

## Submission to the R&D tax environment review

BioIndustry Association – February 2017

### Summary

- The UK's world-leading life sciences sector contributes more than **£60bn a year to GDP<sup>1</sup>**, and **generates exports worth £30bn and a trade surplus worth £3bn<sup>2</sup>**.
- **The R&D tax incentives system is a key feature of the UK's international offering for industries such as the life sciences. R&D Tax Credits, in particular, are viewed as a critical component of the Government's support for innovation.** There have been many welcome revisions to the system in recent years but there is further scope for enhancement. The BIA therefore welcomes this review as an opportunity to make the incentives even more competitive.
- **The BIA proposes the following enhancements to the current R&D tax incentives system:**
  - **Staff recruitment and training** should be included as qualifying expenditure under the SME tax credit scheme and R&D expenditure credit scheme. This would support UK businesses to acquire and maintain the essential human capital required for R&D and business growth in a globally-competitive environment.
  - **The creation, collection, acquisition and analysis of data** should be included as qualifying expenditure under the SME tax credit scheme and R&D expenditure credit scheme. Medical data is increasingly as important to R&D as chemicals and clinical trial participants, which are both covered by current tax incentives.
  - **The R&D Allowances scheme should provide SMEs with cash credits** to incentivise industry to invest in buildings and equipment. Currently, only tax relief is provided, which is of no use to loss-making SMEs.
  - **Expediting payment**, particularly through the use of digital systems, would significantly benefit the cash flows of businesses at minimal cost to the Exchequer.

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<sup>1</sup> Department for Business Innovation and Skills (2016), Press release: *Life science leaders say UK is better off in a reformed EU*: <https://goo.gl/R9Auzg>

<sup>2</sup> ONS Balance of Payments data (2015), provided by Office for Life Sciences in "Overview of the Life Sciences Sector", August 2016, p. 2.

## The UK has a competitive advantage in the life sciences

The UK is globally recognised as a world leader in the life sciences. Beyond the benefits of new and improved treatments for patients, this competitive advantage brings significant rewards to the UK economy. The sector contributes more than **£60 billion a year to GDP<sup>3</sup>, and generates exports worth £30 billion and a trade surplus worth £3 billion<sup>4</sup>**. It sustains high-quality jobs across the UK, with two thirds of the sector's 220,000 jobs being outside London and the South East, and life sciences manufacturing employees have the **highest Gross Value Added (GVA) of any high-technology sector** – over £330,000 per employee<sup>5</sup>. It is therefore key sector for driving productivity gains.

Although the UK life sciences sector is strong, some unique challenges set it apart from others in the economy, even other R&D-intensive industries. Medical research, development and licensing timelines are long – typically over 12 years – due to the need to extensively test products for human use through phased clinical trials<sup>6</sup>. The cost of development can also exceed £1bn. Many biotechnology companies are small, entrepreneurial firms without other assets on the market generating revenue during this period, meaning they must rely on successive fund-raising rounds to maintain cash flow. Due to the long-development timelines and the complexity of the science involved in biomedical R&D, the **early stages of drug development are considered high risk, which limits sources of finance typically to specialist investors and increases the necessity for Government support**. However, these biotech SMEs are the lifeblood of the sector, producing the medicines of tomorrow, growing into profitable companies and feeding innovation into the larger pharmaceutical and healthcare industries.

Bioscience companies based in the UK, whether they are SMEs or multinationals, make their commercial decisions from a global perspective. **As the UK prepares to leave the EU, delivery of an optimal tax environment for the bioscience and life sciences sector, and industry in general, is more important than ever**. The BIA therefore welcomes this review the tax environment for R&D to make the UK an even more competitive place to commercialise research and innovation and to grow successful businesses.

## Comments on the current R&D tax environment

**The R&D tax incentives system is a key component of the UK's international offering for industries such as the life sciences**. R&D tax credits, in particular, are a critical feature of the UK's fiscal support for innovation, helping to stimulate business investment in R&D and attract global companies to base their activities in the UK. **It is a minimal-bureaucracy system that rewards and amplifies companies' own investment in R&D** and provides valuable income in the form of cash credits for pre-revenue early-stage biotech SMEs.

As the precise research project that will lead to innovation can be difficult to predict, **R&D tax credits complement Government grant-based schemes, such as the successful Biomedical Catalyst, by providing universal support for R&D**. It is crucial to note that tax credits are particularly important for the survival of small companies with negative cash flows, as they provide a non-dilutive source of finance. We have provided a number of testimonials on the current tax incentives scheme from biotech companies in Annex 1.

