30 September 2025

Strategic Engagement of Research and Development Secretariat
10 Binara St
Canberra ACT 2601
Via email: rdreview@industry.gov.au

Dear Strategic Engagement of Research and Development Secretariat,

**Re: Strategic Examination of Research and Development (SERD): Issues Paper 3**

Medicines Australia welcomes the opportunity to make a submission to the SERD Issue Paper 3: RD&I incentives. Our submission builds on the medicines and biopharmaceutical sectors prior input and provides new evidence and practical policy additions to ensure Australia attracts and retains globally competitive life sciences R&D, clinical trials, and advanced biomanufacturing.

Issue Paper 3

Medicines Australia supports the following elements of Issue Paper 3: RD&I Incentives, which are key to strengthening Australia's innovation ecosystem and ensuring global competitiveness in life sciences:

a. We support the shift to a more ambitious, growth-oriented R&D tax incentive (RDTI) calibrated to firm stage.
b. We welcome the concrete improvements for startups and SMEs, including a start-up specific RDTI stream, quarterly advanced payments, simplified eligibility, removal of clawback, and clear on/off ramps – which will also benefit biotech and MedTech firms.
c. We endorse collaboration incentives, including a collaboration premium for larger firms partnering with startups and scaleups, and links to visas and PhD programs, aligned with life-sciences partnership models.
d. We support the recognition that both tax and grants play complementary roles in driving RD&I.
e. We welcome the commitment to simpler, clearer RDTI access and eligibility, reducing reliance on third-party consultants.

Issue Paper 3 is strong on generic innovation levers but omits the market-shaping and system levers that uniquely determine life-sciences investment (HTA/PBS access, clinical trials infrastructure, data exclusivity/IP, and national coordination for health innovation). These omissions risk less Foreign Direct Investment, fewer first-wave launches/trials, slower patient access, and weaker sovereign capability. We therefore highlight the following gaps, which reflect key recommendations made in our initial Submission to the Strategic Examination of R&D but are not addressed in the current Issue Paper 3: RD&I incentives.

**Gap 1. No linkage to HTA/PBS Market Access – A Key Driver of Pharmaceutical RD&I**

- The Issue Paper doesn't reference Health Technology Assessment (HTA) or Pharmaceutical Benefit Scheme (PBS) timelines or their predictability, despite their central role in pharmaceutical market access – a key driver of RD&I. Medicines Australia has previously stressed the need to reform Australia's HTA system to support a sustainable life sciences ecosystem. While concerns have been raised about the impact of unpredictable market access pathways on broader investment decisions, it's important to recognise that attracting advanced manufacturing facilities will require substantial incentives and a system that pulls investment rather than passively waits for it. As such both tax benefits and the market attractiveness are important.
- Current access delays are substantial - patients have to wait an average 466 days before a product is reimbursed. This is significantly longer than in comparable OECD countries.

Without addressing HTA/PBS reform, changes to the RDTI will not influence global pharmaceutical site selection. This limits Australia's ability to attract first-wave launches and high-value innovation.

**Gap 2. No Plan for Clinical Trials One-Stop Shop (NOSS) Sustainability**

- The SERD paper does not mention clinical trials or the NOSS. In our initial submission, Medicines Australia highlighted the need for Government to allocate ongoing and sustainable funding for the NOSS for clinical trials, as a lapse in funding would jeopardise Australia's standing as a preferred destination for clinical research.

Without sustained funding, Australia risks losing clinical trials to other countries, reducing early patient access and weakening associated economic benefits such as jobs, skills development, and foreign direct investment.

**Gap 3. No commitment to address Pharma-Specific IP/Data Exclusivity**

- The SERD Issue Paper 3 doesn't address regulatory data protection (RDP), which is a key factor in attracting life sciences investment. In our initial submission, Medicines Australia drew attention to the fact that Australia's current five-year data exclusivity period falls short of international norms—such as the eight-year minimum offered in Canada, Japan, and the EU, and up to twelve years in the United States for biologics. This shortfall places Australia at a disadvantage in competing for early-stage innovation and biopharmaceutical investment.

