BIA response to HMT second consultation on Preventing abuse of the R&D tax relief for SMEs August 2020

UK BioIndustry Association

Introduction

The UK has a thriving life sciences sector developing medicines that save and improve lives. Britain is by far the leader in Europe and second only to clusters in California and Massachusetts. The UK has almost 5,900 life science companies, 80% of which are SMEs, and these employ almost half a million people, with the average GVA per employee over twice the UK average at £104,000. Two-thirds of these jobs are outside London and the South East. Private investment in the UK's life sciences start-ups and scale-ups has also increased 400% since 2012, signalling a bright and innovative future.

A large part of the UK's success is down to the favourable tax regime, including R&D tax credits, which supports start-ups and scale-ups, maintains their presence in the UK, and attracts foreign businesses to base their R&D activities here. R&D tax credits, combined with Innovate UK grants, venture capital incentives and a suite of other pro-innovation policies are key to the continued growth and success of the UK life sciences industry and vital to meeting the Government's target of investing 2.4% of GDP in R&D by 2027.

The BIA supports measures to prevent abuse of the R&D tax relief scheme. We are grateful for the positive engagement offered by HM Treasury and HMRC throughout the consultation process with the intention to develop a nuanced test that protects genuine companies. Due to the reasons previously described and repeated for reference in Appendix 1, the 3X PAYE cap as proposed in the 2019 consultation would have had severe unintended consequences for many genuine biotech companies and we are pleased that our concerns have been listened to and acted upon. We are pleased to be able to further inform the policy design through this second consultation and stand ready to provide further information to HM Treasury and HMRC as required.

Responses to consultation questions

Question 1 *- Does your business subcontract to a related party or use EPWs provided by a related party? Would it be useful to be able to include the PAYE/NICs attributable to these workers in your payable credit?*

Yes. Many members of the BIA either contract out or commission services from related parties for aspects of their R&D or the manufacture of experimental materials (we explain why in the following paragraphs). In some instances, these may be EPWs. We welcome this approach because in most circumstances the related parties will be located in the UK and so their PAYE/NICs will be attributable.

Many life science companies operate as groups. This is either as a result of mergers and acquisitions (M&A), which are common in the sector, or other for other commercial reasons. Notably, it has become common in the life sciences sector to establish "single asset companies", which own distinct IP and sit within a group. Staff, equipment and additional IP required for the development of the asset might be held within another company of the group, thus requiring subcontracting.

This structure has evolved to facilitate fundraising and contain risk for discrete projects developing assets; due to the high costs and risks of R&D, investors may not wish to fund the development of all the assets within a company, but instead focus their investment in just one. The structure also allow out-licensing or sale of those assets efficiently if the need arises.

Subcontracting is required because it is not efficient or usually possible to locate all the staff, equipment and IP required to develop an asset within the same company. This is because those staff, equipment and IP might be used for the development of multiple different assets, and thus need sharing between them. For example, a bioreactor is an expensive and technical piece of equipment for producing biological molecules (e.g. antibody therapies). A company might be producing three different antibody therapies to treat three different diseases, which are funded by different investors and charities with interests in those particular diseases. The three different antibodies each constitute three unique IP assets and are thus owned in separate companies. However, all will require the bioreactor to be produced for clinical trials, so the manufacture is subcontracted to a parent company.

These related parties would usually be located in the UK (if the parent company is UK-based), but if the group has formed in part due to M&A there may be overseas subsidiaries due to the global nature of the sector and need to access highly-specialised research expertise no matter where it is located around the world.

Furthermore, clinical trials are often run in multiple countries due to the location of the expert clinicians and patients. This is especially true for clinical trials involving rare diseases (which most biotechs are focussed on) because the rarity of the condition means no single country will have a large enough patient population to facilitate the trial. Subsidiary companies might be established in different countries to allow for contracting of clinical trials in those territories, thus requiring subcontracting between companies within a group.

The case study provided in Annex 1 illustrates this.

Question 2 *- Would it be practical to obtain information on attributable PAYE/NICs from EPW providers in order to increase the level of your cap?*

For employees of related parties, we would not envisage any limitations or difficulties in obtaining this information in the vast majority of cases.

