R&D TAX INCENTIVE · PHARMACEUTICAL DEVELOPMENT

Unlocking Australia's R&D Tax Incentive

For pharmaceutical development and clinical manufacturing

48.5%

potential refundable tax offset on eligible R&D expenditure for qualifying companies*

*Subject to eligibility — see "Understanding the incentive".



EXECUTIVE SUMMARY

Australia offers international biotechnology and pharmaceutical companies a compelling financial advantage through its Research and Development Tax Incentive (R&DTI), which can substantially reduce the cost of eligible pharmaceutical research, development and clinical manufacturing activities.

For qualifying companies, the program can deliver a refundable tax offset of 48.5% of eligible R&D expenditure, making Australia particularly attractive to emerging drug developers seeking to preserve capital and extend their development runway.

However, the R&D Tax Incentive is frequently mischaracterised as a straightforward government rebate on Australian R&D expenditure. **It is not.**

The R&DTI is a sophisticated, rules-based tax program operating within Australia's broader taxation system. Accessing its benefits requires the careful alignment of three distinct but interconnected areas of law:

- **R&D Tax Law:** Determining whether activities and expenditure satisfy the specific eligibility requirements of the R&D Tax Incentive.
- **Australian Corporate Income Tax Law:** Ensuring that expenditure, funding and commercial arrangements are appropriately treated for Australian income tax purposes.
- **International Tax and Transfer Pricing:** Ensuring that cross-border structures, intercompany arrangements and remuneration satisfy Australia's international taxation and arm's-length requirements.

For foreign-owned pharmaceutical companies, these considerations are particularly important. Establishing an Australian subsidiary and engaging an Australian research or manufacturing provider does not automatically establish entitlement to the incentive.

The underlying corporate structure, contractual arrangements, allocation of responsibilities and financial model must work together to produce an outcome that is commercially appropriate and legally supportable.

When properly structured, Australia offers a significant opportunity for international pharmaceutical companies to improve the economics of their development programs while retaining an appropriate global intellectual property and commercial strategy.

As an established Contract Development and Manufacturing Organisation (CDMO) and registered Research Service Provider (RSP), **IDT Australia** provides specialist development and manufacturing capabilities that can support these opportunities.

01 — UNDERSTANDING THE INCENTIVE

A legislated tax entitlement, not a discretionary grant

The R&DTI is a federal program administered jointly by the Australian Taxation Office (ATO) and the Department of Industry, Science and Resources (DISR). Unlike a grant or a simple reimbursement of costs, it is subject to detailed requirements concerning the claimant, its activities, its expenditure and its financial arrangements.

For companies with aggregated turnover below AUD $20 million, the R&DTI generally provides a refundable tax offset equal to the company's corporate tax rate plus 18.5 percentage points. Companies with turnover above AUD $20 million may instead qualify for a non-refundable R&D tax offset.

43.5% 25% corporate tax rate + 18.5 pts refundable offset

48.5% 30% corporate tax rate + 18.5 pts refundable offset

Cash in a loss year
Companies in a tax-loss position can generally receive the refundable component in cash after assessment, subject to tax liabilities and adjustments.

Group turnover counts
The threshold includes connected entities and affiliates — overseas companies too. The global group's position may affect access.

Above AUD $20M
Companies exceeding the turnover threshold may instead qualify for a non-refundable R&D tax offset.

The distinction between a rebate and a tax incentive matters. Eligibility is not established merely because expenditure has been incurred in Australia on pharmaceutical development. The activities must qualify under R&D legislation, the expenditure must satisfy the relevant statutory requirements, and the associated arrangements must be consistent with Australia's broader taxation framework.

02 — THE THREE PILLARS OF ELIGIBILITY

The advantage is realised when all three are addressed together

1 R&D tax eligibility

An eligible Australian company must undertake eligible R&D activities and incur qualifying expenditure. Activities must meet the legislative definitions of core or supporting R&D, and the claimant must satisfy requirements concerning purpose, benefit and associated expenditure.

Key question: Do the activities and expenditure meet the R&DTI's specific eligibility requirements?

2 Corporate income tax treatment

The deductibility and characterisation of expenditure, its relationship to assessable income, and the commercial substance of the Australian entity can materially affect the overall outcome. An arrangement that looks attractive from an R&D tax perspective alone may produce adverse corporate tax consequences.

Key question: Are expenditure, funding and commercial arrangements treated correctly for Australian income tax?

3 International tax and transfer pricing

Critical for foreign-owned subsidiaries. Intercompany arrangements must reflect the functions performed, assets employed, risks assumed and remuneration earned by the Australian entity. Transfer pricing, funding structures and contractual responsibilities must be commercially supportable.

Key question: Do cross-border structures and intercompany remuneration meet arm's-length requirements?

These three areas cannot be considered independently.

A structure that satisfies the scientific eligibility requirements may still create corporate tax or transfer pricing difficulties.

