BIA response to HMT/HMRC consultation on Preventing abuse of the R&D tax relief for SMEs May 2019

UK BioIndustry Association

Summary

- The BIA supports measures to prevent abuse of the R&D tax relief scheme but strongly urges the Government not to implement the cap as currently proposed due to the significant damage it will cause to the life sciences sector and the development of new medicines for patients
- Modern life sciences R&D is complex and highly-specialised. Increasingly it is not conducted by large companies but by a network of specialist SMEs, each playing a different role. This helps manage risk, reduces start-up costs for new businesses, allows for greater R&D productivity, and "more shots on goal" for drug discovery and development
- At the heart of the UK sector are around 300 companies that own intellectual property for new drugs that they are developing. 80% of these have 10 or fewer employees and largely operate on an outsourcing model whereby they rely on universities and other companies to conduct R&D on their behalf. Furthermore, clinical trials – the most expensive stage of drug R&D – are conducted in hospitals whereby the company pays for use of NHS staff and infrastructure
- Many genuine life science companies therefor have a high R&D spend but no or low PAYE/NIC liabilities, meaning the proposed cap will result in severe reductions in their cash payments
- BIA analysis of 61 companies found that, if the proposals are implemented, 39 (54%) will have their payments capped, with an average reduction of 70%. This will damage the UK's vibrant and scaling life science SME community and runs contrary to the government's Industrial Strategy to grow the life sciences sector and increase R&D investment to 2.4% of GDP
- The BIA proposes a gateway test that both delivers on the HM Treasury and HMRC anti-abuse requirements and enables genuine UK life science companies to prosper. This would be that R&D tax relief cash payments will be capped at 3X PAYE/NICs unless the company can self-certify that it meets one or more of the following:
    1. The R&D activity in the claim is effectively managed by a UK tax-paying professional[1] in the UK
    2. The UK company will own the IP arising from the R&D
    3. The UK company is not caught by the UK hybrid rules[2]

[1] This should not be limited to the claimant company or group/connected parties, to allow for venture-capital funded companies whereby the investor effectively manages the projects

[2] I.e. No alternative R&D benefits (in other territories) are being claimed on the same expenditure. This will require the hybrid rules to be updated to include R&D claims.

Introduction

The UK has a thriving life sciences sector developing medicines that save and improve lives. We are by far the leader in Europe and second only to clusters in California and Boston, Massachusetts. And the sector is growing rapidly – in 2018, £1.1bn venture capital was invested, double that of the previous year[3]. Innovation in the life sciences brings great economic, health and social benefits to the UK.

A large part of the UK's success is down to the favourable tax regime, including R&D tax credits, which supports start-ups, maintains their presence in the UK, and attracts foreign businesses to base their R&D activities here. The introduction of a 3X PAYE/NI cap on SME R&D tax credits would severely reduce the benefits of the regime. It will damage the UK's vibrant and scaling life science SME community and runs contrary to the government's Industrial Strategy to grow the life sciences sector and increase R&D investment to 2.4% of GDP by 2027[4].

In response to the proposal to introduce the cap, the BioIndustry Association (BIA) has sought feedback from its membership to determine the potential impact of this measure and develop proposed solutions. Without question, this proposal will prejudice SMEs in UK life sciences due to the structural necessity to outsource significant elements of R&D in pre-clinical and clinical research.

The BIA is grateful for the positive engagement HM Treasury and HMRC have provided on this issue to date and shares its concerns about fraudulent and abusive use of the tax credit regime. We particularly welcome the constructive dialogue in the Life Sciences Council. This submission to the public consultation provides further evidence of the measure's impact and proposals for how the cap's anti-fraud/abuse policy objective can be met without prejudicing the UK's biotech SME sector.

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[5], and accounts for over a third of all venture capital raised for biotech in Europe[6].

New research published by the Medicines Discovery Catapult and the BIA, based on government statistics[7], finds that approximately 21,000 people work in 1,500 bioscience SMEs across the UK[8]. 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,

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

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 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[9]. 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.

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

The estimated impact of the cap on the UK life sciences sector

The BIA sourced financial data from members and clients of member tax advisory firms to compile a representative sample of 61 companies and applied the cap and mitigating measures suggested in the consultation[10]. Applying the cap without any mitigating measures, 39 companies out of 61 (54%) would have their R&D tax claim capped, with an average shortfall of 70%. For some companies this equates to hundreds of thousands of pounds.

If this cap is introduced in 2020, it will result in a cliff-edge in income for many successful and scaling UK life science SMEs. Companies will have to recast their financial planning, on which venture capital funding has already been secured, to account for this. Cutbacks in R&D programmes are inevitable, which will impact the development of new medicines, and the UK's ambition to reach its target of investing 2.4% of GDP in R&D by 2027.

We firmly believe that fewer companies will start-up and grow in the UK, and existing companies will opt to move some or all of their operations overseas. One BIA member that is researching new antibiotics has told us that they will conduct their clinical trials in Canada rather than the UK, as the change means their R&D tax credit regime will be more favourable. There will be downstream impacts on NHS Trusts and universities that will lose income, and value lost from the UK-based supply chain.

An alternative workable measure to prevent fraud and abuse

The stated purpose of the anti-abuse measure is to prevent claims from companies that were set up to claim the cash available through the payable tax credit even though they had no R&D activity in the UK. The BIA supports preventing such abuse, as well as more serious cases of fraud where no R&D existed at all.