<sup>3</sup> Department for Business Innovation and Skills (2016), Press release: *Life science leaders say UK is better off in a reformed EU*: <https://goo.gl/R9Auzg>

<sup>4</sup> ONS Balance of Payments data (2015), provided by Office for Life Sciences in "Overview of the Life Sciences Sector", August 2016, p. 2.

<sup>5</sup> Calculation performed by The Office of Health Economics. Data supplied from Office of National Statistics (ONS), Note: GVA per worker at industry level has been calculated by dividing industries' GVA at current prices (2013) by the number of workers. Number of jobs at industry level are available at: <https://goo.gl/xTHMWT> [accessed on August 31, 2016]

<sup>6</sup> The Association of the British Pharmaceutical Industry (2012), *Time to flourish – Inside innovation: the medicine development process*: <http://goo.gl/XLQDys>

The Government has made a number of changes to the R&D incentives regime in recent years which have been positively received by the life sciences sector and wider industry. For example, before 2011, many biotech SMEs were unable to benefit from R&D Tax Credits as payment was capped by PAYE/NI contributions and biotechs often employ only a small number of highly-skilled staff. The Advanced Assurance service was also a welcome addition as it helps businesses budget more confidently. There have also been successive improvements in the relief rate since 2010, which have given confidence to industry and investors alike that the system has strong political support, which in turn encourages greater confidence to invest in the UK.

## **Recommended enhancements for improving competitiveness**

Continuing and enhancing the R&D tax system 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. There is little room for complacency. Through consultation with our members, the BIA has identified the following areas for enhancement to improve the UK's competitiveness:

### **1. Staff recruitment and training costs**

In R&D-intensive businesses, having the right knowledge, experience, and skills in the workforce is essential to success. UK biotechnology companies operate at the forefront of global science and must continually develop their human capital to stay ahead. This means recruiting the best people in a global market and keeping their training up to date.

Although salaries, pensions and National Insurance contributions are qualifying R&D expenditure for tax credits, recruitment and training costs are not. This does not align with the needs of businesses nor the Government's policy of promoting businesses to invest in skills.

A change in the legislation is required to address this discrepancy and create the right incentives for companies to invest in their workforce. The qualifying expenditure should allow tax credits to be claimed for costs incurred as part of the recruitment process, such as recruitment agents and travel for interviews, and training, including but not limited to apprenticeships, Masters courses, and post-graduate training, Continuous Professional Development (CPD), and attendance at scientific conferences. To have maximum impact, the policy should cover the SME tax credit scheme and R&D expenditure credit scheme.

### **2. Expenditure on data**

A significant anomaly in the current rules for qualifying expenditure is the purchase of data, and in particular medical data, which is increasingly as important to R&D as chemicals and clinical trial participants (both covered by tax incentives). In order to maintain the incentive the scheme is intended to provide, and to align with other tax rules, we would like to make the case that creation, collection, acquisition and analysis of data is specifically included in the legislation as qualifying expenditure for R&D tax credit purposes.

Data, and the analysis of data, are central to scientific advancement (Annex 2). For example, in biotechnology, it can be used to detect potential faulty genes, identify drug targets, and test treatment efficiency, among a plethora of other uses. As techniques develop, and computer processing power improves, huge volumes of data can be generated in a very short time and so new ways of using the resultant data are being found. One key development in recent years is the advent of personalised medicine. This aims to ensure therapies are targeted to the individual patients' genetic make-up thereby maximising effectiveness. By its nature this requires significant

amounts of patient-level data which, being difficult to obtain, is a valuable asset for many businesses. It is for this reason that the Government established Genomics England in 2014 to make genetic data from the NHS available to researchers (Case study A in Annex 2).

The volume of data analysed in R&D has now reached a point where it is itself considered an essential and costly raw material of the research carried out. For example, we are aware of a UK SME that was unable to include in the claim expenditure on medical data from a European University of approximately €5 million. We view it as a significant anomaly that data and, more specifically, medical data, is not currently considered qualifying expenditure for R&D tax credit purposes and we believe a change in the legislation is required. To have maximum impact, the policy should cover the SME tax credit scheme and R&D expenditure credit scheme.

### **3. Cash credits for Research and Development Allowances (RDAs)**

Capital expenditure is currently not covered in the R&D tax relief or cash credit system. However, there is an existing regime of research and development allowances (RDAs) for capital equipment. This allows 100% tax relief in the year of acquisition but cannot be surrendered for a tax credit. As many UK SMEs have tax losses already, accelerated tax relief is of little benefit. The system is therefore in need of reform to incentivize SMEs to invest in new buildings and equipment, which will have benefits for UK innovation and productivity.

