BIA feedback on R&D tax relief changes

August 2022

UK BioIndustry Association

Introduction

The BIA is grateful for the positive engagement of HM Treasury and HMRC throughout the policy development process for refocusing the R&D tax relief regime on innovation in the UK. The BIA shares the UK Government's ambition to increase R&D activity within the UK. R&D tax reliefs can be a helpful policy tool to help achieve this but will not do so alone; coordinated initiatives across government will be required, from improving the operation of clinical trials within the NHS to ensuring innovative companies can access the skills they need in the UK.

We are pleased with the shared view reached with HM Treasury and HMRC that R&D tax reliefs are a useful policy lever for this objective, but that changes should not unfairly penalise companies that must conduct R&D overseas for necessary purposes. We welcome the published draft legislation and from discussions with our members there is positive sentiment around its objectives. However, its application should be managed carefully so that it does not prejudice companies where they have no choice but to undertake aspects of their R&D outside the UK.

The translation of the legislation into practice within specific and complex sectors of the UK economy will not be straightforward; there remain areas of ambiguity within the legislation. Detailed guidance with sector-specific references will therefore be needed to help companies understand the new rules and comply. Significant changes will be needed in the way companies plan their R&D and the information they gather from contractors.

Companies are already planning R&D activities into 2023 and beyond (as required by the long development timescales of our sector) and agreeing contracts for projects that will be affected by the new rules. There is therefore an urgent need to provide companies with guidance.

We were pleased to host David Harris from HMRC on a webinar for BIA members on 27 July, which attracted 188 attendees and has since been viewed a further 200 times on YouTube[1], showing the interest companies have in these changes. We have collated the questions asked and identified themes, that we hope will be instructive, as HMRC develops its own guidance. We have also raised a few key questions on which early feedback from HMRC would be of significant help for companies currently looking to enter key contracts with suppliers that will extend into periods covered by the new rules. We have also set out our interpretation of the application of the rules based on discissions with HMRC leading up to and during the webinar. If HMRC does not agree we would equally be eager to receive your feedback

We would like to offer to convene a working group of member companies, with expertise from the R&D teams, to help advise HMRC on the intricacies that will need to be addressed in guidance to ensure this legislation is implemented smoothly and achieves the Government's policy objectives. We are also open to assisting HMRC on industry awareness and helping inspectors understand the complexity of R&D in our sector, which we have done in the past.

[1] As of 1 September 2022: https://www.youtube.com/watch?v=A1Cw-oBASzE

Member concerns about interpretation and impact of the proposed legislation

Through feedback gathered from BIA members, including the questions posed by webinar participants (during and after the webinar), we have identified the following themes relating to concerns on the new legislation:

- Capacity – where the UK doesn't have any or enough subcontractors
- Specialism – where the UK doesn't currently have people or sub-contractors with the specialist skills, knowledge or equipment
- Regulatory – the requirements of a regulator
- Contractor – anything to do with how a contractor operates, including location of their people
- Market access – where the location of the R&D can impact your ability to gain access to a market or get reimbursed
- Transitionary – temporary issues related to the introduction of the new rules

The table on the following page explains these themes in more detail and poses questions and recommendations that BIA believes will need to be addressed in the legislation and/or guidance.

A full list of questions asked on the webinar and how they have been classed is provided in Annex 1.

Interpretation of unreasonableness

We also note that much of the interpretation of the legislation rests on inspectors applying subclause (2)(c) and judging what is unreasonable. Due to the very different access to resources, what would be reasonable for a large company to do in the UK may not be reasonable to expect from an SME. This should therefore be reflected in the guidance so that there is not a blanket interpretation of "unreasonable".

Proposed new legislative wording

To capture the circumstances described in our commentary in the following table, we recommend simplifying the draft legislation to remove Clause (3)(a)(i), so the new text reads:

(2) The circumstances are that there are conditions necessary for the purposes of the research and development—

(a) that are not present in the United Kingdom,

(b) that are present in the location in which the research and development is undertaken, and

(c) that it would be wholly unreasonable for the company to replicate in the United Kingdom.