[10] The full data package has been provided to HM Treasury and HMRC separately. Our analysis assumes PAYE/NI is 33% staff costs, therefore PAYE/NI 3x cap affects companies with a cash claim greater than gross staff costs

HMRC already has the tools it needs to determine if a company is conducting or funding R&D in the UK. The challenge is in assessing those that are funding it overseas and claiming R&D tax credits in the UK (which many genuine companies do, as described above). We propose one or more of the following tests could could be introduced as a self-declaring gateway:

1. The R&D activity in the claim is effectively managed by a UK tax-paying professional[11] in the UK
2. The UK company will own the IP arising from the R&D
3. The UK company is not caught by the UK hybrid rules[12]

This could be implemented as a gateway test. If the company cannot self-certify that it meets one or more of these conditions, the 3X cap will apply. This will require the hybrid rules to be updated to include R&D claims. The BIA would be happy to offer any further assistant needed to develop and finalise a workable solution.

Responses to consultation questions

Question 1 *- If the cap is only applied for payable tax credit claims above a defined "threshold", at what level would this be useful at reducing any potential administrative burdens on genuine companies?*

The damaging impact of the cap for genuine businesses will be the reduction in available support and not be the administrative burden. However, a threshold that automatically removes the smallest - and therefore least-resourced – companies from the cap would be of value. Due to the high R&D spend of even the smallest life sciences companies, this should be set at approximately £100,000.

Question 2 *- If a group was only able to submit one payable tax credit claim at or below a certain threshold per year, how would this fit with the way that claims are currently made? How common is it for more than one company in a group or common control entity to make a claim for the payable R&D tax credit?*

We believe the usual approach within our sector is to have one single UK claim. However, there are instances of more than one company in a group conducting or funding R&D activities and each claiming through the R&D tax credit. In these cases, single asset companies have been established within a group structure in order to better manage risk of R&D project failure and new investment. Groups of genuine companies such as this are likely to be caught by the anti-fragmentation limitation proposed in this question and so the cap should be designed to apply a more appropriate test that can identify genuine companies from fraudulent ones, as proposed above.

Question 3 *- If an element of the PAYE and NICs liabilities of another group or connected company were included as a part of the cap (where R&D has been subcontracted to it or EPWs provided by it), to what extent would this benefit companies? How much additional complexity would this add to claiming the payable tax credit?*

We do not believe this would make a material difference to genuine companies. The majority of those impacted are single UK companies that are not part of a group.

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[12] I.e. No alternative R&D benefits (in other territories) are being claimed on the same expenditure. This will require the hybrid rules to be updated to include R&D claims.

Question 4 *- Would it be practical for claimant companies to obtain the PAYE and NICs information from other group or connected companies? Are there any limitations to their doing so? Would the other company be willing to provide this information?*

For companies in a group, we would not envisage any limitations or difficulties in obtaining this information in the vast majority of cases. But we think that the administrative burden in obtaining the information from contractors (EPWs) in a timely manner would 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. But overall we do not think this measure would mitigate the negative impact on genuine companies.

Question 5 *- How beneficial would surrendering carried forward losses, to claim a future payable tax credit when sufficient PAYE and NICs liability has been generated, be to company affected by the cap? Would a time limit of 2 years be appropriate? How straightforward would it be to keep track of the origin year of the losses?*

As described above, clinical trials are conducted largely in hospitals, so as a life sciences company advances, its outsourced expenditure is likely to increase disproportionately to PAYE and NICs liability, so this measure is unlikely to be of value. Nevertheless, if this measure was introduced, the carry forward period should be at least 5 years.

Question 6 *- Would carrying forward losses make companies consider taking on more staff in the future - to unlock some (or all) of the rest of their payable tax credit?*

It would be highly unlikely to. The credit gained would not be large enough to change the clear economic logic and practical necessity of outsourcing R&D, as described earlier in this response. Furthermore, we believe such a policy could act as a perverse incentive to increase bonus pay-outs, in order to artificially raise PAYE/NICs.

Question 7 *- The government is interested in the characteristics of companies that could be affected by the cap. For example, if you are or represent a company likely to be affected by the cap, how large is the company in terms of employees? How many staff are primarily engaged in R&D activity? How old is the company? What sector does it operate in?*

This is answered in detail earlier in this response. However, we would like to reiterate the statistic that almost 80% of SMEs developing new medicines in the UK employ fewer than 10 people. In the start-up stages, many of these staff will also be taking nominal salaries, as they will often have paying roles in other companies or in the venture capital firm funding the start-up. (This is in part a reflection that there is a shortage of experienced biotech management in the UK but also the dedication and entrepreneurial spirit of those involved in the sector.) These staff will include the CEO, finance and business development officers, and some scientifically-trained staff responsible for overseeing outsourced R&D programmes. There may be no-one based within a company-owned laboratory despite the very high R&D spend.

Conclusion

The BIA is grateful for the positive engagement of HM Treasury and HMRC on this issue. We share HM Government's concerns about abuse and fraud in the R&D tax credits system and are keen to work with the Government to ensure its policy aims are met whilst not negatively impacting the UK's vibrant life science SME sector, which we understand is not the cause of the Government's concerns. We hope that our proposed modification of the cap measure will be considered and taken forward. We remain open to further meetings with HM Treasury and HMRC.

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