RDAs should be evolved to reflect the existing enhanced capital allowances for energy efficient assets (ECAs). This provides a cash credit for loss making companies of 19p/£. Such incentives would be hugely beneficial to R&D-intensive SMEs and increase cash availability to support scaling businesses. This enhancement has also been proposed by the Medicines Manufacturing Industry Partnership (MMIP), which the BIA is a member of. We agree with the MMIP that this is a measure that would build on the UK's competitive advantage and expertise in the research and development of treatments, helping the UK to benefit from their commercial manufacture and export.

### **4. Expediting payment**

The testimonials in annex 1 of this paper demonstrate the value of tax and cash credits to innovative businesses in the UK. Although we appreciate there are resource pressures on HMRC, expediting payment would significantly benefit the cash flows of businesses. In some cases, it could make the difference in a promising research project being continued or not.

With the advent of Making Tax Digital, bringing forward and simplifying payment would be a positive way to mitigate the digitisation burden for SMEs, while helping them with cash flow and budgeting.

In the interest of space, we have kept this submission brief. However, we have further information and detail on all of the above proposals, which we would be happy to share with you. We would also be very happy to facilitate meetings between your team and our members to explore the ideas further.

### **About the BIA**

Established in 1989, the BioIndustry Association (BIA) is the UK trade association for innovative bioscience enterprises. BIA members include emerging and more established bioscience companies, pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience

sector. The BIA also runs specialist industry groups in two of the 'Eight Great Technology' areas identified by the Chancellor George Osborne, namely synthetic biology and regenerative medicine.

Our members are responsible for over ninety per cent of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.

For additional information or clarification on any of the points raised please contact Martin Turner, Policy and Projects Manager, at [mturner@bioindustry.org](mailto:mturner@bioindustry.org) or on 020 7630 2192.

## **Annex 1 – Testimonials on the benefits of R&D Tax Credits**

### ***Response A***

I have been involved, over 14 years, in three companies (two medical devices and one pharmaceuticals) which have participated in the R&D Tax Credit (SME) scheme. I have always seen and continue to see the scheme as a hugely valuable addition to the available R&D funding routes. In my experience, the cash that the scheme has provided has both widened the range of R&D projects performed and accelerated the timelines, leading to improved R&D and ultimately commercial outcomes. I believe it is a vital part of making the UK more competitive in the area of R&D.

[CFO of an AIM listed therapeutic company]

### ***Response B***

I worked as the head of finance for a London biotech company developing synthetic vaccines for mutating viruses. It was backed by a number of rounds of venture capital from Swiss, French, Swedish and British investors.

The company developed a new, innovative synthetic influenza vaccine from proof of concept through to completion of a Phase IIa influenza virus challenge study.

Originally started by two people, the company grew to employ 21 staff. Nearly all of these worked directly in research and development and were educated to the PhD level.

All the investors were impressed with the UK's focus on encouraging businesses that develop new technology, particularly the support given through the R&D tax incentives. There is no doubt that this supported the continued investment and growth in the company.

[Group Financial Controller of a Private Vaccines Company]

### ***Response C***

OXB has benefitted greatly from the R&D tax credit scheme over the years and it continues to be very valuable. The UK/European financing environment for biotech companies remains challenging – an upturn in 2014/2015 seems to have fizzled out in late 2015/2016 – and there is no doubt that investors in smaller companies, public as well as private, appreciate non-dilutive funding such as R&D tax credits and also grant competitions such as the Biomedical Catalyst.

[Tim Watts – CFO Oxford Biomedica]

### ***Response D***

R&D tax credits have had two principal impacts on our business. The most obvious one is the impact that they have had on the speed with which we can conduct our R&D and stay ahead of our global competitors. The second impact of R&D tax credits is the message that it sends to investors that the UK is prepared to back its innovation businesses. This was almost certainly a factor in helping us to secure a transformative investment from VCs based in the UK, US and mainland Europe at a time when there were still significant technical risks to address in our R&D programmes.

[CEO – venture backed therapeutic company]

### ***Response E***

Two general comments:

1. In previous companies the R&D tax credit has equated to an offset around 1 months cash burn each year. This has proven invaluable in extending the cash runway such that the companies were able to meet key value inflection points ahead of financing events.
2. During investor roadshows it is clear that the UK R&D tax credit regime is extremely attractive to investors, in particular US specialist healthcare investors looking to make inward investment into UK SMEs. These investors view the cash incentive (along with the patent box regime) as a positive reason for choosing to invest in UK SMEs.