Weak RDP discourages companies from locating pivotal studies and launches in Australia, reducing local R&D, commercialisation, and advanced biomanufacturing opportunities. Medicines Australia recommends reforming the RDTI and related mechanisms to make Australia more competitive for pivotal studies and product launches.

**Gap 4. No whole-of-Government Life Sciences Council**

- While SERD refers to "building a system based on the needs and contribution of each player" (SERD Issues Paper 3, p. 5), it doesn't propose a dedicated life sciences council. Establishment of a Life Sciences Council with a whole-of-government strategic focus, deliberate coordination, and an enduring forum to foster partnership between industry, government and other key stakeholders across the value chain would:
    - drive innovation, investment, jobs creation and competitiveness
    - provide an enduring forum to foster partnership between industry, government and other key stakeholders across the value chain
    - inform a whole-of-government approach to health innovation across the lifecycle – from early-stage research through to clinical trials, translation, development and commercialisation – in partnership with industry
    - help local innovators overcome existing challenges that make it difficult to bring new health innovations from early-stage discovery through to clinical trials, commercialisation and domestic manufacturing.

Fragmentation across Government continues, making Australia difficult to navigate for global sponsors and reducing competitiveness for investment in a global market.

**Gap 5. Limited Recognition of Pharma-Specific Translation Barriers and Patient-Centred Outcomes**

- The Issue Paper focuses on productivity firm growth but doesn't incorporate patient-centred impact metrics that guide health R&D prioritisation. In our initial submission, Medicines Australia underscored the importance of shifting the focus from viewing academic publications as a measure of success to prioritising tangible patient outcomes is critical.

Without embedding patient outcomes in R&D metrics, translation gaps persist, limiting health impact and economic return.

**Gap 6. No Explicit Support for Advanced Biopharma Manufacturing and Public-Private Partnerships (PPPs)**

- Although Issue Paper 3 references large-firm R&D presence but does not outline specific support for advanced biopharma manufacturing or PPP mechanisms. In our initial submission, Medicines Australia stressed that PPPs play a crucial role in advancing the life sciences sector. Pooling resources -funding expertise and infrastructure- helps overcome the high costs and risks inherent in life-sciences R&D. Medicines Australia also notes that investments in advanced manufacturing are long-term and therefore require stable and globally competitive policy environment.

Without targeted support, Australia risks underinvestment in advanced manufacturing and missed opportunities for collaboration and sector growth. In an increasingly complex geopolitical environment, this is key to ensure Australia does not fall behind.

**Gap 7. No commitment to streamline IP and contracting frameworks for faster spinouts**

- The Issue Paper does not address the need to standardise intellectual property (IP) and contracting processes across universities and hospitals. Medicines Australia has previously recommended the development of national model IP terms and a light-touch risk framework to reduce deal cycle times and dead-weight costs. These measures are essential to enable faster licensing, clearer ownership structures, and increased spinout activity.

Without government acknowledgement and action on IP and contracting reform, Australia will continue to face delays and inefficiencies that hinder commercialisation and reduce the global competitiveness of its life sciences sector.

**Gap 8. No use of behavioural levers to overcome cultural and translational barriers**

- While the Issue Paper rightly identifies cultural risk aversion as a barrier, it does not propose practical behavioural interventions to address it. In our initial submission, Medicines Australia recommends operator-in-residence programs within universities, translational fellowships for scientist-founders, and default procurement pilots to reduce the social cost of first adoption. These behavioural nudges are proven tools to shift institutional culture and accelerate translation.

Without embedding behavioural levers alongside economic incentives, Australia risks perpetuating a slow and fragmented translation pipeline, limiting the impact of life sciences R&D on patient outcomes and economic growth.