world are keen to attract high-value, R&D-intensive industries to their shores. These businesses generate many spill-over effects, including down-stream manufacturing jobs, and the co-locating of regulatory, legal, and financial services. There is little room for complacency. The following enhancements would increase the incentives for R&D investment and align the scheme with the realities of conducting life sciences R&D in the 21st Century.

1. *Expenditure on health-related data*

A significant anomaly in the current rules for qualifying expenditure is in the acquisition of data, and in particular health-related data, which is increasingly as important in R&D as chemicals and clinical trial participants (both covered by tax incentives). Big data and its analysis is a key 'feedstock' for research in the sector and is central to the future of life sciences R&D. For example, by studying and linking genetic data, patients' health records and data collected through clinical trials, researchers can better understand disease and develop more effective treatments for sub-populations of patients. This is the principle behind the government's 100,000 Genomes Project, which is providing genetic data linked to health records to academic and industry researchers.

However, data acquisition costs are currently ineligible for R&D tax relief as it is not classed as either computer software nor consumables. The government should legislate to address this problem. The cost of this measure would be limited and well targeted as companies would have to clearly demonstrate the data was used only in R&D to solve scientific uncertainty, as opposed to market research or other commercial uses.

2. *Re-write of R&D Guidance Application to Pharmaceuticals CIRD81920⁶*

This guidance is outdated and could be helpfully enhanced to address the evolution of medical research to include the generation of real-world evidence to address scientific uncertainty and the role of regulatory and other scientific personnel in drug development. We recommend engagement with industry to ensure the revised guidance addresses key areas of uncertainty that are arising now that HMRC Pharmaceutical specialists are no longer reviewing R&D claims. This will lead to much needed clarity around potential areas of misinterpretation.

For example, drug R&D is a lengthy, complex and extremely costly process whose ultimate success depends on the quality and relevance of the clinical data generated to address the scientific uncertainty of whether an experimental treatment works or not. Defining, conducting and analysing suitable studies to address this question requires a highly experienced and qualified multidisciplinary project team, including a specialist in regulatory affairs. However, whilst costs associated with most roles within such a team are eligible for R&D tax credits, current HMRC practice is that expenditure on regulatory affairs is not. We do not believe this to be correct within the scope of the HMRC guidance *Application to Pharmaceuticals CIRD81920⁷* but recognise that an update to this document could resolve clarity issues. The BIA is currently

⁶ <https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird81960>

⁷ <https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird81920>

liaising with HMRC officials to address this and would welcome HM Treasury support to ensure the R&D tax credit system fully supports the whole of the life sciences R&D process.

The recognition of the regulatory role as a key player for R&D success will become even more important in a post-Brexit world where it will be very important for the UK to remain an attractive place for regulatory personnel to be located to support activities both in and outside the UK e.g. global regulatory filings. For a generation the UK has been the natural home for medicines regulatory work in Europe, but with the relocation of the European Medicines Agency from London to Amsterdam due to Brexit, there is a high likelihood that these activities will migrate with it. An R&D tax incentive to support retaining them in the UK would be timely and beneficial for UK Plc.

Update the HMRC RDEC list of eligible foreign institutions

International collaboration is critical to the UK's continued strength in life sciences; British SMEs work with hundreds of institutions around the world to develop IP that can be exploited in the UK to benefit our economy. Through the R&D Expenditure Credits scheme, SMEs can claim 12p for each £1 of expenditure on commissioned research at foreign institutions specified by Statutory Instrument through the powers conferred by section 1142(1)(e), (3) and (4) of the Corporation Tax Act 2009(a). The BIA has identified over 250 institutions with which our members collaborate that are not on the current list⁸. This provides a valuable opportunity for the UK to demonstrate its commitment to global collaboration in research and innovation. The Chancellor should use one of his most highly reported speeches of the year to underline his and the government's global outlook by committing to update this list.

Support start-ups and SMEs to hire top talent to drive growth

Start-ups and early-stage SMEs in the life sciences sector and beyond are often not able to offer salaries of a high-enough value to compete with more established companies when recruiting talent essential to their businesses. This problem is exacerbated by the increasing interdisciplinarity of R&D roles and the scarcity and high demand for individuals with mixed skill sets; a common one in the life sciences is pharmacology and computer programming, for example. Such people are critical to the growth of a wide range of innovative SMEs in the UK. As Brexit and anticipated changes to the UK's immigration regime pose a worrying threat to the availability of skills in the UK, this is an urgent economic issue.

HM Treasury should conduct a review to identify the extent of this issue and its potential impact on economic growth. It should seek to identify fiscal measures that will either reduce the costs for SMEs hiring R&D staff, allowing them to offer higher salaries, or improve the personal tax position of the employee making it more advantageous to work at an SME, for example.

⁸ <http://www.legislation.gov.uk/ukxi/2018/217/made>

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.

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