However, where EPWs are involved, we think that the administrative burden in obtaining the information from contractors (EPWs) in a timely manner may be too high and some claimants unfairly prejudiced where third parties are unwilling to provide the information. An alternative could be to apply notional PAYE/NI based on a fixed percentage of the EPW cost.

Question 3 - *The government welcomes views on the sorts of activities which are undertaken to manage IP, as well as the types of information and evidence on the active management of intellectual property, which genuine claimant businesses would be able to provide in supporting their R&D tax relief claim.*

In the BIA's response to the 2019 consultation, we proposed a test to identify genuine companies rooted in demonstrating R&D and IP activities. We therefore welcome the intention to introduce a nuanced test to identify and exempt genuine companies.

In our earlier submission, the BIA recommended a test that assessed the active management of R&D as this is a regular – often day-to-day – activity of any genuine R&D-intensive company. We therefore believe it

would be more straight forward to demonstrate for genuine companies and difficult for abusive companies, as they would not be able to produce the abundance of evidence expected which would include meeting minutes, R&D strategic and operational planning documentation, and email communications of scientific information, data and decisions (but these might be commercially sensitive and hard to disclose). Experimental protocols could be provided, along with contracts with relevant R&D service and materials suppliers. Staff with relevant technical and scientific qualifications (generally Masters degrees and PhDs) would also be expected to be demonstrably involved and easy to verify.

Active management of IP would also be possible to demonstrate for genuine companies (and in most cases would sit alongside the effective management of R&D) so we welcome the concept, but we caution that it is not managed with the same day to day frequency as R&D and so is an activity that is more portable between companies within a structure. Furthermore, a far greater proportion of the activities for managing IP are outsourced by genuine companies to third parties (patent attorneys). Finally, the management of IP can be largely administered by a specialised team or, for smaller companies, a single individual that does not need to have proximity to the R&D department. In some cases they are employed by other group companies outside the UK.

As described above, group structures involving the sharing of staff are common in life sciences, this extends to staff involved in R&D AND IP management. It would therefore be important that this test is also linked to activities undertaken by staff of related parties for whose PAYE and NI are included in the calculation of the cap as suggested in the commentary in the consultation relating to Q1 and Q2 above.

The activities demonstrating active IP management presented in the consultation are quite broad, and would involve different staff, often the decision-making leadership team of a company. Description of roles is therefore is not a very precise document of evidence. Board minutes, business plans, and licensing agreements are reasonable to expect but as they are produced less regularly and in some cases with less detail involved. Other evidence, which also has this drawback, that could be considered includes: a letter of engagement between managing external counsel and the company; a letter from an external IP managing agent stating that SME firm is the client; correspondence with the UK Intellectual Property Office and/or European Patent Office, however many SMEs would not have an in-house attorney with direct access to this.

Genuine companies that rely on know-how and trade secrets rather than registered IP might also struggle to evidence the IP management test, although these are not common in life sciences.

Whatever approach is taken, we hope that minimum burden will be placed on companies. The company should be able to self-assess that they manage the R&D/IP, as they do with other aspects of R&D tax credit claims, and HMRC would ask questions on an enquiry if they require. The genuine company would then be able to provide evidence in terms of internal paperwork.

Question 4 *- Does your business subcontract work to a related party, (including using EPWs provided)?*

Yes, this is a common feature of BIA members for the reasons described in answer to question 1: life science companies often establish new subsidiary companies within their group for the explicit development of a particular asset. This single asset subsidiary structure is common for companies who develop products in a number of different therapeutic areas to facilitate new investment, out-licensing and commercialisation. R&D and other staff may be employed centrally by the parent company or a single operating company within the group, and their costs charged back to the subsidiaries.

Question 5 - *Where your business does subcontract to a related party, does this represent less than 10% of R&D expenditure? If no, please provide an indication of the percentage of your claim related party subcontracting does represent.*

It is possible that many genuine companies will subcontract R&D totalling more than 10% of their overall claim. Please refer to detailed examples provided in the consultation submissions from Confluence Tax and FTI Consulting, who have also informed this submission.