(3) In subsection (2) "conditions" —

(a) includes— geographical, environmental, social, technical, medical, legal or regulatory conditions, but

(b) does not include conditions so far as relating to—

(i) the cost of the research and development;

(ii) the availability of workers to carry out the research and development.

Theme	BIA comments
Capacity	R&D in life sciences is a global undertaking and cannot be restricted to a single country. UK life sciences companies are producing world leading scientific advances but the UK does not have the patient population, infrastructure or resources to get close to meeting their needs for pre-clinical and clinical development. The two most capital-intensive elements of drug development are: i) running clinical trials and ii) manufacturing new molecules or biologics for the first time under strict regulatory conditions ('clinical manufacture'). There are capacity issues in the UK for both; being available patient population and the specialist manufacturing footprint. Our understanding is that if a claimant can provide evidence that they have sought supply from the UK and taken up the available capacity that is available within a reasonable timeframe, then where the additional trials or manufacturing is undertaken outside the UK the whole activity would be eligible. In some cases, there may simply not be any capacity in the UK. **Recommendation:** It would be very helpful if the constraint on available patients is captured in one of the stated conditions in Section 1138A. Would HMRC regard the absence of sufficient patients to be an 'environmental' or 'social' condition (it would potentially sit at the periphery of both)? If not, could 'medical' be added to list of permitted conditions? If not explicit in Section 1138A, we would request that this is addressed in the guidance. **Question:** A company needed to recruit 200 patients for a clinical trial for a rare disease. It could evidence that it could realistically recruit up to 20 in the UK (but no more) but it could easily recruit all the 200 patients in the US. If it chose to run the whole trial in the US would a valid approach be to treat all of the cost as eligible, or 90%?
Specialism	R&D activity in the biotechnology industry has the following characteristics: • Long timescales (10-15 years to develop a therapy) • A need to obtain regulatory approval, which involves discussion and interaction with the regulators over many years throughout the pre-clinical and clinical R&D phases, and consideration of all of the R&D undertaken, not just a recent snapshot of clinical trial activity or results • Highly complex and poorly understood science, requiring deep specialisms • Limited numbers of specialist suppliers

	• Very high risk of failure (c.5% of drug candidates succeed as approved therapies) Consequently, it is necessary to use the best available suppliers with the specific specialist skills, knowledge and equipment in order to maximise chances of R&D success. While UK biotechnology companies will look to the UK, they are often unable to find the world-leading specialist expertise they need due to the limited size of the UK. The only country that could arguably have all the specialist suppliers to be "self-sufficient" is the United States, but even that is questionable. We are concerned that a harsh view by HMRC of the conditions in s.1138A (3) will result in damage to the UK biotechnology industry. Picking the best supplier with true expertise, who is working overseas, could be considered by an Inspector to fall outside of that list, with Inspectors who are not industry experts claiming that there was relevant expertise, though possibly of lower calibre, in the UK. **Recommendation:** We would therefore suggest that the list in s1138A(3) is expanded to include 'technical'. This could be further refined, if required, to preclude spurious claims, for example by stating 'unique technical'. This is not to be confused with the availability of workers, which is rightly excluded as a condition on which companies can claim necessity. It refers to the highly specialist nature of some R&D activities in which only a few experts or suppliers exist globally.
Regulatory	It is widely recognised that clinical trials will need to be undertaken in certain countries/regions for the development to be approved by international regulators which is essential for the drug/device to be approved for sale in that market. In some cases this is mandated, but in others (most notably the US) it may not be mandated but the likelihood of the medicine being approved would be significantly diminished if it is not. **Recommendation:** The conditions in Section 1138A, include regulatory requirements as a result of which the research and development may not be undertaken in the United Kingdom. This is unhelpful as there will be many cases where a claimant if effectively obligated to undertake clinical trials in other countries but this will not be explicitly mandated by the regulator. We are concerned that the absence of formal evidence from the regulator specifying where clinical trials have to be performed may result in legitimate claims being challenged. For this reason, could 'legal and regulatory' be listed alongside the other conditions without the additional qualification? **Question:**