[BioScience CFO]

***Response F***

Hard to point to a specific, but there is no doubt in my mind that it makes a vital difference to overall cash flow. There have been many years where the cash runway has dipped to a small number of months so having that extended each year by around a month provides a significant impact not only in terms of survival but also buying time for achievement of milestones which then encourages further investment.

[CFO – Healthcare]

***Response G***

It is difficult to give concrete examples but in all of my companies the R&D tax credit has helped keep dilutive funding down and often helped with the runway to a key value inflexion.

It gives foreign investors a feel good factor too that the government is behind R&D based companies.

[Serial BioScience Entrepreneur]

***Response H***

The availability of tax credits fundamentally changes the landscape for our company. In addition to the commercial side of our business, we are a development-stage company. Knowing that our R&D will be partially supported by critical tax incentives directly results in a larger R&D budget for the company. Without this we would potentially either have to reduce the number of active R&D programmes, slow down the speed of development or possibly both. As a result, our innovative cancer therapies would possibly take longer to reach the market and our evolution into a profitable (and tax paying!) business would be extended.

[CFO – AIM listed specialty pharma]

***Response I***

We factor into our investment decisions the benefit of tax credits. I am confident that we would not have invested so heavily without that benefit. We are now reaping the rewards of such investment.

[CFO – private diagnostics company]

## **Annex 2 – Use of data in R&D**

### ***Case Study A – Genomics England***

Genomics England has received investment worth more than £300 million by the government in 2014 for a 4 year project to decode 100,000 human genomes. This will heavily involve the use of medical and biological data with the Medical Research Council to provide £24 million to help provide the computing power to make sure that the data is properly analysed and interpreted securely. Genomics England has since partnered with many data solutions firms throughout this project, showcasing the need for data in the Life Sciences environment. It is looking to partner with industry with a fee of £250,000 allowing access to the consortium.

### ***Case Study B – QuintilesIMS***

In November 2016 QuintilesIMS announced a deal with Pfizer, Bristol-Myers Squibb, Eli Lilly and a number of other large pharmaceutical companies to purchase data to better understand real-world cancer drug use in Europe.

### ***Case Study C – 23andme***

Launched in 2006, 23andme is a personalised genetics service for consumers. They collect data from people whose genomes they sequence and analyse for certain genetic traits including inherited conditions, genetic risk factors and drug response. The data collected in carrying out these reports is then collected and sold for use in scientific research. One reported deal concerned the acquisition of certain data relating to Parkinson's disease, collected by 23andme, being sold to Genentech for \$60 million.

### ***Case Study D – Regeneron Genetics Center (RGC)***

The RGC conduct genetic sequencing projects and has so far sequenced the DNA from over 100,000 people. The data output from these genotype studies is fed into preclinical and clinical pipelines. Their work, in collaboration with partners who may pay for the data, helps mitigate drug target risk through the study of genetic safety profiles, identify genetic variants associated with disease, and identify novel targets for drug development.

### ***Case Study E – The Parker Institute for Cancer Immunotherapy & Cancer Research Institute***

Both The Parker Institute for Cancer Immunotherapy and Cancer Research Institute, based in the US, recently announced a multimillion-dollar joint project to advance cancer immunotherapy treatments through the use of algorithms and personalised medicine. Their work aims to use predictive algorithms to identify the mutated proteins from cancer cells to increase the body's immune response. The use of algorithms is crucial to the success of the project with 30 laboratories applying algorithms to predict responses. However, in order to improve accuracy, it is essential that data is collected about how T cells respond to cancer protein mutations. It is unclear as to whether this data will be collected directly or purchased from outside the project.

### ***Case study F: OECD Science, Technology & Innovation Outlook (STI) 2016***

The recent OECD STI Outlook further emphasises the growing importance of medical data in life sciences. The importance of data is highlighted with big data analytics among the 10 key and emerging technologies while bioinformatics and personalised medicine are among the top 40.

The OECD also comments that 'big data and algorithms are generating huge amounts of data, changing scientific methods, instruments and skills requirements and creating new fields of research'. Further to this



they predict 'digital technologies will massively increase the amounts of medical data available and enhance the power of data analysis in the service of healthcare decision-making'.

Openly shared data is becoming increasingly widespread and despite this being a free resource it showcases the demand for data, which when privately owned could command substantial cost to the acquirer.