We understand that high levels of subcontracting is a feature of abusive structures and agree with the need to set a bar to prevent this activity. However, 10% is a low bar, which we believe strikes the wrong balance between the need to not impinge genuine claims and preventing abusive ones. This exemption is to ensure that the cap is not applied to companies established without any abusive motivation. We believe that it would be highly unlikely for a company with tax abuse in mind to establish two thirds of its activities in a UK company.

35% would be more reasonable, and reduce the impact on the UK's genuine life science SMEs (although we expect there would still be instances of genuine companies being impacted).

There may be some circumstances where very early-stage university spin-outs contract all their R&D activity back to their originating university. If the university took a high equity stake in the spin-out they may be considered a related party, resulting in a severe cap. We expect this to be a rare occurrence but could be avoided by exempting Qualifying Bodies (an R&D credit concept) from the related party test.

About the BIA

The BioIndustry Association (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, and communications agencies

The BIA's members 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 further details on the contents of this submission please contact Dr Martin Turner, Head of Policy and Public Affairs, BIA: mturner@bioindustry.org.

Appendix 1: Background information on the UK life sciences sector provided in the BIA's response to the first consultation

Shape of the UK bioscience sector

The traditional concept of a pharmaceutical company that conducts R&D in its large facilities, taking a medicine from discovery to patient doesn't reflect the UK life sciences sector in the 21st Century. Thanks to an entrepreneurial spirit and supportive industrial strategy, the UK is home to a large and vibrant community of SMEs that work together to discover and develop new medicines and other biotechnologies. This new business model is increasing R&D productivity and leading to new advances in our understanding of biology and disease. The UK has almost twice as many medicinal products in development than our nearest European competitor, France[1], and accounts for over a third of all venture capital raised for biotech in Europe[2].

Research published by the Medicines Discovery Catapult and the BIA, based on government statistics[3], finds that approximately 21,000 people work in 1,500 bioscience SMEs across the UK[4]. Only about 300 of these SMEs are developing their own medicines, and will either own or have legal rights to intellectual property (IP). 60% of these drug development companies employ four or fewer people and a further 18% employ between five and nine people; thus almost 80% of SMEs developing new medicines in the UK employ fewer than 10 people. There are a further 1,200 service and supply companies that employ the majority of people working in the industry. As a result, 2,500 people work in drug-development companies, and 18,500 in the service companies supporting them. The largest employer group in the life sciences SME sector is the contract research and manufacturing organisations (CROs and CMOs), making up 40% of employment in the sector.

Why companies outsource R&D

Modern life sciences R&D is complex and highly specialised. The facilities and equipment required present very high setup costs, and the expert staff required to conduct R&D are few and far between. Furthermore, the research is risky and may fail at any time, rendering the capital investment and staff redundant. SMEs therefore outsource to companies and universities that have the ability to make those capital investments and long-term commitments to facilities and staff.

This business model has enabled a community of innovative SMEs to form in the UK, attracting director foreign investment and leveraging private venture capital investment crucial to reaching the Government's 2.4% target. The model allows entrepreneurs to start-up R&D-intensive companies at a lower cost, which means more discoveries get tested for scientific and commercial viability – supporting such activity is at the heart of the Government's Industrial Strategy. This "many shots on goal" approach also holds the key to developing treatments for the wide range of currently incurable diseases that impact the population.