	What evidence would be sufficient to support the inclusion of costs under the regulatory condition? Many claimants will employ regulatory experts. Will internally generated documentation be sufficient? Alternatively, will a claimant need to produce evidence from i) a 3rd party or ii) the overseas regulator?
Contractor	We understand that the claimant will need evidence from the contractor to confirm where R&D was undertaken and that the associated costs will need to be apportioned between i) UK activities, ii) qualifying overseas activities, iii) non-qualifying overseas activities and iv) pass through costs not related to activities. **Question:** 1) Given a disease type a clinical trial had to be undertaken outside the UK (e.g. in Asia for example Japan). A CRO needs to be appointed and it would be illogical to engage with a supplier without a local presence. A Japanese CRO is appointed that does not have any operations in the UK. Some of the activities it performs do not need to be undertaken at the trial site. In theory, these could be performed in the UK but the Japanese CRO does not have any operations here. Would any of the CRO cost be ineligible? 2) There are many arrangements that comprise a combination of i) the supply of materials and ii) services (activities). Where one element in incidental to the other (less than, say, 10%) would it be reasonable to ignore it? In all other cases the expenditure should be apportioned on a just and reasonable basis.
Market access	We would regard this as falling under the regulatory condition. If a company had not undertaken the R&D in locations where the research would be approved (including effective price reimbursement) then it would not be possible to sell the product in that territory. In order to support the high cost and risk of R&D in Life Sciences,companies need to sell the drug/device on a global basis. If a claimant could not obtain appropriate price reimbursement it would be uneconomic to sell the product in that territory. We believe that this should be eligible provided objective 3rd party evidence can be provided to support this position. Note: this is a regulatory condition and should not be confused with cost. If appropriate regulatory approvals cannot be obtained, the basis for the R&D becomes untenable.
Transition	A number of companies have highlighted this as a key concern. Many claimants have already entered into arrangements for clinical trials or clinical manufacture which will extend into periods covered by the new rules. These are likely to be for substantial amounts with an understanding that the expenditure would be eligible. In some cases it will be impossible for these arrangements to be changed as a complex supply chain involving a number of 3rd parties would have been established. **Recommendation:** Given the long timescales in our industry for entering into and carrying out subcontracted work, particularly with contract research organisations, many companies have already begun working with those vendors, and that work will continue as the proposed changes become effective. Therefore we consider it only fair that, as well as applying to accounting periods beginning on or after 1 April 2023, any changes only apply to expenditure

	incurred on contracts entered into after 1 April 2023. This is a commonly used concept in tax law, and we appreciate that some anti-forestalling rules may be required.

