Submission by the Irish Pharmaceutical Healthcare Association (IPHA) To the Department of Finance Public Consultation on the Research & Development Tax Credit and on Options to Support Innovation Date: May 2025

Introduction

The Irish Pharmaceutical Healthcare Association (IPHA), representing the research-based pharmaceutical industry in Ireland, welcomes the opportunity to respond to the Department of Finance's Public Consultation on the Research & Development (R&D) Tax Credit and related innovation support measures. As a representative body IPHA is deeply invested in the development of policies that strengthen Ireland's global competitiveness in life sciences and enhancing R&D.

The pharmaceutical sector is one of Ireland's most important strategic assets, delivering innovative medicines and vaccines that are fundamental to the long-term health and wealth of the country. Medical innovation continues to play an increasingly important role in maintaining the health of the population and tackling unmet clinical needs.

Clinical trials

However, in the last 20 years Europe has lost 25% of its global R&D investment. The US and China are increasingly attracting investment and production away from Europe due to more ambitious and dedicated strategies to drive growth. Similarly, Europe's share of global clinical trials has fallen from 25.6% to 19.3% in the last decade. In Ireland we are attracting fewer clinical trials than some European countries with similar populations and economic performances. The data on clinical trials in Ireland was compared to that of Denmark over a two-year period (2023-2024): a total of 75 pharmaceutical industry sponsored clinical trials commenced in Ireland during this period compared to 229 in Denmark – just over three times as many as in Ireland[1].

IPHA supports the creation of a harmonised EU clinical trials ecosystem via a single-approval model in addition to multi-country trials. This should support harmonised dossier reviews by National Competent Authorities and Ethics Committees across Europe, ensuring streamlined approval for multi-country clinical trials. There should also be more public investment in geographically strategic Centres of Excellence to bridge research and innovation.

We recommend that the R&D tax credit should be enhanced to drive more clinical trials in Ireland by amending some of the existing structures, allowing companies to claim more of their clinical trial expenditure for tax relief when those trials take part at least partially within Ireland. The UK, as of April 2024, updated their R&D tax credit with specific provisions to allow clinical trial costs to be included in UK claims as long as they were carried out in so far as is practically applicable in the UK. A similar amendment could greatly increase the number of patients in Ireland who get access to clinical trials, given the number of Life Science businesses that are principal IP holders in their groups paying for clinical trial activities.

Existing legislation provides for the ability to include subcontractor costs subject to restrictions and caps against the spend within the company of R&D activities, the caps being the greater of 15% of that internal spend or €100,000. At the point in the development lifecycle when a potential medicine gets to a clinical trial stage, the costs of external providers is often significantly higher than the internal spend. This means that the majority, if not all, of the payments to Contract Research

[1] IPHA Clinical Trial Activity Report 2025

Organizations (CROs), Clinical Trial Sites (Hospitals, Clinics, Research Centres), Principal Investigators (PIs), Study Coordinators, Clinical Staff, Laboratories and Testing Facilities are not claimable within a R&D tax credit claim. This applies even in instances where the Irish company is conducting the trial, and all of those subcontractors are also carrying out those activities within Ireland.

These restrictions and provisions within the legislation act as a disincentive to conduct trials out of Ireland when compared to other jurisdictions that allow for such costs to be claimed.

We ask that the subcontractor restrictions are significantly amended and enhanced to encourage more clinical trials to be conducted in Ireland. This aligns to policy objectives outlined by the Department of Health and would further increase R&D investment and IP ownership within our Life Sciences companies in Ireland.

There is a strong correlation between the location of early stage basic and applied research and early phase clinical trials. The nature of the majority of R&D we see in our sector in Ireland is focused on experimental development activities that are required in order to be able to manufacture the medicine at scale.

We would recommend enhanced rates for applied and basic research over the existing 30% to encourage early phase medicine development. This type of activity would further enhance Ireland's global reputation as a pharmaceutical hub, create new demand for a different type of expertise, attract more PhDs into Ireland and would, consequently, improve Irelands access to early-stage clinic trials, as the medicines developed go right through the R&D lifecycle.

EU Legislation

The current EU legislative landscape has created an unpredictable environment for the pharmaceutical sector across the region and in Ireland. Several policy initiatives undermine competitiveness and are not pro-innovation. For example, the proposed revision of the General Pharmaceutical Legislation, which could potentially weaken IP and the incentives framework, comes at a time when we need to incentivize innovation into Europe.

- In the 1990s, half of all new treatments originated in Europe, that figure is now just one in five.
- In 2002 the US spent €2bn more than Europe on pharmaceutical research and development, today the US is spending €25bn more.
- Employment in the pharmaceutical sector in China has risen by 800% since 2021.

The consultation process has a significant focus on innovation. In the pharmaceutical industry a lot of the operational innovation is driven by the requirement to adapt to new regulation or compliance requirements. We would encourage any expansion of incentive regimes in the innovation space to incorporate support mechanisms around regulatory adoption projects and programs of activities, including the development and integration of digital technologies to comply with these regulations. While we acknowledge that this is not the intention and these policies are driven by desires to achieve the best possible outcomes, the regulatory environment within Europe is acting as a disincentive to operate here, supporting our companies with some of the cost associated with this regulatory burden would hugely enhance the competitiveness of our life science sector.

Geopolitical threats

We are living in uncertain times with industry facing several geopolitical threats that could disrupt its operations, investment landscape, and global competitiveness. These threats include US tax and

trade policy changes, including tariffs; disruptions to global supply chains; and global nationalistic policies, such as export bans and stockpiling, which could disrupt pharmaceutical exports.

Ireland's export-reliant model makes it vulnerable if other countries prioritise domestic access over trade. As a response to these uncertainties and threats, and in a bid to remain globally competitive, we should focus on an enhanced policy for R&D tax credits which is now within Ireland's hands.

Conclusion

Ireland's R&D Tax Credit has been a cornerstone of its innovation success story. However, maintaining leadership in life sciences requires bold policy evolution. By refining the R&D Tax Credit, strengthening clinical trial infrastructure, and implementing a national life sciences strategy, Ireland can solidify its position as a preferred destination for pharmaceutical innovation.

It is important that going forward the EU enhances competitiveness and further supports Intellectual Property rights and R&D, as highlighted in the Draghi Report published last year and the recently published EU Commission's Competitiveness Compass, which aims to close the innovation gap with competitor regions.

Ensuring policy coherence across environmental and chemical legislation to secure a resilient manufacturing and supply chain of medicines in Europe is also required. The pharmaceutical industry in Ireland is working with policy makers on such matters.

IPHA and our member companies stand ready to collaborate with the Government to build a world-class, future-ready innovation ecosystem that benefits patients, researchers, and the Irish economy. We are asking for a significant enhancement to existing provisions and the introduction of new tax incentives, in order to not only protect current investments but continue to drive Ireland forward as a leading global knowledge economy in the pharma sector. In this time of uncertainty, we feel that it is important to send a very clear message to the market and those considering new investment that Ireland is as committed as it always has been to support businesses and continue to invest in core elements of our economy that have driven so much of economic prosperity.