Conversely, a conventional intercompany services arrangement may not deliver the intended R&D tax outcome.

The most effective structures are designed to satisfy all three from the outset.

03 — INTERNATIONAL PHARMACEUTICAL COMPANIES

The Australian Opportunity

Foreign ownership does not, of itself, prevent access to the Australian R&D Tax Incentive. International pharmaceutical developers can establish Australian subsidiaries to undertake eligible research directly or commission activities from Australian clinical research organisations, laboratories and CDMOs.

Importantly, Australian ownership of the underlying intellectual property is not universally required. Depending on the facts and the applicable statutory provisions, an Australian subsidiary may qualify while intellectual property ownership remains with its overseas parent.

However, the contractual, operational and financial arrangements must satisfy the requirements governing the party for whose benefit the R&D activities are conducted, alongside the relevant corporate and international tax rules.

This creates considerable flexibility for international pharmaceutical groups, but also makes the choice of structure critically important.

THE RIGHT STRUCTURE DEPENDS ON THE GROUP'S

Commercial objectives	**Allocation of project responsibilities**	**Ownership & exploitation of results**	**Funding arrangements**	**Transfer pricing model**

For companies contemplating Australian development programs, the structure should be determined before significant R&D expenditure is committed, rather than attempting to adapt existing arrangements retrospectively.

04 — ELIGIBLE R&D

Eligible Pharmaceutical Research and Development

Australia's R&DTI distinguishes between core R&D activities and supporting R&D activities.

Core R&D involves systematic experimental activities whose outcomes cannot be known in advance from existing knowledge, undertaken to generate new knowledge.

Supporting R&D is directly related to core R&D and may include certain development, testing and manufacturing operations. Where it involves producing goods or services, additional dominant-purpose requirements generally apply.

POTENTIALLY ELIGIBLE PHARMACEUTICAL ACTIVITIES

Experimental formulation development & optimisation	Investigation of new drug delivery technologies	Experimental development & evaluation of manufacturing processes
Research on unresolved stability or performance characteristics	Experimental analytical method development	Qualifying preclinical studies & clinical trials

Appropriate identification and documentation of experimental activities is therefore essential to determining qualifying expenditure.

05 — CLINICAL SUPPLY

Clinical Manufacturing and the R&D Tax Opportunity

Producing investigational medicinal products often involves formulation development, process optimisation, stability investigations, analytical development and technical problem-solving. Where these activities involve qualifying experimentation directed towards resolving scientific or technical uncertainty, they may satisfy the definition of core R&D.

Other manufacturing activities may qualify, under the present rules, as supporting R&D where the relevant statutory requirements are satisfied.

For pharmaceutical companies engaging Australian manufacturing providers, clearly identifying experimental activities, supporting operations and routine manufacturing within contractual scopes of work is important. This enables sponsors to distinguish potentially eligible R&D expenditure from other manufacturing costs while maintaining appropriate technical and financial records.

06 — IDT AUSTRALIA

Supporting the Australian Advantage

IDT Australia has more than 50 years of pharmaceutical manufacturing experience and provides specialised contract development and manufacturing services to Australian and international pharmaceutical companies.

IDT Australia is also a registered Research Service Provider under the Australian R&D Tax Incentive framework.

RSP registration recognises a provider's capability to undertake research and development services within specified fields and provides a framework through which companies can engage specialised research expertise.

Although RSP registration does not automatically establish eligibility, engaging an experienced Australian CDMO can assist sponsors in conducting and documenting development activities potentially qualifying under the incentive.

> For international pharmaceutical companies, combining IDT Australia's technical capabilities with an appropriately structured Australian R&D program creates an opportunity to improve the efficiency of development expenditure.

07 — STRUCTURING

Structuring for Sustainable R&D Tax Outcomes

The commercial value of the Australian R&D Tax Incentive depends on more than the headline offset rate.

For foreign-owned pharmaceutical companies, the Australian subsidiary's role, intercompany arrangements, funding model and contractual commitments must be established consistently with its intended activities.

Transfer pricing arrangements must also satisfy Australian arm's-length requirements and appropriately reflect the economic substance of the Australian entity's operations.

Companies must maintain sufficient technical and financial records to substantiate their R&D claims and generally register eligible R&D activities within ten months following the end of their income year.

Integrating R&D tax planning with corporate and international tax considerations from the outset helps reduce compliance risk and supports the financial sustainability of the arrangements.

CONCLUSION

The Australian Advantage

Australia's R&D Tax Incentive is a significant opportunity for international biotechnology and pharmaceutical companies seeking to maximise the value of development capital. For companies that combine an appropriate structure, qualifying activities and robust commercial and technical documentation, the financial benefits can be substantial.

Talk to us before you commit R&D spend.

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This article provides general information only and does not constitute tax, legal or financial advice. Eligibility for the R&D Tax Incentive depends on each company's specific facts and the legislation in force at the time. Companies should obtain advice tailored to their circumstances before committing expenditure or entering into arrangements.