Annex 1: Full list of questions from the 27 July webinar

Theme	Guidance required	Question	Asker Name	Answer
Capacity	Yes	Overseas subcontracted work - would Phase I/II clincial trials in EU /USA count as an exclusion as the UK could not provide all the sites/ patients?	stuart	If patient availability is an issue that is a factor that could justify overseas R&D
Specialism	Yes	For non-UK suppliers - what about expertise? Some European service providers have a track record in delivering challenging outputs, UK providers may be less experienced	Emma Blaney	See comments above
		Payment to unconnected subcontractor – the company can claim 65% of the payment it makes to the subcontractor under SME will this continue	HelenGlen	The subcontract rules are not changing, except for the addition of the overseas condition
Regulatory	Yes	Drug development require overseas trials (eg in US for FDA approval) will these costs still qualify.	Hugh Jackson	See comments above under capacity
	Yes	If the data/cloud provider is based overseas but consumed in the UK could this be restricted?	Catherine Barrance	No
	Yes	If an existing overseas sub-contracting arrangement is in place and if it would be theoretically possible but impractical and not cost efficient to replace this with UK contractors, then is it possible to continue to claim?	Anonymous Attendee	See comments above under transition
	Yes	We do R&D in the UK but we buy the majority of our raw materials from abroad. Can these material costs be inlcuded in the R&D claim?	Anonymous Attendee	Yes
Specialism	Yes	If the work is sub-contacted (preclinical and clinical) to an overseas university from which the UK company is a spin-out and that enables the company to be world-leading in a key therapeutic area, what happens then?	Richard Waterfield	See comments above under expertise
	Yes	Currently, subcontractor costs claimed under RDEC are limited to a list of qualifying bodies that can be included - will this list be updated, or will it become defunct as a result of these changes?	Christopher Evans	It will remain in place
Contractor	Yes	Follow up to current discussion - we contract with the UK entity of an international CRO for a multi country clinical trial. They resource globally and the project team can change location over the course of the contract. Are we supposed to ask the subcontractor what costs have been incurred where? Or is contracting with the UK entity sufficient?	Anonymous Attendee	See comments above under contractor. Note: the rules apply to where the activity is undertaken and not the contracting party.

	Yes	Rare and orphan disease trails are difficult to find patients for so we inevitably have to go overseas to get the patients in sufficient numbers to make the trial commercially cost effective	John Gahan	See comments above under capacity
Contractor	Yes	if you have a ex UK CRO can we include their cost?	Harj Bansel	See comments above under capacity
Transitionary		Effective date Apr '23 - For co's with 31st Dec yr end, will 2023 qualifying expenditure be pro-rated or simply not apply until 1st Jan 2024?	Shabir Hussain	See comments above under transition
Transition		What if it would be a breach of contract to switch the exitsing overseas CRO agreement to a UK provider? (i.e you are tied in to a minimum contract period?)	jcockroft	See comments above under transition
Market access	Yes	Having patients from ex UK countries is beneficial when a drug comes to being reimbursed, for example Germany look favouably on companies with clinical data which includes patients from their population. Is this reasonable grounds for justifying having patients from other countries?	Harj Bansel	See comments above under market access.
Contractor	Yes	What happens if we pay for materials delivered by an overseas company which charges a 10% service charge on top of the materials? Will the materials not be allowable? This cost can be in the £millions for CMC/manufacturing.	Anonymous Attendee	See comments above under contractor
Contractor	Yes	How to justify the "conditions" to which you refer to take into account the associated costs?	Roger# Estelle	See comments above under contractor
Specialism	Yes	Linked to following two questions we have to set up certain collaborations with overseas universities because the UK does not have the specific scientific knowledge required. This is complex biology so how is this justified as a condition? The work does benefit the UK as we would bring this in-house and perform the translational work to develop into drugs (revenue into the UK)	Samantha Macro	See comments above under expertise
Capacity	Yes	There are serious capacity issue in the UK in certain areas -e.g. GMP manfacturing for cell therapy clinical trials. A start-up may not have the time to wait for for the UK to 'skill up' or the capital to forego tax credits.	Anonymous Attendee	See comments above under expertise and capacity.
Transition		What about studies that are ongoing when the new legislation comes into force? So, do we need to think about long trials before this before the legislation comes into force	Douglas Thomson	See comments above under transition.

Specialism	Yes	The overseas CRO we are using already has experience in what we need is this a good enough reason?	HelenGlen	See comments above under expertise.
		Does this mean until 2024 (considering a Dec year end) that we can still claim on overseas CROs costs that are applicable?	HelenGlen	Yes
		Also, what about GMP manufacturing (e.g. prior to clinical trials) that may be undertaken much more cheaply in a country like India than in the UK to the extent that if not allowed it could threaten the feasibility of doing clinical trials and hence furtherance of R&D?	Richard Waterfield	Cost is not a permitted condition.