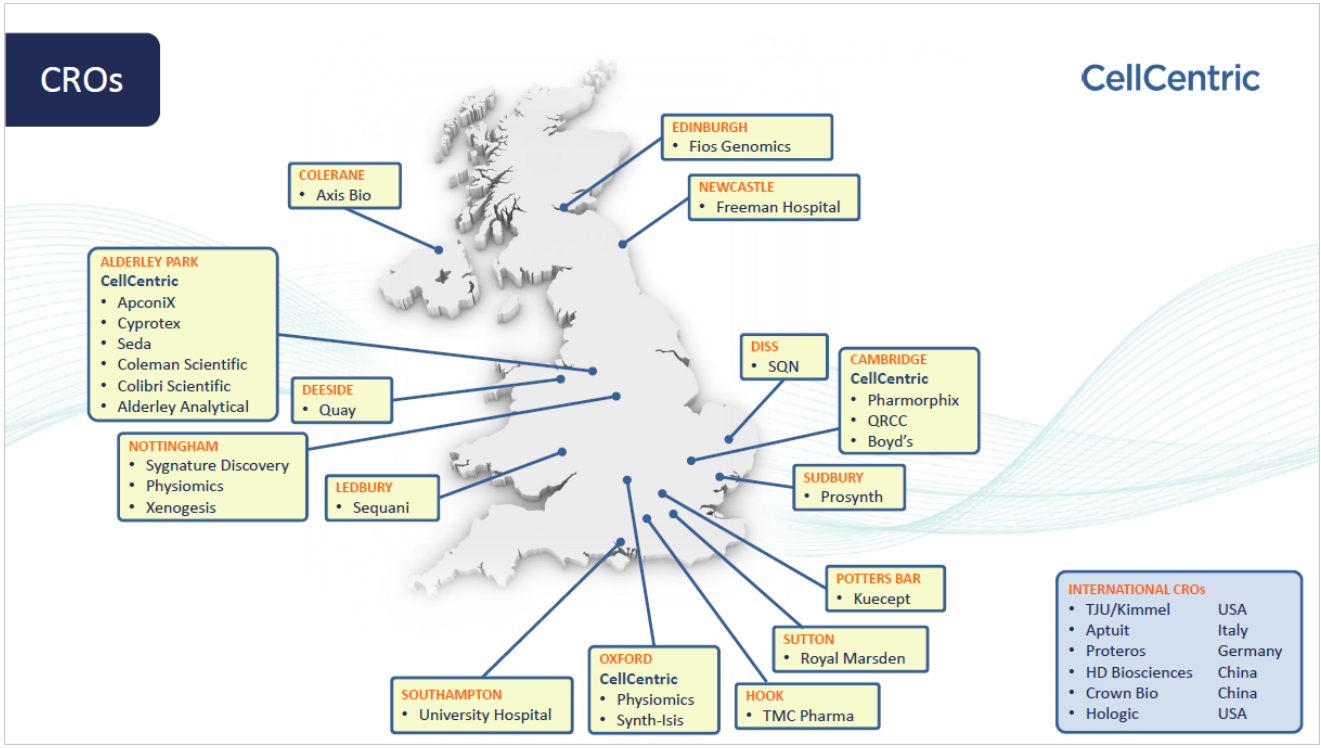
Outsourcing is not just important at the early stages of a life science company's development when it is involved in discovery science. Clinical trials – the process by which candidate medicines are tested for safety and efficacy, which is the most expensive stage of drug R&D – are conducted in hospitals and other

---

[1] BIA/Informa, Pipeline Progressing: The UK's Global Bioscience Cluster in 2017 (Jan 2018)
[2] BIA/Informa, Confident capital: backing UK biotech (Jan 2019)
[3] Office for Life Sciences, Strength and Opportunity 2017 (May 2018)
[4] Medicines Discovery Catapult/BIA (2019), State of the Discovery Nation 2019

healthcare settings. Therefore, the staff conducting the R&D – scientists, doctors and nurses – are largely employed by the hospital, and companies must also pay for the use of NHS infrastructure. In 2014/15, NHS Trusts received almost £7,000 average revenue from life sciences companies for each patient recruited into commercial clinical research studies[5]. R&D expenditure in companies that are at the clinical trial stage of their development therefore have extremely high R&D spends with relatively little additional increase in in-house staff numbers.

Much of this outsourced R&D will be conducted in the UK due to the expertise and world-class facilities and hospitals here. There are pockets of highly-specialised CROs and CMOs across the UK, and clinical trials will often be spread across multiple hospitals throughout the UK to obtain sufficient patient numbers or access medical expertise; in this way, the new model of R&D contributes to regional development rather than concentrating activity in a few large institutions. Overleaf, is an example company from the BIA membership that demonstrates this business model; 26 out of 32 sites of outsourced R&D are in the UK, with every region represented. However, there are many instances when the R&D will be outsourced overseas; these include when the expertise or facilities don't currently exist in the UK or are economically uncompetitive, and when tests and clinical trials are required by regulators overseas to be conducted in their jurisdictions. UK companies will therefore utilise a global network of CROs and CMOs to develop their products at the necessary pace and standard to be internationally competitive.



[5] KPMG (2016), NIHR Clinical Research Network: Impact and Value Assessment